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Life Sciences

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Baker McKenzie has the insider knowledge and global reach to help clients anticipate and manage new risk, being one of the largest dedicated global life sciences and healthcare groups in the legal industry, comprising over 800 lawyers in 45 jurisdictions. The firm's expertise and experience in the global life sciences market stretch over 60 years, further enhanced by lawyers who have higher scientific degrees, hold leadership and advisory positions with industry associations, and bring previous experience working as in-house counsel for big pharma, medtech companies and regulators such as the EMA and other ministries of health. Baker McKenzie provides deep industry expertise in key areas of law, including transactions, tax, compliance, employment, intellectual property investigations, disputes and healthcare regulatory.

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INTRODUCTION

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Life Sciences: an Introduction

The life sciences industry continues to be active and creative. 2022 was a rough year in general terms and the life sciences industry did not escape its own trials and tribulations, but it continues to forge ahead and adapt to challenges caused by economic, social and political strife across the globe. Investment opportunities are reaching near pre-pandemic levels, and traditional M&A activity is expected to pick up slightly. Some industry players have taken advantage of opportunities to expand, including establishing manufacturing operations across the globe in a special effort to secure their supply chain. However, other companies have disappeared, especially those which depended on a few products, and a number of key players have experienced lay-offs.

The global regulatory landscape is hyperactive. The EU pharmaceutical legislation is under review and the far-reaching changes that are being contemplated could have a profound effect on industry players doing business in that region. Despite efforts, regulatory authorities across the globe continue to lag behind when it comes to developing legal frameworks in synchronisation with advances brought about by digital transformation. On a positive note, some countries – such as Costa Rica, Brazil and Mexico – are taking steps towards regulatory harmonisation. It has yet to be seen, however, when and how the harmonised regulatory frameworks will be implemented.

Digital transformation is a fact of life within the industry, bringing important advances in telemedicine, allowing healthcare professionals to make better, more informed decisions and empowering patients. Reliance on AI is especially important in connection with research and development, clinical trials and healthcare.

The industry's response to the supply chain challenges caused by the pandemic has proven effective for many key players. ESG considerations have been overshadowed by other priorities in some cases, although corporate governance remains in the forefront. 2023 will be especially important for the medical cannabis industry as the regulatory framework across the globe becomes more consistent and more favourable to development. Government intervention in pricing is at a level never seen before, including in jurisdictions where such intervention was taboo not that long ago. The industry faces huge pressure as costs increase, but profits are at risk due to tighter budgets, stricter price controls and stricter reimbursement regulations.

Finally, risks to intellectual property are very real concerns for the industry, with loss of exclusivity being the principal worry, be it caused by patent cliffs or the over-riding of patent protection related to public health emergencies.

M&A and transactional activity

The annual JPMorgan conference in January finally occurred in person after several years as a virtual event, and is an example of renewed enthusiasm for industry growth. The industry seems to prefer smaller transactions, with a focus on smaller bolt-on acquisitions and licensing deals. The sector has also seen many spin-offs and carve-outs, with companies continuing the trend of focusing on their core areas and disposing of non-core assets, freeing up cash to drive more investment in prioritised areas and higher growth spaces. Despite the slowdown, digital transformation, supply chain issues, sustainability and portfolio optimisation continue to be drivers for M&A activity and provide opportunities to add or expand capabilities. Numerous ccompanies that fared well during the pandemic

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are investing and are expressly open to acquisitions.

EU life sciences regulatory landscape

Since the pandemic, the regulatory landscape in the EU has changed at a rapid pace, and the role of the EU in health policies has been strengthened in an unprecedented way.

The European Commission is due to publish its proposal for a review of the EU pharmaceutical legislation in the first quarter of 2023. The scope of the review is far-reaching and there is concern amongst industry players that the new legislation may veer towards access and affordability rather than the promotion of innovation. The contemplated changes include is a proposed reduction of regulatory data protection periods and orphan market exclusivities.

The review also addresses shortages and security of supply, and making medicines more sustainable. All this will translate into added responsibilities for the industry and stronger EU control.

Digital transformation

Digital transformation is no longer a hot topic; it's a given. With the help of this transformation, companies are innovating at lightning speed and continuing to partner with tech companies through collaboration agreements or outright acquisitions. Corporate cultural shock continues to be a challenge but less so than in the past, since the new generation of life sciences executives is more than prepared to lead the digital transformation of the industry.

We are seeing a flurry of legislation attempting to keep up with these advances and to manage the vast amount of data generated. The alignment of this upcoming legislation with all relevant sectoral and horizontal laws remains a crucial aspect.

Telemedicine

Telemedicine and remote healthcare were forced upon patients because of the pandemic, as governments quickly implemented temporary regulatory frameworks to accommodate the emergency. This rapid transformation has led to new players in telemedicine, online pharmacies and other forms of the digital delivery of healthcare. Many governments have now converted the temporary frameworks into permanent regulations, and other governments have implemented full-blown regulatory frameworks for telemedicine and remote healthcare. The result is that telemedicine and remote healthcare, especially involving medical devices, has been legitimised in patients' eyes. Once hesitant, often resistant to accept telemedicine and remote care when it was forced upon them by the pandemic, patients have now learned to trust and even prefer the options.

Research and development

The active biotech and pharmaceutical pipeline nurtured by the pandemic has calmed down as companies prefer to be more focused and more conservative in their research and development activities. This is due largely to the fact that many players have faced costly failures with what were expected to be promising success stories over the past year. As focus narrows, areas of special interest include treatments for rare diseases, cancer, Alzheimer's, diabetes, obesity and vaccines, including mRNA-based vaccines and therapies. Artificial intelligence has invaded R&D and brings with it promises for speed, efficiency and lower costs; however, this new and somewhat unknown world triggers regulatory demands that will be hard to meet in the short term.

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Clinical trials

Clinical trials were a huge challenge during the pandemic but, as with telemedicine, the solutions around clinical trials that evolved during the pandemic have now been adopted to make trials more efficient. Virtual clinical trials, hybrid clinical trials and decentralised trials coexist with in-person trials, where feasible. In addition, the area of clinical trials is heavily influenced by AI, although the regulations have not yet caught up with AI's influence. Diversity and inclusion have fortunately spread to clinical trials as well, with companies heeding consumer demands for diversity in clinical trials as statistics reveal the damage that lack of diversity has caused on health in diverse communities.

AI

Artificial Intelligence is the new industry buzzword, and is especially key to R&D and clinical trials. It has also proven to be both useful and effective in medical imaging. The most recent example reveals that radiologists in Hungary used AI technology on real patients and, after a test on more than 275,000 breast cancer cases, AI software matched the performance of human radiologists when acting as the second reader of mammography scans. This is only one of many trials using AI with medical imaging, with similar success.

Conclusion

The complexities of the life sciences industry continue to grow exponentially, as do the accompanying legal issues. These complex legal issues must be analysed by viewing the whole picture, taking into account the geographic scope and effects as well as the broad legal reach, which often goes well beyond one area of law. Most importantly, however, the analysis must be supported by deep knowledge of the life sciences industry. Counsel must be not only legal experts, but also trusted partners, and industry knowledge is essential in order to be a trusted partner.

AUSTRIA

Law and Practice

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Herbst Kinsky Rechtsanwälte has become one of Austria's leading commercial law firms since its establishment in 2005. Its specialised and highly committed lawyers combine many years of experience gained abroad and in reputable Austrian law firms. The firm's practice covers a full range of services in all areas of commercial, corporate, civil and public law, including banking, insurance and capital markets, corporate and M&A, IP, IT and life sciences, antitrust and competition, data protection, real estate, dispute resolution and arbitration. Herbst Kinsky Rechtsanwälte has established a particularly strong presence in the field of life sciences and healthcare. The firm's clients range from large international privately held and publicly listed companies to SMEs, as well as start-ups.

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HERBST KINSKY

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Austrian medicinal products law is strongly determined by EU legislation. However, at a national level, the Austrian Medicinal Products Act (*Arzneimittelgesetz*, or AMG) constitutes the primary legal basis with regard to pharmaceuticals ("medicinal products") for human use. It implements the main EU legal acts in this respect – specifically, Directive 2001/83/EC.

Specific provisions in relation to medicinal products can also be found in other Austrian laws, such as the Austrian Pharmaceutical Products Import Act (*Arzneiwareneinfuhrgesetz*, or AWEG) or the Austrian Prescription Act (*Rezeptpflichtgesetz*). Furthermore, the manufacture and distribution of medicinal products is governed by several national ordinances (*Durchführungsverordnungen*), which are based on the AMG, including the Medicinal Products Operations Ordinance (*Arzneimittelbetriebsordnung*, or AMBO).

Medicinal products law is also increasingly regulated by directly applicable EU regulations – for example, Regulation (EC) 726/2004 (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices**), Regulation (EU) 536/2014 ("Clinical Trials Regulation", or CTR), and Regulation (EC) 1394/2007 ("Advanced Therapy Medicinal Products Regulation", or ATMPR).

As of 26 May 2021, medical devices are mainly governed by the Regulation (EU) 2017/745 ("Medical Devices Regulation", or MDR), which is complemented by the Austrian Medical Devices Act 2021 (*Medizinproduktegesetz*, or MPG) providing for rules regarding the safety, functionality and quality of medical devices with regard to their construction, operation, use and maintenance. Since 26 May 2022, in vitro diagnostic (IVD) devices have been governed by Regulation (EU) 2017/746 ("In Vitro Diagnostics Regulation", or IVDR), which is likewise complemented by the MPG. The MPG came into force on 1 July 2021 for medical devices and on 26 May 2022 for IVD devices.

The competent national authority for medicinal products, medical devices and IVD is the Austrian Federal Office for Safety in Healthcare (*Bundesamt für Sicherheit im Gesundheitswesen*, or BASG). The BASG is responsible for the approval and control of medicinal products in Austria, as well as for the control and approval of clinical trials (see **2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial**). Together with the competent European agencies, the BASG further monitors nationally the medicinal products, medical devices and IVD devices already on the market with regard to their efficacy, safety, production, transport and storage.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions by regulatory bodies qualify as specific administrative acts (*Bescheide*), which can be challenged by the addressee – or by a third party having a legal interest, if applicable – by lodging an appeal with the regulatory body that has issued the administrative act. The decision on the appeal is made by the competent administrative court.

Appeals against administrative acts must be made in writing and – unless regulated otherwise in the respective regulation – filed within

four weeks of the date of the decision to be challenged. There is no legal obligation for the appellant to be represented by an attorney.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In Austrian medicinal products law, various criteria exist on the basis of which medicinal products are categorised and regulated differently. By way of an example, the AMG distinguishes between medicinal products that are available for the patient only upon prescription and OTC medicinal products available without prescription. Medicinal products requiring prescription may not be advertised to the general public ("lays") but, rather, only to healthcare professionals under the preconditions laid down in the AMG.

The AMG makes another relevant distinction between medicinal products that are, in principle, subject to marketing authorisation – known as "medicinal specialties" (*Arzneispezialitäten*) – and medicinal products not subject to such authorisation. Furthermore, the AMG differentiates on the basis of the material composition of a medicinal product (eg, biological medicinal products, herbal medicinal products, radioactive medicinal products, or homeopathic medicinal products).

Likewise, medical devices may be qualified by the Ministry of Health as requiring a prescription or as only available through certain specialised dealers. Prescription-only medical devices may not be advertised to the general public either. However, in practice, the vast majority of medical devices are freely available and not qualified as prescription-only or exclusively available in specialist stores.

There is also an essential distinction between IVD devices – to which the IVDR applies – and other medical devices, which are subject to the MDR. In addition, the MDR/IVDR differentiate on the basis of the purpose or use of a medical device (eg, active device, implantable device, invasive device, or single-use device) and its inherent risks (Class I, IIa, IIb, III medical devices/ Class A, B, C and D IVD devices).

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulatory system for clinical trials of medicinal products has undergone a comprehensive restructuring as of 1 February 2022, aimed at further harmonising the rules on the conduct of clinical trials within the EU member states. The legal framework of clinical trials on medicinal products is now essentially defined by the CTR, thereby replacing the former system for clinical trials based on Directive 2001/20/EC. Supplementary provisions for national implementation and within the scope of so-called opening clauses of the CTR have been introduced into the Austrian legal system through the AMG by an amendment in Federal Law Gazette I 2022/8.

If genetically modified organisms (GMO) are used for therapeutic purposes – as defined in Section 4(24) of the Austrian Gene Technology Act (*Gentechnikgesetz*, or GTG) – in the course of a clinical trial, a prior permit according to Section 74 of the GTG must be obtained in addition.

Clinical trials of medical devices (known as "clinical investigations") are mainly regulated by the MDR and clinical trials of IVD devices (known as "performance studies") are regulated by the IVDR. Supplementary provisions have been included in the MPG.

For non-interventional studies, the provisions of the CTR and the MDR/IVDR do not apply. Instead, there are specific national provisions in the AMG and the MPG for these studies, including provisions concerning data protection and inspections by the BASG. The following may also apply:

- general provisions of civil, criminal and data protection law;
- specific rules for clinical research under, for example, the Austrian Hospital and Sanatoria Act (*Krankenanstalten- und Kuranstaltengesetz*, or KAKuG) or the Austrian University Act 2002 (*Universitätsgesetz*, or UG).

The ordinance concerning the reporting obligation on non-interventional studies of medicinal products was repealed by Federal Law Gazette II 2022/374, so there is no longer an obligation to report such studies on medicinal products performed in Austria. Also with regard to medical devices, the legislator has thus far not made use of its authorisation to provide for a reporting obligation on non-interventional studies through ordinance.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

As of 31 January 2023, all new applications for clinical trials of medicinal products must be submitted in accordance with the CTR. The authorisation procedure is initiated by the sponsor sending the application dossier to the EU member states concerned via the EU portal, known as the Clinical Trials Information System (CTIS). The reporting member state must then carry out a validation within ten days and notify the sponsor via the portal of the results. In Austria, the BASG is responsible for the validation procedure, whereby the ethics committee can issue an opinion on certain parts of the application (Section 31, paragraph 4 of the AMG). The validation procedure is followed by the evaluation procedure, which is divided into the following two parts.

- In Part I, a co-ordinated assessment of the application between the reporting and concerned member states takes place, in which aspects of the clinical trial – such as whether it is minimally interventional, the expected therapeutic and public health benefits, and the risk of harm posed to the trial subjects – are evaluated. The assessment report must be prepared and submitted within 45 days of validation; however, this term may be extended under certain conditions. The responsibilities regarding Part I of the assessment procedure are divided nationally between the BASG and an assessing ethics committee (Section 35 of the AMG).
- Part II of the evaluation procedure includes the aspects that are to be assessed nationally by each member state – for example, requirements for informed consent, patient recruitment, and subject insurance. The evaluation report must also be submitted within 45 days of validation. In Austria, the responsibility for preparing the assessment report in Part II is assigned to the evaluating ethics committee.

The decision to authorise the clinical trial must then be taken by each member state within five days of the conclusion of the evaluation procedure. If a timely notification is not made, the conclusion regarding Part I of the assessment report is automatically deemed to be the decision of the respective member state.

The approval of a clinical investigation into a medical device for the purposes of the conformity assessment referred to in Article 62, paragraph 1 of the MDR essentially follows the MDR.

Depending on the type of investigation, different procedures are provided for (eg, authorisation procedure / notification procedure / instruction procedure).

An application for authorisation must be submitted electronically to the BASG. Upon receipt of the application, the BASG shall carry out the validation within ten days.

With regard to Class I investigational devices or Class IIa/IIb non-invasive devices, the clinical investigation may be commenced immediately after validation – provided that the BASG has confirmed proper notification and the ethics committee has given a favourable opinion (ie, notification procedure).

In the case of other investigational devices (Class III investigational devices or Class IIa/IIb invasive devices), the clinical investigation may only commence after notification of the authorisation by the BASG – again with the prerequisite that a favourable opinion by the competent ethics committee must be provided. The decision about the authorisation must usually be communicated to the sponsor within 45 days of validation (ie, authorisation procedure).

For clinical investigations of medical devices that already bear a CE marking, thereby confirming *conformité européenne* ("European conformity"), a different procedure applies under certain conditions (Article 74 MDR). The sponsor must notify the BASG of the conduct of such investigation at least 30 days before it begins. In this case, the BASG will confirm the notification without further subsequent assessment (ie, information procedure).

Clinical investigations of medical devices for other purposes than the demonstration of conformity are also subject to prior approval by the BASG if they have an impact on the diagnostics and/or therapy of a trial subject (Article 82 of the MDR, in conjunction with Section 13, paragraph 3 of the MPG); otherwise, it is only necessary to conduct an information procedure.

For performance studies on IVD devices, the provisions of the MPG are largely applicable mutatis mutandis – although there are certain exceptions (see Article 66 et seq of the IVDR and Section 36 of the MPG for comparison).

The foregoing does not apply to non-interventional studies. At the national level, there is currently no obligation to report such to the BASG.

2.3 Public Availability of the Conduct of a Clinical Trial

For medicinal products, information on clinical trials initiated under the CTR as of 31 January 2022 (including start and end dates of the trial, details of the sponsor, and trial results) is publicly available on the EU Clinical Trials website. Information on clinical trials initiated under the former system of Directive 2001/20/EC (before 31 January 2022) may still be accessed via the EU Clinical Trials Register.

For clinical investigations and performance studies under the MDR and the IVDR, currently no publicly accessible register is provided at EU or national level. However, information on such trials will be accessible via the EUDAMED database as soon as the entire EUDAMED system has been declared fully functional. According to recent estimates, full functionality shall be achieved in the second quarter of 2024.

At national level, the former register for non-interventional studies of medicinal products was discontinued following the repeal of the

ordinance concerning the reporting obligation on non-interventional studies in 2022 and has not been (publicly) accessible since 1 December 2022. The option to provide for the maintenance of a (publicly accessible) register for non-interventional studies of medical devices via ordinance was likewise not exercised by the legislator.

2.4 Restriction on Using Online Tools to Support Clinical Trials

In Austria, it is not generally prohibited to conduct the consent procedure remotely or to remotely supervise certain tasks/procedures carried out at home by a physician. Remote access to source data for the purpose of monitoring is also permissible; however, this only applies to original electronic medical records and where a correspondingly validated record system is being used.

In December 2022, a recommendation paper on decentralised (remote) elements in clinical trials was published by the EU Decentralised Clinical Trial (DCT) project team, comprising experts from the Clinical Trial Coordination Group, the Clinical Trial Expert Group, European Medicines Agency (EMA) scientific committees, EMA working parties, and EMA staff. This document also includes guidance concerning national provisions on the use of online tools in clinical studies within the EU.

As regards special measures due to COVID-19, see **11.2 Special Measures Relating to Clinical Trials**.

2.5 Use of Data Resulting From the Clinical Trials

Clinical studies involve the processing of patients' contact and health information, which may qualify as personal data as defined by Article 4(1) of the General Data Protection Regulation (EU) 2016/679 (GDPR). To the extent that patients are identified or at least identifiable in data resulting from the clinical trial, these data sets must also be qualified as personal (sensitive) data.

The processing of personal data in the context of a clinical trial is generally based on the patient's consent pursuant to Article 6, paragraph 1(a) in conjunction with Article 9, paragraph 2(a) of the GDPR. Accordingly, any disclosure of personal data to third parties must be covered by this consent.

2.6 Databases Containing Personal or Sensitive Data

The processing of personal data (including sensitive data) within databases is subject to compliance with the GDPR and the Austrian Data Protection Act (*Datenschutzgesetz*, or DSG).

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The distinction between medicinal products and medical devices is made in accordance with the product definitions as set forth in the AMG (Section 1, paragraph 1) and the MDR (Article 2(1)).

"Medicinal products", within the meaning of the AMG, are substances or preparations of substances that either:

- are intended for use in or on the body and as agents with properties to cure or alleviate or prevent diseases or pathological complaints

(so-called presentation medicinal products); or
- may be applied in or on the body or administered to a human or animal (so-called functional medicinal products) with a view to either:
  (a) restoring, correcting or modifying physiological functions by a pharmacological, immunological or metabolic action; or
  (b) making a medical diagnosis.

According to the MDR, the term "medical device" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Furthermore, devices for the control or support of conception, as well as certain products specifically intended for the cleaning, disinfection or sterilisation of devices shall be deemed medical devices.

The distinction between medicinal products and medical devices can be made, in most cases, on the basis of the principal mode of action of the product (see Article 1, paragraph 6(b) of the MDR). A product with an essentially pharmacological, immunological or metabolic action is not to be classified as a medical device. The principal mode of action of medical devices is mostly of a physical or mechanical kind.

In the case of diagnostic devices, distinction must be made on the basis of the nature of the product (substance/instrument, apparatus, etc) and the place of application (in vivo or in vitro). Detailed – albeit not legally binding – guidances for the delimitation of borderline products can be found in a document entitled "MDCG 2022-5: Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices", published by the Medical Device Co-ordination Group in late April 2022, and in the "Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices".

In Austria, manufacturers of products (or their representatives) may initiate a procedure with the BASG, whereby questions concerning the product classification – including the demarcation between the medicinal product and the medical device status of the product – will be clarified (Section 10 of the MPG and Section 49a of the AMG).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Within the meaning of the AMG, the term "biological medicinal products" comprises:

- certain immunological medicinal products;

- certain medicinal products manufactured by using human blood or blood plasma as a starting material; and
- medicinal products listed in Annex I(1) and (1a) Regulation (EC) 726/2004, such as:
  (a) medicinal products developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes (including transformed mammalian cells), or hybridoma and monoclonal antibody methods; and
  (b) ATMP.

Austrian law does not provide for a marketing authorisation procedure specific to biological medicinal products. However, for medicinal products listed in Annex 1(1) and (1a) Regulation (EC) 726/2004, a central marketing authorisation according to said regulation is mandatory. In addition, differences with regard to the required application documents may arise for different types of biological medicinal products.

Furthermore, the AMG contains specific provisions for certain immunological medicinal products, as well as medicinal products manufactured by the use of human blood or blood plasma. According to Section 7, paragraph 6e of the AMG, for example, blood and blood components intended for direct transfusion are exempt from the obligation to obtain a marketing authorisation. Also, there may be an additional requirement of a batch release as a prerequisite for supplying certain biological medicinal products in national Austrian law (see Section 26 of the AMG). Lastly, specific provisions for so-called biosimilars can be found in Section 10, paragraph 8 of the AMG.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

A national marketing authorisation of a medicinal product is generally granted by the BASG for a period of five years (Section 20, paragraph 1 of the AMG). An extension of the marketing authorisation (at the request of the marketing authorisation holder) is valid without a time limit, unless the BASG again sets a time limit of five years for reasons of pharmacovigilance.

If an authorised medicinal product has not actually been placed on the domestic market within three years of the marketing authorisation being granted or has not been on the market for three consecutive years, the marketing authorisation may expire in accordance with Section 22 of the AMG (the so-called sunset clause). In certain cases, the marketing authorisation must also be revoked. Similar rules apply according to Regulation (EC) 726/2004 with regard to the period of validity of marketing authorisations for medicinal products authorised under the centralised procedure.

The placing on the market of medical devices is not subject to a marketing authorisation; however, the manufacturer must perform a conformity assessment procedure (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices**). According to Article 56 of the MDR, certificates of conformity issued by the notified bodies will be valid for the period they indicate, which must not exceed five years. Upon application by the manufacturer, the validity may be extended for further periods (of no more than five years), based on a re-assessment. The CE marking will be suspended, restricted or withdrawn if a notified body finds that the requirements of the MDR are no longer met by the manufacturer.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

There are, in practice, four different procedures for obtaining a marketing authorisation for medicinal products.

- For medicinal products according to Annex I Regulation (EC) 726/2004 (eg, ATMP), marketing authorisation must be obtained via the centralised procedure. Under certain conditions (see Article 3, paragraph 2), the centralised procedure is also available for other medicinal products. A marketing authorisation obtained in the centralised procedure is issued by the European Commission and is valid in all EU member states. Applications must be submitted to the EMA.
- For other medicinal products, marketing authorisation may be obtained under the national procedure according to Sections 7 et seq of the AMG via application to the BASG. The BASG is also the competent authority for issuing the national marketing authorisation, which is only valid on Austrian territory.
- Where a national authorisation already exists in a member state, it may be extended to the territory of other member states through a mutual recognition procedure (Section 18a of the AMG).
- For medicinal products that cannot be authorised under the centralised procedure, a marketing authorisation in different EU member states may be applied for through a decentralised procedure (Section 18a of the AMG).

Variations to marketing authorisations are governed by Regulation (EC) 1234/2008 for all types of authorisations. Depending on the degree of health risk and the impact on quality, safety and efficacy, either a simple notification procedure, a notification obligation with a prohibition reservation or a prior authorisation procedure is required. In contrast, applications for authorisation extensions (eg, in the case of relevant changes to the active substance) must be evaluated according to the same procedure as the application for the original authorisation.

Transfers of marketing authorisations obtained under the centralised procedure must be applied for with the EMA according to the procedure set down in Regulation (EC) 2141/96. Otherwise, the procedure is governed by Section 25 of the AMG according to which a declaration of waiver of the authorisation by the previous marketing authorisation holder and a declaration of acceptance by the transferee must be submitted to the BASG.

Placing medical devices and IVD devices on the market is not subject to obtaining a marketing authorisation. Medical devices or IVD devices, however, may only be placed on the market or put into service if they comply with the MDR/IVDR. Specifically, they must meet the general safety and performance requirements, taking into account their intended purpose. Also, an assessment of the conformity of the device must be conducted and a corresponding declaration of conformity issued. Depending on the risk classification of a medical device, a notified body must be involved in the process. Conformity with the applicable requirements is indicated by CE marking of the product. Transfers of CE markings are not provided for in the MDR/IVDR.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

As far as medicinal products are subject to a marketing authorisation, the marketing authorisation is a prerequisite for lawful placing on the market in Austria. For this reason, opportunities

to supply such medicinal products to patients without a marketing authorisation are limited. Nevertheless, there are a number of exceptions to this principle. The following are among the exceptions to the authorisation requirement.

- Named Patient Use (Section 8, paragraph 1(2) of the AMG) – no marketing authorisation is needed if a physician or dentist authorised to practise independently in Austria certifies that:
  (a) a medicinal product is urgently needed to prevent a threat to life or serious damage to the health of a specific patient; and
  (b) this threat or damage cannot be prevented with an authorised and available medicinal product according to the state of the art.
- Compassionate Use Programmes (Section 8a of the AMG and Article 83 of Regulation (EC) 726/2004) – marketing authorisation is not needed within Compassionate Use Programmes, which may be established (subject to prior approval by the BASG) for a defined group of patients suffering from a debilitating chronic or severe disease or whose disease is life-threatening and cannot be satisfactorily treated with an authorised and available medicinal product.
- Clinical trials (Section 8, paragraph 1(1) of the AMG) – medicinal products intended for the use in non-clinical or clinical studies or clinical trials do not need a marketing authorisation.
- Hospital exemption (Section 7, paragraph 6a of the AMG and Article 28 of Regulation (EC) 1394/2007) – ATMP that are manufactured on a non-routine basis in Austria on the basis of an individual medical prescription specifically for a particular patient, in order to be used on that patient in an Austrian hospital under the exclusive professional responsibility of a physician, are not subject to a marketing authorisation.
- Officinal and magisterial medicinal preparations (Section 7, paragraphs 2 and 3 of the AMG) – certain medicinal products manufactured in pharmacies are not subject to a marketing authorisation.

Further exemptions are listed in Sections 7 et seq of the AMG.

It should be noted that the marketing authorisation is a prerequisite for placing medicinal products on the market, but not for their use. For this reason, medicinal products can in principle be used on patients beyond the scope of their marketing authorisation (off-label use). In this context, however, there are increased obligations on the part of the physician to provide information to the patient.

With regard to medical devices and IVD devices, the MDR/IVDR provide for exemptions from the obligation of CE marking for custom-made devices, investigational devices and devices for performance studies (Article 20 of the MDR and Article 18 of the IVDR). Furthermore, the placing on the market and putting into service of a medical device for which no conformity assessment has been carried out may be authorised by the BASG in specific cases upon request for reasons of public health or patient health and safety (Article 59 of the MDR, Article 54 of the IVDR and Section 12 of the MPG).

As per the above-mentioned definition of Named Patient Use, if a physician or dentist authorised to practise independently in Austria confirms that a medical device is required for a specific patient in order to avert a danger to life or a serious impairment of health – and that the treatment cannot be expected to be successful with

a medical device for which conformity assessment procedures have already been carried out – then such authorisation is not necessary. The same applies to medical devices used in connection with certain deployments of the Federal Armed Forces (Section 12, paragraphs 2 and 3 of the MPG).

Finally, under certain conditions there are far-reaching exemptions from the obligations of the MDR/IVDR for in-house products that are manufactured and used only in healthcare facilities (Article 5, paragraph 5 of the MDR/IVDR and Section 9 of the MPG).

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Holders of a marketing authorisation for a medicinal product must operate a pharmacovigilance system (Section 75i et seq of the AMG). Within the framework of this system, the holder must, among other things:

- appoint a pharmacovigilance officer;
- keep a pharmacovigilance master file;
- operate a risk management system;
- monitor the results of risk minimisation measures;
- monitor pharmacovigilance data; and
- subject the pharmacovigilance system to regular audits.

The applicable law also provides for reporting obligations (Section 75j of the AMG, Article 28 of Regulation (EC) 726/2004 and Article 107 of Directive 2001/83/EC) and information obligations of the holder (Section 75m of the AMG). In addition, holders are obliged to regularly prepare periodic safety update reports (PSUR) and transmit them electronically to an archive maintained by the EMA.

Other obligations of the holder include the following:

- The holder must inform the BASG about the date of actual placing on the market of a medicinal product, as well as a temporary or permanent removal from the market (Section 21 of the AMG).
- The holder must ensure that complete documentation of all activities related to the marketing authorisation or the medicinal product is available at all times (Section 24b of the AMG).
- If there are concerns regarding the risks of the medicinal product, the holder may face additional requirements or conditions imposed by the BASG, such as the performance of post-authorisation safety studies. If findings on the disease or clinical methodology indicate that previous assessments of efficacy may need to be significantly corrected, an efficacy study must be imposed (Section 19a of the AMG).

For medical devices and IVD devices, the MDR/IVDR require the manufacturer to plan, establish, document, implement, maintain and update a post-market surveillance system as part of the quality management system in a manner appropriate for the risk class and type of the product (Article 83 of the MDR and Article 78 of the IVDR). To this end, a post-market surveillance plan must be established (Article 84 of the MDR and Article 79 of the IVDR) and post-market surveillance reports must be prepared and updated (Article 85 of the MDR and Article 80 of the IVDR). Further obligations concern, for example, the preparation of PSUR (Article 86 of the MDR and Article 81 of the IVDR), the reporting and analysis of serious incidents and safety corrective measures (Articles 87 and 89 of the MDR and Articles 82 and 84 of the IVDR) and trend

reports (Article 88 of the MDR and Article 83 of the IVDR).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

On an EU level, a list of medicinal products under current evaluation under the centralised procedure is published monthly by the EMA. A list of all medicinal products that have received a marketing authorisation under the centralised procedure is provided in the "Union Register" published by the European Commission. This register includes information on the name of a product, the registration number, name and address of the marketing authorisation holder, the active substance, the therapeutic indication, and relevant documents – as well as suspended, withdrawn or refused marketing authorisations.

On a national level, the BASG keeps a public register of all medicinal products for which a national marketing authorisation has been obtained (*Arzneispezialitätenregister*). Any granting, variation, cancellation and transfer of a marketing authorisation must be entered into this register. Entries regarding the granting of a marketing authorisation include information on the authorisation number, the name of the product, the authorisation holder, prescription-only or narcotic status, and the composition of the medicinal product.

Furthermore, the BASG operates an internet portal on medicinal products for public information purposes. In addition to information on the granting of a marketing authorisation and the variation of a medicinal product, the BASG shall (inter alia) publish the technical information and approved directions for use, information on approved variations, and the conditions and constraints of marketing authorisations. Also, every expert opinion provided in the context of an application for marketing authorisation shall be published after all confidential information in the party's commercial interest has been removed.

For products authorised via a mutual recognition procedure, information can be found in the MRI Product Index. Information on medical devices and IVD devices (including summaries of safety and clinical performance) and their manufacturers and importers, as well as certificates, may be publicly accessed via the EUDAMED database.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The core Austrian regulations concerning the protection of the legal supply chain against falsified medicinal products and active substances were implemented in the AMG by Federal Law Gazette I 2013/48 in implementation of Directive 2011/62/EU. These include, inter alia, the following (legislative) measures.

- The outer packaging of specific medicinal specialties intended for human use must bear safety features and a mechanism to detect possible tampering with the outer packaging (Section 17, paragraph 5a of the AMG) (see also the AMBO).
- The counterfeiting of medicinal products, active substances or excipients – as well as the stockpiling, exporting and importing of counterfeit medicinal products, active substances or excipients with the aim of transferring them to another person – and the offering, procuring, transferring of such products are criminal offences punishable by imprisonment, as are the counterfeiting and falsification of commercial packages or other documents relating to medicinal products, active substances or excipients.

- There are increased obligations for entities involved in the distribution chain – for example, when a medicinal product is authorised, a manufacturer must attach written confirmation to the application that they have verified and established the active substance manufacturer's compliance with Good Manufacturing Practice (GMP) by means of audits.
- Counterfeit medicines, active ingredients, excipients and related documents can be confiscated by the authorities (Section 82c of the AMG).

With regard to medical devices and IVD devices, Section 5 of the MPG prohibits the erection, installation, putting into service, or use of such products if there are reasonable grounds for suspecting or establishing that they are falsified. According to the MDR and the IVDR, importers of medical devices and IVD devices are obliged to inform the competent authority if they suspect such product to be falsified (Articles 13 and 14 of the MDR/IVDR). Authorities may confiscate, destroy or otherwise render inoperable falsified devices or IVD devices if it is necessary to protect public health (Article 93 of the MDR and Article 88 of the IVDR).

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

If certain facts indicate that falsified medicinal products, active substances, excipients or documents are being transported to or from Austria, the customs authorities are authorised to seize them. They shall immediately report the seizure to the competent public prosecutor's office (Section 82d of the AMG).

With regard to medical devices and IVD devices, border controls may suspend the release of falsified products for free circulation on the community market on the basis of Article 27, paragraph 3 of Regulation (EC) 2008/765. In this case, they shall immediately notify the market surveillance authorities of such suspension.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacture of medicinal products (including packaging, labelling and final release of the finished product) may only be carried out based on a manufacturing authorisation (known as an "operating licence") to be applied for in accordance with the AMG.

The authorisation is granted by the BASG upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended manufacturing activity;
- the nature, size, equipment, dedication and location of the premises (as well as their furnishings and equipment);
- the nature of the technical equipment; and
- the appointed Qualified Person (QP) (*sachkundige Person*) who needs to be appropriately qualified, experienced and reliable.

Another prerequisite for the manufacturing licence is a trade permit for the manufacturing of medicinal products. This is issued, in accordance with the Trade Act (*Gewerbeordnung*, or GewO), by the Trade Authority – ie, the competent district administrative authority (*Bezirksverwaltungsbehörde*) at the intended manufacturing site. Such permit requires the nomination of a

"managing director under trade law" (*gewerberechtlicher Geschäftsführer*) who is appropriately qualified (as further defined in the GewO).

The manufacturing licence will only be issued after a successful on-site inspection of the manufacturing premises by BASG in which the authority checks compliance with the requirements of the AMBO and that the quality of the medicinal products as required for the health and life of humans (or animals) is ensured on the basis of the provided facts. The statutory timeframe for issuing a manufacturing licence is 90 days from the submission of a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock-stop.

The manufacturing authorisation is granted for a specific site, for specific manufacturing activities and types of medicinal products as specified in the application, and – in principle – for an unlimited period. However, the authorisation remains subject to regular GMP inspections by the BASG, and can be withdrawn in the case of any detected and non-remedied deficiencies.

The manufacture of medical devices and IVD devices is not subject to a specific governmental authorisation. However, requirements as applicable to any manufacturing activity – for example, those under construction law and under trade law regarding operating plants – will apply.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

In order to be able to carry out wholesale distribution of medicinal products, a wholesale dealer licence (WDL) is required (also called an "operating licence"). Such WDL is required not only if the respective entity actually carries out physical handling and storage of medicinal products, but also for selling and supplying medicinal products – even though the actual logistics are outsourced to a third party (likewise requiring a WDL itself).

The WDL is granted by the BASG upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended distributing activity;
- the nature, size, equipment, dedication and location of the premises as well as their furnishings and equipment;
- the nature of the technical equipment;
- the appointed responsible person (*fachkundige Person*) for wholesale distribution being appropriately qualified, experienced and reliable.

Furthermore, a trade permit is also required for the wholesale of medicinal products (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**). Such permit requires the nomination of a managing director under trade law who is appropriately qualified.

The WDL may only be issued after a successful on-site inspection of the wholesale distribution site by the BASG. The statutory timeframe for issuing a WDL is 90 days from the submission of a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock-stop.

The WDL is granted for a specific site and for specific distribution activities as specified in the

application, and in principle for an unlimited period. However, the authorisation remains subject to regular Good Distribution Practice inspections by the BASG, and can be withdrawn in the case of any detected and non-remedied deficiencies.

For the distribution of medical devices, no licence comparable to the WDL is necessary. However, a trade licence and an appropriately qualified managing director under trade law are necessary.

Finally, according to Section 67 of the MPG, registration in the publicly accessible Medical Devices Register is mandatory for all persons or entities who are responsible for placing medical devices on the market for the first time in the European Economic Area (EEA) and who are domiciled in Austria.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The importation and transfer of "pharmaceutical products" (*Arzneiwaren*) is regulated under the AWEG. In this context, it should be noted that the term "pharmaceutical products" is not identical with the term "medicinal product" as defined in the AMG or Directive 2001/83/EC – rather, it is based on the customs tariff regulations of Regulation (EEC) 2658/87. The AWEG therefore does not apply to all medicinal products. Also, medical devices are explicitly excluded from its scope (Section 1, paragraph 2 of the AWEG).

Provisions for parallel imports of medicinal products are regulated in the AMG (in particular, Section 10c). Products that have been authorised for parallel import are exempt from the notification obligation under the AWEG. Furthermore, obligations for importers and exporters are provided by the AMBO (see, for example, Section 4a). Specific provisions for the importation of investigational medicinal products are regulated in the CTR (Articles 61 and 63). The transfer of investigational medicinal products within the EEA (and Switzerland) is exempt from the notification obligation under the AWEG (Section 6, paragraph 2 of the AWEG).

The BASG is competent to issue import certificates and receive notifications under the AWEG and to supervise compliance with the AMG, the AWEG and the CTR. In addition, certain powers are granted to the customs administration under the AWEG.

General and specific obligations with regard to the importation of medical devices and IVD devices are laid down in the MDR/IVDR (see, in particular, Articles 13 and 60 of the MDR and Articles 13 and 55 of the IVDR) and enforced by the BASG as the competent authority.

6.2 Importer of Record of Pharmaceutical and Medical Devices

According to Section 4 of the AWEG, the following entities are entitled to apply for an import permit or carry out an importation notification for pharmaceutical products:

- public pharmacies;
- hospital pharmacies; and

- companies authorised to distribute pharmaceutical products in a state within the EEA.

The entitlement to apply for a parallel import authorisation is granted to the following entities, according to Section 9 of the AMG:

- professionals authorised to manufacture or wholesale the medicinal product concerned;
- operators of domestic public pharmacies; and
- pharmaceutical companies established within the EEA who are authorised to place the medicinal product concerned on the market.

Depending on their activities (eg, repackaging), importers may be subject to the operating licence requirement of Section 63 of the AMG (see also **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices** and **5.1 Wholesale of Pharmaceutical and Medical Devices**).

The MDR and the IVDR do not provide for specific legal requirements to act as the importer of record of medical devices or IVD devices. However, they define the importer as "any natural or legal person established within the Union that places a device from a third country on the Union market". Importers shall register in accordance with Article 28 of the MDR/IVDR.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Under the AWEG, importation of pharmaceutical products from a state outside of the EEA is subject to a prior importation permit issued by the BASG. Importation of pharmaceutical products from a state within the EEA shall be notified to the BASG in advance.

Section 11 of the AWEG, however, provides for extensive exceptions to these requirements, including exceptions for:

- medicinal products for which a marketing authorisation or an authorisation for parallel import has been obtained;
- medicinal products for Named Patient Use;
- medicinal products for use in a Compassionate Use Programme;
- medicinal products needed in event of emergencies; or
- medicinal products for personal use, in an amount corresponding to the usual personal needs of the traveller concerned.

Parallel importation of medicinal products is subject to a prior authorisation by/notification to the BASG in accordance with Section 10c of the AMG (see also Article 57, paragraph 1(o) of Regulation (EC) 726/2004 for medicinal products authorised under the centralised procedure).

The importation of medical devices and IVD devices does not require any specific authorisation under the MDR/IVDR or the MPG.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Which products are subject to the restrictions under the AWEG is determined by the classification of goods according to the tariff and statistical nomenclature of the EU pursuant to Regulation (EEC) 2658/87. Only products that fall under the subheadings of the combined nomenclature taxatively listed in Section 2(1) of the AWEG (eg, subheading 3002 20, 3002 30, 3004) are to be considered "pharmaceutical products" within the meaning of the AWEG.

6.5 Trade Blocs and Free Trade Agreements

Austria is a member of the WTO. Furthermore, as a member state of the EU, Austria participates in free trade agreements concluded by the EU member states. It is worth noting that the current EU sanctions against Russia do not provide for trade blocs of medicinal products and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The price basis of a medicinal product is the manufacturer's factory or depot selling price (*Fabriksabgabepreis*/*Depotabgabepreis*, or FAP/DAP). Furthermore, the respective "mark-ups" (wholesale and pharmacy mark-ups, regulated by law) and VAT are added to this price. The FAP/DAP can be freely determined by the company authorised to distribute and the Ministry of Health needs to be informed of this price.

For those medicinal products that are included in the list of reimbursable medicinal products, the so-called Reimbursement Code (*Erstattungskodex*, or EKO), the "EU average price" is relevant. This average price constitutes the maximum possible FAP/DAP for reimbursable products. For the purpose of calculating the EU average price, the Price Commission of the Ministry of Health considers the medicinal products with the same active ingredient, active ingredient strength, dosage form and identical (or approximately identical) package size.

The determination of the EU average price by the Price Commission takes place six months after the application for inclusion in the EKO is submitted. This is repeated 18 months after the first price determination and 24 months after the second price determination. The Price Commission can initiate a new price determination 18 months after the third price determination.

In the case of medicinal products that are not included in the EKO but exceed an annual turnover of EUR750,000 at the expense of the public health insurance (based on the FAP, in the previous 12 months), the Umbrella Organisation of the Austrian Social Insurance (*Dachverband*, or DVB) must immediately notify the Price Commission, which then has eight weeks to determine an EU average price for the medicinal product. If the determined EU average price is lower than the applied price, the company authorised to distribute must reimburse the difference to the social insurance institutions within six months of the date on which the sales threshold was exceeded.

The DVB applies the principles of price determination in accordance with the rules of procedure for the issuance of the EKO, as well as the economic evaluation criteria of the Therapeutic Products Evaluation Commission, and negotiates the reimbursement price with the manufacturer on this basis. Once an agreement has been reached, the reimbursement price specified in the EKO is binding, albeit subject to adaptation in accordance with the EU average price. If, on the other hand, a medicinal product is removed from the EKO by decision of the DVB, the companies authorised to distribute the drug have the option to appeal to the administrative court.

Furthermore, specific price regulations apply if a successor product with the same active ingredient (generic or biosimilar) is available in the EKO.

With regard to generics, the price of the first generic successor product must be at least 50% below the price of the original branded product whose patent protection has expired. The price of the second generic successor product must be 18% lower than the price of the first successor product, and the price for the third successor product must be 15% lower than the price of the second successor product. The price of the original product must be reduced by at least 30% within three months of the inclusion of the first generic product in the EKO. If there is a third successor product, all other providers must reduce the price to the price of the third product. Additional successors must offer price reductions of at least EUR0.10 in order to be included in the EKO.

With regard to biosimilars, the price of the first successor product must be at least 38% lower than the original product. The price of the second successor product must be at least 15% lower than that of the first successor product, and the price of the third successor product must be at least 10% lower than that of the second successor product. After that, the same regulation applies as for generics (ie, the original product must reduce its price by 30% within three months, etc).

No legal price control mechanisms are available, in principle, for medical devices and IVD devices.

7.2 Price Levels of Pharmaceutical or Medical Devices

The price of a medicinal product can in principle be freely determined by the company authorised to distribute it but is limited by the EU average price of said product (as further detailed in **7.1 Price Control for Pharmaceuticals and Medical Devices**).

No legal price-control/price-setting mechanisms are available, in principle, for medical devices and IVD devices.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Austrian General Social Security Act (*Allgemeines Sozialversicherungsgesetz*, or ASVG) states that, in case of illness, the insured person is entitled to health treatment comprising the provision of remedies (*Heilmittel*) – a term that includes medicinal products, in particular. According to the ASVG, the medical treatment must be sufficient and appropriate, but it must not exceed the extent of what is necessary.

Austria is one of the few EU countries in which the costs of reimbursable medicinal products prescribed by a physician are, in principle, covered in full for the patients insured in the public insurance system. Patients only have to pay a flat fee ("prescription fee") in pharmacies. Exemption from the prescription fee is possible under certain conditions.

Medicinal products that have been included in the EKO can be prescribed at the expense of the health insurance institutions (see **7.1 Price Control for Pharmaceuticals and Medical Devices**). Other medicinal products are only reimbursed in medically justified individual cases.

Regarding medical devices and IVD devices, no system comparable to the EKO exists. The Austrian Social Security Act does not refer to "medical devices" as such but to *Heilbehelfe* and *Hilfsmittel* (therapeutic aids), which are reimbursed – subject to a 10% deductible (or a current minimum of EUR39) – if they are prescribed by a physician. Typically, medical device/IVD device manufacturers sign contracts with the

social insurance institutions in order to avoid the social insurance institutions requesting a cost estimate in advance regarding devices if no contract between the social insurance institutions and the manufacturer is in place.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Any entity authorised to distribute a medicinal product approved and available in Austria may apply for inclusion in the EKO. The medicinal products undergo a pharmacological, medical-therapeutic and health economic evaluation with regard to their eligibility for reimbursement. In this process, the DVB is supported by the Medicines Evaluation Commission (*Heilmittel-Evaluierungs-Kommission*, or HEK), an independent advisory body that is not bound by instructions. The HEK's recommendations form the basis of the DVB's decisions.

The EKO is divided into three areas (known as "boxes").

- The Green Box contains medicines that the health insurance institutions reimburse to the socially insured without special authorisation. These are freely prescribable.
- The Yellow Box includes those drugs that the social insurance institutions consider to have a significant additional therapeutic benefit for patients, but which were not included in the Green Box for medical or economic reasons. For these medicines, health insurers reimburse the insured if the prescription has been approved by their chief medical office (dark yellow area RE1). In some cases, a retrospective control is also accepted (light yellow area RE2).
- The Red Box contains medicinal products for a limited time while the company's request for inclusion in the EKO is being reviewed. During this period, the costs are covered only if there is approval from the chief medical office of the social insurance institutions.

Finally, even the so-called "no-box" medicinal products – ie, products for which no application has been made to be included in the EKO – can be reimbursed if the individual prescription has been approved by the chief medical office. As this option is usually chosen for very expensive medicines, the Austrian legislator has introduced a requirement that the EU average price shall be relevant to these products if turnover exceeds EUR750,000 (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

Changes within the boxes and deletions from the EKO are possible both at the request of the company authorised to distribute the product and the DVB (supported by the HEK's recommendations).

If the social insurance institution refuses reimbursement in an individual case, the patient can file an action before the civil courts (in social law matters). In these proceedings, the court reviews the social insurance institution's decision typically with the help of a specific expert and is entitled to decide on the reimbursement. The court's decision may be challenged before the Higher Regional Court and, eventually, before the Supreme Court.

Regarding medical devices and IVD devices, no system comparable to the EKO exists. For reimbursement of medical devices and IVD, see **7.3 Pharmaceuticals and Medical Devices: Reimbursement from Public Funds**.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Essentially, retailing of medicinal products may only be made by pharmacies. Medicinal products requiring prescription may only be provided to patients upon prescription by a physician.

So far, the aut idem rule has not been implemented into Austrian law. Pharmacists are required to dispense to the patient the actual medicinal product prescribed (even if, for example, a generic product is available). The pharmacist can only offer the patient a pharmaceutical equivalent if the prescribed product is not available in the pharmacy.

Medical devices and IVD devices are not pharmacy-only products.

8. Digital Healthcare

8.1 Rules for Medical Apps

For medical apps that qualify as medical devices, the MPG as well as the MDR constitute the major regulatory framework.

Software (including apps) qualifies as a medical device if:

- it is intended for human use, as determined by the manufacturer;
- it is intended – alone or in combination – to fulfil one or more of the specific medical purposes listed in Article 2(1) of the MDR (see **3.1 Product Classification: Pharmaceutical or Medical Devices**); and
- it does not achieve its principal intended action by pharmacological, immunological or metabolic means – in or on the human body – but may be assisted in its function by such means.

Guidance on the qualification and classification of software in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 is provided in the "MDCG 2019–11".

In addition, medical apps may also be qualified as an "accessory of a medical device", according to Article 2(2) of the MDR. An accessory of a medical device is "an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)".

8.2 Rules for Telemedicine

The term "telemedicine" is not defined by Austrian law. The Ministry of Health defines "telemedicine" as the provision or support of healthcare services using information and communication technologies, where either the patient and healthcare provider or two different healthcare providers are not present at the same location.

The legal permissibility of telemedical services must be assessed on the basis of Section 49, paragraphs 1 and 2 of the Austrian Physicians Act 1998 (*Ärztegesetz*, or ÄrzteG), according to which the medical profession must be practiced lege artis and "directly and personally". These obligations are also contained in the professional laws of the non-physician healthcare professions – for example, in the Austrian Health Care and Nursing Act (*Gesundheits- und Krankenpflegegesetz*, or GuKG). In the absence of specific rules governing telemedicine, the permissibility of telemedical applications in an individual case needs to be judged on the basis of whether the physician can obtain all the infor-

mation necessary to clarify the state of health via the digital channel and whether the requirements of Section 49 of the ÄrzteG are therefore fulfilled.

According to the current specifications of the Austrian Health Insurance Fund (*Österreichische Gesundheitskasse*, or ÖGK), which is the largest Austrian health insurance fund, telemedical services may only be reimbursed if the patient concerned has already been treated personally by the specific physician conducting the telemedical service.

Further, as regards the applicable legal framework for telemedicine from a data protection point of view, the GDPR, the DSG and the Austrian Health Telematics Act 2012 (*Gesundheits-Telematikgesetz*, or GTelG) must be observed.

8.3 Promoting and/or Advertising on an Online Platform

There are no special regulations for the promotion and advertising of medicinal products and medical devices on online platforms available in Austria. Therefore, the general requirements and restrictions (eg, prohibition of lay promotion for prescription-only medicinal products or medical devices) as set out in the AMG (for medicinal products) or in the MPG and MDR/IVDR (for medical devices/IVD devices) apply.

8.4 Electronic Prescriptions

Every person insured in the Austrian public social insurance system receives an "e-card", which provides information regarding the health insurance coverage of the respective person. Austria further provides for an optional, free-of-charge central digital health solution known as the Electronic Health Record (*Elektronische Gesundheitsakte*, or ELGA).

Electronic prescription (*e-Rezept*) is available in Austria for prescriptions issued for medicinal products at the expense of the social insurance institutions. These are no longer issued on paper, but electronically, and saved in the e-card system. The respective medicinal product can be collected at the pharmacy either with the e-card or the respective e-prescription code or the e-prescription ID. Paper prescriptions are still used for medicinal products that are not reimbursed by the social insurance institutions.

Electronic medication (*e-Medikation*) is an optional, free-of-charge application of ELGA that can be used to prevent unwanted interactions and multiple prescriptions of medications. Physicians and pharmacists thus have a better overview of which medications have been prescribed and dispensed for a patient. Patients can opt out of ELGA and e-Medikation.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicinal products is only permitted for pharmacies complying with the requirements set forth in the AMG and the corresponding Distant Selling Ordinance (*Fernabsatz-Verordnung*). The Ordinance sets out the quality criteria for pharmacies to comply with if they wish to sell medicines via the internet.

The pharmacies willing to engage in online sales need to be registered with the BASG for this purpose. Only OTC medicinal products may be sold online; the online sale of medicinal products requiring prescription is not permitted.

The online sale of medical devices/IVD devices is subject to the provisions set forth in Article 6 of the MDR/IVDR – in particular, medical devices distributed via online channels must comply with all obligations set out in the MDR.

8.6 Electronic Health Records

In Austria, ELGA is operated as a central electronic health record (see **8.4 Electronic Prescriptions**). The GTelG contains special regulations for the electronic processing of health data and genetic data by healthcare providers (see Article 4(13) and (15) of the GDPR). In the context of health telematics, a healthcare provider is a professional who – as a controller or processor (as defined in Article 4(7) and (8) of the GDPR) – regularly processes health data or genetic data in electronic form for the following purposes:

- medical treatment or care;
- nursing care;
- invoicing of health services;
- insurance of health risks; or
- exercise of patient rights.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Austrian Patent Act (*Patentgesetz*, or PatG) is applicable in this regard. Medicinal products, medical devices and IVD devices can be protected as patents, in principle, if they fulfil the requirements as set forth in the PatG. There are no special requirements with regard to patents for medicinal products and medical devices. In Section 2 of the PatG, however, it is clarified that no patent protection is available for certain biotechnological inventions (such as cloning) or surgical or therapeutic procedures and diagnostic procedures, owing to ethical and social factors.

9.2 Second and Subsequent Medical Uses

The question of whether a second or subsequent medical use of a known product is patentable must be answered based on the principle requirements for patentability. In practice, the main obstacle to patentability might be the question of whether the subsequent indication is actually new.

New dosage regimes would not be patentable, even if these regimes make the medicinal product more effective. The discovery of the use for new patient populations might only be patentable if the new patient group can be clearly distinguished from the previously known group and therefore regarded as new (and where the use for this patient group is not already covered by the previous patent).

9.3 Patent Term Extension for Pharmaceuticals

An Austrian patent is granted for a maximum of 20 years. The patent holder, however, may apply for a so-called Supplementary Protection Certificate (SPC) to extend a patent for ingredients of medicinal products for up to five years in accordance with Regulation (EC) 469/2009 concerning the SPC for medicinal products (SPCR).

Third parties may challenge the granted SPC on the grounds of invalidity according to Article 15 SPCR, whereby the application must be filed with the Austrian Patent Office (Section 5 of the Austrian Supplementary Protection Certificates Act 1996 (*Schutzzertifikatsgesetz*)). For details of an exemption from SPC protection, see **9.7 Procedures Available to a Generic Entrant**.

Moreover, patented medicinal products that are suitable for use in children (ie, paediatric medicinal products) may be granted six months addi-

tional patent protection upon submission of a Paediatric Investigation Plan (PIP).

9.4 Pharmaceutical or Medical Device Patent Infringement

According to Section 22 of the PatG, the patent owner has the exclusive right to manufacture, place on the market, display or use the subject matter of the invention, or to import or possess it for the aforementioned purposes. Any infringement of that right without the consent of the patent owner constitutes a patent infringement.

However, the effect of the patent does not extend to studies or trials and related practical requirements, if these are necessary to acquire marketing authorisation, approval or registration under medicinal products law (as per the so-called Bolar provision implemented in the PatG in accordance with Directives 2004/27/EC and 2004/28/EC). Given that no marketing authorisation is required, no Bolar provision is available for medical devices.

The scope of protection of the patent is limited to the patent claims in the original patent application (rather than the entire content of the patent or the descriptions, which may nonetheless serve as interpretation guidance). In line with Section 22b of the PatG, the protection of a patent for biological material endowed with certain properties by virtue of the invention covers any biological material obtained from such biological material by generative or vegetative propagation in the same or a different form and endowed with the same properties.

In case of patent infringement, the patent owner is entitled to injunctive relief, removal of unlawful condition, damages/payment, and publication of the judgment. The PatG further provides the opportunity to ask for a preliminary injunction regarding the mentioned claims (except publication).

Injunctive relief may already be sought if the infringement is imminent – ie, if there are reasonable grounds to assume that the third party will interfere with the patent rights in the near future.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

As mentioned in **9.4 Pharmaceutical or Medical Device Patent Infringement**, studies, trials, and the resulting practical requirements therefrom are excluded from the effects of the patent as long as they are necessary for acquiring marketing authorisation, approval or registration under medicinal products law. The PatG does not otherwise differentiate between actual products that can be protected by a patent and, as such, does not contain any rules specific to medicinal products (with the above-mentioned Bolar exemption) or medical devices.

The defendant in a patent infringement case will typically try to claim that the patent in question is null and void – for example, that the patent was granted in error because the invention was not new or is not patentable.

According to Section 36 of the PatG, the owner of a newer patent can claim a licence to a prior third-party patent – and consequently avoid patent infringement – if the newer invention constitutes an important technical progress of considerable economic significance and cannot be realised without such licence. In case the patent owner of the older patent refuses to grant such licence, the Patent Office can decide upon the licence grant (including an appropriate remuneration therefore) upon application of the patent owner of the younger patent.

The PatG further provides for compulsory licences in the context of plant variety rights, in case of public interest (see **11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments**) or because the third-party patent-holder is not exercising its patent invention in Austria accordingly.

9.6 Proceedings for Patent Infringement

In Austria, the patent-owner and the exclusive licensee may file a patent infringement action. The exclusively competent court for patent infringement cases is the Vienna Commercial Court (*Handelsgericht Wien*) – the decision of which may be challenged before the Higher Regional Court Vienna (*Oberlandesgericht Wien*) and, ultimately, before the Supreme Court (*Oberster Gerichtshof*).

The remedies available include claims for injunctive relief, removal of unlawful condition, damages/payment and accounting, and publication of the judgment.

In cases where the defendant claims that the allegedly infringed patent is null and void, the court may assess that question at its own discretion in the first instance and can suspend the proceedings if it regards the nullity to be likely. In such cases, the defendant must file a revocation action with the Patent Office within one month; otherwise, the court decides without further considering such defence.

9.7 Procedures Available to a Generic Entrant

Generic medicinal products can be approved in a related approval procedure if there is no patent or document protection and can be offered on the market after the patent of the original product has expired. Owing to the aforementioned Bolar provision (see **9.4 Pharmaceutical or Medical Device Patent Infringement**), studies or trials necessary to acquire marketing authorisation, approval or registration under medicinal products law do not infringe patent law and may therefore be carried out even though the patent is still in force.

Since 2019, an exemption from the SPC protection – starting six months before the SPC expires – is available for the generic production for the purpose of exporting and for generic production and storage for the first placing on the market in the EU. National patent offices must be informed about the production. An EU export logo (as applicable) must be indicated on the outer packaging for exports to third countries.

No patent linkage is in place – ie, the authorisation procedure for medicinal products and medical devices does not take patent protection into account.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Medicinal products and medical devices/IVD devices – in particular, their names, design and packaging – might be subject to trade mark, design or (eventually) copyright protection. Trade mark and design protection requires an application and registration, whereas copyright protection is granted from the date the copyrighted work is created.

In case the name, design or packaging is subject to such protection, the Austrian Trade Mark Act (*Markenschutzgesetz*, or MSchG), Design Act (*Musterschutzgesetz*, or MuSchG) and Copyright Act (*Urheberrechtsgesetz*, or UrhG) essentially provide for claims for injunctive relief, removal

of unlawful condition, damages/payment, and publication of the judgment. Furthermore, trade mark, design and copyright infringement may even be criminally sanctioned (as a private prosecution offence). The laws provide for sanctions of imprisonment of up to two years or monetary fines of up to 360 daily rates.

In addition to the remedies provided under the respective IP laws, Regulation (EU) 608/2013 enables the right-holder of products protected by specific IP rights (trade marks, designs, patents, SPC) to prevent counterfeit products from being imported. The respective right-holder can request the customs authorities to detain products believed to infringe the right-holder's IP rights for further examination.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

As a general rule, medicinal products may not be marketed under names that are misleading, particularly with regard to the efficacy and safety of the product (Section 6 of the AMG).

Furthermore, the EMA has issued the "Guideline Regarding the Acceptability of Names for Human Medicinal Products Processed Through the Centralised Procedure". The BASG issued a similar guideline for nationally approved medicinal products ("Guideline on the Designation of Medical Specialties", version 9/2021).

As per the AMG for medicinal products, both the MDR and the IVDR prohibit in their (respective) Article 7 the use of any trade mark, name or text in the labelling, instructions claims, marketing and promotion if it could mislead the patient regarding the medical device's or IVD device's intended purpose, its safety or performance.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress, design and packaging of medicinal products and medical devices may be protected by copyright and design rights – and, potentially, as trade marks – if the requirements for such protection are met and protection is sought for trade mark or design.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity (or dossier protection) is relevant for innovative (original) medicinal products. According to the data exclusivity rules, a generic applicant may not refer to the documents of an original medicinal product until eight years after the first approval of the original product in the EU. The generic product may be marketed for the first time only after a further two years (ie, after ten years in total) – this is known as the "8+2 rule". If the marketing authorisation holder of an original product expands the authorisation to a new therapeutic indication within the first eight years of the first marketing authorisation, the data exclusivity period is extended from ten to 11 years (the "8+2+1 rule") – meaning the generic entry will be delayed for another year.

For medical devices and IVD devices, this is not applicable as no marketing authorisation is required.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The COVID-19 pandemic has resulted in a great number of new provisions in the Austrian legal system, which cannot be depicted in their

entirety in this setting. However, with regard to medicinal products, medical devices and IVD devices, a number of special regulations can be highlighted.

Section 94d of the AMG provides for an authorisation of the Federal Minister of Health to establish complementary regulations to the general provisions of the AMG by ordinance in the case of epidemics and pandemics, if the necessary supply of the population is seriously and substantially endangered and as long as special regulations are necessary owing to the specific situation. While this authorisation has been included in the AMG since 2005, a corresponding provision in the MPG was only introduced during the pandemic (now Section 81 of the MPG). The validity of such ordinances was initially limited to a maximum of six months and is now limited to a maximum of one year.

On the basis of these provisions, a number of implementing ordinances have been issued in recent years, including an Ordinance on Provisional Measures to Ensure the Availability of Medical Devices (*Verordnung betreffend vorläufige Maßnahmen zur Sicherstellung der Verfügbarkeit von Medizinprodukten*, or VVMP), as well as several COVID-19 Medical Device Ordinances (*COVID-19 MedizinprodukteV*) and COVID-19 Medicinal Products Ordinances (*COVID-19 ArzneimittelV*). The special regulations contained therein concerned, in particular, the following aspects:

- marketing of medicinal products beyond the expiry date under certain conditions (eg, demand of the Austrian population cannot otherwise be met, no alternative medicinal products available, and exclusive use in hospitals);
- special requirements for clinical trials (see **11.2 Special Measures Relating to Clinical Trials**);
- measures to ensure the supply of medical oxygen (eg, filling in cylinders not approved for medical purposes);
- dispensing of medicines to emergency hospitals by public pharmacies and hospital pharmacies;
- separation of commercial packs by pharmaceutical wholesalers when dispensing COVID-19 vaccines to local authorities and by pharmacies when dispensing free COVID-19 antigen tests for self-use;
- allocation of medicinal products for treatment and prophylaxis against COVID-19 in the intramural sector;
- dispensing of syringes and needles for COVID-19 vaccination with English labelling and instructions for use to users;
- deviations from the inspection periods for periodic inspections and metrological controls under the Medical Devices Operator Ordinance (*Medizinproduktebetreiberverordnung*);
- placing on the market of non-CE-marked medical face masks (see **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**); and
- reprocessing of medical face masks.

Also worth mentioning is the Austrian Law on the Placing on the Market of Oral-Nasal Quick-masks during the Corona COVID-19 pandemic (*Bundesgesetz über das Inverkehrbringen von Mund-Nasen Schnellmasken während der Corona COVID-19-Pandemie*, or MNSM-G) enacted in 2020, as well as Section 113b of the former MPG and – prior to that – Section 323, paragraph 18 of the Austrian Federal Tax Code (*Bundesabgabenordnung*, or BAO) (see **11.2 Special Measures Relating to Clinical Trials**).

As of 1 January 2023, most of the special regulations mentioned are no longer in force.

11.2 Special Measures Relating to Clinical Trials

With regard to clinical trials of medicinal products, medical devices and IVD devices, the implementing ordinances mentioned in **11.1 Special Regulation for the Commercialisation or Distribution of Medicines and Medical Devices** provided certain special regulations. The provisions of the AMG and MPG – according to which clinical trials/investigations/performance studies may not be conducted on persons who are detained by order of the authorities – should not apply to specific detentions in connection with COVID-19 (eg, participants in home quarantine). However, data from clinical investigations of medical devices and performance studies on such persons could only be used for the purposes of that specific investigation/study.

Guidelines for ongoing clinical trials have been provided at EU level, including "Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic" and "Implications of Coronavirus Disease (COVID-19) on Methodological Aspects of Ongoing Clinical Trials". Supplementary information on clinical trials in Austria – for example, regarding direct shipping of trial medication to trial subjects by the trial site, conducting remote audits and remote monitoring visits, access to hospitals for the purpose of monitoring – can be accessed on the BASG website.

Furthermore, applications for approval of clinical trials or Compassionate Use Programmes in relation to COVID-19 treatments were prioritised by the BASG.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

With regard to medicinal products, Article 14-a of Regulation (EC) 726/2004 provides for a legal opportunity to obtain a "conditional marketing authorisation" if certain requirements are met. Specifically, the product in question must fulfil an unmet medical need, its benefit–risk balance must be positive, it must at least be likely that the applicant will be able to provide comprehensive data post-authorisation, and the benefit of the product's immediate availability must outweigh the risk incurred by the fact that additional data is still required. The marketing authorisation holder must meet special obligations after the authorisation has been granted. The validity of a conditional marketing authorisation is one year, with the opportunity for annual renewal. During the pandemic, this procedure was applied in connection with the available COVID-19 vaccines and treatments.

The conditional marketing authorisation procedure is to be distinguished from that of the "marketing authorisation under exceptional circumstances" pursuant to Article 14, paragraph 8 of Regulation (EC) 726/2004. Such authorisation may be issued under exceptional circumstances if, for objective reasons, comprehensive data cannot be obtained even post-authorisation. In addition, Article 14, paragraph 9 of Regulation (EC) 726/2004 provides for the opportunity to request an accelerated assessment procedure if a medicinal product is highly in the interest of public health.

It should also be mentioned that Section 8, paragraph 1(4) of the AMG permits placing on the market in Austria even without a marketing authorisation if a medicinal product is to be used for the prevention of – or in connection with – a dangerous situation arising from a disaster and

success in this respect cannot be achieved with an authorised and available medicinal product. However, although this is an emergency regulation, it does not lead to (accelerated) approval. Once the conditions are no longer met, the product may no longer be placed on the market without a marketing authorisation.

In the course of the COVID-19 pandemic, special regulations were implemented to ensure the sufficient availability of protective masks for a restricted period of time. The VVMP and the MNSM-G stipulated certain conditions under which protective masks without CE marking could be placed on the market in Austria. Under the conditions set out in Section 113b of the former MPG (Section 323, paragraph 18 of the BAO), COVID-19 rapid tests could be used for self-testing, even though they have not previously been placed on the market for such purpose by the manufacturer.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

In light of the difficulties arising from COVID-19, GMP certificates for sites (as well as time-limited manufacturing and import authorisations) have been automatically extended until the end of 2023.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

At the EU level, several implementing regulations were adopted during 2021 that required an export authorisation for the export of vaccines against SARS-related coronaviruses and for the export of active substances used for the production of such vaccines. These have expired in the meantime. Subsequently, Commission Implementing Regulation (EU) 2021/2071 was adopted, thereby requiring export surveillance for such products since 1 January 2022 and for a period of 24 months thereafter.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The GTelG, which regulates the electronic transmission of health data and genetic data by healthcare providers, included temporary provisions until 30 June 2022 in order to combat the spread of COVID-19. These provisions facilitated identity verification of patients in the context of remote prescriptions.

For more on the possibility of remote management and conduct of clinical trials, see **2.4 Restrictions on Using Online Tools to Support Clinical Trials** and **11.2 Special Measures Relating to Clinical Trials**.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Even before the COVID-19 pandemic, the PatG provided for the possibility of granting compulsory licences to patented inventions in specific cases (see **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**). Pursuant to Section 36, paragraph 5 of the PatG, everyone is entitled to a non-exclusive licence to a patented invention for their business, provided that the granting of the licence is required in the public interest. This also applies to the federal administration, although the latter does not have to prove the operation of a business.

In order to obtain a compulsory licence, the licence applicant must seek to obtain the patent-owner's consent to licence on market terms in the first step (Section 37, paragraph 1 of the PatG). If the patent-owner does not consent to such licence, the Austrian Patent Office decides on the request of the licence applicant, whereup-

on it shall determine an appropriate remuneration for the compulsory licence. In the case of a national emergency or other circumstances of extreme urgency, the licence applicant shall be dispensed of the requirement of seeking the patent-owner's consent first and the Austrian Patent Office may immediately grant a provisional authorisation to use the invention (Section 37, paragraph 3 of the PatG).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

As far as is evident, no liability exemptions for COVID-19 treatments or vaccines have been introduced into Austrian national law during the pandemic. The Vaccine Damages Act (*Impfschadengesetz*, or ISG) outlines the preconditions for a legal claim against the Austrian Federation to compensation for vaccine damages, irrespective of the existence of fault. Applications for compensation of damage caused by COVID-19 vaccinations may also be filed on the basis of the ISG. Moreover, damages can be claimed on the grounds of the general rules of civil law and on the grounds of the Product Liability Act.

11.9 Requisition or Conversion of Manufacturing Sites

As far as is evident, no manufacturing sites have been requisitioned or legally conversed owing to COVID-19 in Austria.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

In April 2020, the COVID-19 Accompanying Procurement Act (*COVID-19 Begleitgesetz Vergabe*) was passed, thereby introducing special provisions regarding "emergency procurements" in connection with COVID-19, deadlines and online negotiation options for procurement procedures, and exceptions to the opposition procedure in the context of procurements. However, such simplifications related to procurement procedures are expected to expire on 30 June 2023.

A specific provision regarding procurement was also introduced in Section 741 of the ASVG. According to this provision, the ÖGK is obliged for the duration of the COVID-19 pandemic (as declared by the World Health Organization) to procure the products necessary for the provision of services by professionals (eg, physicians, pharmacists, midwives and dentists) and to make such products available to the respective statutory or professional interest groups for distribution, unless a regional authority takes over the procurement. The ÖGK may use the services of the *Bundesbeschaffung GmbH* for this purpose. This provision is applicable with regard to the following "necessary products":

- respiratory protection masks;
- disposable aprons, protective gowns, and coveralls;
- total face protection (face shield) and protective goggles;
- surgical gloves, surgical overshoes, surgical face masks and surgical bonnets;
- examination gloves (sterile and non-sterile);
- disinfectant (surface, hands, instruments); and
- hygiene protection kits.

The distribution of the protective equipment to the individual service providers must be carried out by the statutory or professional interest groups. In the event that the reported needs cannot be fully covered, the ÖGK may distribute the products to the statutory or professional interest groups on a pro rata basis. The Austrian Federation will reimburse the ÖGK for the reported actual costs for the procured products,

as well as the costs for the necessary logistics and warehousing from the COVID-19 crisis management fund.

BELGIUM

Trends and Developments

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QUINZ is a boutique life sciences law firm, offering top-tier transactional and advisory services to pharma, biotech, medtech and digital health companies and investors. Its team has over 15 years of expertise in sector-specific regulatory matters, strategic transactions (M&A, licensing, investments and divestments), as well as R&D/supply chain operations. QUINZ is ranked among the best life sciences firms in Europe and its sector focus is truly unique in the legal landscape. QUINZ is based in Brussels and offers its services EU-wide.

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Introduction

In 2022, the European legislature worked diligently to further develop the European Pharmaceutical Strategy proposed in late 2020. As the pandemic appeared to lose vigour in 2022, European and national policy makers and authorities could switch from "firefighting" to taking effective steps to further develop the outlines announced at the end of 2020, thereby implementing lessons learned during the crisis.

Firstly, providing continued access to qualitative, innovative, effective and affordable treatments remains high on the agenda. In addition, the need to ensure competitiveness of the European biopharmaceutical industry and turning the sector "greener" and more sustainable are key drivers of the legislative reform. Evidently, these are also the issues that have kept Belgian authorities and policymakers up. Below, we highlight a number of Belgian developments and initiatives that are closely related to these themes and that were on the agenda in 2022.

Accessibility, Availability and Affordability

Ensuring rapid access to novel therapies remains one of the main concerns of policymakers and health authorities. Encouraging innovation is one thing, but at least as important is ensuring that these innovative therapies are subsequently accessible to patients, and this, on a continued basis.

Primarily, this means ensuring that the price tag of novel therapies does not prevent these treatments from becoming a "real" option for patients upon approval. Unfortunately, European figures collected by EFPIA evidence that this remains a sore point, as only half of the therapies approved between 2017 and 2020 by the EMA

had received a (positive) reimbursement decision in Belgium by 2022.

The concern towards affordability is all the more acute given the increasing personalisation and complexity of new therapies often resulting in a high price tag. Unsurprisingly, policymakers are constantly looking for measures to control spending on expensive medicines without compromising the quality of care. Compulsory licences are, as in other European member states, put forward by Belgian policymakers as a potential instrument to bring expensive drugs to the market at a lower price.

In that light, the Belgian Knowledge Center for Economy (KCE) was asked to study the feasibility of the mechanism of compulsory licences as a means of ensuring access to expensive therapies. (Van Zimmeren Esther, Minssen Timo, Paemen Liesbet, Van Dyck Walter, Luyten Jeroen, Janssens Rosanne, Barbier Liese, Simoens Steven, Pouppez Céline, Cleemput Irina, Vinck Imgard. *Compulsory licensing for expensive medicines*. Health Services Research (HSR). Brussels. Belgian Health Care Knowledge Centre (KCE). 2022. KCE Reports 356. DOI: 10.57598/R356C. English). The study shows that the current legislative framework for compulsory licensing of patent rights is ill-suited to ensure affordable access to medicines as it disregards a number of other existing legal obstacles (such as regulatory data and market exclusivities and the protection of know-how). In addition, the report highlights that the use of compulsory licences could potentially have counterproductive effects in terms of investments in research and development, clinical research, production capacity and competitive position... (also an important pillar of the current pharmaceutical policy goals). The key takeaway is that compulsory licences to make medicines accessible should only be used in exceptional circumstances and as part of a broader toolbox of possible instruments that can contribute to the affordability of medicines. A focus on developing robust, transparent and coherent policies around pricing and reimbursement remains key to ensure the affordability of medicines, according to KCE.

At least as important as ensuring initial access to therapies is ensuring availability on a continued basis. Unavailability of medicinal products was definitely one of the sore points revealed during the pandemic. However, at the end of 2022, the shortages experienced by Belgian pharmacists made the news again, when almost 300 medicines were officially unavailable, according to figures from the Belgian health authority. Not surprisingly, the Belgian legislature continued to work on measures to tackle future unavailability. The result was presented in early 2023, in the form of a Royal Decree which formalises the possibility of introducing an export ban in certain situations of unavailability. The far-reaching measure can only be used for medicines of which the administration is urgent and necessary and has a major impact on the patient's life and for which no other authorised medicines with the same therapeutic effect are available.

Ensuring access to healthcare is not limited to ensuring access to medicinal products. In early 2022, Belgium's Health Minister announced that a new inter-federal plan for integrated healthcare is being developed. The Minister believes that the current organisation of the Belgian healthcare system is designed for the management of acute diseases rather than focusing on multidimensional care which is needed to manage chronic conditions. The Interfederal Integrated Care Plan is expected to be presented in early 2024. Several preparatory steps were already taken in 2022: KCE was asked to prepare a

report on the state of integrated care in Belgium and the formulation of a number of recommendations to that effect, which was published in October of 2022 (Lambert Anne-Sophie, Op de Beeck Susanne, Herbaux Denis, Macq Jean, Rappe Pauline, Schmitz Olivier, Schoonvaere Quentin, Van Innis Anna Luisa, Vandenbroeck Philippe, De Groote Jesse, Schoonaert Lies, Vercruysse Helen, Vlaemynck Marieke, Bourgeois Jolyce, Lefèvre Mélanie, Van den Heede Koen, Benahmed Nadia. *Towards integrated care in Belgium: stakeholders' view on maturity and avenues for further development*. Health Services Research (HSR). Brussels. Belgian Health Care Knowledge Centre (KCE). 2022. KCE Reports 359. DOI: 10.57598/R359C. English). The KCE points to the importance of a co-ordinated approach across policy levels and stresses the importance of revising the current financing mechanisms in healthcare (which today are mainly limited to a fee-per-service system). In the same context, the Belgian National Institute for Health and Disability Insurance also gave green light to further invest in 12 pilot projects for integrated care.

The affordability of less traditional forms of healthcare such as digital health applications has also been a focus of attention in recent years. Belgium took a pioneering role by being one of the first member states to establish an evaluation framework for digital medical applications – ie, the mHealth Belgium validation pyramid process in 2019. However, despite the existing framework, only one application has been reimbursed and only a handful have been evaluated to date. A study published in November 2022 by the Belgian KCE exposes certain bottlenecks in the current Belgian evaluation framework and makes certain recommendations to revise the Belgian evaluation process to create an efficient and streamlined process to ensure the smooth integration of valuable digital medical applications into the country's healthcare practice. (San Miguel Lorena, Obyn Caroline, Vinck Imgard, de Meester Christophe, Jespers Vicky, Pouppez Céline. *Evaluation of Digital Medical Technologies*. Health Technology Assessment (HTA). Brussels. Belgian Health Care Knowledge Centre (KCE). 2023. KCE Reports 362. DOI: 10.57598/R362C. English.)

Fostering Development

Whereas certain disease areas have seen unprecedented progression in the past decade, other less-researched diseases are left without effective cures.

With a view to rapidly developing new, innovative treatments for unmet medical needs, real-world data can complement clinical trials by providing evidence of long-term use of therapies in large and diverse populations. To avoid losing Belgium's frontrunner position for clinical trials, various stakeholders have advocated for the development of a strategy to strengthen Belgium's position with regards to the use of Real World Evidence (RWE). Policy makers have realised that RWE is a crucial tool throughout the entire healthcare decision-making process. In 2021, the Belgian government announced the "#dataforbetterhealth" initiative, including the establishment of an independent Belgian Health Data Authority (BE HDA). In 2022, work continued diligently behind the scenes to set up this independent authority, which is planned to be established in 2023, as an autonomous service within the FPS Public Health.

One of the most surprising "unmet medical needs" today is the lack of development of new antibiotics in recent decades. This is a cause for concern as antimicrobial resistance is put forward as one of the biggest threats to pub-

lic health. Whereas the European legislature is expected to create incentives for companies to develop and commercialise a new effective antimicrobial, Belgium is committed to reducing and improving the use of existing antimicrobials and is doing so through a national action plan, "One Health". In this context, the BELMAP Report was published by the FPS Public Health in early 2023. It contains results and trends from existing monitoring programmes, identifies potential gaps and formulates a number of general recommendations to improve current monitoring. In November 2022, a new awareness campaign was launched in which healthcare professionals are given a central role. In addition, the Belgian health authority also announced that it will take stricter action against illegal antibiotics.

Authorities are not just thinking about developing novel therapies for unmet medical needs. The FAMHP is actively participating in the European pilot project on repurposing medicines. The aim of this project is to support non-profit organisations and academia in collecting or generating sufficient evidence about the use of existing medicines for a new indication. The role of the FAMHP (and other participating national authorities) is to provide regulatory support through scientific advice to develop a robust data package that can support a future authorisation application for a novel indication.

Sustainability

For obvious reasons, sustainability is a topic high on the agenda of each and every policy maker. The Pharmaceutical Regulatory Framework cannot lag behind and one of the focal points of the European restructuring of pharmaceutical regulation is therefore "sustainability". Belgium has not been idle in this regard, with two pilot projects in particular receiving attention in 2022.

- In 2022, the European Commission approved an extension of the e-PIL pilot project until mid-2025. This Belgian-Luxembourg project was initiated in 2018 and allows certain medicines delivered in hospital pharmacies to no longer be accompanied by paper but rather digital prescribing information.
- In addition, Belgian patients are also encouraged to return expired medicinal products to their pharmacist instead of disposing of them at home. Pharmacists work together with wholesalers who collect the expired medicines and proceed to destroy them in a safe way. Pharmaceutical companies bear the cost of such destruction.

Crisis Readiness

One of the harshest lessons from the COVID-19 pandemic was the lack of crisis preparedness of the European member states. In September 2022, the European project BE READY (the European Partnership for Pandemic Preparedness, part of Horizon Europe) was launched to improve the EU's preparedness to predict, prevent and respond to emerging infectious health threats by better co-ordinating funding for research and innovation at EU, national (and regional) levels towards jointly agreed objectives and an agreed strategic research and innovation agenda. The Belgian FPS Public Health is one of the 24 partners of this project.

Digital Health

Finally, the digitalisation of the healthcare sector remains a hot topic since it can offer certain answers to all of the above-mentioned pillars. It can improve the accessibility of healthcare by offering certain services remotely where possible; an important part of innovative therapies will be inextricably linked to digital technologies; and of course, digital health (and especially the remote provision of certain health services) also

means that the ecological footprint of healthcare can be reduced. For a detailed overview of developments in the digital health landscape, see the Belgium Law & Practice Digital Healthcare 2022 chapter.

BRAZIL

Law and Practice

Contributed by:
Henrique Frizzo, Marcela Trigo, Carla Bacchin Fernandes de Moraes Cox and Felipe Zaltman Saldanha
Trench Rossi Watanabe

Contents

Trench Rossi Watanabe has been at the forefront of the life sciences industry in Brazil for more than 60 years. With extensive experience in handling complex corporate transactions, registering regulated products, drug pricing, drafting technology licensing agreements and defining market access strategies, the highly specialised multidisciplinary team helps clients to navigate conflicting regulatory regimes, file and protect patents, conduct clinical trials in order to gain approval for new drugs and products, and comply with rules relating to the collection, use and treatment of patient data. To this end, Trench Rossi Watanabe has an excellent standing with the Brazilian Health Regulatory Agency, the National Research Ethics Commission, the Drug Market Regulation Chamber, the National Supplementary Health Agency, and the Ministry of Agriculture, Livestock and Supply – as well as state health secretariats and municipal health authorities. The firm has a strong presence in litigation involving product liability and unfair competition and participates in the drafting of bills and regulations affecting the industry.

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Henrique Frizzo has been a partner at Trench Rossi Watanabe since 2014 and co-leads the firm's life sciences group. Henrique advises pharmaceutical and medical device manufacturers and other companies in the sector on a wide range of matters, including market access strategies, and represents companies in administrative proceedings before Brazil's Drug Market Regulation Chamber. Henrique prepares consultations on clinical research and regulatory issues, reviews promotional materials, and acts in administrative litigation involving local health authorities and the Brazilian Health Regulatory Agency. Additionally, he provides support in compliance issues and analysis of the constitutionality of legislation. Due to his expertise, Henrique participates in the drafting of bills and regulations that affect the industry.

Marcela Trigo joined Trench Rossi Watanabe in 2014 as a partner in the IP and IT group. She is now head of the firm's life sciences industry and healthcare groups, President of Licensing Executives Society (LES) Brazil, and co-chair of the dispute resolution committee of the Brazilian Association of Intellectual Property. Marcela has extensive experience in legal disputes involving patents, industrial secrecy, protection of confidential data, data package exclusivity, unfair competition and regulatory compliance – particularly in the pharmaceutical, biotechnology and telecommunications areas. She served as an international lawyer in Finnegan's Washington, DC office, where she focused on patent litigation in the bio and pharmaceutical industry.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The pharmaceutical and medical devices sectors in Brazil are regulated and supervised by the National Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA), which is linked to the Brazilian Ministry of Health and part of the Brazilian National Health System (*Sistema Único de Saúde*, or SUS). ANVISA has administrative independence and financial autonomy, in addition to being responsible for the stability of its directors.

Its statutory role is to protect public health by executing sanitary control over the production, importation, distribution, use and commercialisation of a broad range of products (including drugs, cannabis-based products, medical devices, sanitisers, cosmetics, food and tobacco), as well as licensing conditions for health-related companies and healthcare institutions. ANVISA is also responsible for authorising the importation and exportation of products that are subject to health surveillance, governing the sanitary aspects of clinical trials, and defining health standards for pesticides. State and municipal health authorities assist ANVISA in its role.

The core rules on health surveillance in Brazil are Federal Law No 6,360/1976 and the Federal Decree No 8,077/2013.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The Brazilian legal system provides for a minimum of two levels of defence. Usually, regulated company defendants will be able to file a rebuttal with the authority that rendered the decision. If the decision is upheld, the company may file an appeal to the hierarchically superior authority. It is important to highlight that the rules that provide for administrative procedures (eg, Federal Law No 9,784/1999 and local laws) may contain specific provisions and formalities regarding the preparation of appeals and defences. These proceedings have an administrative nature and may be subject to judicial review.

Finally, the Brazilian constitution guarantees the right of access to court for all matters. Therefore, companies may still file a judicial lawsuit to challenge the final decision issued at the administrative level.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Depending on the type of regulated product, the Brazilian regulatory framework can be extremely detailed. The main set of regulations are listed here; however, there are several other rules that may apply, depending on the specifics of the case.

Drugs are currently regulated by the following main resolutions:

- Resolution RDC No 753/2022 – for synthetic drugs (including generic and similar drugs);
- Resolution RDC No 205/2017 – for orphan drugs;
- Resolution RDC No 55/2010 – for biological drugs and biosimilars;
- Resolution RDC No 721/2022 – for dynamised drugs; and
- Resolution RDC No 26/2014 – for phytotherapic drugs.

Cannabis-based products are ruled by Resolution RDC No 327/2019.

The key rules for medical devices are:

- Resolution RDC No 185/2001 – procedures for registration of medical devices;
- Resolution RDC No 751/2022 – procedures for the enrolment of medical devices;
- Resolution RDC No 36/2015 – procedures for registration of in vitro diagnosis medical devices; and
- Resolution RDC No 657/2022 - procedures for regularisation of software as medical device (SaMD).

These rules are updated constantly by ANVISA.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are subject to approval from Committees for Ethics in Research (*Comitês de Ética em Pesquisas*, or CEPs) and, in certain cases, from the National Committee for Ethics in Research (*Comissão Nacional de Ética em Pesquisa*, or CONEP) and ANVISA. CEPs are interdisciplinary and independent collegiate bodies organised by research institutions to defend the interests of research subjects and contribute to the development of research within ethical standards. CONEP is an independent collegiate body under the National Health Council. Its main mission is to analyse the ethical aspects of clinical trials through the evaluation and follow-up of protocols in thematic areas such as genetics, human reproduction, and the storage of biological material or human genetic data abroad. CONEP is also responsible for registering CEPs and for enforcing the duties established by the rules issued by the National Health Council.

ANVISA is responsible for approving the clinical trials and controlling the importation and use of investigational products.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials must be submitted to the CEP for the analysis of its ethical aspects. In some cases, specified in the regulations, the clinical trial dossier must be submitted to CONEP for its approval. Among the documents to be presented with the clinical trial dossier is the informed consent form.

After the protocol is submitted to the CEP/CONEP, an opinion will be issued. If approval is denied, it will be possible to appeal to the CEP and/or CONEP within 30 days. ANVISA's approval must also be obtained if the research involves a pharmaceutical or medical device product.

There is a special expedited procedure to obtain authorisation for performing clinical trials with drugs for rare diseases. The documents needed may vary, depending on whether the investigational product is a drug or a medical device.

2.3 Public Availability of the Conduct of a Clinical Trial

The National Health Council developed an electronic system (*Plataforma Brasil*), which is a national and unified research database involving human beings, for the entire CEP/CONEP system. The system allows one to monitor clinical trials from their submission until the final approval by the CEP and/or CONEP (where necessary). The system also allows the presentation of documents in digital media, providing the population with access to public data from all approved clinical trials. All research protocols

involving human beings must be submitted to the CEP/CONEP system through the platform.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Legislation does not provide for any restrictions for using online tools to support clinical trials.

2.5 Use of Data Resulting From the Clinical Trials

According to Federal Law No 13,709/2018, health data is considered sensitive personal data. Thus, data resulting from clinical trials is considered sensitive. According to Resolution CNS No 466/2012, data obtained from research participants cannot be used for purposes other than those provided for in the research's protocol and/or in the free and informed consent executed by the patient. Thus, any transfer of data to a third party should be provided for in the research's protocol or authorised by the patient through informed consent.

2.6 Databases Containing Personal or Sensitive Data

Resolution CNS No 466/2012 stipulates that data obtained from research participants cannot be used for purposes other than those provided for in the research's protocol and/or in the free and informed consent executed by the patient.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Federal Law No 5,991/1973 defines "medicine" as "any pharmaceutical product – technically built or elaborated – with prophylactic, curative, palliative or for diagnostic purposes". Thus, any product that has therapeutic purposes – regardless of whether they are of vegetable, animal, mineral or synthetic origin – must be considered a medicine.

Meanwhile, according to Resolution RDC No 185/2001, "medical product" is defined "as equipment, devices, materials, articles, or systems for medical, dental or laboratorial use or application, intended for prevention, diagnosis, treatment, rehabilitation, or anti-conception, and that does not use pharmacological, immunological, or metabolic means to fulfil its main function in human beings, but which can have its functions assisted by such means".

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological products are regulated by ANVISA Resolution RDC No 55/2010 that stipulates that there are two types of biologic products:

- "new biological products" (for products not yet registered before ANVISA); and
- "biological products" (for products that are not new or that contain an already known molecule of a biological nature).

Additionally, the regulation establishes two different routes to register biological products:

- "by comparison", which (by definition) "is the scientific comparison – with regard to non-clinical and clinical parameters in terms of quality, efficacy and safety, of a biological product with a comparator biological product – in order to establish that there are no detectable differences in terms of quality, effectiveness and safety between the products"; and
- "by individual pathway", defined as "the regulatory route that may be used for obtain-

ing the registration of a biological product in which it is necessary to present total data on development, production, quality control and non-clinical and clinical data to demonstrate quality, efficacy and safety of the product".

The "by comparison" route is actually the method used for the registration of biosimilars (although "biosimilar" is not an official designation).

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The marketing authorisation for drugs and medical devices is valid for up to ten years. The renewal of both types of marketing authorisation must be requested from 12 months up to six months before the marketing authorisation's expiry date.

A marketing authorisation may be revoked under the following circumstances:

- for a product whose revalidation was not requested within the validity period of the expired registration;
- for a product that is not classified as a drug that has not been industrialised within the validity period of the expired registration;
- for a drug that has not been marketed for at least the time corresponding to the final two thirds of the validity period of the expired registration;
- for failure to comply with the regulations related to the regularisation of the product;
- upon request from the manufacturer; and
- upon request due to transfer of ownership.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

All requests must be forwarded to ANVISA with the required documents. A marketing authorisation application should be submitted with the product's dossier and the technical information of the product (such as clinical data, clinical studies, legal documents and proposed labelling). The same applies for the change of the product's marketing authorisation.

The transfer of a marketing authorisation is allowed. According to Resolution RDC No 102/2016, the transfer procedure will be authorised upon the occurrence of:

- a corporate transaction (merger, spin-off or amalgamation); or
- a commercial transaction that is defined only as a "transaction between companies resulting in the sale of assets or a set of assets, without any corporate transaction between them" (the above-mentioned rule does not exemplify the eligible operations).

The transfer procedure is applicable for tobacco, agrochemicals, medical devices, drugs, cosmetics and foods, subject to a registration procedure before ANVISA (simplified procedures such as enrolment or notifications are not subject to transfer).

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

ANVISA sets out, through Resolution No 38/2013, the types of programmes related to pre-approval access to medicines, as follows:

- expanded access;
- compassionate use; and

- post-study drug supply.

Expanded access comprises the provision of a promising new drug that is:

- still without ANVISA's registration;
- not commercially available in Brazil;
- aimed at a group of patients who are carriers of serious debilitating and/or life-threatening diseases; and
- without a satisfactory therapeutic alternative registered product.

Compassionate use is the provision of a promising new drug that is:

- for the personal use of patients who are not participants of an expanded access programme or of clinical trials;
- without ANVISA's registration;
- in the process of clinical development;
- aimed at patients who are carriers of serious debilitating and/or life-threatening diseases; and
- without a satisfactory therapeutic alternative product registered in Brazil.

Post-study supply relates to the provision of drugs to patients who are the subject of the study. This applies in cases of study termination or when the participation of the patients has been completed. According to Article 4 of Resolution No 38/2013, these programmes must be voluntarily started by the sponsor (manufacturer) or its representative through a formal application to ANVISA (this is applicable for all the aforementioned commercial pre-registration programmes). Approval for compassionate use is granted for each patient on a personal basis and is non-transferrable. ANVISA's approval for Expanded Access is granted for a group of patients.

Finally, there is no formal Named Patient Programme in Brazil. The most similar practice is the importation of the unregistered drug by the patient or by a health institution upon a specific prescription by a physician. In these cases, the costs are borne by the patient – or, in cases where patients file a lawsuit against the government and obtain the right to receive the drug from the government without cost, by the government.

There is no equivalent programme for medical devices.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

According to the current applicable rules, marketing authorisation holders are obliged to comply with either pharmacovigilance or technovigilance obligations. For drugs, it is necessary to implement a traceability system.

Other general ongoing obligations imposed on marketing authorisation holders are as follows:

- to maintain the validity of their permit (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices** for examples of said permits);
- to update the marketing authorisations properly;
- to communicate to ANVISA any changes to the products and, if necessary, obtain the appropriate prior approval; and
- to comply with the promotion of drugs and medical devices in accordance with the requirements of the relevant rules.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties can only have access to information about the administrative procedures provided for on ANVISA's website. ANVISA only discloses the status of the request and the department that is analysing it. Approval or denial is likewise reported in the system.

The protection of the company's commercially confidential information is provided for in Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"): "Members, when requiring – as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities – the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

It is also provided for in Article 195, XIV of the Industrial Property Law (the "IP Law"), as follows: "A crime of unfair competition is committed by he who divulges, exploits or uses, without authorisation, the results of tests or other undisclosed data the elaboration of which involved considerable effort, and which has been presented to government entities as a condition for approving the commercialisation of products."

Federal Decree No 3,029/1999, which approves ANVISA's regulation, provides in Article 30 that ANVISA will treat the technical, operational, economic, financial and accounting information that it requires from the companies as confidential – so long as its disclosure is not directly necessary in order to prevent:

- discrimination against the consumer, producer and service provider; or
- circumstances that pose a risk to the population's health.

3.8 Rules Against Illegal Medicines and/or Medical Devices

According to Federal Law No 6,437/1997, falsified or illegal commercialisation/distribution of drugs and/or medical devices may subject the company to any or all of the following penalties:

- warning;
- seizure;
- destruction and/or interdiction of product;
- the shutting down of facilities; and
- a fine (from BRL2,000 up to BRL1.5 million).

From a criminal law perspective and according to the Brazilian Criminal Code (Article 273), it is a crime to falsify, modify, import, sell, distribute, or offer for sale products for medical and pharmaceutical, cosmetic, therapeutic and diagnostic use. The same criminal prohibition extends to products that are not registered by ANVISA or those that are registered in a different format, products with a reduction in their therapeutic value, or products that are of unknown origin and/or acquired from unauthorised establishments.

Penalties range from ten to 15 years of imprisonment, in addition to a fine. If the offence is committed with negligence, the penalty is a prison sentence of one to three years, and a fine.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

In order to monitor the entry of counterfeit pharmaceuticals and medical devices into Brazil, there are customs checkpoints at ports and airports staffed by ANVISA. If the patent or trade mark owner has knowledge of specific imports, it may also alert customs agents for further enforcement activities. In addition, baggage inspections and special ANVISA operations are carried out by the police at ports and airports, as well as other establishments where irregularities are suspected. Inspections executed by Customs in relation to medicines and pharmaceutical supplies target commercial passenger and cargo flights alike.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Activities related to manufacturing (of drugs and of medical devices) are subject to a health regulatory system. The permits/licences required for the regular operation are as follows:

- an Operating Authorisation (*Autorização de Funcionamento*, or AFE), to be issued by ANVISA;
- a Special Operating Authorisation (*Autorização Especial*, or AE), to be issued by ANVISA if the company performs activities using products subject to special control;
- an Operating Licence (*Licença de Funcionamento*, or LF), to be issued by local municipal or state health authorities; and
- a Good Manufacturing Practices Certificate (GMP Certificate), if applicable, to be issued by ANVISA.

Note that the AFE and the AE are not subject to renewal. However, the LF is subject to renewal within a period defined in the legislation issued by the local health authority (usually one year). Additionally, the inspections in the company's premises are performed by the local health authority every time the LF is up for renewal and at any time for a periodic supervision.

A GMP Certificate is valid for two years and is required for drug manufacturers and manufacturers of medical devices framed in class III or IV.

The procedure for obtaining the licences is as follows:

- the company should obtain approval from the Technical Evaluation Panel (*Laudo Técnico de Avaliação*, or LTA) after the analysis of the architectural project of the premises;
- the company will be able to apply for the LF after obtaining approval from the LTA;
- the company will undergo an inspection and the authority will issue its report;
- the company may apply for the AFE following a favourable report from the local health authority;
- ANVISA will analyse the report and, if it determines that the company's premises comply with the legislation, the AFE will be published in the Official Gazette;
- the company may request the issuance of the LF upon publication of the AFE; and
- the company may thereafter apply for the registration of the products and for a GMP Certificate - the approval of the latter will be published in the Official Gazette.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in the wholesale of pharmaceutical and medical devices are subject to a health regulatory system. The permits/licences required for the regular operation can be summarised as follows:

- the AFE is to be issued by ANVISA;
- the AE is to be issued by ANVISA for a company that performs activities using products that are subject to special control; and
- the LF is to be issued by local municipal or state health authorities.

For more on renewal procedures for the AFE, AE and LF, please see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**.

5.2 Different Classifications Applicable to Pharmaceuticals

The classifications that apply to pharmaceuticals in Brazil are as follows:

- OTC; and
- drugs subject to medical prescription:
  (a) red stripe – drugs subject to a prescription;
  (b) red stripe – controlled drugs subject to a prescription and that require the retention of a medical prescription; and
  (c) black stripe – controlled drugs subject to a prescription and that require the retention of a medical prescription.

The difference in the classification is related to the drugs' risk level, according to the relevant rules.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

Resolution RDC No 81/2008 issued by ANVISA is the main regulation governing the importation and exportation of pharmaceutical and medical devices. Note that specific rules may apply, depending on the category of the product (eg, biologics). The importation and exportation of these devices is also subject to the Federal Revenue's regulation.

ANVISA is the entity responsible for applying and enforcing such rules, as they are physically present at Brazilian ports, airports and borders (as mentioned in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**).

6.2 Importer of Record of Pharmaceutical and Medical Devices

In general, marketing authorisation holders of pharmaceuticals and medical devices and their authorised companies can act as the importer of record of pharmaceuticals and medical devices. Note that marketing authorisation holders may authorise duly licensed third parties to import regulated products directly.

The product to be imported must be also registered – or, where applicable, enrolled – before ANVISA. Exceptions apply in the case of investigational products.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Companies that import pharmaceuticals and medical devices must obtain the AFE or the AE for importation issued by ANVISA and obtain the prior approval of ANVISA via registration of the importation request in the Federal Revenue's import/export system, Siscomex. Exceptions may apply in specific cases, such as in the importation of pharmaceutical or medical devices by individuals for their own use. In this case, the AFE/AE and the prior approval of ANVISA are not required. The procedures are also somewhat different for products imported in the context of clinical trials.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

As a rule, non-tariff regulations and restrictions are imposed based on the tariff classification under the Common Nomenclature of Mercosur (NCM). The list of products subject to control are usually provided in the legislation issued by the relevant regulatory agencies. For ease of reference, the federal government regularly publishes a list of the NCM codes that are subject to importation licences on its Foreign Trade website.

6.5 Trade Blocs and Free Trade Agreements

Besides Mercosur, Brazil has free trade and complementary economic agreements with Bolivia, Chile, Colombia, Cuba, Ecuador, Egypt, India, Israel, Mexico, Panama, Peru and Venezuela. The trade facilitations depend on the agreement and on the type of products. However, there is still no regulatory harmonisation.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of drugs are regulated in Brazil by the Drugs Market Regulation Chamber (CMED) that, based on certain criteria, analyses the prices proposed by the companies as part of the registration process. The prices are regulated for different links of the supply chain:

- the ex-factory price (*Preço Fábrica*, or PF) is the maximum price allowed for the commercialisation of a drug to pharmacies, drugstores and public administration entities; and
- the Maximum Price for the Consumer (*Preço Máximo ao Consumidor*, or PMC) is the maximum price allowed for commercialisation of a drug to the final consumer.

The CMED also defines the Maximum Price for the Government (*Preço Máximo de Venda ao Governo*, or PMVG), which is a mandatory discount on the PF and is applicable to sales to the government when the drug to be purchased is must comply with a court order or in cases where the drug is listed in the CMED's Notice (*Comunicado*) No 3/2020. In all other sales to the government that do not fall under those situations, the company must at least observe the PF.

It is important to clarify that not all drugs have their prices regulated - for example, some OTC drugs are not subject to this regulation.

Prices of medical devices are not regulated by ANVISA. However, certain economic information about prices is required by ANVISA whenever a company intends to register or renew the registration of a product.

7.2 Price Levels of Pharmaceutical or Medical Devices

In order to determine the maximum price of the drug, companies must submit economic data on the product and propose a suggested price. The rationale to establish the maximum PF will depend on the category of the drug. New drugs cannot exceed the lowest price charged between the following nine countries: the USA, New Zealand, Australia, Greece, Portugal, Italy, Spain, France and Canada. Generic drugs cannot exceed 65% of the price of the corresponding reference drug. For drugs with a new presentation, the price cannot exceed the arithmetical average prices of the presentations of medicines marketed by the company with the same concentration and pharmaceutical form. Medical device companies must present similar information for certain medical devices (as defined by ANVISA); however, it is used for monitoring the market, not for defining price levels.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Brazilian Federal Constitution of 1988 determines that health is the right of all and a duty of the State. Brazil has a public healthcare system (SUS) funded by the government and this provides free and universal coverage. The universality extends to drugs and therapies. As such, all individuals have the right to receive drugs and medical devices free of charge, whenever they cannot afford it.

In view of this, the government has established the Clinical Protocol and Therapeutic Directive (*Protocolos Clínicos e Diretrizes Terapêuticas*, or PCDT) in order to define the products/procedures that may be provided for individuals by the public healthcare system. There are public pharmacies where the individuals may acquire some of these products free of charge, and there are public hospitals that may provide the products/procedures. Moreover, the SUS provides financial support to private health institutions through financial grants and the reimbursement of medical procedures, devices, and drugs upon agreement between the private entity and the Ministry of Health. The reimbursement values and covered procedures and therapies are formally listed.

In 2020, the Supreme Court decided that:

- the State cannot be obliged to provide experimental drugs;
- the absence of registration with ANVISA generally prevents the supply of the drug by court decision;
- actions demanding the supply of drugs without registration with ANVISA must necessarily be brought against the Union; and
- it is possible, exceptionally, for a court to grant a drug without sanitary registration in the case of an unreasonable delay by ANVISA in reviewing the request (term exceeding that provided for in Law No 13.411/2016), when three requirements are met:
  - (a) the existence of a registration request for the drug in Brazil (except in the case of orphan drugs for rare and ultra-rare diseases);
  - (b) the existence of the registration of the drug in renowned regulatory agencies abroad; and
  - (c) the absence of a therapeutic substitute with registration in Brazil.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The main regulation determining the rules for price registration is the CMED's Resolution No 2/2004. According to this rule, the price depends

on the assessment of the improvement to the treatment in relation to pharmaceuticals already used for the same therapeutic indication. There is no cost-benefit analysis.

The cost-benefit is analysed by the Ministry of Health in order to include a drug list of products supplied by the SUS – with the support of the National Commission for Incorporation of Technologies in the SUS (*Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde*, or CONITEC), a multidisciplinary body composed of government representatives and civil society members – with advisory attributions related to the incorporation, exclusion or alteration of health technologies supplied by the SUS, as well as in the constitution or alteration of the PCDT. The analysis of the incorporation in the SUS list includes a cost-benefit assessment but does not impact the prices registered with the CMED.

A similar analysis is made by the National Supplementary Health Agency (*Agência Nacional de Saúde Suplementar*, or ANS), which is responsible for the regulation of private health insurance plans and for defining the covered products and events. Recently, Federal Law No 14,307/2022 was published, aimed at increasing the scope of coverage in the context of supplementary health and ensuring, for example, that the technologies evaluated and positively recommended by CONITEC (whose decision to incorporate the technology in the SUS has already been published) will be included in the list of procedures and events covered by the scope of supplementary health within 60 days. Another important provision refers to the deadline for the ANS to conclude the analysis on the incorporation of new procedures, which must be within 180 days. If the analysis is not completed by the ANS, the procedure will be of mandatory coverage until the ANS' decision is issued – thereby guaranteeing the continuity of the initiated assistance, even if ANS' decision is unfavourable to the incorporation.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Prescriptions by physician are regulated by ANVISA and by the Medical Council through Resolution No 2,217/2018 and the Medical Code of Conduct.

With regard to dispensation by pharmacies, the main legal frameworks are:

- Federal Law No 5,991/1973, which defines and regulates the sanitary control of drug stores and pharmacies; and
- Federal Law No 13,021/2014, which classifies pharmacies as health establishments and defines the responsibilities of the owners and technical responsibility.

There are also other rules issued by ANVISA that are extremely important for the business, such as Resolution RDC No 275/2019 (which provides the AFE and AE necessary for the pharmacies' operation) and Resolution RDC No 44/2009 (which provides Good Pharmaceutical Practices for the sanitary control of the functioning, dispensing and commercialisation of products and the provision of pharmaceutical services in pharmacies and drugstores).

8. Digital Healthcare

8.1 Rules for Medical Apps

In order to keep up with scientific and technological advances in the healthcare sector, Resolution RDC 657/2022 recently came into force, which provides for the regularisation of SaMD.

SaMDs must be registered with ANVISA and are defined as "software that meets the definition of medical device, which may be in vitro diagnostic (IVD) or not, intended for one or more medical indications, and that accomplishes these purposes without being part of medical device hardware". Mobile applications, software to be used for in vitro purposes and software licensed on a subscription basis and centrally hosted (software as a service, or SaaS) are also classified as SaMD if their indications fall within the definition of medical devices.

The provisions of Resolution RDC 657/2022 do not apply to software that is:

- for well-being – and intended to encourage and maintain well-being or control health and lifestyle – when they do not have prevention, diagnosis, treatment, rehabilitation or contraception purposes;
- classified as non-regulated products by ANVISA;
- used exclusively for administrative and financial management in health services;
- that process medical demographic and epidemiological data, without any clinical, diagnostic or therapeutic purpose; and
- embedded in medical devices under sanitary regulation.

SaMD menus should preferably be in Portuguese and the company needs to present a declaration of compliance with international standards or, alternatively, the technical justification and documents demonstrating the product's safety and efficacy.

8.2 Rules for Telemedicine

Telemedicine in Brazil is ruled by Resolution No 2,314/2022, issued by the Federal Council of Medicine, and Federal Law No 14,510/2022, which authorises and disciplines the practice of telehealth in Brazil.

Telemedicine is defined as the rendering of medical services through Digital Technologies for Information and Communication (TDICs), for the purpose of assistance, education, research, diseases and injuries prevention, and health management and promotion. Telehealth has a very similar definition. Telemedicine can be exercised through teleconsultation, tele-interconsultation, telediagnosis, telesurgery, telemonitoring or telesurveillance, and tele-triage and teleconsulting in the following ways.

- Teleconsultation – non-face-to-face medical consultation, mediated by TDICs, with the doctor and patient located in different spaces. The patient must be informed about the limitations of the teleconsultation, and both doctor and patient have the right to interrupt the remote services and choose a face-to-face consultation.
- Tele-interconsultation – exchange of information and opinions between doctors through TDICs (with or without the presence of the patient) for diagnostic, therapeutic, clinical or surgical aid. The physician responsible for the tele-interconsultation must be the same physician responsible for the face-to-face follow-up.
- Telediagnosis – medical act performed at a geographic or temporal distance, with the transmission of graphics, images and data, for the issuance of a report or opinion by a physician with a specialist qualification record in the area related to the procedure.
- Telesurgery – surgical procedure at a distance, using robotic equipment and mediated by safe interactive technologies.
- Telemonitoring or tele-surveillance – act performed under the co-ordination, indica-

tion, orientation and supervision of a physician for remote monitoring or surveillance of health and/or disease parameters by means of clinical evaluation and/or direct acquisition of images, signs, and data from equipment and/or aggregate or implantable devices in patients either:
(a) at home;
(b) at a medical clinic that specialises in chemical dependency;
(c) at a long-stay institution for the elderly
(d) at a clinical or domiciliary hospitalisation regime; or
(e) in the transfer of the patient until their arrival at the health establishment.

Telemonitoring involves the collection of clinical data, along with its transmission, processing and management, without the need for the patient to go to a healthcare facility. It must be performed at the direction and justification of the responsible physician. The transmission and receiving of data shall be secure and confidential.

- Tele-triage – evaluation of the patient's symptoms by a physician, at a distance, for outpatient or hospital regulation, including assessment and direction of the patient to the appropriate type of assistance needed or to a specialist.
- Teleconsulting – act of consulting mediated by TDCIs between doctors, managers and other professionals, for the purpose of providing clarifications about administrative procedures and health actions.

The current legislation provides that:

- the health professional is assured freedom and complete independence to decide whether or not to use telehealth;
- telehealth will be provided by free and informed consent of the patient, or their legal representative, and under the responsibility of the healthcare professional;
- the provision of telehealth services may be subject to other health rules, including the ones issued by the SUS authorities; and
- the provisions of General Data Protection Law (*Lei Geral de Proteção de Dados*, or LGPD) must be observed.

8.3 Promoting and/or Advertising on an Online Platform

Drug advertising is strongly regulated by ANVISA Resolution RDC No 96/2008, which provides that prescription drugs must not be advertised to the general public and instead only to prescribing or dispensing healthcare professionals (HCPs) – provided that all required conditions are met.

OTC drugs may be advertised through electronic means. However, there are several conditions to be met, such as the following:

- off-label promotion is prohibited;
- a product's registration numbers before ANVISA must be indicated in advertising materials;
- unregistered products must not be promoted;
- clinical and therapeutic claims in advertising material related to the drug are based on substantiated scientific data that has clinical and statistical significance;
- information inserted in advertisement material is consistent with the information provided to ANVISA and with duly published and approved technical literature and scientific papers, as well as in accordance with regulatory and legal requirements; and
- advertisements include the required warning messages.

8.4 Electronic Prescriptions

The issuance of electronic medical documents is governed by Resolution No 2,299/2021 from the Medical Federal Council. There are also guidelines contained in CFM Resolution No 1,821/2007 (regarding electronic health records), and Resolution No 2,314/2022 (regarding telemedicine services), which apply to the prescription procedure.

In general terms, the practice must respect the technical standards of traditional medical prescriptions and follow strict safety criteria. Electronic prescriptions can be issued both face-to-face or in remote consultations and must include:

- the physician's identification details (name, Regional Council of Medicine registration number, and address);
- Specialist Qualification Record (*Registro de Qualificação de Especialista*, or RQE) in the case of a specialty or practice area;
- the patient's identification details (name and legal document number);
- the date and time; and
- the physician's digital signature.

The patient data must be properly and securely registered, and delivered through the internet in compliance with the Medical Federal Council rules regarding the safekeeping, handling, integrity, veracity, confidentiality, privacy and the guarantee of professional secrecy of the information. The LGPD must also be integrally observed. If the prescription is provided by means of a portal or platform, it must be enrolled with the Medical Regional Council.

8.5 Online Sales of Medicines and Medical Devices

According to the applicable regulation (notably, ANVISA Resolution RDC No 44/2009), the sale via the internet of drugs and medical devices by pharmacies and drugstore chains is possible; however, certain special conditions must be met. Sales can only be made by pharmacies and drugstores with physical premises and that are open to the public, are duly licensed, and have a technically responsible person present at the premises during the entire time that the establishment is open, if the release of drugs is to be ordered remotely, such as by telephone, facsimile and the internet.

However, the online sale and home-delivery of drugs subject to special control is prohibited. There are no restrictions regarding medical devices.

8.6 Electronic Health Records

Health/medical data is regulated in the Brazilian Code of Medical Ethics and in complementary regulations issued by the Federal Medical Council and by the Ministry of Health. Basically, these rules provide for the general integrity and confidentiality of medical data and determine that a patient's prior and express consent is an essential element for the use of any medical data – whether by the physician who collected the data or by any third parties, including healthcare providers. Disclosure without prior consent may be deemed a violation of doctor–patient confidentiality.

In general, Federal Law No 13,787/2018 allows the scanning and use of digital systems to keep, store and handle patients' medical records. According to this law, the scanning must ensure the integrity, authenticity and confidentiality of the documents. The digital version must repro-

duce all the information contained in the original document.

In addition, digital documents must be controlled through a specialised electronic document management system, in accordance with the characteristics and requirements to be defined in a specific regulation. Although no regulation has been issued since 2018 for defining any such characteristics and requirements, Resolution No 1,821/2007 and Resolution No 2,314/2022, issued by the Federal Medical Council, should be used as a guideline. According to the resolution, an electronic management system is required to:

- have enough capacity to utilise the stored data;
- have an index method allowing for simple research and filing organisation; and
- ensure the level of information security (Level II – NGS2, which is granted by an accredited entity in Brazil).

In the services provided by telemedicine, patient data and images from the medical records must be preserved in accordance with the legal and CFM norms regarding the safekeeping, handling, integrity, veracity, confidentiality, privacy, irrefutability, and the guarantee of professional secrecy of the information, as well as the provisions of General Data Protection Law (LGPD).

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patents are regulated in Brazil through Federal Law No 9,279/1996 (the IP Law).

Although the Brazilian Patent Office's examination criteria and guidelines for pharmaceuticals and biotech inventions are generally aligned with international standards, the issues most commonly encountered by pharmaceutical and medical devices products historically under the legislation relate to secondary inventions – for example, inventions on formulations, combinations of new compounds, second and further medical uses, salts and polymorphic forms of known compounds, and selection inventions. In addition, restrictions on the opportunity to submit claim amendments and file divisional applications after the examination request are a concern of applicants in general.

As for the patentability requirements, under Article 8 of the IP Law, the main requirements for the grant of a patent are novelty, inventive step and industrial application. Other requirements, such as sufficient descriptions and enablement, are also provided by the law. Those requirements apply to all kind of patents and there is no specific requirement for pharmaceuticals or medical devices. In the past, the Brazilian patent law established that the granting of pharmaceutical patent applications was subject to ANVISA's prior approval, pursuant to Article 229-C of the Patent Act. This has recently been revoked.

In addition, under the Brazilian IP Law, all products, substances and processes can be protected, apart from those that are included in the prohibitions under Articles 10 and 18 of the IP Law, as follows:

- operating or surgical techniques and therapeutic or diagnostic methods for use on the human body or animals (possibly patentable if rewritten as Swiss-type claims);
- natural living beings (in whole or in part), and biological material (including the genome or

germ plasma of any natural living being) when found in nature or isolated therefrom, and natural biological processes;
- inventions that are contrary to morals, good customs, and public security, order and health; and
- substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of their atomic nucleus.

9.2 Second and Subsequent Medical Uses

In Brazil, second and subsequent medical uses of a known product can be patentable as long as the patent requirements of Article 8 of the aforementioned IP Law are met. However, the showing of new and surprising effects and the submission of test results are normally required by the Patent Office.

Meanwhile, inventions related to new dosage regimes, and new or selected patient populations, are often rejected because of a lack of clarity (Article 25) or if they are considered related to a method of treatment.

As a general rule, the manufacture, use, sale, or offering for sale – or the import for such purposes – of a process or product directly obtained from a patented process without consent is considered patent infringement. For a patent on second or subsequent uses, a product that is alleged to infringe must have been approved for the same new use – otherwise a demonstration of off-label use must be provided.

9.3 Patent Term Extension for Pharmaceuticals

According to Article 40 of the IP Law, a patent is valid for 20 years from its filing date.

Considering the backlog at the Brazilian Patent and Trademark Office (BPTO), a sole paragraph of Article 40 was used to establish that the term of protection could not be less than a period of ten years from the date a patent is granted. This article, however, was declared unconstitutional by the Supreme Court, in the judgment of ADI No 5,529. In summary, the Supreme Court decided as follows.

- All pharmaceutical and medical device patents granted from 8 April 2021 will be valid for 20 years from the date of filing.
- In all lawsuits filed before 7 April 2021 in which there is a discussion about the sole paragraph's constitutionality, the rule will be considered unconstitutional.
- Pharmaceutical and medical device patents that on the day of publication of the Supreme Court's decision are valid only owing to the provision of the sole paragraph will have their dates reduced in accordance with the 20-years-from-filing rule.
- However, regardless of the reduction of the term, all "concrete effects" derived from patents that were effective only owing to the sole paragraph will still be considered valid until the date of publication of the decision.
- Other patents granted with the application of the sole paragraph that are not pharmaceutical patents or medical device patents will not have their terms reduced and can still count in accordance with the term provided in the sole paragraph.
- As of the time when the minutes of the judgment session were published (13 May 2021), the BPTO will no longer be able to apply the

extension provided in the sole paragraph of Article 40 of the Patent Statute.

Due to this reduction of the term, there are currently different judicial lawsuits with the aim of extending the patent term based on the BPTO's backlog and its effects on the reduction of patent terms.

9.4 Pharmaceutical or Medical Device Patent Infringement

Article 42 of the IP Law defines the acts that constitute patent infringement. Applying for marketing approval is permitted by the IP Law, under what is called the "Bolar exemption". However, if the patent-holder is able to prove that the other party is taking all necessary steps to infringe its patent during the patent term, it is possible to obtain a restraining order against the possible infringer. The requirement for this "imminent" infringing may include the marketing approval request and other information that indicates that the other party will (or is required by law) to launch or pursue other infringing activities during the patent term.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

As previously mentioned, applying for marketing approval is exempt from infringement under the Bolar exemption. Experimental use is also allowed in Brazil and is a common defence in patent infringement cases. Defendants in patent infringement cases also often argue the invalidity of the plaintiff's patent as a defence argument.

One trend in pharmaceutical patent infringement cases is an argument related to Article 32 of the IP Law, which is interpreted by the BPTO in a very restricted way to limit the applicant's ability to present voluntary amendments after the examination request.

According to the IP Law, the patent-holder may be compelled to provide a compulsory licence under the following circumstances:

- if it exercises the rights resulting from a patent in an abusive manner;
- if it practises abuse of economic power that is proven under the terms of the law by an administrative or court decision;
- if the object of the patent is not explored in the Brazilian territory, by lack of manufacture or incomplete manufacture of the product or, furthermore, by a lack of complete use of a patented process (except in the case of non-exploitation due to economic unviability, when importation will be admitted); and
- if commercialisation does not meet the needs of the market.

The provisions on compulsory licences were also changed in 2021, as a result of the COVID-19 pandemic. A bill was approved to change the Patent Statute. It provides that, in cases of national or international emergencies (and other scenarios), a compulsory licence may be granted ex officio if the patent-holder or licensee does not meet the market's needs. The new provisions also include a rule that – if in accordance with a treaty to which Brazil is a party and for humanitarian reasons – compulsory licences may be granted for products that are destined to be exported to countries with insufficient or no capacity to manufacture the pharmaceutical product for the local population.

9.6 Proceedings for Patent Infringement

According to Article 42 of the IP Law, the patent-holder has the right to prevent a third party – without their consent – from producing, using,

offering for sale, selling, or importing the product covered by the patent or the process or product obtained directly by the patented process.

As a general rule, the burden of proof falls on the plaintiff (except in the case of infringement of a process patent), who often presents documentary evidence in advance, including technical and legal opinions.

Invalidity is an available defence and may be argued in the same infringement case in the answer brief. Alternatively, a separate invalidity case may be filed before federal courts, including the BPTO as a mandatory defendant.

In a typical proceeding, after the defendant is duly served of the complaint, they normally have 15 days to file an answer – in which all possible defences, including counterclaims of invalidity, are presented together with the supporting evidence. In an infringement case, both parties often ask the court to allow the production of further evidence during the proceeding – most importantly, the production of technical evidence by an expert to be appointed by the court at a later stage.

The plaintiff then has a ten-day term in which to file a reply brief before the judge decides on the requests made by each party regarding evidence production. At this stage, the court may also identify issues that are not under dispute and decide on any preliminary argument raised by the parties.

If the production of technical evidence is required, the judge will then appoint a trusted expert to prepare a technical report that will be used to assist the court. Given their importance, the court expert may be challenged by the parties owing to lack of technical expertise, credibility, or partiality. Parties may elect their own experts to interface with the court-appointed expert and provide any necessary clarification. Parties may also submit technical questions to be answered by the court expert pertaining to infringement and validity.

After the court-appointed expert files their report with the court and the parties submit their own arguments regarding said report, the judge will then set a date for closing arguments (on paper) and a date for trial. If no oral evidence is needed, the court may also render a final judgment without a trial. The pre-trial stage may take six to 12 months. Depending on the complexity of the case, this schedule may be substantially delayed if any party contests the court-appointed expert's nomination.

In patent infringement actions, one of the remedies is to request a preliminary injunction. If the legal requirements set out in Article 300 of the Code of Civil Procedure are met, the court can grant such a remedy that has the most varied scope, such as immediately ceasing the marketing of the product allegedly infringing the patent and guaranteeing the payment of compensation for moral damages. Therefore, if the patent-holder is able to prove that the other party is taking all necessary steps to infringe its patent during the patent term, it is possible for them to obtain a restraining order against the possible infringer through a request for a preliminary injunction by the plaintiff (patent-holder).

9.7 Procedures Available to a Generic Entrant

There is no patent linkage or established proceeding for a potential generic entrant during the process of marketing approval. At the same time, ANVISA will not prevent or delay marketing approval based on exclusivity rights. There-

fore, a generic company will usually need to file a patent invalidity case before launch to be on the safe side or else wait for the patent term to expire.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

According to Articles 183 to 186 of the IP Law, anyone who commits a crime against the patent should be held criminally liable if:

- they manufacture a product that is the subject of a patent without authorisation from the patent-holder; or
- they use a means or process that is the subject of a patent without authorisation from the patent-holder.

The penalty for those who commit this crime is ten to 15 years' imprisonment and a fine. In addition, according to Article 273 of the Penal Code, the counterfeiting, corruption, adulteration or alteration of a product intended for therapeutic or medicinal purposes constitutes a crime against public health. The penalty for those who commit this crime is imprisonment for three months to one year, or a fine.

It is important to mention that ANVISA also has a substantial role in the inspection of pharmaceutical products and medical devices, through the implementation of the National Medicines Control System, set out in ANVISA's Resolution RDC No 59/2009. In addition, ANVISA is the public body responsible for registering medicines and authorising the operation of pharmaceutical laboratories and other companies in the pharmaceutical chain.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

As a general rule, pharmaceutical products with different therapeutic indications are considered similar to some extent, mostly in the following respects:

- they are inserted in the same market segment (ie, the pharmaceutical industry);
- they are ultimately used for the same purpose, that is, treating and healing medical diseases and disorders; and
- the heterogeneous profile of drug consumers, all of which can give rise to an enduring potential risk of confusion and the chance of wrongful association between these products.

Accordingly, the BPTO's Trademark Examination Guidelines establish that trade mark conflict analyses involving products that interfere with human health (eg, medical devices and pharmaceutical substances and preparations) must be carefully examined owing to the serious impacts that the confusion between the trademarks may cause.

Moreover, Article 5 of Federal Law No 6,630/76, which deals with sanitary surveillance in Brazil, establishes that medicines, drugs, pharmaceutical inputs and related products may not have names, designations, labels or packages leading to error. Paragraph 1 of the same article also states that the adoption of an equal or similar name for products having different compositions is forbidden, even if they are from the same manufacturer. Although ANVISA has its own rules for naming pharmaceutical products, those rules and the decisions arising from their application do not legally impact the BPTO's assessment of a likelihood of confusion.

As the main authority responsible for regulating the pharmaceutical market in Brazil, ANVISA has the power to authorise the operations of companies manufacturing, distributing and importing medicines and medical devices in general.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress of a product (ie, representation of the packaging containing the mark and additional visual elements) or of a service (ie, representation of the physical space where the products or services are offered) cannot be registered as a trade mark. However, the trade dress of a label may be protected as a word-and-design mark. In fact, this type of registration has become quite common in Brazil, including in the pharmaceutical area.

Trade dress cannot be protected under Brazilian Copyright Law either. Some elements forming the trade dress, such as artistic drawings, may be subject to copyright protection. However, the label, packaging or visual representations of a space, as a whole, do not fit the requirements for protection under copyright laws.

Likewise, trade dress cannot be protected as industrial design. This is because Brazilian IP Law provides that industrial designs are the ornamental plastic form of an object or the ornamental set of lines and colours that can be applied to a product, thereby creating a new and original visual result in its external configuration, and that may be applied in industrial manufacturing.

Brazilian IP law does not address the registration of trade dress, which means that the trade dress of pharmaceuticals and medical devices is not registrable before the BPTO.

In order to be protected in Brazil, a trade dress must satisfy three conditions:

- distinctiveness (which may be inherent or acquired);
- no functional character; and
- likelihood of confusion.

In Brazil, the protection and enforcement of trade dress results from provisions against unfair competition and must be recognised by a state court through the filing of a lawsuit.

According to the Civil Procedure Code, it is possible for trade dress owners to obtain injunctions against infringers in order to demand that they cease the manufacturing, launching, use, reproduction, offering for sale, sale or importation of the infringed trade dress in the market. Injunctions are only granted:

- when there is risk of irreparable harm caused by the infringement and delay in having a final court decision; or
- to anticipate the effects of the final decision in light of strong evidence that the plaintiff's claim is well grounded.

In both cases, strong evidence of the alleged infringement and of the potential of irreparable harm must be submitted to the judge.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

The IP Law provides that it is a crime of unfair competition to use and exploit data, test results and other undisclosed information submitted to the health authorities for marketing approval. This is provided in Article 195, IV of the IP Law, as well as in Article 39.3 of the TRIPs Agreement, internalised by Decree 1,355 of 1994, and Articles 6, III and 22 of Law 12,527 of 2011. How-

ever, the law does not use the term "data package exclusivity" – nor does it define "protection".

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In view of the end of the Public Health Emergency of National Importance (*Emergência em Saúde Pública de Importância Nacional*, or ESPIN) declared by Ordinance GM/MS 913/2022 from the Ministry of Health, several rules that were applicable during the pandemic period and that addressed extraordinary and temporary conditions were revoked (the ones listed in Resolution RDC 702/2022 from ANVISA), and others (mentioned in Resolution 683/2022) had their validity extended until 21 May 2023.

Commercialisation or Distribution of Medicinal and Medical Devices

For this purpose, ANVISA issued Resolution RDC No 346/2020 and Resolution RDC No. 606/2022, which simplified the procedure for the certification of good manufacturing practices, registration, and post-registration of medicines and medical devices that are directly related to the commercialisation of the product, once it is a prerequisite for companies of the industry. In view of the end of the ESPIN, both resolutions are no longer valid.

Relaxation of the Applicability of the Legal Framework

The applicability of the public tender procedure was initially dismissed in the case of the acquisition of goods, services and inputs aimed at containing the COVID-19 pandemic, based on Federal Law No 13,979/2020 (and Ordinance No 188 of 3 February 2020, which provides that the COVID-19 pandemic shall be deemed a public health emergency) published by the federal government. However, this law was linked to Legislative Decree 6/2020, which is no longer in effect as of 31 December 2020.

Although Federal Law No 13,979/2020 expired on 31 December 2020, the Federal Supreme Court, while ruling on Direct Unconstitutionality Action 6.625, decided that Articles 3, 3-A, 3-B, 3-C, 3-D, 3-E, 3-F, 3-G, 3-H, and 3-J remain in full force and effect. Therefore, the extraordinary approval of the importation and distribution of products that are not registered in Brazil subsisted, under certain conditions defined in the above-mentioned law.

However, as of 1 April 2022, ANVISA revoked all rules that supported the relaxation measures applicable to the importation of unregistered COVID-19 products. Therefore, from a practical perspective, the importation of unregistered products may lead to sanitary exposure for the company.

11.2 Special Measures Relating to Clinical Trials

ANVISA issued Technical Note No 3/2020 as guidance for sponsors, researchers and institutions involved in ongoing clinical trials.

In view of the public health emergency, ANVISA recently published Resolution RDC No 601/2022, which provides – as an exceptional and temporary measure – a simplified analysis procedure in the case of petitions related to clinical trials. This resolution will only be in force until 21 May 2023.

Special Regulations in Relation to COVID-19 Treatments or Vaccines

In order to enable the immunisation of the Brazilian population in an emergency basis, ANVISA

issued Resolution No 475/2021 and Guide No 42/2020. This provides for the temporary authorisation, on an experimental basis, of COVID-19 drugs and vaccines.

This regulation also encompasses imported vaccines, which must comply with the requirements provided for in both the resolution and the guide.

Owing to the end of the ESPIN declared by Ordinance GM/MS 913/2022 from the Ministry of Health, the above-mentioned Resolution was revoked and ANVISA issued Resolution RDC No 688/2022 to establish requirements for the maintenance of the authorisations already granted and new requests for temporary use. Resolution RDC No. 688/2022 will only be valid only until May 2023.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

ANVISA issued Resolution No 346/2020, which established the extraordinary and temporary requirements for the approval of pharmaceutical and medical devices. This resolution was revoked by Resolution RDC No. 606/2022.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The flexibility consisted of the opportunity to use remote inspection mechanisms rather than face-to-face inspection and it was provided for in Resolution RDC No 346/2020, which is no longer valid.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Restrictions

The exportation of medical devices – ie, personal protective equipment for healthcare use (eg, latex gloves, surgical masks, face shields, respiratory connections) and other devices used to contain COVID-19 – was prohibited, according to Federal Law No 13,993/2020. Nonetheless, in view of the end of the ESPIN, this rule lost its efficacy.

Flexibilities

Customs authorities issued several provisions regarding the measures to stop COVID-19 transmission, which were mostly related to tariff reduction and suspension of trade defence measures. Owing to the end of the ESPIN, these flexibilities may have been revoked or extended, as set forth in Resolutions RDC 683/2022 and 702/2022 from ANVISA.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The most relevant digital health innovation in Brazil related to the COVID-19 pandemic is the permitting of telemedicine by the Ministry of Health – through Ordinance No 467/2020 – in both the public and private health systems while the coronavirus pandemic persists. Even after the end of the ESPIN, the Federal Medicine Council and ANVISA issued rules governing telemedicine and telehealth, regardless of the pandemic.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

To date, no compulsory licences related to COVID-19 have been granted.

According to the IP Law, legal provisions regarding compulsory licences are provided in Articles 68–74 and Decree 3.201/1999, which regulate the compulsory licence based on Article 71 and in compliance with the IP Law (national emergency and public interest), which has been recently modified by an approved bill. These provisions would be applicable to a compulsory licence scenario in Brazil.

It is important to note that, in certain circumstances – including in the event of national emergencies or public interest declared by the Executive Branch – a temporary and non-exclusive compulsory licence may be granted ex officio if the patent-owner or its licensee does not meet market needs.

This matter is under discussion, with favourable evaluation on the part of the National Congress; but meeting resistance from the Executive Branch. Nevertheless, it should be noted that the government sometimes sees compulsory licences as a negotiation strategy and in the past the federal government has used the threat of compulsory licensing as a strategy to drive down drug prices acquired by the Ministry of Health.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Recently, Federal Law No 14,125/2021 – which provided that the union, states, federal district and municipalities could agree to be exclusively liable for the potential adverse events related to vaccines, thereby exempting manufacturers from that liability – was revoked.

11.9 Requisition or Conversion of Manufacturing Sites

Article 5, item XXV of the Brazilian Federal Constitution provides that the government may utilise private property in the event of an urgent public emergency.

Specifically, in respect of the COVID-19 pandemic, Federal Law No 13,979/2020 established that the public authorities may require goods and services from both individuals and legal entities. This remains in full force and effect, in light of the decision rendered by the Supreme Court in Direct Unconstitutionality Action 6.625.

These regulations ensure a legal basis for the requisition or conversion of manufacturing sites during the COVID-19 pandemic. In both cases, the public authorities must duly compensate the private party.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

All changes to the public procurement procedures authorised during the pandemic are no longer valid, in view of the end of the ESPIN declared by Ordinance GM/MS 913/2022 and of the consequent expiration of laws and provisions that were not covered in the decision issued by the Supreme Court.

CANADA

Law and Practice

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Contents

Markwell LLP is a Canadian law firm with extensive experience in patent litigation and regulatory issues impacting the life sciences industry. The firm helps clients navigate the complex regulatory system governing the approval and sale of health products in Canada, including data protection, patent linkage, patent term restoration, pricing, formulary interchangeability, product listing agreements and advertising. Its counsel attend meetings with regulators and appear as litigation counsel at hearings before the Patented Medicine Prices Review Board (PMPRB) and judicial review applications. Markwell LLP also represents clients in patent infringement and impeachment actions, injunction motions, appeals and interventions, including cases under the Patented Medicines (Notice of Compliance) Regulations. The founding partners have appeared as counsel in many precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal, the Federal Court and the PMPRB.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Health Canada regulates, evaluates and monitors pharmaceuticals pursuant to the Food and Drugs Act (FDA) and its associated regulations. It regulates controlled substances under the Controlled Drugs and Substances Act (CDSA) and its associated regulations. The Cannabis Act is the legislative framework for controlling the production, distribution, sale and possession of cannabis in Canada.

Medical devices are regulated under the FDA and the Medical Devices Regulations (MDR), administered by Health Canada.

The distribution of pharmaceuticals and medical devices is governed by various territorial/provincial legislation and regulatory bodies, such as provincial colleges of pharmacy and public drug benefit formularies.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Health Canada has various internal complaint/appeal resolution processes to challenge its decisions. Once those internal resolution processes have been exhausted or where a decision is not subject to such resolution processes, a party with standing may challenge a Health Canada decision by filing an application to the Federal Court of Canada for judicial review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Health Canada classifies health products into certain categories, such as drugs and medical devices. With respect to drugs, Health Canada further classifies products into subcategories such as controlled substances, biologic products, prescription drugs and non-prescription drugs.

Medical devices are categorised by Health Canada according to risk: Class I is the lowest perceived risk, while Class IV is the highest. The classification determines the type of submission and information that must be filed with Health Canada for marketing approval and post-market surveillance.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Health Canada regulates clinical trials/investigational testing of pharmaceuticals and medical devices through the FDA and its regulations.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Health Canada must authorise all clinical studies of authorised and unauthorised pharmaceuticals, biologic drugs and medical devices before they begin, with limited exceptions.

To perform a drug clinical trial, the sponsor must submit a clinical trial application (CTA) to Heath Canada. The sponsor must also have a Research Ethics Board (REB) Attestation and complete certain Qualified Investigator Undertaking forms and a Clinical Trial Site Information form. For biologics, Health Canada also requires that the lot release information be provided by the CTA sponsor/manufacturer before its use in the trial. A CTA is not required for phase IV clinical trials. If the CTA is approved by Health Canada, a No Objection Letter (NOL) will be issued.

To perform medical device investigational testing, the sponsor must submit an investigational testing application (ITA) to Health Canada. The ITA approval process is required for trials involving the use of all unlicensed Class II, III and IV medical devices. REB approval must be obtained prior to study initiation. An ITA is not required for Class I (low risk) medical devices, nor is it required for conducting a study using a licensed device according to its licensed indications for use. Under the MDR, only manufacturers and importers can apply for authorisation. If the ITA is approved by Health Canada, an NOL will be issued.

2.3 Public Availability of the Conduct of a Clinical Trial

In 2019, Health Canada launched its Public Release of Clinical Information initiative. Since that time, Health Canada has developed a Clinical Trials Database (CTD) which provides certain publicly available information on phase I, II and III clinical trials of human pharmaceuticals and biological drugs. The information provided in the database includes drug name, medical condition, study population, study start/end dates and trial status. However, the database is not a registry and does not contain comprehensive information about each trial. The CTD also does not include information on clinical trials in healthy volunteers (eg, bioavailability/bioequivalence trials) or phase IV trials.

In addition, after a final regulatory decision, the following information (with certain exceptions) in respect of clinical trial and medical device applications will no longer be considered confidential business information and will be publicly available through Health Canada:

- clinical summaries; and
- reports and supporting data of clinical trials in support of a drug submission and clinical trials or investigational testing in humans in support of any Class III or Class IV medical device application.

Health Canada will not release individual patient records and clinical case report forms to the public.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Online tools and systems to support clinical trials may be used so long as they comply with applicable requirements (privacy, confidentiality, informed consent etc) and good clinical prac-

tices. For example, the sponsor should ensure online tools conform to its established requirements for completeness, accuracy, reliability and consistency of intended performance.

2.5 Use of Data Resulting From the Clinical Trials

Two federal privacy laws set out how federal government institutions and certain businesses must deal with personal information including personal health information. The Personal Information Protection and Electronic Documents Act (PIPEDA) addresses the personal information handling practices of federal government departments including Health Canada, and the Privacy Act regulates private businesses' data protection practices. Many provinces and territories also have laws that deal specifically with the protection of personal information, including health information. Whether data constitutes personal health information depends on several factors.

Personal data resulting from clinical trials is generally considered to be confidential, although in certain scenarios the sponsor and other agencies will have access to such information, including patient-identifiable information, to conduct and analyse the data from the study properly. If the data is de-identified or anonymised, then it generally is not considered confidential.

Data can be transferred to a third party or an affiliate so long as it is in accordance with all applicable privacy requirements, contractual agreements and informed consents.

2.6 Databases Containing Personal or Sensitive Data

A database containing personal or confidential data may be subject to contractual and statutory obligations, including certain security and privacy measures. For example, Ontario's Personal Health Information Protection Act requires custodians to take reasonable steps to ensure the personal health information they hold is always protected and secure.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

In general, classification decisions are made by the appropriate group at Health Canada upon the submission of required information or an application for market authorisation. In instances where a product could be classified in multiple ways, such as drug/device combination products, classification requests can be sent to the Office of Science (OoS) within the Therapeutic Products Directorate of the Health Products and Food Branch at Health Canada for guidance.

Product classifications are based on the FDA and its associated regulations. The classification criteria are generally based on the product composition, product purpose and intended use, as well as product format and representations (eg, labelling claims and indications).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Health Canada is responsible for the review and approval of new drug submissions (NDS), including those for biologic drugs.

To obtain marketing authorisation for a biologic drug (innovator or biosimilar), a manufacturer must file an NDS with the Health Products and Food Branch at Health Canada. The submission must include preclinical and clinical results to

support the safety, efficacy and quality of the biologic. Given the nature of biologics, Health Canada requires more detailed chemistry and manufacturing information than it does for other drugs. An on-site evaluation may be conducted at the manufacturing site and samples may be subject to evaluation through a lot release programme overseen by Health Canada to ensure consistency of the manufacturing process.

A manufacturer can request a brief consult with the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada to discuss the details of their submission and any areas of concern prior to filing.

Health Canada will issue a notice of compliance (NOC) and Drug Identification Number (DIN) upon satisfactory completion of the NDS review. The approval process typically takes one to two years. However, there are regulatory mechanisms for expediting the approval process in some cases.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

While there is no specific requirement to renew market authorisations for pharmaceuticals, a manufacturer of a drug must notify Health Canada each year before October 1st that the drug is still on the market and that all information previously provided is accurate and up to date.

The MDR requires every manufacturer of a medical device to inform Health Canada each year before November 1st that the information contained in their licence application is accurate. Manufacturers of licensed Class II, III and IV medical devices are also charged an annual fee. Failure by the manufacturer to renew the licence application may result in cancellation of the licence.

There are circumstances when a marketing authorisation can be revoked, for example, failure to comply with the FDA or its regulations. Typically, Health Canada will attempt to work with manufacturers to obtain compliance before a suspension or revocation is issued.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

To obtain marketing authorisation for a drug, a manufacturer files an NDS with Health Canada. This submission includes preclinical and clinical data to support the safety, efficacy and quality of the product, as well as manufacturing details. Health Canada will issue an NOC and DIN upon satisfactory review of the NDS. This approval process generally takes one to two years but there are certain mechanisms to expedite the process in some cases. If the manufacturer changes the strength, format/dosage form or indications, etc, of the drug, then a Supplemental New Drug Submission (SNDS) must be approved by Health Canada.

Generic drugs are approved through an abbreviated new drug submission (ANDS) and are based in part on comparisons to the brand-name reference product. Supplemental abbreviated new drug submissions (SANDS) are required for certain product changes (eg, packaging, labelling) or new indications. As with an NDS, an applicant for an ANDS or SANDS will receive an NOC upon approval by Health Canada, subject to any patent issues.

Medical devices are categorised and regulated by Health Canada according to risk: Class I indicates the lowest perceived risk, while Class IV

indicates the highest perceived risk. The classification determines the type of submission and information that must be filed with Health Canada for the device to be approved for marketing.

Generally, marketing authorisations can be transferred from one entity to another in situations where the only change to the product is the manufacturer's name, such as in a merger, buy-out or other corporate restructuring. In such cases, a submission to Health Canada for each affected drug product must filed with supporting documentation.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Healthcare professionals may access drugs and medical devices not currently authorised for sale in Canada through the Special Access Program (SAP) to treat patients with serious or life-threatening conditions where conventional treatments have failed, are unsuitable or not available in Canada.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

In certain situations, an NOC with conditions may be granted by Health Canada with the condition that the sponsor undertake additional studies to verify the clinical benefit of the drug.

For drugs, manufacturers are required to report all information related to serious adverse drug reactions (ADR) that occurred in Canada and all serious, unexpected ADRs that occurred outside of Canada to the Canada Vigilance Program of the Marketed Health Products Directorate of Health Canada within 15 days of receiving or becoming aware of the information. Manufacturers must prepare an annual summary of ADRs and serious ADRs during the previous 12 months.

For medical devices, records relating to complaints and incidents must be maintained by the manufacturers/importers and must be provided to Health Canada with an incident report if the medical device was sold in Canada and if the incident:

- occurs within Canada;
- occurs outside Canada for a Class I medical device;
- relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use; and
- has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur.

In addition, certain holders of medical device authorisations in Canada (ie, an MDL holder for a Class II to IV device, an MDEL holder that imports a Class II to IV device, and a holder of an ITA for a Class II to IV device) must also notify Health Canada of certain foreign risks.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

For drugs, Health Canada has a Submissions Under Review (SUR) list for new active substances (pharmaceuticals and biologics with active ingredients not approved in Canada) as well as SNDSs for new uses.

There are four SUR lists: NDSs currently under review; SNDSs currently under review; NDSs formerly under review; and SNDSs formerly under review.

For NDS/SNDS currently under review, the list includes the medicinal ingredient(s); month/year the submission was accepted for review; and the therapeutic area populated with the WHO Anatomical Therapeutic Chemical Code. For any submission that was accepted into review on or after 1 October 2018, the SUR list also includes the company name and submission class (eg, extraordinary use submission; new active substance; biosimilar; review under priority review; review under NOC with Conditions; reviewed under submissions relying on third party data; aligned review with a health technology assessment organisation; and COVID-19 use).

For the NDS/SNDS formerly under review, the SUR list includes the medicinal ingredient(s); month/year the submission was accepted into review and concluded; therapeutic area populated with the WHO Anatomical Therapeutic Chemical Code; and a hyperlink to the regulatory decision summary or cancellation.

There is a separate list for generic drug submissions (ANDS) accepted for review on or after 1 October 2018, but it does not disclose the name of the sponsor that filed the submission.

There is no corresponding publicly available list of medical device submissions. However, the Medical Devices Bureau at Health Canada maintains a list of all licensed Class II, III and IV medical devices marketed in Canada, as well as a list of active MDEL.

Confidential Business Information (CBI) is defined in the FDA as business information:

- that is not publicly available;
- in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available; and
- that has actual or potential economic value to the person or their competitors because it is not publicly available, and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

Health Canada has discretionary authority to disclose CBI about a therapeutic product (including prescription, non-prescription drugs and medical devices), without notifying the person to whose business the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or public safety and the disclosure is to:

- a government;
- a person from whom the Minister seeks advice; or
- a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Health Canada may also disclose CBI about a therapeutic product without notifying the person to whose business the information relates or obtaining their consent, if they believe that the product may present a serious risk of injury to human health.

Personal information in records considered for disclosure by Health Canada will be protected in accordance with federal privacy legislation and applicable provincial/territorial privacy laws.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Health Canada monitors the marketing of drugs and medical devices and takes necessary

enforcement actions to prevent the illegal marketing of products. It may take various types of enforcement action to address any such illegal activity, including imposing fines, undertaking activities related to seizure, detention and forfeiture of products and recommending criminal charges, where appropriate.

In addition, physicians and healthcare professionals are required to adhere to provincial/territorial legislation and to meet their respective professional standards in handling drugs and medical devices.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Health Canada has the authority to take appropriate enforcement measures regarding the importation and sale of counterfeits. This responsibility is also shared with other provincial/territorial regulators, government bodies and healthcare professionals.

The sale of counterfeit health products also violates Canada's Criminal Code. As such, cases of suspected counterfeit health products are also referred to the Royal Canadian Mounted Police (RCMP) and to the Canadian Border Services Agency (CBSA), where appropriate. The CBSA assists Health Canada with the administration and enforcement of regulated goods at the border.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

With respect to pharmaceuticals, the FDR requires that an establishment engaged in fabricating, packaging/labelling drugs (among other activities) hold a drug establishment licence (DEL) issued by the Minister of Health. The process involves submitting an application, along with a prescribed fee payment, setting out certain required information.

It takes Health Canada approximately 250 days to consider the application, verify GMP compliance and determine whether to issue an establishment licence. An initial on-site inspection of the establishment will be performed during that period.

Once issued, a DEL authorises an establishment to perform one or more of the regulated activities (eg, fabricate, package/label) in respect of one or more categories of drugs (eg, pharmaceuticals, vaccines, biologics).

The FDR also requires that drugs are fabricated in accordance with certain GMP. An establishment that holds a DEL is subject to inspection by the Minister of Health to verify compliance with GMP.

In order to maintain the DEL, the holder of the licence must submit an application to Health Canada before April 1st of each year for the review of their licence.

For medical devices, an MDEL is required for most classes of medical devices. The applica-

tion for such a licence is submitted to Health Canada along with a prescribed fee payment. In order to maintain the MDEL, the holder of the licence must submit an application to Health Canada before April 1st of each year for the review of their licence.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

A DEL is required (with some exceptions) to import, distribute and wholesale a drug. A completed application, along with a prescribed fee payment, setting out certain required information, such as evidence of GMP, must be submitted to Health Canada. A licence review application must be submitted each year before April 1st by companies that hold a valid DEL.

Provincial/territorial drug legislation also applies to the wholesale distribution of drugs, including regulations issued by Colleges of Pharmacy and Pharmacy Boards.

For medical devices, an MDEL is required (with certain exceptions) for distributing medical devices in Canada. The application for an MDEL is submitted to Health Canada along with a prescribed fee payment. In order to maintain the MDEL, the licence holder must submit an annual review application to Health Canada before April 1st. Manufacturers of Class II, III or IV medical devices also require an MDL to import or distribute their medical devices in Canada and such licences must be annually renewed before November 1st.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified both at the federal and provincial/territorial levels.

Health Canada classifies drugs into certain categories such as controlled substances, biologic products, prescription drugs and non-prescription drugs. Controlled drugs listed in the schedules to the CDSA are not on the Prescription Drug List, but their prescription status is conferred by their respective regulations.

A drug with a prescription status at the federal level requires a prescription in all provinces/territories.

When a newly marketed drug is given a non-prescription (over the counter/OTC) status or it is removed from the Prescription Drug List by Health Canada, the conditions of sale are determined at the provincial/territorial level. The National Drug Scheduling Advisory Committee (NDSA) reviews the submission and categorises the drug into National Drug Schedules that have been adopted to some extent by provinces/territories, except Quebec.

- Schedule I drugs require a prescription and are provided by a pharmacist.
- Schedule II drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access, but do not require a prescription.
- Schedule III drugs can be sold from the self-selection area of the pharmacy operated under supervision of the pharmacist, but do not require a prescription.
- Unscheduled drugs can be sold without professional supervision.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices is regulated under the FDA and its associated Regulations. Some health products have additional restrictions placed on them by other Acts, such as the CDSA.

The Medical Devices Directorate (MDD) at Health Canada helps to ensure the safety, effectiveness and quality of medical devices sold in Canada. MDD works with other agencies such as CBSA to prevent the importation and exportation of medical devices that do not comply with the FDA and the MDR.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of authorised pharmaceuticals and medical devices must have an establishment licence. Unauthorised drugs may be imported into Canada under certain conditions such as when authorised under a clinical trial in Canada. Controlled substances have additional restrictions under the CDSA. For prescription drugs, the importer must, with certain exceptions, be a practitioner, drug manufacturer, wholesaler or pharmacist.

Anyone who imports a medical device into Canada must also meet the applicable requirements of the FDA including the following:

- for Class I devices, the importer must have a valid MDEL, unless exempted;
- for Class II, III or IV devices, the device must be licensed by having an MDL and the importer must have a valid MDEL, unless exempted; and
- for all medical device classes, the importer must ensure that the company from whom they import has an MDEL that includes the appropriate licensable activities, unless exempted.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Generally, the importation of pharmaceuticals and medical devices requires prior authorisations. However, there are certain exceptions for importers. Unlicensed medical devices and drugs may be imported through a request by a healthcare professional to the Special Access Program (SAP). Certain drugs may also be imported to address urgent public health needs through the Access to Drugs in Exceptional Circumstances regulatory pathway.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Upon entry into Canada, declaration forms must utilise the Harmonized Commodity Description and Coding System (HS) codes and provide information required by Health Canada. Such importations are subject to regulations issued by CBSA and Health Canada.

6.5 Trade Blocs and Free Trade Agreements

Canada is a member of the World Trade Organization and has free trade agreements with 51 different countries. Canada also has several Mutual Recognition Agreements with other countries (eg, EU, Switzerland, Australia, UK) covering the Good Manufacturing Practices compliance programmes for drugs/medicinal products.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Canada, the Patented Medicine Prices Review Board (PMPRB) ensures that rights-holders do not sell patented medicines in Canada at an excessive price. The PMPRB is governed by the Patent Act and the Patented Medicines Regulations.

The Board only has jurisdiction if there is a patent or certificate of supplemental protection pertaining to the medicine sold in Canada. The Board takes a very broad view of its regulatory powers. Rights-holders who are subject to the Board's jurisdiction (ie, patentees and CSP holders) must submit pricing information on a prescribed basis.

If the PMPRB has jurisdiction, it will review the prices at which the medicine is sold in any market in Canada to determine whether it is excessive. In doing so, they are empowered to consider several factors, including the price at which the medicine is sold in certain other countries, the price at which medicines in the same therapeutic class are sold, the pharmacoeconomic value of the medicine and the size of the market in Canada.

The price of generic medications is also regulated by some provinces. For example, in Ontario, regulations made under the Ontario Drug Benefit Act provide that generic medications will only be reimbursed by the public plan at a certain percentage of the price for the interchangeable innovative product. The permitted percentage depends on the dosage form (oral solid versus other) and the number of other generic versions on the market. Additionally, certain designated molecules have lower percentage caps on their pricing.

Similar restrictions do not exist for medical device companies.

7.2 Price Levels of Pharmaceutical or Medical Devices

The PMPRB may consider domestic and international prices of the same medicine in other markets. As of 1 July 2022, the comparator countries are Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom (PMPRB11). However, the PMPRB has indicated that no price review will be conducted for new patented medicines until new guidelines are in place.

The price of a medical device does not generally depend on its price in other countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Provincial health insurance plans reimburse the cost of some pharmaceuticals and medical devices in an outpatient setting. Some individuals (eg, indigenous people, military members and federal penitentiary inmates) are covered by federal plans. The eligibility requirements and coverage vary depending on the plan.

Public hospitals cover the cost of most medications/medical devices for inpatients.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-benefit analyses are often applied in determining the reimbursement price of pharmaceuticals and medical devices on public and private drug benefit formularies. The specific rules vary by payor.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Many provinces and territories have implemented switching policies for generic drugs and biosimilars. Such interchangeabilities are governed by specific provincial/territorial regulations and by rules adopted by provincial/territorial colleges or boards.

8. Digital Healthcare

8.1 Rules for Medical Apps

Health Canada has specific rules for medical apps. Software is deemed to be a medical device when the following conditions are met:

- it is intended to be used for one or more medical purposes as outlined in the definition of device in the FDA; and
- it performs these purposes without being part of a hardware medical device (ie, it is not necessary for a hardware medical device to achieve its intended medical purpose).

Health Canada generally interprets "medical purposes" to be those:

- intended to acquire, process or analyse a medical image, or a signal from an in vitro diagnostic device or a pattern/signal from a signal acquisition systems or imaging device; or
- intended for the purpose of supporting or providing recommendations to healthcare professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment or mitigation of a disease or condition.

8.2 Rules for Telemedicine

The practice of telemedicine is regulated at a provincial/territorial level. The Colleges of Physicians and Surgeons in each province/territory also have policies regarding the practice of medicine, including telemedicine.

Generally, physicians may provide medical services through a mobile device if they follow the obligations and policies set by the Colleges and any applicable privacy legislation.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the online promotion or advertising of drugs and medical devices in Canada. The promotion and advertising of such products, whether by print, broadcast or internet, is regulated under the FDA and associated regulations. Only medical devices and prescription drugs that have been authorised for sale by Health Canada may be advertised legally in Canada. Additional regulatory restrictions apply for prescription drugs and opioids.

Market authorisation holders and advertisers can obtain advertising pre-clearance through various independent agencies such as the Pharmaceutical Advertising Advisory Board (PAAB).

8.4 Electronic Prescriptions

Electronic prescriptions are regulated primarily at the provincial/territorial level. For example, the Saskatchewan College of Pharmacy, relying on Health Canada's policies and provincial legislation, provides that an electronic prescription is equivalent to the written format and is acceptable, provided certain requirements are met. Health Canada has said that electronic prescriptions are permissible if they achieve the same objective as a written prescription.

8.5 Online Sales of Medicines and Medical Devices

Online sales of drugs and medical devices are permitted and regulated under the FDA. Additional requirements for the online sale of drugs have been set by some provinces/territories.

8.6 Electronic Health Records

Regulations and policies regarding the creation, maintenance, retention and destruction of hard copy medical records typically extends to electronic health records. Additional requirements for electronic health records may apply at the provincial and territorial level.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Patent Act and its regulations, including the Patent Rules and the Patented Medicines (Notice of Compliance) (PMNOC) Regulations, govern patent protection in Canada. Canadian jurisprudence is also a source of patent law (eg, double patenting).

To be patentable, an invention must claim new, useful and non-obvious subject matter. There are no specific patentability requirements for pharmaceuticals or medical devices; however, various issues commonly arise in patent cases involving pharmaceuticals and medical devices, including whether the patent claims are directed to a method of medical treatment (not patentable) or are ambiguous, lack utility, or are invalid on the basis of anticipation, obviousness, insufficiency of written description or double patenting.

The PMNOC Regulations create a linkage regime which ties the approval of subsequent entry products (generics, biosimilars) to the patent status of the brand-name reference product.

The pricing of patented medicines is regulated by the PMPRB pursuant to the Patent Act and the Patented Medicines Regulations.

9.2 Second and Subsequent Medical Uses

Patent protection is available for new uses of known compounds, so long as they satisfy the requirements of patentability and are directed to new, useful and non-obvious subject matter. Methods of medical treatment and surgery are not considered to be patentable subject matter, whereas claims to the use of a vendible product are permitted. This distinction often turns on whether a specific dosage amount and/or specific administration is recited in the claims.

A new dosage regimen or use of a medicine in selected patient population may be patentable if it satisfies the requirements of patentability and does not require the exercise of skill and judgement by a physician such that it is considered a method of medical treatment.

Any activity that interferes with the full enjoyment of the monopoly granted by the patentee is an infringing activity. This can include both direct and indirect infringement by way of inducement. Three factors are required to establish indirect infringement. First, the act of infringement must have been completed by the direct infringer. Second, the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place. Third, the influence must knowingly be exercised by the inducer.

9.3 Patent Term Extension for Pharmaceuticals

In Canada, a patentee or licensee may obtain a Certificate of Supplementary Protection (CSP) pursuant to the Patent Act and Supplementary Protection Regulations. CSPs provide a maximum of up to two additional years of patent-like protection for eligible patent claims directed to pharmaceutical products. To be eligible for a CSP, the patent must pertain to a medicinal ingredient, or a combination of medicinal ingredients contained in a drug which is authorised for sale. The additional protection begins on the 20-year expiration date of the patent provided it remained in force at that time. The CSP allows for the continued rights of the patentee; however, third parties are permitted to make, construct, use or sell the medicinal ingredient or combination of ingredients for export from Canada. Only one CSP is available for a given medicinal ingredient or combination.

The Patent Act provides the Court with the authority to declare that a CSP application is invalid or void. However, only CSP applicants having a CSP application of the same priority may commence such a proceeding.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement of a pharmaceutical or medical device includes any act that interferences with the full enjoyment of the monopoly granted by the patentee. This can include direct and indirect infringement by way of inducement.

A party can bring an action for a quia timet injunction in situations where it can be established that the anticipated infringing activity will be imminent. There is a stringent test for such injunctions, and they are rarely granted.

The PMNOC Regulations also effectively allow for quia timet patent actions by permitting a patent owner to prevent the sale of unapproved biosimilars or generic drugs for up to two years.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

There are several exemptions to patent infringement in Canada in relation to pharmaceuticals and medical devices. Section 55.2 of the Patent Act permits the use of a patented invention to obtain governmental regulatory approval and Section 55.3 further permits experimental use. There is also a common law exemption from infringement for experimental use.

The Patent Act also permits the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention only to the extent necessary to respond to a public health emergency. A compulsory licence issued under such conditions may be active for up to one year. The Commissioner of Patents also has the authority to grant a compulsory licence in certain cases of patent rights abuse.

9.6 Proceedings for Patent Infringement

An action for patent infringement may be brought by the patentee and all persons claiming under the patentee pursuant to section 55(1) of the Patent Act. A person claiming under the patentee is someone who obtained rights to use the patented invention from the patentee – eg, exclusive and non-exclusive licensees. The patentee must be a party to any infringement action such that if they decline to be named as a co-plaintiff, they must be named as a defendant or "mise en cause" under Quebec law.

The presumptive remedy for patent infringement is damages. However, the Court may allow the patentee to elect an accounting of the infringer's profits in some cases. The Court also has jurisdiction to issue a permanent injunction and require the delivery up or destruction of any infringing goods.

The typical litigation process requires the patentee (or any person claiming under the patentee) to serve and file a Statement of Claim alleging one or more acts of infringement. Actions can be filed in the Federal Court of Canada or in the superior court of the province where the alleged infringement took place. The defendant may respond by serving and filing a Statement of Defence alleging non-infringement and/or patent invalidity as a common defence. The defendant will also typically allege a counterclaim that the patent is invalid. (This relief may only be sought in the Federal Court). The defendant may also bring several preliminary motions including a motion to strike and or motion for summary judgment.

9.7 Procedures Available to a Generic Entrant

The PMNOC Regulations allow a subsequent-entry manufacturer (generic, biosimilar) to allege that patent(s) listed on a register against the brand-name reference product are not valid and/or would not be infringed by the manufacture, use or sale of the subsequent-entry product in Canada. Upon receipt of such an allegation, the patent owner may commence an infringement action against the subsequent-entry manufacturer in the Federal Court. By commencing an action, Health Canada's decision on whether to approve the subsequent-entry product is frozen for 24 months or until the disposition of the action in Federal Court, whichever is earlier. There are certain scenarios whereby a subsequent-entry manufacturer may launch its product "at risk", including instances in which the patentee waives its right to a 24 month stay.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The sale of counterfeit pharmaceuticals and medical devices is governed primarily by the Customs Act, the Combatting Counterfeit Products Act (CCPA), the Trademarks Act, the Patent Act, the Copyright Act and the Criminal Code. Counterfeit health products and associated activities also constitute violations of the FDA and its Regulations.

Through the CCPA, registered copyright and trademark owners may obtain assistance from the CBSA by filing a Request for Assistance (RFA) for border officials to detain commercial shipments suspected of containing counterfeit goods. The RFA is valid for two years and can be renewed before expiry. Once an RFA is filed, the CBSA can provide information to the RFA holder in respect of shipments and samples of the suspect goods.

If counterfeit goods are discovered, customs officers are permitted to temporarily detain them for a period of five days, in the case of perishable items, and ten working days for non-perishable items, and to provide information to the IP rights-holder about the items detained. To extend the detention period, the IP rights-holder must bring a court action to enforce the prohibitions on counterfeit goods and provide notice of the legal proceeding to the Minister before the detention period expires.

In addition, health products are examined for compliance at the board or at a Canadian establishment during compliance verifications or inspections. If the Health Products and Food Branch Inspectorate suspects or confirms counterfeit health products, then Health Canada may take several types of enforcement action, including notifying the RCMP, recommending the refusal or seizure of imports at the border, ordering the removal or destruction of imports at the border, as well as seizure and detention, forfeiture and destruction.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Under the FDR, Health Canada must approve a drug's proposed brand name. This process is distinct from the trade mark registration process conducted by the Canadian Intellectual Property Office. Both processes deal with the potential for consumer confusion, but Health Canada also examines the name from a health and safety perspective. Review of marks pursuant to the Trademarks Act is conducted based on the likelihood of confusion with another mark as to the source of origin.

Health Canada's approval for medical device names is not required.

There are no specific restrictions for parallel importation under the Trademarks Act. However, there are certain labelling and language requirements under the FDR for drugs and the MDR for medical devices being imported into Canada.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Certain trade dress or non-traditional marks can be protected under the Trademarks Act and at common law. Pursuant to the Trademarks Act, the requirements for non-traditional trade marks – eg, a hologram, moving image, scent, taste, colour, shape, mode of packaging good, and/or texture, will depend on the nature of the trademark and will be subject to examination by the Trademarks Office for distinctiveness.

Unregistered trade dress may also be protected under the tort of passing off at common law. Generally, there are three necessary elements to establish passing off: the existence of goodwill or reputation in the trademark; deception of the public due to misrepresentation; and actual/potential damage.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Canada provides eight years of data exclusivity for an "innovative drug" that contains a medicinal ingredient not previously approved and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. Data protection applies to chemical drugs and biologics.

Canada will not issue market authorisation for a drug based on a comparison, either direct or indirect, to an innovative drug for eight years from the issuance date of the innovative drug's first market authorisation. In addition, manufacturers that seek approval on the basis of a comparison are prohibited from filing a submission for a copy of that innovative drug until six years after the first market authorisation has elapsed.

The data protection period may be extended by a further six months if, within the first five years of the eight-year period, the results of paediatric clinical trials, designed and conducted for the purpose of increasing knowledge of the use of the drug in paediatric populations, are also submitted and found acceptable.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Health Canada made various interim orders (IOs) to establish a temporary regulatory pathway for drugs and vaccines related to COVID-19 to expedite their authorisation. Following these temporary measures, amendments to the FDR were introduced to facilitate the review, authorisation and oversight of COVID-19 drugs and vaccines.

On 22 February 2023, the Regulation Amending the MDR (Interim Order No 3 respecting the Importation and Sale of Medical Devices for use in relation to COVID-19) was adopted to facilitate access to medical devices related to COVID-19. This created a permanent regulatory framework for COVID-19 medical devices while also maintaining most of the flexibilities introduced by earlier IOs for devices on the List of Medical Devices for an Urgent Public Health Need in Relation to COVID-19 (UPHN list).

Other IOs were adopted to prevent or ease shortages of drugs and medical devices by allowing the importation of foreign drugs and medical devices that met similar high quality and manufacturing standards as Canadian-approved products in addition to other provisions. Another IO authorised the Minister of Health to compel anyone, under certain conditions, who sells drugs to provide information about shortages or potential shortages of that drug related to COVID-19. These provisions have since been incorporated into the amended FDR.

11.2 Special Measures Relating to Clinical Trials

Health Canada adopted special measures to assist with the running of ongoing clinical trials as a result of the pandemic. Sponsors were required to document any measure they took to reduce the risk of COVID-19 infection. If the physical site for visits changed, trial participants were required to consent to the transfer of any identifiers from the original site to the new site. Additional guidelines for the management of ongoing clinical trials included consideration of safety monitoring measures; informing study participants of any changes to the study and monitoring plan; and identification of all participants affected by a COVID-19 study disruption with a unique participant identifier.

The interim IOs were replaced by the Clinical Trials for Medical Devices and Drugs Related to COVID-19 Regulations, which came into effect on 27 February 2022. These new regulations are intended to facilitate the regulatory pathway for clinical trials for drugs and medical devices related to COVID-19. The regulations are expected to remain in force until additional measures under Canada's Clinical Trials Modernization Initiative plan are adopted. Applicants for COVID-19 drug trials can either apply for authorisation under the FDR or under the Medical Devices and Drugs Related to COVID-19 Regulations. Trials under the Medical Devices and Drugs Related to COVID-19 Regulations are subject to modified requirements. Similarly, applicants for COVID-19 medical device trials can either apply for authorisation under the MDR or under the Medical Devices and Drugs Related to COVID-19 Regulations.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

IOs respecting the sale of drugs for use in relation to COVID-19 were put in place temporarily to facilitate the emergency approval of COVID-19 related drugs, including prescription and non-prescription pharmaceuticals, radiopharmaceuticals and biologic products. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through the NDS regulatory pathway. The amendments maintain some of the earlier mechanisms from the IOs, thus continuing to facilitate the approval of COVID-19 related drugs.

Similarly, IOs were put in place respecting the sale of medical devices for use in relation to COVID-19. On 22 February 2023, Health Canada subsequently introduced the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19) that provide for accelerated access to, and approval of, COVID-19 medical devices that have an urgent public health need.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Health Canada introduced several temporary measures to provide greater regulatory flexibility for drug establishment licensing and good manufacturing practices during the pandemic. This included accelerated regulatory pathways and modified schedules for Health Canada inspections related to drugs manufactured in Canada and abroad. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs. COVID-19-related Drug Establishment Licence applications submitted under the amended Regulations are processed by Health Canada in an expedited manner on a case-by-case basis.

Similar amendments to facilitate the regulatory approval of medical devices, including drug establishment licences, were put in place through the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19).

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

IOs respecting the importation of drugs for use in relation to COVID-19 were put in place to facilitate the emergency approval of COVID-19 related drugs, including prescription and non-prescription professional use pharmaceuticals, radiopharmaceuticals, biologics such as vaccines and veterinary drugs. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs. The amendments maintain some of the mechanisms introduced through the IOs.

Similarly, IOs were put in place respecting the importation of medical devices for use in relation to COVID-19. On 22 February 2023, Health Canada introduced the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19) that provides for accelerated access to COVID-19 medical devices that have an urgent public health need.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Many measures have been put in place to accelerate the use of virtual and digital healthcare in light of COVID-19:

- a Virtual Care Task Force (VCTF) report was released by the Canadian Medical Association (CMA), the College of Family Physicians of Canada (CFPC) and the Royal College of Physicians and Surgeons of Canada on 11 February 2020, to provide a framework for expanding the use of virtual care;
- all jurisdictions in Canada revised their healthcare fee codes to facilitate the virtual delivery of care;
- a Virtual Care/Digital Table organised by all levels of government endorsed a policy framework for virtual healthcare services within Canada;
- a Canadian Network for Digital Health Evaluation was created to strengthen Canada's capacity to evaluate digital health interventions;
- the Federal Government signed several bilateral agreements with various provinces/territories including Ontario to enhance virtual health services at the provincial and territorial level; and
- several provinces and territories also developed virtual care action plans.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The COVID-19 Emergency Response Act was enacted in response to the pandemic. It provides that the Commissioner of Patents may, on the application of the Minister of Health, authorise the Government of Canada (and any person specified in the application) to make, construct, use and sell a patented invention in order to respond to a public health emergency. Such an authorisation ceases after the earlier of one year or the day on which the public health emergency ends. The patentee is provided compensation by the Government of Canada (or the person specified in the application), but the amount is discretionary taking into account the economic value of the authorisation and the extent the patented invention is used.

The Patent Act also provides that the Commissioner of Patents in Canada may authorise the use of a patented invention by a provincial government or government of Canada.

To date, there has been no public announcement of a compulsory licence being granted for COVID-19-related treatments in Canada.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Canada did not invoke liability exemptions through the Emergencies Act in response to COVID-19.

11.9 Requisition or Conversion of Manufacturing Sites

Health Canada and other government departments collaborated with the health product industry to provide medical supplies, including manufacturing scale-up and re-tooling of sites.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The federal and provincial/territorial governments made changes and updates to the systems of public procurement due to COVID-19.

At the federal level, the Treasury Board of Canada published a Contracting Policy Notice 2020-1 – Response to COVID-19 on 23 March 2020, which provided that the Board had approved time-limited increases to emergency contracting limits including that the Minister of Public Services and Procurement had unlimited emergency contracting limit for the research development, acquisition and deployment of vaccines related to COVID-19 until 31 March 2021. This Notice

also set out that Public Services and Procurement Canada was co-ordinating the centralised purchase of specific goods, such as personal protective equipment on behalf of the federal and provincial/territorial governments.

There were also some changes at the provincial/territorial level. For example, in Ontario, the Coronavirus (COVID-19) Response and Recovery Regulations (O. Reg. 92/20) were introduced under the Supply Chain Management Act. Under this regulation, the Ministry of Government and Consumer Services and the Ministry of Health were designated as the supply chain management entities for the purposes of responding to COVID-19. Quebec also authorised the Minister of Health Services and Social Services to enter into any contracts necessary for public health.

Trends and Developments

Contributed by:
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Markwell LLP is a Canadian law firm with extensive experience in patent litigation and regulatory issues impacting the life sciences industry. The firm helps clients navigate the complex regulatory system governing the approval and sale of health products in Canada, including data protection, patent linkage, patent term restoration, pricing, formulary interchangeability, product listing agreements and advertising. Its counsel attend meetings with regulators and appear as litigation counsel at hearings before the Patented Medicine Prices Review Board (PMPRB) and judicial review applications. Markwell LLP also represents clients in patent infringement and impeachment actions, injunction motions, appeals and interventions, including cases under the Patented Medicines (Notice of Compliance) Regulations. The founding partners have appeared as counsel in many precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal, the Federal Court and the PMPRB.

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Introduction

The life sciences sector is an important part of Canada's innovation economy. It employs hundreds of thousands of people and contributes billions of dollars to its gross domestic product. The ecosystem includes universities, public research institutions and private companies operating across a wide range of industries, including pharmaceuticals, biotechnology, medical devices, agriculture, agrifood, cosmetics and environmental technologies.

Several regulatory initiatives have been implemented or proposed in recent years to achieve certain public policy goals relating to life sciences, including a national life sciences strategy, proposals on national pharmacare, strategies for rare diseases, pricing reform for patented medicines, updates on biosimilar switching policies, and changes to certain food labelling rules, as well as reports and investigations by the Competition Bureau. Each of these is discussed below with an emphasis on key trends and developments.

National Life Sciences Strategy

Canada has a record of success in the development of new drugs. However, the COVID-19 pandemic highlighted the critical need to boost Canada's domestic biomanufacturing capabilities.

In June 2021, the federal government announced a ground-breaking "Biomanufacturing and Life Sciences Strategy" that was driven by two main objectives: (i) to grow a strong, competitive domestic life sciences sector, with cutting-edge biomanufacturing capabilities, while creating good jobs for Canadians; and (ii) to ensure Canada is prepared for pandemics and other public health emergencies in the future.

This "new era of health innovation" consists of five pillars: (i) strong and coordinated governance; (ii) strengthening research systems and the talent pipeline; (iii) growing businesses by "doubling down" on existing and emerging areas of strength; (iv) building public biomanufacturing capacity; and (v) enabling innovation by ensuring "world class regulation".

Since this strategy was announced, the government has invested billions of dollars in new life science projects across the country, including the construction of a new Biologics Manufacturing Centre to produce large quantities of vac-

cines; the creation of a Bioscience Research Infrastructure Fund to support research institutions and hospitals; a Stem Cell Network to support research in regenerative medicine; and investments in private companies to support scale-up and commercialisation.

This comprehensive federal strategy has the potential to be historic and transformative. However, it remains to be seen how the government will balance its post-COVID pledge to expand the life sciences sector with its pre-COVID commitment to reduce the price of commercialised drug products.

National Pharmacare

Universal public healthcare is a pillar of Canada's national identity.

In 2015, the Liberal Party, led by now Prime Minister Justin Trudeau, promised that if it were to be elected to office, the government would "make prescription drugs more affordable" by creating a national pharmacare programme with three foundational elements: (i) a national agency to assess pharmacoeconomic value and to negotiate lower prices; (ii) a national formulary of insured drug products; and (iii) reform of the federal agency that regulates the prices of patented drugs (PMPRB). This was said to be the "most significant suite of changes proposed [to health policy] in over two decades". The party was elected to a majority government in October 2015.

In February 2018, the government created an Advisory Council on the Implementation of National Pharmacare to "ensure every Canadian has access to the medicine they need" and to "make prescription drugs more affordable and accessible". This led to a sweeping report in June 2019 which held that the amount Canadians currently spend on prescription drugs is "unacceptable" and that the federal government should "work with provincial and territorial governments and stakeholders" to establish a universal, single-payer, public pharmacare system. This new programme would comprise a Canadian Drug Agency to negotiate prices on behalf of public payors, a national formulary of "essential medicines", and a national strategy for access to expensive drugs for rare diseases.

In April 2019, the government announced its intention to "move forward" with a national pharmacare programme and to work with provinces, territories and other partners in the "coming months" to "develop a vision and mandate" for a new Canadian Drug Agency. The Liberal party was re-elected to a minority government in October 2019.

Throughout 2020 and 2021, the federal government was focused on the COVID-19 pandemic and ensuring that Canadians had timely access to vaccines and other therapeutics. As such, most of the proposed healthcare reforms were put on hold, officially or otherwise, while the country addressed more urgent needs.

In September 2021, the Liberal party ran for re-election on a promise to "put health and safety first" and to "provide better healthcare for everyone". National pharmacare was mentioned briefly in the campaign platform but was not identified as a "top priority". Instead, the party noted that "[o]ne of the key lessons of COVID-19 is that fundamental science and research is vital to our long-term well-being and prosperity". The Liberal party was elected to form its second minority government in October 2021.

In March 2022, the Liberal government entered into an agreement with the left-leaning New

Democratic Party (NDP) to secure the necessary votes to pass a budget and withstand a confidence vote. In return, the government promised to "make progress towards a universal national pharmacare programme by passing a Canada Pharmacare Act by the end of 2023 and then tasking the National Drug Agency to develop a national formulary of essential medicines and bulk purchasing plan by [June 2025]".

In January 2023, the NDP leader said publicly that he "wants to see a national framework for pharmacare presented in Parliament and passed in Parliament by the end of the year". On 28 March 2023, the federal government tabled its budget in the House of Commons, and it did not include spending on a national pharmacare programme. Despite the omission of pharmacare from the recent budget, the NDP has indicated that it will continue to support the Liberal government.

It is expected that the development of a pharmacare programme in Canada will continue to be a major issue in the coming years.

Rare Diseases

The 2019 report on the Implementation of National Pharmacare recommended that Canada adopt a national strategy to provide fair, consistent, and evidence-based access to expensive drugs for rare diseases. More specifically, the Advisory Council proposed that the to-be-formed "Canadian Drug Agency" create a "distinct pathway" for rare disease drugs to "ensure that innovative, life-changing drugs" are made available to patients on a timely basis. The Advisory Council did not suggest that Canada should provide economic or intellectual property incentives to encourage the development and sale of drugs for rare diseases, such as the type of "orphan drug" protection that is available in many other industrialised nations.

In its 2019 Budget, the federal government committed to invest up to CAD1 billion over two years, starting in 2022-23, with an on-going investment of CAD500 million annually thereafter.

In January 2021, Health Canada "invited Canadians to share their ideas and views on what a national strategy [for rare diseases] could look like." Feedback received from over 650 individuals and organisations was reflected in a July 2021 report entitled "Building a National Strategy for Drugs for Rare Diseases: What We Heard from Canadians". Health Canada promised to continue discussions with stakeholders "over the summer" and to engage in further public consultation in the Fall "to build a strategy that will work for all Canadians", with a view "towards launching a national strategy for rare diseases in 2022".

On 22 March 2023, the Minister of Health announced measures supporting a National Strategy for Drugs for Rare Diseases including an investment of up to CAD1.5 billion over three years.

PMPRB Reform

The Liberal party promised in its 2015 election platform to reform the federal agency that regulates the prices of patented drugs (PMPRB).

The PMPRB (or "Board") has a statutory mandate to ensure that patented medicines are not sold in Canada at an "excessive price". To meet this objective, patentees must submit ex-factory sale prices for medicines at launch and on a semi-annual basis thereafter. The Board then compares the sale price in Canada to the sale

price in certain other industrialised nations. If the Board believes that the Canadian price is "excessive", then it may launch an investigation and start a quasi-judicial administrative proceeding to recover "excess revenue" from the patentee.

In May 2017, the Minister of Health announced consultations on a suite of regulatory changes related to the work of the PMPRB. This was followed by a white paper entitled "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations" and a consultation period in which the government heard from interested stakeholders.

In August 2019, the government proposed regulations to "provide the Board with new price regulatory factors and information to protect consumers against excessive prices of patented medicines". This included a new schedule of countries for international price comparisons and a pharmacoeconomic analysis to assess value. Draft guidelines were published in June 2020.

The proposed regulatory amendments and draft guidelines were challenged by the innovative pharmaceutical industry. In February 2022, the Quebec Court of Appeal held that the proposed pharmacoeconomic analysis and reporting of net prices were not a valid exercise of federal jurisdiction under the Constitution Act. These same provisions were later held to be invalid by the Federal Court of Appeal. The revised basket of comparator countries was upheld by both courts.

In April 2022, the government announced that it would abandon the impugned aspects of the Regulations and move forward only with the revised basket of comparator countries. Those provisions came into force on 1 July 2022.

In October 2022, the PMPRB released revised draft guidelines to explain how it would review prices under the new regime. Eighty-eight stakeholders provided feedback during the 60-day consultation period.

- Private insurers were in favour of the proposed guidelines because they will lower the price of drugs and the corresponding quantum of claims.
- Patient advocacy groups were generally opposed to the new guidelines because they prioritised price over value and because there was insufficient consultation with stakeholders.
- The innovative pharmaceutical industry association (IMC – Innovative Medicines Canada) submitted that the draft guidelines were inconsistent with the government's existing health and life sciences priorities, including the National Strategy on Drugs for Rare Diseases and the Biomanufacturing and Life Sciences Strategy, and would have a negative impact on patients' access to new medicines.
- The generic drug industry association (CGPA – Canadian Generic Pharmaceutical Association) was concerned that the new guidelines would have a negative impact on the price of generic and biosimilar medicines, which are set by reference to the price of the corresponding brand-name product. CGPA argued that the further price cuts to generic pharmaceutical products would "threaten the supply of medicines upon which Canadians rely".
- Health Canada was concerned that the "new version of the guidelines includes a number of differences from existing or previously proposed guidelines", including "pivotal changes from a long-standing practice of includ-

ing price tests and price ceilings to instead include investigation criteria".

IMC, CGPA and Health Canada called on the PMPRB to suspend the implementation of the guidelines to allow for further consultation and collaboration with stakeholders.

On 28 November 2022, the Minister of Health asked the Board to suspend the guideline consultation process to allow for further consultation. One week later, on 5 December 2022, the Acting Chairperson resigned from the Board. This was followed by the resignation of a Board member on 1 February 2023, and the subsequent resignation of the executive director on 24 February 2023. A new Board chair was recently appointed.

We do not know if or when new PMPRB guidelines will be introduced, or what type of framework will ultimately be employed by the Board to determine if a medicine is sold at an excessive price. The lack of guidance in respect of the new regulations is causing significant uncertainty for all stakeholders.

Biosimilars

Biosimilar drugs have been available for sale in Canada since 2014.

Manufacturers that want to sell a biosimilar drug in Canada must file a new drug submission to establish the quality of the product and perform comparative studies to demonstrate highly similar structure, function, safety and efficacy to a previously authorised reference biologic drug. Manufacturers must also comply with the federal Data Protection Regulations (six-year no filing; eight-year no approval) and PMNOC Regulations (patent linkage), if applicable. Once approved, each provincial/territorial government must decide whether pharmacists may dispense the biosimilar instead of the reference product (also known as interchangeability) and the reimbursement criteria.

To date, 50 biosimilars of 16 innovator reference products have been approved for sale and nine submissions have been accepted into review, but have not yet been approved. Eight public drug plans, including those in the four most populous provinces (British Columbia, Alberta, Ontario and Quebec), and several large private insurers have implemented mandatory switching policies to reduce drug costs.

Medical Devices

Medical devices are a major component of the Canadian life sciences ecosystem.

The key business segments of the Canadian market in 2020 were: diagnostic imaging (21%); consumables (15%); patient aids (16%); orthopaedic and prosthetic (10%); dental products (8%), and "other", including wheelchairs, ophthalmic instruments, anaesthesia apparatus, dialysis apparatus, blood pressure monitors, endoscopy apparatus and hospital furniture (30%). There is a very low level of industry concentration, with no single large company controlling the market. Most manufacturers are small and medium-sized enterprises.

Medical devices are regulated federally by Health Canada. In 2018, the government proposed a Medical Device Action Plan (MDAP) to reform the existing regulatory framework in accordance with three pillars: (i) improving how devices get on the Canadian market; (ii) strengthening the monitoring and follow-up of medical devices used by Canadians; and (iii) providing more information to Canadians about the medical devices they use.

Since the 2018 MDAP was released, Health Canada has taken many important steps to improve the regulatory framework for medical devices, including the following.

- Regulations requiring hospitals to report medical device incidents. This allowed Health Canada to better assess the efficacy of personal protective equipment during the COVID-19 pandemic.
- Regulations allowing Health Canada to request tests, studies and new assessments from manufacturers.
- Regulations requiring manufacturers to inform Health Canada within 72 hours if there are new warnings in certain other markets about serious risks associated with their products.
- Searchable public web portals of medical device clinical data, medical device incidents, and regulatory decision summaries.

In May 2021, the government published a progress report and undertook to do three things in furtherance of the 2018 MDAP: (i) create an environment that encourages and supports the conduct of clinical trials; (ii) design and implement a new approval pathway for innovative products that do not fit easily under the existing regulations; and (iii) create more agile and flexible rules to regulate medical devices throughout their lifecycles based on the level of risk they present.

Competition Policy

The Competition Bureau is an "independent [federal] law enforcement agency that protects and promotes competition for the benefit of Canadian consumers and businesses".

In January 2022, the Bureau and Health Canada gave notice that they will "continue to work together" to address four "increasingly complex issues of mutual importance", namely: (i) general information sharing; (ii) co-operation on Bureau enforcement actions; (iii) access to medicines (including "designing laws, regulations and policies in a way that balances policy objectives, including access to safe and effective therapies with competition considerations"); and (iv) providing feedback on competition-related issues that impact access to medicines for Canadians.

In May 2022, the Bureau announced that it had closed two recent investigations into potentially anti-competitive patent litigation settlement agreements involving two unspecified pharmaceutical drugs, as the "evidence gathered" from undisclosed sources "did not contravene the Act". Nonetheless, the Bureau reminded stakeholders that it will "proactively monitor these cases using publicly available information" and will "take appropriate enforcement or advocacy action in the future, if warranted", as set out in its Intellectual Property Enforcement Guidelines (2019).

In June 2022, the Bureau completed its investigation into potential anti-competitive harm arising from relabelled biologic drugs – ie, drugs that are identical to originator biologic drugs but marketed under a secondary brand name. The Bureau closed the investigation because the drugs in question had not been marketed in Canada. Nonetheless, the Bureau noted that "in some cases, relabelling drugs could harm competition by… reducing incentives for pharmaceutical companies to develop and market biosimilars". The Bureau said that it will "continue to closely monitor the Canadian biologic and biosimilar industry to respond to developments that have the potential to disrupt competition in this critical sector of the economy".

In November 2022, the Bureau released a final report arising from its study of the digital healthcare market. The Bureau found that digital healthcare is not being used to its full potential in Canada, as only 14% of patients had visited their provider virtually by 2021. The Bureau made three recommendations to "take advantage of the forces of competition": (i) review existing healthcare provider payment models to support the appropriate use of digital healthcare; (ii) implement licensing frameworks that allow providers, where appropriate, to practice beyond provincial and territorial borders to improve digital healthcare delivery; and (iii) review and modernise policies to facilitate the effective uptake of digital healthcare.

Food Labelling

In June 2020, Health Canada announced new nutrition labelling regulations for certain packaged foods "to help Canadians make informed food choices". The regulations require a new symbol in the shape of a magnifying glass to be placed on the front of packaged foods that are high in saturated fat, sugars and/or sodium. Manufacturers have until 1 January 2026, to change their labels and comply with the new requirements. This initiative is part of Canada's ongoing "healthy eating strategy".

In July 2022, Health Canada announced new regulations for pre-packaged foods containing one or more added ingredients, such as vitamins, mineral nutrients, amino acids, caffeine or herbal extracts ("supplemented foods"). Under the new regulations:

- supplemented foods must have a standardised Food Facts table that discloses the amount of each supplemental ingredient added;
- supplemented foods containing specific ingredients must be labelled to provide information for consumers on the cautions and directions for use, if appropriate; and
- supplemented foods are subject to strict compositional limits and conditions of use.

The new regulations apply to supplemented foods that are submitted for approval on or after 21 July 2022. Existing products have until 1 January 2026, to come into compliance.

Conclusion

The life sciences industry in Canada has faced significant challenges in recent years due to COVID-19, regulatory amendments and policy changes. As Canada recovers from the pandemic, the trends and developments mentioned in this paper will continue to shape the evolution of the industry.

CHINA

Law and Practice

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Contents

Global Law Office (GLO) has become one of the largest, leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. Its life sciences and healthcare practice group was one of the first in China and provides "one-stop" legal services for every area of the industry, including M&A, investment and funding, licence in and out, daily operation, IP protection, and advice on compliance, including internal and government investigations as well as anti-bribery matters and dispute settlement. Under a changing regulatory environment, GLO's team has the perfect combination of international experience and local knowledge to support various innovation or pilot projects, including digital healthcare and MAH/cMAH trial cases. The team participates in the formulation of local codes of conduct and benchmark policies/rules, and also co-operates closely with associations such as the CPIA, the RDPAC and the ACCP.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Legislation and Regulations

The primary statute regulating pharmaceuticals in China is the Drug Administration Law (DAL). Together with its implementing rules, referred to as the DAL Implementing Regulations, the DAL governs various drug-related activities, including drug development, registration, manufacturing and distribution.

In order to address statutory requirements under the DAL for each of these activities, GxP (good practice) rules on laboratory, clinical trials, manufacturing, distribution and pharmacovigilance (PV) have also been enacted, as well as administrative measures on matters such as drug registration, manufacturing, distribution and recall. Product-specific laws, rules and guidelines, such as the Vaccine Administration Law and the Administrative Measures on Blood Products, also apply to the respective products.

The Regulations for the Supervision and Administration of Medical Devices (RSAMD) have been enacted to set up the regulatory framework for the administration of medical devices. The development, registration/filing, manufacturing and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules and administrative measures. Product-specific rules and guidelines have also been released and implemented.

RSAMD were amended in 2021 to officially incorporate marketing authorisation holder (MAH), conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. RSAMD 2021 also significantly increase administrative punishment for violation and impose legal liabilities on the legal representatives and persons in charge of the entities violating RSAMD. Furthermore, the Administrative Measures on the Registration and Record-filing of Medical Devices ("Device Registration Measures") and the Administrative Measures on the Registration and Record-filing of In Vitro Diagnosis (IVD) Reagents were released to respectively update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

The SAMR is the authority on the national level for the market supervision, administration and law enforcement of pharmaceuticals and medical devices, in the areas of anti-monopoly, product quality safety, food safety, IP, fair competition and commercial bribery, the issuance of business registrations, and certifications and accreditations, among other things. The SAMR is a ministry-level government agency directly under the State Council.

National Medical Products Administration (NMPA)

As a national bureau operating under the supervision of the SAMR, the NMPA regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, and supervision and inspection of pharmaceuticals and medical devices.

The NMPA also supervises permit/filing receipt issuance and law enforcement on pharmaceuticals and medical devices on the provincial level, while the local administrations for market regulation are in charge of certain permit issuance

and law enforcement on pharmaceuticals and medical devices on the city and county levels.

National Health Commission (NHC)
The NHC is a constituent department of the State Council and is mainly responsible for national health policies, the reform of the medical and healthcare system, disease prevention and control, national drug policies, and the national basic drug system. The NHC supervises the National Administration of Traditional Chinese Medicine.

National Healthcare Security Administration (NHSA)
The NHSA is mainly responsible for the preparation and implementation of regulations and policies related to basic medical insurance (BMI), including policies regarding reimbursement, pricing and procurement for pharmaceuticals and medical services. The NHSA is a sub-ministry-level government agency directly under the State Council.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies that apply and enforce regulations of pharmaceuticals and medical devices can be challenged through an administrative review or administrative litigation; these procedures also apply in general vis-à-vis administrative regulatory bodies for other regulated products.

Citizens or legal entities who wish to challenge regulatory body decisions may first apply for administrative review. If they refuse to accept decisions made by the reviewing body, they may file a lawsuit in court, unless the administrative review decisions are final as prescribed by law. Alternatively, they may institute proceedings directly with a court, except in certain circumstances where laws and regulations provide that they must apply for an administrative review first. Once the court has accepted the case, citizens or legal entities may no longer ask for an administrative review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals
The DAL classifies drugs as prescription drugs and non-prescription (over-the-counter – OTC) drugs, and they are regulated differently. A patient must present prescriptions when purchasing prescription drugs, while OTC drugs can be bought without prescriptions. China further subdivides OTC drugs into Class A and Class B, according to their safety level.

Medical Devices
The RSAMD classify medical devices into Class I, Class II and Class III according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices are those with the highest risk level, and their safety and effectiveness should be ensured by strict control and regulation.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials for pharmaceuticals are regulated by laws and an array of guidance and technical review standards. Specifically, the DAL and the Administrative Measures for Drug Registration (2020 Revision) establish the primary principles and statutory requirements for clinical trials. Guidance and technical review standards such as Good Clinical Practice (GCP) for Drug Trials and Pharmaceutical Research Information Guide for phase III Clinical Trials of Innovative Drugs (Chemical Drugs) provide guidance detailing the

obligations of the parties involved, operational procedures, technical requirements, etc.

Likewise, for clinical trials for medical devices, the RSAMD and Device Registration Measures set out the legal framework on whether and how clinical trials of medical devices should be conducted, while an array of review standards and guidance such as GCP for Medical Devices Trials further specify operation guidance and technical requirements for conducting clinical trials. It is noteworthy that GCP for Medical Devices Trials was amended in 2022 to be consistent with the latest regulatory framework of medical devices. For IVD reagents (a special type of medical devices), the NMPA published a separate guideline to provide special principles for IVD clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisations, unless otherwise exempted by law (such as certain generic drugs and IVD administrated under drug-related laws). Before a clinical trial can be conducted, it must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA. The general steps for securing clinical trial authorisation are as follows:

- a review by an ethical committee prior to initiation;
- a sponsor may need to apply for a pre-consultation meeting with the NMPA;
- the sponsor may conduct a clinical trial for a pharmaceutical if it has not received any objection or query from the CDE within 60 days of the date the clinical trial application is accepted;
- if there is no objection from the CDE, the sponsor may implement the clinical trial at the conclusion of the 60-day period – if the sponsor is required to submit supplementary documents, the 60-day review period will be re-calculated; and
- if the CDE issues an objection to the sponsor, the sponsor may reply in writing with regards to all issues raised by the CDE and reapply for approval of the clinical trial. The CDE will further review and determine whether to approve that clinical trial within 60 days of receiving the reapplication, and the sponsor is only allowed to implement the clinical trial upon receipt of the CDE's written approval.

Generally, clinical trial requirements for medical devices are divided according to relevant classification. Specifically, Class I medical devices are exempted from clinical evaluations. A clinical evaluation or even clinical trials could be triggered for Class II and III medical devices, subject to their safety and effectiveness.

- Clinical evaluation – unless otherwise exempt from a list issued by the NMPA, Class II and III medical devices are subject to clinical evaluation. Clinical evaluation will be conducted by the NMPA according to the technical guidance.
- Clinical trial – if the existing clinical literature and clinical data are insufficient for evidencing the safety and effectiveness of a medical device, a clinical trial should be implemented instead.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform (www.chinadrugtrials.org.cn) hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration.

There is no publicly available database for clinical trials of medical devices in China.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions on using online tools to support clinical trials, provided that the use of such online tools is subject to generally applicable laws and regulations with respect to personal information protection, online advertising, etc.

2.5 Use of Data Resulting From the Clinical Trials

Raw data generated from clinical trials may consist of trial subjects' personal information, health data, genetic resources, etc.

The Personal Information Protection Law of the People's Republic of China (PIPL) came into effect on 1 November 2021 and provides a legal framework for the administration of handling personal information. During the conduct of clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties such as site management organisations may access trial subjects' personal information. However, sponsors will not generally receive any information that may identify trial subjects, but will receive other anonymised data from the trial. Moreover, the sharing and transfer of personal data are subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc.

Human genetic resource sample and data (HGR) are governed by the Biosecurity Law, which came into effect on 15 April 2021, and by the Administrative Regulation on Human Genetic Resources (the "HGR Regulation"). According to the HGR Regulation, HGR collection, use, storage and transfer to foreign parties may be subject to strict statutory requirements. For the time being, foreign parties are only permitted to use Chinese HGR upon filing/approval by the HGR authority. Failing to obtain such approval/filing may result in administrative liabilities or even criminal liabilities.

2.6 Databases Containing Personal or Sensitive Data

In addition to the statutory requirements set out in **2.5 Use of Data Resulting From the Clinical Trials**, the Guidelines for Clinical Trial Data Management issued by the NMPA set out the basic standards for the responsibility, qualification and training of parties responsible for data management, and requirements for the design of data management systems, standardisation of clinical trial data, quality control and the assessment of clinical data.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The DAL defines a "drug" as a substance that is used to prevent, treat or diagnose human diseases and that is intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. The list of types of drugs now includes traditional Chinese medicines, chemical drugs and biological products. The CDE evaluates drug marketing authorisation applications submitted by manufacturers or development institutions.

The term "medical devices" refers to instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or related articles (including com-

puter software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention and monitoring) and whose effectiveness is primarily achieved by physical or other similar means rather than by pharmacological, immunological or metabolic means (or under circumstances where these latter means serve only auxiliary functions). The NMPA's affiliated organisation, the Center for Medical Device Evaluation (CMDE), is responsible for the technical evaluation of medical devices.

The following applies for products containing both a drug and a device (ie, a combination product):

- if similar products on the market are categorised as a drug or a medical device, the product under discussion shall follow the same recognition standard for registration; and
- if no similar products are registered on the market, the applicant shall apply for the product attribute identification with the NMPA and thereafter submit an application for registration to either the CDE or the CMDE.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Market authorisation application for biologic medicinal products generally follows a similar process as mentioned in **3.1 Product Classification: Pharmaceutical or Medical Devices**. Having said that, it is compulsory to conduct verification and examination on manufacturing sites for biologic medicinal products that are being registered, while such verification and examination for other drugs are subject to the CDE's discretion.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Marketing authorisations for drugs and Class II and III medical devices are valid for five years and can be renewed for another five years. Marketing authorisations for Class I medical devices (ie, filing receipts) do not expire.

The NMPA has the power to revoke marketing authorisation for reasons such as the conduct of clinical trials without pre-approval, the use of unapproved package materials or containers, the use of unapproved labels or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc. Conversely, even after obtaining market authorisation, the NMPA could cancel the market authorisation if a product that has been approved lacks effectiveness, has material adverse effects or risks human health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

There are three types of registration applications for drugs:

- drug registration applications;
- re-registration applications; and
- supplemental applications.

Drug Registration

Regarding the requirements under traditional Chinese medicines, chemical drugs and biological products, the following steps are generally required in a drug registration:

- study prior to clinical trials;
- clinical trials;
- submission of a drug registration application;
- registration verification and examination; and
- registration inspection.

The NMPA further provides four kinds of special procedures to shorten the time or facilitate the registration review, including:

- registration for drugs with breakthrough effects;
- registration for drugs with additional approval conditions;
- fast-track registration for drugs with obvious clinical values; and
- registration for drugs that are required to confront public health emergencies.

Re-registration

This is applicable when renewing a valid drug marketing authorisation before expiry.

Supplemental Applications

These are generally required when there are changes to drugs with market authorisation, such as material changes in the drug manufacturing, changes related to drug effect and risks in the instructions, changes of the market authorisation holder, etc. It is worth noting that, when changing the market authorisation holder, the transferee is required to be capable of quality management, risk prevention and control, and of providing liability compensation to ensure drug safety, effect and quality control.

Medical Devices

Class II and III medical devices are administrated by the registration process, while Class I medical devices are administrated by the filing process.

The following processes are generally required to obtain a new marketing authorisation:

- submission of technical product testing report;
- submission of the clinical evaluation for the clinical data to confirm the safety and effectiveness, if required by law;
- examination of the quality management system, which shall comply with good manufacturing practice;
- submission of registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial medical products administration (MPA).

There are certain special procedures to shorten the time or facilitate the registration review, under relevant regulations, including the following.

- A registration procedure for an innovative medical device.
- A priority registration procedure for the following specific medical devices:
  (a) those that have obvious clinical advantages for certain diseases or that are in urgent clinical demand without homogeneous approved medical devices;
  (b) those that are listed in the national key R&D projects; and
  (c) those that are needed in public health emergencies.
- Changes to these marketing authorisations are divided into modification registration item variations (eg, change of product specification or technical requirements) and filing item variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/provincial MPA. Changes to modification registration items may trigger an additional technical review by the CMDE. There is no definitive regulation to permit the transfer of market authorisation of medical devices.
- With respect to the application for Class I devices, the municipal MPA (for domestic

devices) or the NMPA (for imported devices) must be notified. Filling an application for a Class I device generally requires the same materials as those for Class II and III medical devices administrated by the registration process. For any changes to the filing items of Class I devices, the MAH must apply to the original filing authority.

Subject to the above procedures, the NMPA promotes the e-application to accelerate the process of application and approval. It has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The DAL explicitly establishes an expanded access programme allowing physicians and patients access to pre-approval, investigational drugs if:

- the drug is in a clinical trial;
- the drug is used for diseases that threaten life but lack effective treatment;
- the drug has potential effectiveness based on medical observations;
- the drug usage complies with ethical principles;
- the drug usage has been reviewed and the patient's informed consent has been obtained; and
- the drug is used only within the clinical trial site and used on patients outside of the clinical trial setting but with similar conditions.

In addition to the above requirements under the DAL, the Regulations of Shenzhen Special Economic Zone on the Promotion of Cell and Gene Industries permit expanded access programmes regarding cell and genetic drugs held in Shenzhen on certain premises, such as approval for the expanded clinical trials and submission of the market authorisation application to the CDE for such drugs.

Under the RSAMD, there are similar requirements as for drugs for an expanded access programme for investigational medical devices.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

A drug MAH (and its local MAH deputy, if it is an overseas MAH) has the following post-marketing obligations under the DAL and the detailed Provisions on Supervision and Administration:

- making a pharmacovigilance system;
- conducting regular post-market launch appraisals;
- establishing a release process for drug market launches;
- establishing and implementing a drug tracking system; and
- establishing an annual report system.

The newly promulgated Guidelines on Pharmacovigilance Inspections (2022) and Good Practice for Pharmacovigilance Systems (2021) guide marketing authorisation holders of drugs to establish a pharmacovigilance system.

A medical device MAH is also responsible for post-marketing obligations, including:

- establishing and maintaining a quality management system;
- setting up and implementing the post-marketing research and risk management and control plan;

- monitoring and re-evaluating the medical device adverse events; and
- establishing a tracking and recall system, etc.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The CDE's official website (for drugs), the CMDE's official website (for medical devices) and the NMPA's official website (for both drugs and medical devices) enable third parties to gain access to certain information regarding pending, rejected and approved marketing authorisations.

Pharmaceuticals

For drugs pending approval, information such as acceptance number, drug name, drug type, application type, registration category, company name, accepted date and registration application status is publicly available on the CED official website. The public can also access granted marketing authorisation information such as approval number, manufacturing enterprise with its production site, approved date, dosage form and specification via the relevant database of the NMPA official website. Third parties can access the refused application information via the search function on the NMPA's official website.

Medical Devices

Third parties can access less information relating to medical devices than they can access relating to drugs. The pending marketing authorisation information is only available to applicants. Refused marketing authorisation information for refused devices, including acceptance number, device name, applicant and its local deputy (if it is an overseas medical device), can be accessed via the search function on the NMPA's official website. Marketing authorisation information for permitted devices is publicly available on the NMPA's official website, including the marketing authorisation number, the MAH's name and address, the manufacturing site, the device's name, type, specifications, structure, components, applicable scope and intended use, the approval date, the effective date and modified information.

The government is prohibited from disclosing any commercial secrets (such as manufacturing processes, key technical parameters, know-how, tests and data) or personal privacy accessed in the course of review and examination, unless the rights-holder has granted its consent or unless non-disclosure will have a material adverse effect on public interests.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The DAL and the RSAMD, respectively, regulate administrative penalties for:

- the production, distribution or use of counterfeit or substandard drugs and medical devices; and
- the production, importation or distribution of prohibited or unregistered drugs and medical devices.

Administrative penalties include warning, confiscation, suspension, fines and licence revocation. The personnel in charge and the legal representative of the violating entity could also face personal liabilities. Such wrongdoing may also trigger criminal liability.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") sets out the provisional

measures and special requirements related to border measures and criminal procedures against counterfeited products. As a member of the WTO, China follows the obligations outlined by the TRIPS Agreement.

China Customs will help rights-holders to protect their IP under the Regulations of Customs Protection of Intellectual Property Rights and its implementing measures. If a rights-holder discovers infringing drugs or medical devices by itself, it could request Customs to seize the infringing goods upon the provision of certain evidence. Furthermore, if a rights-holder voluntarily completes the IP Customs Filing, it would obtain more assistance from Customs, which will proactively notify the rights-holder of suspected infringing drugs or medical devices when they are discovered.

Customs will seize the goods if the rights-holder confirms that they are counterfeit and provides a bond. The 2020 Economic and Trade Agreement between the PRC and the United States of America (the "China–US Trade Agreement") further strengthens China's obligation to implement border measures.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs who lack manufacturing capacity and outsource manufacturing work to other manufacturers. Although such MAHs do not need to build up their own plants, they are still required to establish manufacturing standard operating procedures, designate quality personnel, etc. MAHs who need to change the package specification of imported products shall appoint a Chinese legal person to submit the sub-packaging filing to the CDE. In the event of outsourcing the manufacturing and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub-packaging shall also obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years six months before expiry.

In accordance with the Measures for the Supervision and Administration of Medical Device Production (2022 revision), types of authorisation for medical device manufacturers are different based upon the classification of devices.

- Class I devices: the manufacturer shall conduct a filing with the municipal MPA for the manufacturing of Class I devices. The manufacturer will complete the filing and obtain the filling number after submitting all required documents.
- Class II and III devices: a manufacturing licence will be granted by the provincial MPA following the result of the review and on-site examination.

A filing for Class I devices does not specify the duration of authorisation, while a manufacturing licence for Class II and III devices is valid for five years and can be renewed for another five years within 30 to 90 working days prior to expiry.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale distributors of drugs or medical devices are required to obtain the following authorisations from the relevant MPA prior to distribution.

Drug Distribution Licence

Generally, a wholesale drug distributor must maintain a drug distribution licence, with an exception for drug MAHs that sell their drugs as a wholesaler without obtaining a drug distribution licence. The licence is valid for five years and can be renewable six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve the application.

If a wholesale drug distributor (including a MAH) is an online seller, it shall report to the provincial MPA by filing an information report form, including information such as the company name, name of the website, name of the app, IP address, domain name, drug manufacturing licence or drug distribution licence, etc. Any changes to such information shall be reported to the provincial MPA within ten business days.

Class I, II and II Devices

The wholesale distribution of Class I devices does not require authorisation. For Class II devices, a distributor should maintain a distribution filing receipt from the municipal MPA, which will grant the receipt if all the required documents are submitted. The wholesale distribution of Class III devices requires a distribution licence from the municipal MPA, which will review the application, conduct examinations when necessary, and decide whether to approve the application.

A filing receipt for Class II devices does not specify a validity period, while a distribution licence for Class III devices is valid for five years and can be renewed for another five years, subject to application for renewal within 30 to 90 working days before expiry.

5.2 Different Classifications Applicable to Pharmaceuticals

For different classifications that apply to pharmaceuticals (such as "available only on prescription"), see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices are subject to the Customs Law of the PRC, the DAL and various relevant regulations, such as the Implementing Regulations of the DAL, Administrative Measures for the Import of Drugs, the RSAMD, etc.

The SAMR, the NMPA, the NMPA's designated drug test institutions and China Customs all have the power to enforce the laws and regulations relating to the import and export of pharmaceuticals and medical devices. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to conduct a filing with Customs as the Customs Declaration Enterprise (either as a customs broker or as a consignee of imported or exported goods). A Consignee of Imported or Exported Goods must complete a filing with the Ministry of Commerce (MOC) as a Foreign Trade Business Dealer and then apply to Customs for the filing as a Customs Declaration Enterprise.

If the importer of record concurrently acts as the applicant for the NMPA's import filing (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**) and port inspection for imported pharmaceuticals, it must maintain a drug distribution licence.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Prior Authorisations for Drug Importation

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation – an additional special import permit issued by the NMPA is required for narcotic drugs and psychotropic drugs;
- in exceptional cases, pharmaceuticals can be imported by means of a special approval by the NMPA instead of the aforementioned marketing authorisations;
- a small number of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
- drug samples for drug registration purposes; and
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs.

Individuals bringing drugs to China for their personal use are exempted from the above requirements.

Prior Authorisations for Medical Device Importation

The following applies:

- imported medical devices shall first be filed/registered with the NMPA and obtain marketing authorisations;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, a China Compulsory Certification is required; and
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The non-tariff regulations and restrictions are scattered across different rules. Generally, the importation of drugs or medical devices is subject to the registrations/permits as set forth in **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**. Another example would be that imported medical devices should meet the compulsory national standards or industrial standards. Special drugs and medical devices are subject to specific regulations – for instance, products subject to compulsory inspection as per their Harmonized Tariff Schedule (HTS) Codes shall be inspected upon the relevant importation.

6.5 Trade Blocs and Free Trade Agreements

For trade/regulatory facilitation, China has 24 Free Trade Agreements (FTAs) under construction, 16 of which have been signed and implemented already. China maintains FTAs (including FTA Upgrade) with Australia, Korea, Switzerland, Iceland, Singapore, New Zealand, Chile, Mauritius, Maldives, Georgia, Costa Rica, Peru, Pakistan, Hong Kong, Macao and Cambodia. It is also part of the Regional Comprehensive Economic Partnership and the Framework Agreement on Comprehensive Economic Cooperation with other members of the Association of Southeast Nations (ASEAN), and one Preferential Trade Agreement (the Asia-Pacific Trade Agreement). Based on the official website of the China FTA Network, several other FTAs are also under negotiation and consideration.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Drugs

The prices of most drugs are not directly controlled by the government but are mainly determined by market competition, while the prices for narcotic drugs and Class I psychotropic drugs are capped by the government.

Although the government aims to leave the pricing of drugs to the market, government policies may nonetheless have a significant effect on the pricing of drugs. For example:

- prices for drugs reimbursed by the BMI funds are determined by authorities including the NHSA, and prices for certain drugs covered by the BMI funds are fixed through negotiations between the NHSA and suppliers thereof;
- the government centralised procurement, which offers strong bargaining power to the procuring side, gives a favourable procurement price to hospitals and drug stores participating in centralised procurement, and may set pricing rules for manufacturers and wholesalers, such as demanding the lowest price compared to certain other provinces, requiring re-evaluation of price after procurement (for COVID-19 drugs involved in the centralised procurement, the NHSA has promulgated further guidelines to specify the conditions under which the relevant enterprises shall re-evaluate the prices of drugs for COVID-19 and fulfil the price adjustment commitment);
- the "Two-invoice System" (ie, a maximum of two invoices are allowed between agents of imported products/domestic manufacturers and public hospitals) eliminates multi-tiered distribution channels and lowers drug prices; and
- the enforcement of a "zero mark-up policy" means that public hospitals may not add any mark-up when selling drugs to patients.

Medical Devices

There is no nationwide regulation or policy specifically and directly controlling the pricing of all medical devices. However, the pricing of medical devices may be significantly influenced by regulatory factors, as follows:

- the pricing of certain medical devices is indirectly restricted because national and local rules limit the amount that a public hospital may charge patients for medical services, and the cost of medical devices used in such services may be included in those charges;

- procurement of certain costly medical devices by hospitals is strictly controlled by planning at the central and provincial levels; and
- centralised procurement, the two-invoice system and the zero mark-up policy may also be applied to the procurement of certain high-value medical consumables by public hospitals, etc.

7.2 Price Levels of Pharmaceutical or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise be set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as references during negotiations between the NHSA and suppliers of drugs with respect to BMI funds coverage.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Drugs

The NHSA and the Ministry of Human Resources and Social Security (MOHRSS) have jointly issued the latest version of the National Reimbursement Drug List 2022 (NRDL), which lists the drugs currently covered by the BMI funds. Under the NRDL, pharmaceuticals are classified into Class A and Class B, with each class being reimbursed differently by the BMI funds. Patients assume full costs for drugs excluded from the NRDL.

The latest effective NRDL, officially implemented on 1 March 2023, stipulates that all provincial authorities shall implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Device

Medical consumables may be considered "diagnosis and treatment items" or parts of such items for BMI reimbursement purposes. Certain local healthcare security administrations at the provincial level have promulgated effective lists of medical consumables that can be reimbursed by local BMI funds.

As public hospitals are supported by state financial funds, the procurement of medical devices by public hospitals above the designated amount would be regulated by rules regarding government procurement.

It should be noted that reform measures regarding BMI funds reimbursements, such as reimbursement based on the diagnosis-related groups payment method (DRGs) and the big data diagnosis-intervention package (DIP), are aimed to be fully implemented and expanded to all medical institutions by the end of 2025; if finally implemented, these measures may significantly affect how drugs, medical consumables and medical services are reimbursed in the future.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economics analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmaco-economic materials may be required to be submitted by applicants in order to add a drug into the NRDL or to adjust its reimbursement coverage.

Cost-benefit analysis would also be considered when assessing which medical consumables are to be covered by BMI funds.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians and pharmacists must follow the principles of safety, effectiveness and economy when issuing or dispensing prescriptions.

A physician may decide what drugs are to be prescribed based on such physician's professional judgement that the prescription is rational and appropriate to a patient's condition. In no event shall the prescription be formulated by artificial intelligence (AI). The quantity of drugs a physician may prescribe is specifically limited for each prescription in order to avoid wasting medical resources or taking advantage of the BMI fund.

Government policies may affect or guide a physician's prescription decisions. For instance:

- the BMI fund is currently subject to budget management and total amount control, and hospitals are responsible for a portion of any over-expenditure so are incentivised to require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI fund;
- hospitals are required to prioritise drugs and medical consumables that are centrally procured, and the use of such drugs and medical consumables may be taken into consideration in the performance assessment of public hospitals and medical professionals;
- the DRGs and the DIP, being piloted in multiple cities, will pressure hospitals to control medical expenses, and thus may influence physicians' prescription behaviours; and
- the Regulations on the Supervision and Administration of the Use of BMI Fund specifically regulate the reimbursement by the BMI fund, and local authorities of the NHSA – along with other departments – conduct examinations of the use of BMI funds. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI ("Designated Institutions") in the Regulations on the Supervision and Administration of the Use of BMI Funds, as well as the mechanism and rewards for reporting incompliant use of BMI funds, aim to restrain fraudulent activities in the use of BMI funds, to strengthen the internal management control of the Designated Intuitions and to further standardise the medical services provided.

A pharmacist will dispense prescription drugs according to a physician's prescription. The examination of a prescription by an eligible pharmacist focuses on the appropriateness, rationality and correctness of the use of the drugs, rather than economic considerations.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps that have diagnostic or treatment functions that meet the regulatory definition of medical devices will be regulated as medical devices under PRC law.

Medical apps that fall within the scope of medical devices are subject to the same regulatory requirements as general medical devices, and must also meet the requirements under the standard of relevant registration review guidelines issued by the NMPA and the CMDE. The

NMPA and the CMDE have also promulgated specific guidelines to address the principles of reviewing the registration application and classification of AI medical apps.

8.2 Rules for Telemedicine

There are separate rules for telemedicine in the PRC.

Under the Measures for the Administration of Telemedicine Service, hospitals can hold hospital-to-hospital consultations on diagnoses and treatment by means of modern information and communication technologies.

Physicians can conduct online diagnoses and treatments for patients whose initial appointment or treatment is at an offline hospital for the same symptoms, provided that such online diagnoses and treatments comply with the Administrative Measures for Online Diagnoses and Treatment (Trial) and the rules for relevant supervision and administration.

Please see **11.6 Drivers for Digital Health Innovation Due to COVID-19** regarding the special regulations for encouraging telemedicine services during the COVID-19 pandemic.

8.3 Promoting and/or Advertising on an Online Platform

Besides the general legal requirements on the promotion and/or advertising of pharmaceuticals and medical devices, online promotion and/or advertising are specifically regulated. Online advertisements for pharmaceuticals and medical devices are subject to the examination and approval of the relevant local authorities under the SAMR, and must indicate the approval number for the advertisement. An entity providing information on pharmaceuticals or medical devices via the internet to online users is subject to the Qualification for Internet Drug Information Services issued by the relevant provincial MPA.

Information on pharmaceuticals and medical devices presented online shall be accurate and science-based. The publication of any information about narcotic drugs, drugs for mental health, toxic drugs for medical use, radioactive drugs, anti-drug medicines or the preparation products of hospitals is prohibited.

8.4 Electronic Prescriptions

Currently, there are no national laws or regulations that specifically regulate the use of electronic prescriptions in the PRC. In practice, all electronic prescriptions must be issued with a physician's e-signature and reviewed by a pharmacist.

For the online distribution of prescription drugs, there are some special rules related to the use of electronic prescriptions under the newly promulgated Measures for the Supervision and Administration of Online Sales of Pharmaceuticals (MSAOSP):

- online distributors of pharmaceuticals shall be responsible for the authenticity and reliability of the electronic prescription; and
- the third-party platform for the online sales of pharmaceuticals shall be responsible for verifying the electronic prescriptions.

The first electronic prescription centre at the provincial level has been listed in Hainan since the end of 2022, enabling the online distribution of all prescription drugs, except those expressly prohibited from being distributed online, without further requirement of approval in Hainan.

8.5 Online Sales of Medicines and Medical Devices

According to the MSAOSP, online sales of drugs are generally permitted, except for drugs that are subject to special administration. The NMPA also announced the first list of drugs prohibited for online sales in 2022. In addition to the requirements applied to an offline drug distributor, an online distributor of drugs is subject to the following further requirements:

- reporting certain information to the local MPA (ie, the website name, app name, IP address and domain name, among other information of the distributor);
- displaying certain information on the home page or the frontpage for distribution, such as its drug manufacturing or distribution permit information and the qualifications of designated pharmacists or other medical technical personnel; and
- being responsible for the authenticity, accuracy and consistency of the information displayed.

If the drugs are distributed online to individuals, the distributor should further conduct prescription examination, set up an online pharmaceutical service system, and comply with special rules about the information display for the prescription drug.

The third party providing the platform for the online distribution of drugs is subject to filing requirements of recording its information such as name, legal representative, unified social credit code, website name and domain name with the local MPA, which will publish the filing information. The MSAOSP further requires such third party to supervise the online distribution taking place on its platform.

Online sales of medical devices are permitted. According to the Measures for the Administration and Supervision of Online Sales of Medical Devices, besides the requirements applicable to a general medical device distributor, an online distributor is subject to additional filing requirements for its sales activities with the local MPA. Under RSAMD 2021, relevant information regarding the sale of a medical device online shall be notified to the local MPA, except for the online sale of Class I medical devices and certain Class II medical devices, which are exempted from filing in offline sales.

8.6 Electronic Health Records

Electronic health records may contain the following data types:

- personal information – any collection, use, storage or transfer of such data records is subject to the newly issued PIPL and the handling of sensitive personal information shall be subject to more stringent requirements;
- medical records, the storage or use of which is subject to the Use and Administration Rules for Electronic Medical Records (for Trial Implementation) and the Provisions on the Administration of Medical Records of Medical Institutions;
- human genetic resources, which are subject to the restrictions under the Biosecurity Law and Administrative Regulation on Human Genetic Resources mentioned in **2.5 Use of Data Resulting from the Clinical Trials**; and
- aggregated electronic health records in hospitals, which may be deemed population health information and medical big data.

According to the Data Security Law, the Guide for Health Data Security and the National Management Measures on Health and Medical Big Data Standards, Safety and Service, any health

information and medical data of PRC citizens generated in the territory of the PRC shall be subject to national regulation and use based upon concerns regarding national security and citizens' life and health. Medical big data must be stored in a reliable server located within the territory of the PRC, in a way that satisfies the national standards of data storage, disaster recovery, and back-up and security management. Regarding the transfer of data, the Data Security Law requires security assessment by cyberspace administration prior to the outbound transfer of certain data as stipulated by the law. The Measures for the Security Assessment of Data Outbound Transfer and relevant guidelines have been promulgated to instruct applications for the security assessment of outbound data transfer.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The main sources of legislation that govern patents in China are:

- the Patent Law;
- the Rules for the Implementation of the Patent Law;
- the Administrative Measures for Prioritised Patent Examination;
- the Administrative Measures for Centralised Examination of Patent Applications (for Trial Implementation);
- the Measures on Compulsory Patent Licensing;
- the Provisions of the Supreme People's Court on Several Issues Concerning Application of Law in Trial of Administrative Cases involving Patent Grant and Confirmation (I) (Interpretation on Patent Grant and Confirmation);
- several Provisions of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Cases on Patent Disputes;
- the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Dispute Cases;
- the Interpretation (II) of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Dispute Cases;
- the Guidelines for Patent Examination;
- Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation);
- the Administrative Adjudication Measures for Early Resolution Mechanism of Drug Patent Disputes; and
- the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Disputes over Patent Rights Relating to Drugs under Application for Registration.

Patent applications for pharmaceuticals and medical devices are most commonly rejected due to a lack of:

- inventiveness;
- enablement; or
- specifications' support on claims.

Generally speaking, an invention or utility model must possess novelty, inventiveness and usefulness in order to be patentable.

Supplemental Data

The extent to which applicants are allowed to submit supplemental data after the patent appli-

cation date has always been a difficult point in the drug-related patent examination system. This issue was also raised in the China–US Trade Agreement. The Guidelines for Patent Examination as amended in 2020 clearly provide that the examiner shall examine the supplemental data submitted by the applicant to meet the requirements of the Patent Law after the filing date, and the technical effect proved by the supplemental data should be able to be obtained from the published contents of the patent application by persons skilled in the art.

In terms of patentability requirements that are specific to pharmaceuticals or medical devices, the following are not patentable:

- inventions or creations that are in violation of Chinese laws or social morality, or detrimental to public interests;
- inventions or creations that are accomplished by relying on the basis of genetic resources, where their acquisition or use breaches Chinese laws and regulations;
- scientific discoveries;
- rules and methods of intellectual activities; and
- methods for diagnosing or treating diseases.

9.2 Second and Subsequent Medical Uses

A second and subsequent medical use of a known substance that takes the typical written form as "use of substance X in the preparation of a medicament for the treatment of disease Y" (Swiss-style claims) could be patentable in China.

If new dosage regimes and new or selected patient populations are merely present in the course of administration as distinguishing features but fail to define the procedure of manufacture per se, a claim for such use does not possess novelty and thus is not patentable.

Exploitation of a patent on a second or subsequent use of a drug, such as making, utilising or selling without the permission of the patentee, may constitute an infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

The Patent Law provides two situations for Patent Term Extension:

- to compensate for unreasonable delay during the patent examination process, and is applicable to all types of patents; or
- to compensate for the time spent during review and approval for new drugs – this only applies to patents related to new drugs.

Any party can challenge the Patent Term Extension decision before the China National Intellectual Property Administration (CNIPA), whose decision in turn can be appealed through administrative action before the court.

9.4 Pharmaceutical or Medical Device Patent Infringement

Without the permission of the patentee, the following exploitation for production or commercial purposes may constitute an infringement of patents:

- the manufacture, utilisation, offer for sale, sale or import of the pharmaceutical or medical device containing a patented invention or utility;
- the utilisation of the patented process of an invention or utility;
- the utilisation, offer for sale, sale or import of the pharmaceutical or medical device directly

obtained through the patented process of invention or utility; or
- the manufacture, offer for sale, sale or import of any pharmaceutical or medical device containing the patented design.

The Patent Law provides an exemption from patent infringement where anyone manufactures, uses or imports patented drugs or medical devices to provide information that is necessary for the marketing authorisation (Administrative Approval Exemption).

Preliminary Injunctions

If a patentee or an interested party has evidence that proves the threatened infringement of a patent which, if not stopped promptly, will cause irreparable damage to its lawful rights and interests, the patent rights-holder may apply to the court for a preliminary injunction and an order for the preservation of infringing evidence and assets, even prior to the commencement of the court action. To be actionable, such a threat of infringement is required to be "imminent".

The China IP court will take the following factors into consideration in granting a preliminary injunction:

- the factual and legal basis, including the stability and validity of the patents at issue;
- whether the applicant's legitimate interests would be irreparably damaged if no injunction were issued;
- whether the loss caused to the applicant would exceed the loss incurred by the respondents through the issuance of the injunction if no injunction were issued;
- whether the injunction would harm public interests; and
- whether the applicant provides a sufficient bond.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The specific defences to patent infringement in relation to pharmaceuticals and medical devices include the Administrative Approval Exemption (see **9.4 Pharmaceutical or Medical Device Patent Infringement**) and Experimental Use Type Defences (where the alleged infringement is used for research and experimentation), which collectively could be equivalent to the Bolar exemption. The patent exhaustion defence, prior art defence and transit exception could also apply to pharmaceuticals and medical devices as a general defence.

Compulsory licences are available for pharmaceutical products and medical devices to be used in China in the following circumstances:

- if a patentee has failed to exploit a patent without justification for more than three years since the date of granting the patent right and four years since the patent application date;
- if the patentee's act of exercising the patent right is determined to be monopolistic, and a compulsory licence would remove or reduce the anti-competitive effects of such patent use;
- if it concerns a national emergency, extraordinary State affairs or the public interest;
- for the manufacture and export of patented drugs to countries or regions that comply with the relevant international treaties to which China has acceded for the purpose of public health; or
- if a patented invention or utility model representing major technical advancements with remarkable economic impact relies on earlier patents. A compulsory licence could be granted to exploit both earlier and later patents in this scenario.

The party that is granted a compulsory licence enjoys neither an exclusive right of exploitation nor a right to authorise others to exploit, and such a party shall pay reasonable royalties to the relevant patentee.

9.6 Proceedings for Patent Infringement

The following main options are available to enforce patent rights in China:

- administrative actions:
  (a) the CNIPA – the patentee or any interested party can file complaints with competent evidence before the CNIPA (and its local counterparts). Also, the local IPA can conduct regular investigations against patent infringements. Remedies include ordering the infringers to cease the infringement, seizing/destroying infringing items, and the imposition of fines; and
  (b) Customs – border measures as discussed in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**;
- civil litigation remedies include preliminary injunctions, permanent injunctions and monetary damages; and
- criminal penalties (in cases of severe patent counterfeiting).

For civil cases, the patentee or any interested party can bring proceedings for patent infringement. Interested parties can be the legitimate heirs of the property right of the patent or licensees.

The Infringement Procedure

The typical procedure for a patent infringement proceeding is as follows:

- the claimant submits a pleading to the court and files a copy of the pleading for each defendant;
- the court will serve a copy of the pleading to each defendant within five days of accepting the case, and the defendant must submit a statement of defence within 15 days of receipt;
- the claimant and defendant submit evidence, and the court will arrange the exchange of evidence;
- the defendant may also choose to file a patent invalidation application with the Re-examination and Invalidation Department under the CNIPA;
- the court will conduct oral hearings and make its decision; and
- an appeal to a higher court can be filed by either party within 15 days of receiving the judgment.

The typical procedure of administrative enforcement for a patent infringement action includes the following:

- an administrative complaint is lodged with the CNIPA or its local counterparts;
- the CNIPA or its local counterpart conducts an investigation and takes action to obtain evidence of infringement; the defendant can submit a formal defence and rebuttal evidence;
- oral hearings may take place;
- the CNIPA or its local counterparts issue a decision; and
- either party may choose to appeal the decision by filing an administrative lawsuit with the court.

The patent validity challenge is not a non-infringement defence that can be heard by a civil court. Generally, an accused infringer will

bring patent invalidation proceedings with the Re-examination and Invalidation Department of the CNIPA parallel with the civil litigation as a litigation strategy.

9.7 Procedures Available to a Generic Entrant

A potential generic entrant can conduct research and development and clinical trials, and file a product application with the NMPA under the Administrative Approval Exemption and Experimental Use Type Defences to patent infringement.

The Patent Law establishes the Chinese efficiency-first patent linkage system, which is further explained by the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation). The latter stipulates that a MAH shall register the patent information of the drug on the Chinese listed drug patent information registration platform, while a generic drug applicant should make one of the four categories of declarations with respect to the registered patents. Among others, the Category IV declaration claims that the registered patents should be declared invalid or do not cover the generic drug.

The patentee or the interested party (ie, the licensee of the patents or the MAH of the drug) can challenge the Category IV declaration before the court (judicial link) or the CNIPA (administrative link) within 45 days after such declaration being published. Within 15 business days of the case being accepted by the court or the CNIPA, the patentee or the interested party should provide the evident documents to the NMPA, which will withhold the administrative examination of the application for the generic drug for up to nine months to wait for an effective judgment or administrative decision, during which time the technical examination of the application will not be ceased. A 12-month exclusive period will be granted following the issuance of the marketing authorisation to the first chemical generic to successfully challenge a patent. Marketing authorisation of generic drugs of the same kind will not be approved within the aforementioned exclusive period.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

With regard to counterfeit pharmaceuticals and medical devices, the following ways may be used to protect the public interest and the lawful rights of the rights-holder.

- Administrative proceeding – a rights-holder can file an infringement complaint with supporting evidence to the administrative authorities, such as the local Administration for Market Regulation, the local MPA, Customs, etc. Also, the administrative authorities may conduct investigations ex officio against counterfeit pharmaceuticals and medical devices, and will issue a punishment ruling when infringement is affirmed. The dissatisfied rights-holder or the infringer can bring an administrative lawsuit to the court regarding the local authority's ruling.
- Civil proceedings – the patentee and the interested party can bring infringement actions before the courts. Punitive damages are allowed under the Trademark Law.
- Criminal proceedings – the manufacture and distribution of counterfeit pharmaceuticals and medical devices constitute violations of the Criminal Law of the PRC.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for pharmaceuticals and medical devices are subject to the general requirements of the Trademark Law (such as prohibitions on containing fraudulent content). In addition, the NMPA places special restrictions on trade marks to be used for pharmaceuticals and medical devices. For example, pharmaceuticals' generic names cannot be registered as trade marks, and unregistered trade marks cannot be used in the specifications and labels of pharmaceuticals.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for the trade dress or design of pharmaceuticals and medical devices under various PRC laws. Trade dress is regulated under the Anti-unfair Competition Law, which prohibits any unauthorised use of the mark that is identical or similar to the package or decoration of another's commodity that is influential.

The patented design of pharmaceuticals and medical devices can be protected under the Patent Law. In addition, the trade dress or design of pharmaceuticals and medical devices could be protected as a copyrightable industrial design or product design under the Copyright Law and as a registered two-dimensional/three-dimensional trade mark under the Trademark Law.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity is currently only available for pharmaceuticals, not for medical devices. PRC law provides six-year protection from the date of the marketing authorisation, which prohibits unauthorised third parties from using undisclosed trial data and other data to apply for manufacturing or distribution approval of new chemical pharmaceuticals.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, the distribution of medicines and medical devices was subject to distribution permits, as discussed in **5. Distribution of Pharmaceutical and Medical Devices**. China issued special regulations to severely crack down on the illegal manufacture and distribution of counterfeit and inferior pharmaceuticals, medical devices and hygienic materials, especially for pharmaceuticals and medical devices used for the treatment and prevention of COVID-19, such as pandemic prevention clothing, medical masks, diagnostic kits, ventilators, etc.

Since China announced its decision to manage COVID-19 with measures against Class B instead of Class A infectious diseases, the NMPA issued a special notice to emphasise the regulation on drug dividing distribution management (ie, the distribution of drugs by splitting the minimum package) and to ensure the supply of drugs commonly used to treat COVID-19.

11.2 Special Measures Relating to Clinical Trials

To ensure the effectiveness of safety management of clinical trials during COVID-19, the CDE published guidelines to ensure the progress of clinical trials under the condition of protecting the trial subject from COVID-19, with key measures focusing on reducing the trial subject's exposure to the virus and controlling the spread of infection.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Two regulatory pathways have applied for emergency approvals of pharmaceuticals or medical devices in China since before the outbreak of COVID-19: emergency approvals and conditional approvals.

Regulatory pathways of special approvals greatly reduce the required time for the approval of pharmaceuticals and medical devices due to a public health emergency.

The other regulatory pathway is to obtain market authorisation for pharmaceuticals (including vaccines) or medical devices upon additional approval conditions being met. Conditional approvals for pharmaceuticals often occur when pharmaceuticals (including vaccines) have curative effects and predictable clinical value based on the data in clinical trials, and when they are used for the treatment of serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health. Conditional approvals for medical devices often occur when medical devices are used for the treatment of rare diseases or serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

During the COVID-19 pandemic, many provinces and cities introduced special regulations to facilitate the application for manufacturing permits for medical devices. For example, the registration and manufacturing of medical masks and medical protective closing are no longer subject to approval by the provincial MPA: a simplified filing with the municipal MPA is sufficient.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Importation

For importation, China Customs issued special regulations to ensure the rapid customs clearance of donations for COVID-19 research and treatment. Pursuant to the special regulations, the clearance of imported pharmaceuticals, disinfectants, protective suits, rescue and treatment devices and relevant materials may be carried out before completing the required customs procedures, such as declaration and tariff reduction and exemption.

Exportation

For exportation, China devotes greater efforts and adopts various measures to ensure the quality and safety of the exported pharmaceuticals and medical devices, including publishing the “white list” and the “blacklist”, and requiring the exporting enterprise to provide a written or electronic statement undertaking when making customs declarations that the exported products have obtained marketing authorisations of medical devices in China and meet the quality standard requirements of the importing countries (regions). China Customs and its local counterparts have promulgated measures to accelerate the import and export process of COVID-19-related vaccines and reagents.

11.6 Drivers for Digital Health Innovation Due to COVID-19

China introduced new rules to encourage digital healthcare innovation and digital transformation due to COVID-19, including but not limited to online health assessment, health guidance, health education, follow-up visits for chronic diseases, etc. It specially proposes to actively develop telemedicine services and to standardise internet diagnosis and treatment consulting services.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Compulsory licensing of IP rights is regulated in the Patent Law, as discussed in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

So far, COVID-19 treatments or vaccines are not exempted from liability under the PRC law.

11.9 Requisition or Conversion of Manufacturing Sites

In China, the Emergency Response Law and the Prevention and Treatment of Infectious Diseases Law provide that the requisition or conversion of manufacturing sites are allowed due to the outbreak of a public health emergency, including COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Generally, public hospitals shall purchase medicines and medical devices that have been listed on a centralised procurement platform. After the outbreak of COVID-19, many provinces and cities issued special measures to allow public hospitals to procure the pharmaceuticals and medical devices to prevent and treat COVID-19 from certain suppliers directly.

Furthermore, to ensure the accessibility of COVID-19 therapeutic drugs, the NHSA issued the Guidelines for Price Formation for COVID-19 Therapeutic Drugs (for Trial Implementation), based on which the first-sale price of COVID-19 therapeutic drugs will be approved by one of the six appointed provincial Healthcare Security Administrations and applied to the whole country to ensure the newly approved COVID-19 therapeutic drugs can get to market faster.

Trends and Developments

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Life Sciences in China after COVID-19

The COVID-19 pandemic has left an indelible mark across entire economies, and has provided an array of challenges and opportunities for every sector. The healthcare and life sciences sector in China has seen enormous interest. There were profound changes in the Chinese legal, regulatory and market landscapes during 2022, including market participants investing in life-saving treatments, the Chinese government providing ample support for facilitating transactions, innovations in high-quality technologies, protections for intellectual property and personal information, and a fairer and more open business environment. This article will examine these and other trends and developments in China's healthcare and life sciences sector.

Pharmaceutical Industry Transactions During the Pandemic Period

IPOs

The number of newly listed Chinese pharmaceutical companies in 2022 decreased significantly compared to 2021. A majority of these 2022 issuances fell below their initial offering prices, marking a return to more rational valuations in the pharmaceutical industry. In the future, investors are increasingly likely to favour pharmaceutical companies with solid track records of innovation and cutting-edge technologies that stand out in the market.

Venture capital/private equity financing

The pharmaceutical industry's downbeat performance in the capital markets may have dampened investors' enthusiasm and confidence in capital markets more broadly. The number and amount of Chinese pharmaceutical companies' primary market financings in 2022 dropped sharply, most notably in early-stage financings (series angel and series A). Given the shortage of financing and cash flow, biotech start-ups had to consider cutting pipelines (especially those lacking innovation or facing fierce competition, such as from "me-too" drugs). At this stage, the pharmaceutical industry had two principal concerns:

- how to reduce costs and increase efficiency to overcome the cold winter of financing; and
- how to enhance innovation capacity to become more competitive.

License-in/out

Government policies and market incentives have driven Chinese pharmaceutical companies to place more efforts on the research and development (R&D) of innovative products, and 2022 witnessed remarkable achievements in pharmaceutical license-out transactions. Sources show that the total transaction value of license-out deals involving innovative drugs/new technologies in China reached a record high of USD27.55 billion in 2022, doubling the amount in 2021. The aggregate number of license-out transactions for China's innovative drugs/new technologies exceeded 220 by the end of 2022.

By contrast, the number of pharmaceutical license-in transactions in 2022 decreased significantly compared to the large increase in 2021, and no large-scale license-in transactions were concluded involving an amount of more than USD1 billion. The reasons for this decrease in pharmaceutical license-in transactions may include:

- cash flow shortages of potential licensees in China, particularly biotech companies;
- the lack of innovative target products;
- inflated transaction prices and tough competition for desirable target products; and
- the "fast follow" of Chinese pharmaceutical companies in developing their own innovative products.

Of note, ophthalmology has become an emerging area for license-in transactions, in addition to established fields such as oncology, infection, neuroscience and autoimmunity.

Mergers and acquisitions

Chinese pharmaceutical companies have been actively deploying high-quality technologies and pipelines. High-quality innovative biotech companies such as AI drug R&D and small-molecule targeted drug R&D companies continue to be popular M&A targets. Sources indicate that 21 major M&A transactions in China's pharmaceutical industry were concluded in 2022, with an aggregate deal value of more than RMB16 billion.

Regulatory Trends

In 2022, China continued to update regulatory policies frequently, with active contributions from the National Medical Products Administration (NMPA), the National Health Commission (NHC) and the Ministry of Science and Technology (MOST). Major regulatory issues among the various new policies include the regulation of human genetic resources (HGR), clinical trials and the expanding role of internet-based medical and pharmaceutical services.

In 2022, the regulatory authorities persisted in their efforts to safeguard biosecurity, particularly with respect to HGR regulation. As the authority responsible for formulating and implementing guidelines and policies for the development of national science and technology, MOST issued successive regulatory documents on HGR regulation, including two Q&A releases that clarify certain controversial questions in HGR administration and compliance practice, providing a more limited scope of HGR information subject to administrative filing and approval.

In addition, significant industry attention has been focused on two draft rules:

- the Rules for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comment); and
- the Measures for the Implementation of Administrative Penalty of the Ministry of Science and Technology (Draft for Comment).

These two draft rules reflect the regulatory authority's latest views, which could result in tightening regulation of certain matters while relaxing others, with a trend toward increased enforcement action in the future.

Regulations on clinical trials have been updated and specified to promote the orderly conduct of drug R&D. The NMPA has announced the Annex of Investigational Drugs to the Good Manufacturing Practices for Drugs, which responds to the implementation and enforcement of Good Manufacturing Practice (GMP) for investigational drugs, further strengthening the guidance on and regulation of the preparation of investigational drugs. The release of the Technical Guidelines for the Modification of Protocols during Clinical Trials for Drugs (for Trial Implementation) fills a previous policy gap, providing sponsors with guidelines to amend the protocols for ongoing clinical trials from both substantive and non-substantive perspectives.

Due to the pandemic, China accelerated the optimisation of its remote medical and pharmaceutical services policies in 2022. Internet hospitals and the online sale of prescription drugs are supported by new regulations, which inevitably bring challenges to traditional regulatory methods. The announcement of the Rules for the Regulation of Internet Diagnosis and Treatment (for Trial Implementation) set forth more transparent and effective requirements for the development of internet-based diagnosis and treatment. The Provisions for Supervision and Administration of Online Drug Sales were released, and the policy on the online sale of prescription drugs was gradually loosened. Notably, the online sale of prescription drugs was explicitly allowed.

In 2022, China started to pilot cross-border contract manufacturing arrangements by launching and implementing a new policy on cross-border contract manufacturing of drugs and medical devices in the Guangdong–Hong Kong–Macao Greater Bay Area. This policy is a significant step toward exploring new regulatory modes. Cross-border contract manufacturing will provide drug marketing authorisation holders (MAHs) and medical device MAHs with more flexibility in their arrangements for licence holding and manufacturing.

In respect of data security in healthcare industries, the Measures for Security Assessment of Cross-border Data Transfers, issued in 2022, specify the application of security assessments, the requirement of self-assessment before applications, and key requirements for security assessment of cross-border data transfers, which pose a challenge to international collaborative R&D and distribution in healthcare industries.

In addition to the aforementioned general introductions to policy updates that are applicable to both drugs and medical devices, the following regulatory highlights apply to drugs or medical devices respectively.

Drug highlights

During 2022, the NMPA released a series of regulations focused on clarifying the responsibilities and roles of MAHs. Since the implementation of the MAH system in 2019, the NMPA and other regulatory authorities have accumulated and updated a large number of supplementary rules, which are scattered across various regulations and guiding principles. On 9 May 2022, the NMPA released the Regulations for Implementation of the Drug Administration Law (Draft for Comment), which would integrate the aforementioned supplementary rules while refining and adding a number of provisions that were not

clarified in the Drug Administration Law. In addition, the latest amendment to the Measures for Administration of Drug Recalls has adjusted the regulatory requirements for drug recalls based on the MAH system.

The Center for Drug Evaluation (CDE) also released the Working Procedures on Speeding Up the Review of Innovative Drug Applications (for Trial Implementation), clarifying the requirements at various stages of the review process for marketing applications for innovative drugs that are included in breakthrough therapies. In this way, the CDE is making efforts to encourage the R&D of innovative drugs and thus meet certain clinical needs.

Medical device highlights

In 2022, the State Administration for Market Regulation (SAMR) released the Measures for the Supervision and Administration of Medical Device Distributions and the Measures for the Supervision and Administration of Medical Device Manufacturing, which serve as supporting documents for the Regulations on Supervision and Administration of Medical Devices (Revised in 2021). These documents effectively construct the distribution and manufacturing segment of the entire medical device life cycle regulatory system based on the needs of system reform and regulatory practice.

The Good Clinical Practice for Medical Device Trials (Revised GCP) has been updated in response to the requirements specified under heatedly revised regulatory provisions for medical devices. The Revised GCP emphasises ethical responsibility, explicitly includes in vitro diagnostic (IVD) reagents within the administrative scope, further clarifies the responsibilities of each party involved in clinical trials, and resolves certain issues and pain points in the industry.

In order to strengthen the on-site verification of quality management systems in the registration of medical devices, the NMPA amended the Guidelines for Medical Device Registration Quality Management System Verification in 2022. The latest guidelines clearly state that an applicant will fail to pass the verification if authenticity problems are found during on-site verifications.

Compliance Practices

Commercial bribery in the medical and healthcare industries

Rigorous monitoring and enforcement against commercial bribery focusing on the medical and healthcare industries are expected to continue, including dawn raids, cross-referrals of cases to other competent agencies, and collaboration among different government agencies. As law enforcement efforts against commercial bribery intensify, an increasing amount of complex hidden bribery schemes are being identified and penalised by law enforcement agencies. Such schemes include tailor-made bidding such as bid rigging, exclusive profit sharing, entertainment disguised as training or conferences, and using ad hoc rebates and discounts to distributors as indirect payments to healthcare professionals.

Strengthening regulation of national medical insurance fund usage

To increase scrutiny of medical insurance fund usage, new regulation methods will be trialled, including increasing unannounced inspections, and implementing fraud prevention mechanisms based on data collection from mobile applications and new payment methods for off-site supervision.

Continuous advancement of national centralised procurement of medical devices and pharmaceuticals

National centralised procurement became institutionalised in 2021, and remarkable achievements and valuable experience have since been obtained in pharmaceutical chemicals and high-value consumables such as coronary stents and artificial joints. Deeper coverage of national centralised procurement over regular pharmaceutical chemicals is expected. Companies should enhance self-monitoring of compliance efforts to prevent procurement issues related to commercial bribery or taxation issues. Law enforcement agencies hope that the reduced profit margins due to centralised procurement will lead to less commercial bribery by life sciences companies involving healthcare professionals.

Trade secret protection

In 2022, relevant policies regarding trade secret protection were initiated at both national and local levels. Enterprises are encouraged to enhance internal control mechanisms, self-protection capabilities and management organisation, for the purpose of establishing systematic compliance. Meanwhile, local governments intend to strengthen the protection of key and specialised industries, especially new industries, new business models and trends. Priority will be given to the protection of knowledge- or technology-intensive, innovative and time-honoured businesses.

Changes in Chinese Intellectual Property Laws and Regulations

Revision of patent-related laws and regulations

The China National Intellectual Property Administration (CNIPR) published the Revised Draft Patent Examination Guidelines (Draft for Comment) in August 2021. On 31 October 2022, it published the Draft Amendments to the Patent Examination Guidelines (Second Draft for Comment). As a chapter closely related to the fields of life sciences and chemistry, the Draft Amendment to the Patent Examination Guidelines (Draft for Comment) adds several provisions on the examination of patent applications for inventions in the field of traditional Chinese medicine to provide guidance for patent examination of traditional Chinese medicines. Once the guidelines are finally revised, they will also provide detailed guidance for the operation of the patent term adjustment (PTA) process, patent term extension (PTE) and the Early Resolution Mechanism for Pharmaceutical Patent Disputes (also called the drug-patent linkage system).

Developments in litigation and adjudication cases in life sciences and chemistry

The first drug-patent linkage ruling case in China

On 25 April 2022, the CNIPR announced that it had concluded the first batch of administrative ruling cases of the Early Resolution Mechanism for Pharmaceutical Patent Disputes. These were the first administrative cases of this type concluded nationwide since the implementation of the new Patent Law on 1 June 2021. The three cases concluded this time involved the patent for "oxycodone hydrochloride sustained-release tablets" belonging to Purdue Pharmaceutical, which requested confirmation that the generic drug-related technical solutions of Yichang Renfu Pharmaceutical Co., Ltd. fell within the scope of protection of the above-mentioned patent rights. After trial, the CNIPR held that the technical solutions related to generic drugs did not fall within the scope of protection of the above patent rights.

The first drug-patent linkage litigation case in China

On 15 April 2022, the Beijing Intellectual Property Court made a first-instance judgment in the first Chinese patent linkage litigation case (between Chugai Pharmaceutical Co., Ltd. and Wenzhou Haihe Pharmaceutical). On 5 August 2022, the Supreme People's Court made a second-instance final judgment in the case, which lasted eight months from the date of filing on 8 November 2021; compared with the trial time of drug-related patent litigation before the implementation of the patent linkage system, the current trial time is greatly shortened. Predictability is enhanced for both the MAH and the generic pharmaceutical company, and the possible losses caused by later rights protection or infringement are reduced.

With the improvement of relevant laws and regulations, it is expected that there will be more and more drug-patent linkage cases.

Tax Concerns

As one of the most encouraged sectors currently in China, healthcare and life sciences companies may enjoy a wide range of tax incentives, mainly including the following tax preferential treatments.

High and new technology enterprise (HNTE)

The HNTE policy offers a reduced 15% corporate income tax rate (as opposed to 25% for normal enterprises). Many life sciences companies find it relatively easy to qualify for this tax preference, although certain others may encounter difficulties, particularly PRC subsidiaries of multinationals, due to a lack of PRC-generated IP. Over the past few years, more pharmaceutical companies, particularly biotechnology start-ups, have devoted themselves to developing first-in-class or best-in-class drug products, which places them in a better position to enjoy HNTE tax incentives.

R&D expense super-deduction

China's R&D expense super-deduction policy is similar to those of many other jurisdictions, and allows an extra deduction for qualified expenditures. Life sciences companies are qualified to enjoy a 100% extra deduction by being recognised as either a "manufacturing enterprise" or a "small and medium technology enterprise".

Input VAT refunds

In terms of VAT treatment, a major incentive is the input VAT refund mechanism, under which small-scale or manufacturing life sciences companies can have their qualified accumulated input VAT refunded. This is particularly beneficial for life sciences companies that incur significant input VAT out of payments due to R&D or licence activities during their early stages when they have no chance to book revenue.

From a transaction perspective, it is also important to have a proper understanding of the relevant tax implications. For example, apart from the potential input VAT refunds, one of the key tax considerations in in-license deals is the identification of a permanent establishment for overseas licensors that plan to assign personnel to work in China for the licence project. The entire revenue package of the licensor may be subject to 25% PRC corporate income tax if it is deemed to have set up a permanent establishment in China.

Post COVID-19 tax incentives shrinking

While the COVID-19 pandemic is not yet over, some tax incentives for small enterprises in China are shrinking – eg, VAT tax exemption/super-deduction reduction. These preferential tax poli-

ECUADOR

Law and Practice

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Contents

Meythaler & Zambrano is one of the most prestigious law firms in the Ecuadorian market. Founded in 1995, the firm specialises in national and international legal counselling and litigation for international and domestic corporations. The firm's highly qualified team focuses on regulatory counsel (in the pharmaceutical, medical, food, and cosmetic sectors), IP, competition and antitrust, arbitration and mediation, corporate and commercial affairs, dispute resolution, taxes, public procurement, and public law. The firm has offices in Quito and Guayaquil. These offices work throughout Ecuador and belong to a wide network of correspondents throughout America, Europe and Asia. Meythaler & Zambrano is a member of the International Bar Association (IBA), the International Trademark Association (INTA), the Inter-American Intellectual Property Association (ASIPI), the Ecuadorian Association of Mediation and the Ecuadorian Association of Tax Law.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The legislation applicable to pharmaceuticals and medical devices is very broad and includes constitutional norms, laws, regulations, resolutions, instructions and other lower-ranking provisions – all of which are part of the central public administration.

The main rules to take into account are:

- the Constitution of the Republic of Ecuador;
- the Organic Health Law;
- the general regulations of the Organic Health Law;
- the Law on Production, Import, Trade and Sale of Human Generic Medicines (2005) (the "Law on Generic Medicines for Human Use"); and
- the regulations for sanitary registration of medicines in general and biological drugs;
- Substitute Technical Sanitary Regulation for the Sanitary Registration of Natural Processed Products for Medicinal Use, and Good Manufacturing Practices for Pharmaceutical Laboratories of Natural Processed Products for Medicinal Use;

- regulations for obtaining the sanitary registration of homeopathic medicines and for the sanitary control of the manufacturing establishments, storage, import, export, and commercialisation of such medicines;
- regulation on the pricing of medicines for human use and consumption;
- the Technical Sanitary Regulation for the Registration and Control of Medical Devices;
- regulations on the advertising and promotion of medicines in general, processed natural products for medicinal use, homeopathic medicines and medical devices; and
- regulations on the regulation and control of products for human use and consumption containing cannabis.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

All administrative acts or decisions issued by sanitary and regulatory entities may be challenged both administratively and judicially.

The following appeals are available through administrative proceedings.

- An appeal that may be filed within ten days of the date on which the superior hierarchical authority is notified of the administrative decision or act. The maximum term for resolving and notifying the resolution of the appeal is one month from the date of filing.
- An extraordinary appeal for review of a final administrative act or decision, which may be filed on the following specific grounds:
  - (a) evident and manifest error of fact or law affecting the merits of the case;
  - (b) the appearance of new documents of essential value;
  - (c) the resolution was essentially influenced by acts declared null or by documents or testimonies declared false; or
  - (d) the resolution was issued as a consequence of a punishable conduct and has been declared as such in an enforceable judicial sentence.
- Once admitted, the extraordinary appeal for review must be resolved within a period of one month – at the end of which, if the public administration has not made an express decision, it is deemed to have been dismissed.

Administrative acts or decisions may also be challenged via judicial processes, as follows.

- The action of full or subject-matter jurisdiction in order to protect a subjective right of the plaintiff that was allegedly denied, unknown or not recognised totally or partially by administrative acts or decisions that produce direct legal effects. This action may also be brought against regulatory acts or decisions that violate subjective rights. It may be filed within 90 days from the date of notification of the administrative act or decision.
- The objective annulment of an abuse of power in order to protect the compliance with the objective legal rule of an administrative nature can be proposed by whoever has a direct interest in requesting the nullity of the challenged act or decision for having a legal defect. The time limit for filing an action is three years from the day after the date on which the challenged act or decision was issued.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In Ecuador, pharmaceuticals are regulated differently, depending on their category.

- OTC drugs are authorised to be dispensed without prescription, owing to their composition and the pharmacological action of their active ingredients.
- Medicines containing scheduled controlled substances have specific regulations regarding their production, importation, exportation, commercialisation, distribution, prescription and dispensation.
- Finished products containing non-psychoactive cannabis or hemp (or derivatives of non-psychoactive cannabis or hemp) are also specifically regulated in terms of therapeutic use, prescription, sowing and cultivation.

For the purposes of the sanitary registration, however, medical devices for human use will be classified in the following ways:

- according to their level of risk, as either:
  - (a) Level I (low risk);
  - (b) Level II (moderate-to-low risk);
  - (c) Level III (moderate-to-high risk); or
  - (d) Level IV (high risk); and
- according to their type, as either:
  - (a) active medical device (*dispositivo médico activo*, or DMA);
  - (b) invasive medical device (*dispositivo médico invasivo*, or DMI);
  - (c) non-invasive medical device (*dispositivo médico no invasivo*, or DMNI); or
  - (d) in vitro diagnostic medical device (*dispositivo médico de diagnóstico in vitro*, or DMDIV).

Additionally, the class, type and level of risk will determine the requirements that must be satisfied in each case – in addition to having a direct effect on the way the devices can be marketed.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Ecuadorian legislation contains limited regulation on clinical trials. No regulations have been published for the purpose of regulating trials on medical devices.

The Organic Health Law establishes basic guidelines and general principles in the field of clinical trials. It states that the Ministry of Public Health is the national health authority responsible for controlling clinical studies.

In order to carry out a clinical trial in Ecuador, a request must be submitted to the National Health Regulation, Control and Surveillance Agency (*La Agencia Nacional de Regulación, Control y Vigilancia Sanitaria*, or ARCSA). Before it can be conducted in the country, any clinical trial protocol must first be approved by a Human Research Ethics Committee and then submitted to ARCSA for approval.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In Ecuador, the procedure for securing authorisation to conduct a clinical study of a pharmaceutical product or medical device is regulated by Ministerial Agreement 0075-2017. ARCSA is responsible for evaluating, approving and controlling clinical trials.

In order to authorise a clinical trial, ARCSA will request the study sponsor to submit at least the following documents:

- a clinical trial fact sheet;
- approval of the clinical trial protocol by a Human Research Ethics Committee;
- a legal contract or agreement, in which the obligations of each party are stated, between the sponsor and a single contract research organisation concerning the delegation of the development of the clinical trial (where applicable);
- the researcher's protocol;
- the researcher's manual, according to the established Good Clinical Practices;
- the informed consent form that corresponds to the submitted version of the research protocol previously approved by a Human Research Ethics Committee;
- the pharmacological report for marketing approval of the investigational product issued by ARCSA (in the case of a post-marketing study);
- the letters of declaration of institutional interest and availability of the health facility;
- the commitment letter signed by the principal researcher of each clinical research centre participating in the clinical trial, stating that they will participate as a researcher in the study and have been trained in the research protocol, as well as confirming the monetary value that they will receive and a list of their responsibilities in the study;
- a list of the clinical research centre or centres that includes details of all the researchers – and their work teams – who would participate in the trial and specifies the type of health establishment, as well as the professional titles of each member and their role in the study;
- evidence of registration of the principal researchers in the study;
- the CV of the principal researcher and their collaborators for each clinical research centre;
- the chronogram of the study;
- the Quality Management System certificate for the clinical laboratory or institution;
- details of the investigational product and other drugs to be used in the trial;
- health risk assessment reports for the previous phases of the studies (Phase I, II and III);
- the Good Manufacturing Practices (GMP) certificate for the manufacturing plant of the investigational drug;
- the batch certification of the investigational drug;
- the general budget of the trial;
- a copy of the contract signed between the principal researcher and the sponsor;
- the adverse event and adverse reaction management flowchart;

- the Clinical Trial Suspected Serious Unexpected Serious Adverse Reaction and/or Serious Adverse Event Reporting Form;
- the sponsor's sworn commitment to submit the final trial report to ARCSA; and
- a copy of the civil liability insurance policy issued by an insurance company established in Ecuador and authorised for such purpose.

Once ARCSA verifies that the application and the documentation submitted meet all the established requirements, it will prepare the corresponding technical report – regardless of whether or not it is favourable to the approval of the proposed study. This report will be sent by ARCSA to the Technical Advisory Committee for Clinical Research, so that the latter may provide specific and specialised support to the evaluation process of a clinical trial.

ARCSA has 60 days (counted from the date on which the procedure was admitted) to issue the evaluation report of the research protocol. The Executive Director of ARCSA must then communicate the approval or non-approval of the clinical trial in question to the applicant or request additional information. In case of Phase IV clinical trials, the report must be issued within 45 days of the date on which it was admitted for processing.

2.3 Public Availability of the Conduct of a Clinical Trial

The conduct of clinical trials is publicly available; however, their results are not.

In accordance with the law, ARCSA created the National Clinical Trials Registry, which observes the requirements of the World Health Organization's Primary Registry. This registry is available on the ARCA website, where links to the following information can be found:

- a list of contract research organisations (*Registro Nacional OIC (Organizaciones de Investigación por Contrato)*);
- National Register of Clinical Research Centres, which includes general information such as name, date of registration, tax identification number, address and telephone number; and
- National Register of Clinical Trials, which includes both those that were rejected and the studies approved to be developed in Ecuador.

ARCSA does not publish the results of clinical studies on its official web page. Publication in national or international scientific journals is optional, although the researcher must send a copy of said publication to ARCSA and the Ministry of Public Health. Such publication may not, under any circumstances, contain identification data of the subjects of the study.

2.4 Restriction on Using Online Tools to Support Clinical Trials

With regard to the use of electronic tools in the development of clinical trials, there is no specific limitation contemplated in the laws or regulations on this subject.

2.5 Use of Data Resulting From the Clinical Trials

If the results of clinical studies include personal data of patients, this is classed as sensitive information, according to the Organic Law on the Protection of Personal Data.

The transference or processing of sensitive personal data is generally prohibited in Ecuador, except in certain circumstances, which – in the context of the execution of clinical trials – may include:

- when the data holder has explicitly consented to the processing of their personal data for clearly specified purposes;
- when the processing is necessary to protect the vital interests of the data owner, in the event that the owner is not able – physically or legally – to give their consent; or
- when the processing is necessary for scientific or historical research or statistical purposes.

Thus, the institutions involved in the execution of clinical studies may collect and process data relating to the health of patients only when these conditions are met.

2.6 Databases Containing Personal or Sensitive Data

In Ecuador, the processing of sensitive data is regulated by the Organic Law on the Protection of Personal Data. This law defines databases or files as a structured set of data, irrespective of:

- the form, modality of creation, storage, organisation, type of support, treatment, processing, location or access;
- whether they are centralised or decentralised; or
- whether they are distributed functionally or geographically.

According to this law, processing is considered to be any operation or set of operations carried out on personal data – whether by automated, partially automated or non-automated technical procedures – and, in general, any use of personal data. As a consequence, the creation of a database with personal or sensitive data is a form of processing and therefore requires the prior obtaining of informed consent.

Also, consent may be revoked at any time without providing a reason. The person responsible for the processing of personal data must establish mechanisms for this withdrawal that guarantee speed, efficiency, effectiveness and gratuity, along with a simple procedure that resembles the procedure through which the consent was obtained.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The classification of a product as a pharmaceutical will depend on whether its characteristics fit the legal definition of any of the following categories:

- general drug;
- biological drug;
- homeopathic medicine; and
- processed natural product for medical use.

Medical devices for human use will be classified as such, provided they are considered instruments, apparatus, appliances, artifacts or mechanical inventions (including their components, parts or accessories) that are manufactured, sold or recommended for use in the diagnosis, curative or palliative treatment, or prevention of a disease, disorder or abnormal physical state or its symptoms by replacing or modifying the anatomy or a physiological process or controlling it. They include amalgams, varnishes, sealants and other similar dental products.

Any instrument, apparatus, appliance, implement, machine, appliance, implant, in vitro rea-

gent, software, material or other similar or related item may also be considered a medical device for human use if intended by the manufacturer to be used (alone or in combination) for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of an injury;
- research, replacement, modification or support of anatomy or a physiological process;
- support or maintenance of life;
- birth control;
- disinfection of medical devices; and
- provision of information by in vitro examination of specimens from the human body.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The authorisation to commercialise biological medicinal products is regulated by Ministerial Agreement 385, which establishes specific conditions for the sanitary registration of these products. In addition to the general requirements for sanitary registration, which are determined in Chapter II, this regulation establishes specific requirements by category.

- Vaccines, allergens and immune serums – the applicant must comply with the requirements contained in Chapter II of the present regulation and, in addition, submit the following:
  - (a) details of the owner of the vaccine at international level;
  - (b) declaration of the name, address, telephone and e-mail of the producer of the diluent (in the case of lyophilised vaccines);
  - (c) statement acknowledging responsibility for the release of finished product batches by the manufacturer;
  - (d) evidence of an environmental risk assessment;
  - (e) summary of production and quality control protocol in the case of domestic and foreign-manufactured vaccines;
  - (f) lot release certificate issued by the health authority of the country of origin of the product or by the health authority of the region in charge of its release (in the case of imported products);
  - (g) information about the experts connected with the product; and
  - (h) other technical information concerning the manufacturing process of the active ingredient, Finished Product Information, etc.
- Processed hemoderivatives and related products – in addition to the general requirements for sanitary registration of a product, the following must be attached to the application:
  - (a) the plasma master file;
  - (b) contract between (i) the manufacturer of hemoderivative drugs and/or the establishment that deals with plasma fractionation or treatment and (ii) the health establishments/blood services that collect and analyse the blood or plasma;
  - (c) description and number of nucleic acid amplification tests performed on the finished (hemoderivative) product, including the number of samples that make up the pool;
  - (d) certificate of batch release of the hemoderivative issued by the sanitary authority of the country of origin (country of importation); and
  - (e) non-clinical and clinical reports.
- Biotechnological drugs require the submission of a complete dossier that contains the following modules:

(a) administrative information and prescribing information (Module 1);
(b) summaries of common technical documents (Module 2);
(c) quality information (Module 3);
(d) non-clinical study reports (Module 4); and
(e) clinical study reports (Module 5).

- In order to obtain sanitary registration of a biosimilar drug, the applicant must comply with the requirements contained in Chapter II of the regulation – with the exception of Modules 4 and 5, corresponding to non-clinical studies and clinical studies, as applicable. The applicant must also comply with the following additional requirements.
- Physical–chemical and biological characterisation studies of the active pharmaceutical ingredient and the finished product must be submitted, together with studies of the biological activity, immunochemical properties and impurities in comparison with the reference biological drug (and the report of such studies), must be submitted in order to demonstrate that the biosimilar drug is comparable to the reference biological drug.
- Non-clinical comparability studies of the biosimilar drug in comparison with the reference biological drug must be submitted.
- In specific circumstances, a comparative clinical efficacy study may not be necessary if the similarity of the physicochemical characteristics and biological activity/potency of the biosimilar drug and the reference biological drug can be demonstrated, and similar efficacy and safety can be evidenced from such data and comparative pharmacokinetic/pharmacodynamics data.
- In the event that the biosimilar drug does not demonstrate its biosimilarity with the reference biological drug in a substantiated and documented manner, the applicant must submit extended clinical comparability studies and periodic safety reports of the biosimilar drug to be registered, together with a sworn statement stipulating that the manufacturer of the biosimilar drug has carried out its comparative studies with the reference biological drug.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

According to the Organic Health Law and its regulations, the sanitary registration for pharmaceutical and medical devices is granted for a term of five years. The renewal of sanitary registrations for an additional five-year period is automatic if the product is proven not to have been subject to significant changes.

The revocation or cancellation of sanitary registrations of pharmaceutical products and medical devices may occur if:

- it is proven that the drug or the manufacturer does not comply with the requirements and conditions established in the law and its regulations;
- health alerts related to the safety and efficacy of the drug are presented or it is detected that the pharmaceutical or medical device may cause harm to health; or
- the BMP certificate or operating permit of the pharmaceutical establishment is suspended, cancelled or not renewed as a result of surveillance and control actions.

In addition, registration of drugs that are not marketed for a period of one year will be cancelled.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

In Ecuador, the procedure for the issuance of the sanitary registration of medicines is as follows.

- The user will apply electronically via the automated system for granting the Sanitary Registration Certificate and will enter the required information in the application form for sanitary registration.
- The user must file all the documents listed as requirements.
- Once the user files the application form and the required attached documents, as established by the present sanitary regulations, ARCSA – or whoever exercises its competences – will review the form.
- In the event that the review is not favourable, the process will be returned to the user only once so that they can correct the objection within a maximum term of five days. In the event that this is not done within the established time or the objection is not corrected, the application will reflect the status of "application not approved" and the process will be definitively cancelled.
- If the review is favourable, the system will notify the user of the amount to be paid, after which they will have ten days to pay the corresponding amount of the economic right (fee) – otherwise the application will show the status of "application not approved" and the process will be definitively cancelled.
- ARCSA, or whoever exercises its competences, will carry out the technical–chemical and safety–efficacy analysis.
- If the technical–chemical or safety–efficacy analysis report does not contain objections, the respective Sanitary Registration Certificate will be issued.
- In the event that the technical–chemical or safety–efficacy analysis contains objections, a single objection report will be generated through the system, which will authorise the user to overcome the objections.
- In the event that the objections have not been adequately solved or have not been solved within the established timeframe, ARCSA will authorise the user for the second and final time to solve the objections of the initial objections report.
- Once the corrected objections are received, if they are reviewed favourably, the respective Sanitary Registration Certificate will be issued through the information system established by the agency.
- In the event that the objections have not been corrected or have not been delivered within the established timeframe for a second time, the process will be definitively cancelled.
- ARCSA may convene its committee of internal advisors or external experts if required after sending the user the single objections report.

Modifications to sanitary registrations follow the above-mentioned procedure; however, they may only be requested in certain circumstances.

- The sanitary registration of a drug may be modified for the following reasons:
  - (a) change in the nature of the packaging material, provided that the manufacturers submit:
    - (i) technical specifications of the material of the new packaging; and
    - (ii) certificate of analysis and stability data sheets proving that the new packaging does not affect the stability of the product in any way and that the quali-quantitative formula of the product is no different to the one

that was presented and approved in the sanitary registration procedure;
(b) inclusion of a new therapeutic indication, provided that the therapeutic indication is within the same Anatomical Therapeutic Chemical (ATC) group;
(c) modification of the name/company name or domicile of the manufacturer, applicant for/holder of the sanitary registration, packager and/or distributor, or owner of the product;
(d) replacement or change of the manufacturer, applicant for/holder of the sanitary registration, packager and/or distributor, or owner of the product;
(e) change of city or country of the manufacturer;
(f) change of product name;
(g) change of the forms of presentation;
(h) change of size and/or colour of the capsules;
(i) change (increase or decrease) in the excipients that does not affect the stability or bioavailability specifications of the product;
(j) variations in the shelf-life period of the product; and
(k) inclusion, termination or change of alternate manufacturer.

- For the approval of any of the above-mentioned modifications to the sanitary registration, the applicant for/holder of the sanitary registration must notify ARCSA of such changes and attach the respective supporting technical and/or legal requirements, as per the instructions prepared by ARCSA for such purpose.
- As regards medical devices, modifications to the sanitary registration will not require obtaining a new sanitary registration, provided they are approved by ARCSA prior to the commercialisation of the product with such changes. The holder of the sanitary registration must make the request for approval of such changes through the automated system that ARCSA uses for such purpose, attaching justification documents for the proposed changes. The abbreviated process for approval of modifications will follow the regular procedure established in the current regulation.

Medical devices only require a new sanitary registration if there is:

(a) a change in the level of risk of the registered device generated by a change in the type of medical device with regard to the model, intention of use, conditions, chemical composition of raw materials, or energy source; or
(b) a change to the quali-quantitative formula of formulated medical devices for human use.

In respect of drugs and medical devices alike, the transfer of a sanitary registration from one holder to another is allowed as a cause for modification – provided the following required documents are presented:

- power of attorney or letter of authorisation of the product holder; and
- labels, package inserts and manuals stating the new holder of the sanitary registration.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

In accordance with the Organic Health Law, medicines in general, biological products, processed natural products for medicinal use, dental products, medical devices and biochemical diagnostic reagents – whether manufactured

domestically or abroad – must obtain a sanitary registration for their importation, commercialisation, dispensation and sale.

As an exception, ARCSA established procedures that allow the importation and use of pharmaceuticals and medical devices without health registration or for a therapeutic indication not contemplated therein when dealing with rare and catastrophic diseases, specialised treatments or a state of emergency. In other countries, this concept is understood as compassionate use of medicines; however, in Ecuador it is not regulated under this denomination.

According to the definition provided by the Organic Law of Health, a public health emergency is any situation where a risk to health is caused by natural disasters or by the actions of people, the absence or precariousness of basic sanitation conditions, or climatic phenomena that favour the increase of communicable diseases. A public health emergency requires the special intervention of the State to mobilise human, financial or other resources aimed at reducing the risk or mitigating the impact on the health of the most vulnerable populations.

In order to supply pharmaceuticals and medical devices without a marketing authorisation in a public health emergency, the following must be presented:

- a document by means of which the public health emergency was declared by the competent authority; and
- a document duly signed, issued and approved by the person in charge of a National Health System or Complementary Private Network health facility, in which the following details of the product(s) to be imported are contained:
  - (a) commercial name of the product(s);
  - (b) International Nonproprietary Name (INN) of the drug or, where there is no INN, the name of its active ingredient;
  - (c) Generic Universal Common Denomination of the device(s) to be imported;
  - (d) pharmaceutical form and concentration of the drug;
  - (e) storage conditions;
  - (f) the total quantity of the product to be imported;
  - (g) current sanitary registration number (or its equivalent) of the product in its country of origin or the country where it is marketed; or
  - (h) letter from the manufacturer or owner stating that the product to be imported has the respective current health registration (or its equivalent) in the country and indicating the countries where it is marketed.
- In order to obtain authorisation to supply specialised treatments that are not available in Ecuador, the applicant must include the following in the application:
- details of the product or products to be imported, such as:
  - (a) commercial name of the product(s) (where applicable);
  - (b) INN of the drug or, where there is no INN, the name of its active ingredient;
  - (c) pharmaceutical form and concentration of the drug;
  - (d) current health registration number (or its equivalent) of the product in its country of origin or the country where it is marketed;
  - (e) Certificate of Pharmaceutical Product or Certificate of Free Sale;
  - (f) letter from the manufacturer or owner stating that the product to be imported has the respective current health registration (or its equivalent) in its country of

origin and indicating the countries where it is marketed;
(g) total quantity of the product to be imported (indicating the number of units of the medicine and/or medical device for human use);
(h) expiration date (where applicable in medical devices);
(i) lot or serial number (as applicable); and
(j) invoice or proforma containing details of the product(s) to be imported;

- justification documents for the products to be imported, which must address the medical prescription (dosage) of the patient(s) who will receive the treatment and indicate the estimated number of patients who will receive the treatment (where applicable); and
- medical report (signed by the treating physician or medical director of the health establishment providing the patient(s) with assistance) outlining the medical justification, which must contain at least the following information:
  (a) diagnosis of the disease, according to the International Classification of Diseases (ICD);
  (b) reason why the patient(s) require the product(s); and
  (c) the estimated time of therapeutic treatment.

In the case of medicines that are difficult to access, this modality is available for the supply of the public sector with the following:

- hard-to-access medicines that do not come from international organisations; and
- dietetic substances with therapeutic indications or specially prepared foods that replace special dietary regimens.

In all cases, once the import authorisation by exception or the import authorisation by donation is issued, the applicant must notify ARCSA of the date and place of arrival or departure of the product within two months. In so doing, the applicant must include the expiration date of the product(s), lot or serial number, invoice or any other document that ARCSA considers pertinent, in case they were not submitted in the initial application.

ARCSA may carry out control inspections during the arrival of the product in order to verify compliance with the information provided by the applicant. In cases where the requested documentation is not presented prior to the arrival or where corrections are not made based on the inspection, ARCSA may revoke the authorisation.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Among the obligations of the holder of sanitary registrations for drugs and medical devices is the respective execution of pharmacovigilance and technical surveillance programmes.

Through Resolution No ARCSA-DE-020-2016-YMIH, ARCSA resolved to issue the substitute Technical Sanitary Regulation for the National Pharmacovigilance System (*Sistema Nacional de Farmacovigilancia*, or SNFV), which aims to define the functions of the SNFV for its members and establish the process for the detection, identification, notification, quantification, evaluation, prevention, understanding and management of the risks associated with the use and consumption of products subject to control and surveillance.

The scope of application of this resolution is circumscribed to medicines in general, biological medicines, medicines containing scheduled substances subject to control and processed natural products for medicinal use that have Ecuadorian sanitary registration and are manufactured and marketed in the country – as well as those authorised by exception and those entering from abroad by homologation – so that their efficacy, effectiveness, quality and safety can be monitored in order to safeguard the health of the population.

Resolution No ARCSA-DE-020-2016-YMIH establishes conditions designed to make the system work efficiently. The first condition concerns mandatory compliance with pharmacovigilance standards. Specifically, those who are the first to learn of an adverse event must notify the competent authority.

Notification is one of the responsibilities of the holders of medical device sanitary registrations. As a consequence of the foregoing, the holders of medical device sanitary registrations must comply with a specific process indicated in the regulations in force, so as to correctly and efficiently carry out the notifications, reports and management of information related to adverse events or incidents involving the medical devices for human use that they manufacture, distribute or market.

In general, all serious adverse events and incidents must be reported.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

In accordance with the regulations in force for the sanitary registration of drugs and medical devices, the information and documents that are part of the dossiers are confidential and must only be used for the sanitary registration procedures.

3.8 Rules Against Illegal Medicines and/or Medical Devices

In Ecuador, crimes involving counterfeit medicines are addressed by the Organic Integral Penal Code (*Código Orgánico Integral Penal*, or COIP). The COIP establishes that whoever is responsible for producing, manufacturing, marketing, distributing, importing, storing or dispensing counterfeit or adulterated medicines – ie, medicines without registration or sanitary notification that have no active ingredients (or lack adequate ingredients or adequate amounts of active ingredients) and a falsified or adulterated container or packaging – will be subject to a penalty of between five and seven years in prison.

However, if the person who commits this crime is a health professional, they will be punished with a prison term of between seven and ten years and barred from practising their profession or trade for one year after serving their prison sentence. Further, if someone is killed as a consequence of the consumption of these products, the person(s) responsible will be sentenced to between ten and 13 years in prison.

Such regulation is linked to the Organic Law of Health, which determines that medicines must not be introduced clandestinely into the country and must not be counterfeit or adulterated.

Finally, ARCSA's obligations in relation to the foregoing include:

- receiving and verifying in a timely manner reports and complaints of products subject to sanitary control and surveillance that could be

considered counterfeit, adulterated or altered – as well as co-ordinating the execution of the corresponding actions with the other competent authorities – and other control activities.
- carrying out periodic inspections of establishments engaged in the manufacture, packaging, exportation, donation, importation, distribution, storage, transportation, commercialisation, dispensation and sale of products for human use and consumption – according to the annual schedule and with the purpose of identifying counterfeit, adulterated or altered products – and taking the appropriate actions and sanctions (as the case may be);
- taking samples for corresponding analysis through ARCSA's reference laboratory where a medicine or medical device is presumed to have been falsified, adulterated or altered;
- co-ordinating with the competent institutions the necessary mechanisms for the seizure, confiscation, destruction and final disposal of products for human use and consumption that have been proven – by means of a reasoned resolution – to be counterfeit, adulterated or altered;
- publishing informative notes or alerts on counterfeit, adulterated or altered products on the ARCSA website or via other means of communication; and
- exchanging information on cases where counterfeit, adulterated or altered products have been detected with the National Liaison Centre for subsequent communication at the international level.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Ecuador is a subscriber of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") and the Andean Decision 486 – both of which are international regulations that contemplate border measures as a mechanism to suspend the customs clearance of infringing products. The local regulation, the Organic Code on the Social Economy of Knowledge, Creativity and Innovation outlines how border measures operate as an impediment to importation, based on IP rights.

The National Customs Service (*Servicio Nacional de Aduana del Ecuador*, or SENAE) is responsible for the surveillance of goods, as well as alerting the holder of the IP rights registered in Ecuador, and will suspend customs operations containing products that violate an IP right for five days. The rights-holder or their representative may request the suspension of an allegedly infringing operation and ask the Ecuadorian IP authority to rule on the infringement.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

ARCSA is the competent authority to grant authorisations for manufacturing plants of pharmaceutical and medical devices to operate in Ecuador.

Every applicant or holder of a sanitary registration for pharmaceutical and medical devices must maintain the Good Manufacturing Practices (GMP) certificate of the foreign pharmaceutical laboratory, issued by the competent authority in the manufacturer's country of origin, throughout the process of obtaining the sanitary registration and for the duration of the period in which the product is marketed in Ecuador. The GMP certificate must then be registered with ARCSA.

In the case of local manufacturing plants, national pharmaceutical laboratories that are setting up for the first time must obtain the GMP certificate prior to obtaining the operating permit, for which they must compile – within a minimum period of six months – the records and other documentation evidencing the implementation of the quality control standards during the process of manufacturing the pilot batches.

The GMP is valid for three years from the date of its issuance and can be renewed for equal periods.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in the wholesale of pharmaceutical products and medical devices are subject to an annual authorisation granted through an operating permit issued by ARCSA.

The categories under which annual wholesale permits are granted are as follows.

- Houses of representation – these are the pharmaceutical establishments authorised to carry out medical promotion, importation and wholesale to third parties of the products manufactured by their representatives. They must comply with good storage and distribution practices, as determined by ARCSA. They require, for their operation, the technical direction of a professional pharmaceutical chemist or a pharmaceutical biochemist.
- Pharmaceutical distributors – these are the pharmaceutical establishments authorised to import, export and wholesale drugs for human use, pharmaceutical specialties, products for the pharmaceutical industry, medical–surgical auxiliaries, medical devices, medical supplies, cosmetics and hygienic products. They must comply with the good storage and distribution practices as determined by ARCSA. They will operate under the representation and technical responsibility of a pharmaceutical chemist or pharmaceutical biochemist.

To obtain the authorisation, an application must be submitted through an automated system, with the following attached:

- the company's or society's constitution documents;
- documents that prove the legal representation; and
- supporting documents related to the drugs or medical devices to be marketed (eg, powers of attorney and GMP certificates), as required by ARCSA.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals can be classified as follows:

- by the type of product, which can be brand name or generic;
- by form of sale, which may be OTC or prescription-only; and
- by drug category (ie, drug or biological drug).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The law governing the import and export of pharmaceutical products and medical devices is the Organic Code of Production, Commerce and Investment (*Código Orgánico de la Producción, Comercio e Inversiones*, or COPCI), in conjunction with the Organic Health Law. ARCSA applies and enforces regulations to authorise the import/export of medicines through SENAE.

6.2 Importer of Record of Pharmaceutical and Medical Devices

In Ecuador, any natural or legal person qualified as an importer by the Ecuadorian customs system (ECUAPASS) may import pharmaceutical products and medical devices with prior authorisation from ARCSA, which will verify the respective health registrations required.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of medicines and medical devices is subject to prior authorisation by ARCSA in order to nationalise medicines and/or medical devices.

Should the donation of medicines and/or medical devices be required in an emergency, ARCSA does foresee substitutive regulations to authorise their importation in these situations (Resolution ARCSA 16).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The basic law governing import regulations and restrictions in Ecuador is the COPCI and the Customs Title Facilitation Regulations, in conjunction with Foreign Trade Committee Resolution No 20 (COMEX), which codifies the Nomenclature of Designation and Codification of Goods of Ecuador and establishes general rules for the interpretation of this tariff nomenclature.

6.5 Trade Blocs and Free Trade Agreements

Ecuador has the following trade agreements in force:

- The Cartagena Agreement (CAN), Partial Scope of Negotiation Agreement No 29 with Mexico;
- Chile–Ecuador Trade Agreement;
- Partial Scope Agreement of Economic Complementation between Ecuador and Guatemala;
- Trade Agreement between Ecuador and the EU;
- Partial Scope Agreement between Nicaragua and Ecuador;
- Partial Scope Agreement of Economic Complementation between Ecuador and El Salvador; and
- Inclusive Economic Partnership Agreement between Ecuador and the European Free Trade Association states (Iceland, Principality of Liechtenstein, Kingdom of Norway and Swiss Confederation).

Ecuador also has an agreement with United Kingdom and is party to the WTO Trade Facilitation Agreement (having been a member of the WTO since 1996).

Additionally, Ecuador is part of the Andean Community of Nations (*Comunidad Andina*, or CAN) and the Community of Latin American and Caribbean States (*Comunidad de Estados Latinoamericanos y Caribeños*, or CELAC). It is also an associated state of the Southern Common Market (MERCOSUR).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Ecuador, according to the Organic Health Law, medicines are subject to price control by the State through the National Council for the Pricing of Medicines for Human Use and Consumption. Medical devices are not subject to price control, so their retail price (*precio de venta al público*, or PVP) can be freely set.

7.2 Price Levels of Pharmaceutical or Medical Devices

As indicated in **7.1 Price Control for Pharmaceuticals and Medical Devices**, medical devices are not subject to price control.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In accordance with the provisions of the Organic Law of the National Public Procurement System, medicines and supplies are acquired by the Comprehensive Public Health Network for use in health facilities such as hospitals and medical centres.

The concept of reimbursement with public funds is not executed in Ecuador.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

As a general policy in cases of procurement of medicines or medical supplies by the State, a cost-benefit analysis is not carried out in Ecuador, as it is always sought in order to acquire the product that offers a lower cost. However, for certain treatments, many medical specialists recommend the purchase of a certain product if the quality is analysed, even though it may have a higher price.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

There are no specific regulations regarding how prescriptions are regulated, mainly to curb pharmaceutical spending. Drug prices, howe er, are determined by the State. It is nonetheless worth mentioning that whoever sells a drug must inform the buyer about the existence of the generic drug and its price (which is usually lower).

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no specific rules for medical apps and they are not considered medical devices in Ecuador.

8.2 Rules for Telemedicine

Ecuador has yet to implement a specific regulation on telemedicine that comprehensively develops the management and procedures for the provision of this service. As such, telemedicine is governed by general rules that allow its application in both the public and private spheres. Nonetheless, it is worth noting that telemedicine is widely used in Ecuador.

8.3 Promoting and/or Advertising on an Online Platform

According to Article 143 of the Organic Health Law and the Ministerial Agreement No 179, "promotion" refers to all informative and persuasive activities carried out by manufacturers and distributors of medicines aimed at prescribers for the purpose of inducing them to prescribe, supply or purchase these products through a medical visit.

The regulation of advertising and promotion of medicines and medical devices does not reduce or limit the activities that can be carried out as part of the promotion. There is no prohibition or legal restriction on the sending of promotional material via digital means during a medical visit. Additionally this mechanism can also be executed if it is directed exclusively at physicians, as part of the continuing medical education programmes provided by the laboratories. Continuing medical education is not regulated by law; however, there is no legal provision that prohibits it.

In other words, drug promotion activities by digital means can be carried out if it complies with the following legal requirements:

- it must be directed exclusively at health professionals who are authorised to prescribe (ie, physicians, dentists and midwives, according to the Organic Law on Health);
- it must be carried out by medical visitors who are duly licensed by the laboratory or directly by the representation house; and
- it must be part of continuing medical education for health professionals authorised to prescribe (optional).

In the case of promotion by digital means, it is also worth taking into account the Law on Electronic Commerce, Signatures and Data Messages, which provides for the need for voluntary adhesion (with consent to receive data messages).

8.4 Electronic Prescriptions

Ministerial Agreement No 31 of 7 July 2020 issued the Regulation to Establish the Content of the Medical Prescription, which regulates the content and requirements for the prescription of medicines.

This regulation establishes that the medical prescription may be electronic, requiring it to be validated with the electronic signature of the health professional. The signature must be certified by an accredited entity.

The following are important points regarding the electronic prescription.

- The "indications" must be readable through an electronic medium in a format clearly understandable by the user/patient; otherwise they must be delivered in physical form.
- Pharmacies that dispense medicines through electronic prescriptions must have a system in place that includes the recording of the phrase "completely dispensed" or "partially dispensed", along with details of the quantity dispensed and the respective date.
- The filing and custody of dispensed electronic prescriptions is mandatory.

8.5 Online Sales of Medicines and Medical Devices

According to the Organic Health Law, pharmacies are the only establishments authorised to dispense and sell medicines for human use and consumption, pharmaceutical specialties, processed natural products for medicinal use, biological products, medical supplies and devices,

cosmetics, dental products, as well as to prepare and sell officinal and magistral formulas.

Online sales of pharmaceutical products and medical devices are not prohibited according to the the Organic Health Law and, as such, are carried out in Ecuador. However, the only requirement that must be complied with is that they are carried out by an establishment that is permitted to operate as a pharmacy and that complies with good practices for the transportation and delivery of the products.

8.6 Electronic Health Records

Article 7 of the Regulations for the Management of Confidential Information in the National Health System mentions that "documents containing health information are understood to be medical records" and, as such, "the data contained therein shall be confidential". In this sense, as medical records are sensitive documents that contain detailed information on all the data related to the patient or user, they must be properly handled and comply with certain parameters for their preservation and handling.

Digital records are permitted in Ecuador. However, their processing is prohibited unless any of the following circumstances apply.

- The holder has given his explicit consent to the processing of his personal data, clearly specifying its purposes.
- The processing is necessary for the fulfilment of obligations and the exercise of specific rights of the controller or the holder in the field of labour law and social security and protection.
- The processing is necessary to protect the vital interests of the data subject or another natural person, in the event that the data subject is physically or legally incapable of giving their consent.
- The processing relates to personal data that the data subject has manifestly made public.
- The processing is carried out by order of a judicial authority.
- The processing of health data is subject to the provisions contained in the Regulations for the Management of Confidential Information in the National Health System.
- The processing is necessary for public archiving purposes, scientific or historical research purposes or statistical purposes, which must be proportionate to the aim pursued.
- The processing essentially respects the right to data protection and provides for adequate and specific measures to protect the interests and fundamental rights of the data subject.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Ecuador, the main laws that apply to patents are:

- local norms such as:
  - (a) Organic Code of the Social Economy of Knowledge, Creativity and Innovation;
  - (b) Regulations for the Organic Code of the Social Economy of Knowledge, Creativity and Innovation;
  - (c) Regulations for Knowledge Management; and
  - (d) Organic Administrative Code.
- supranational norms such as:
  - (a) Decision 486 of the Cartagena Agreement;
  - (b) Andean Patent Manual;

(c) Patent Co-operation Treaty (PCT);
(d) the TRIPS Agreement; and
(e) Paris Convention for the Protection of Industrial Property.

As for medical devices, there is no specific regulation in Ecuador. In this case, protection is sought through other mechanisms such as industrial designs, utility models or trade marks. This situation changes with patents, as there is a specific regulation – according to which, patent protection is granted or not.

One problem that significantly affects protection is the time it takes for the authority to grant or deny a patent. On many occasions, it is possible to obtain a favourable resolution right at the end of the exclusivity of the patent.

Finally, in Ecuador, there are the following patentability requirements:

- novelty – an invention will be considered new if it is not included in the state of the art;
- inventive level – an invention is considered to have an inventive level if it would not have been obvious to a person of the trade normally versed in the corresponding technical subject matter nor would it have been derived in an evident manner from the state of the art; and
- industrial application – an invention will be considered susceptible to industrial application if its object can be produced or used in any type of industry (where industry is understood to refer to any productive activity, including services).

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are not regarded as patentable in Ecuador.

9.3 Patent Term Extension for Pharmaceuticals

A patent term extension in Ecuador may not be requested under any circumstances.

9.4 Pharmaceutical or Medical Device Patent Infringement

If a product is claimed in the patent, an infringement of the patent occurs when a person, without authorisation of the patent-holder, performs any of the following acts:

- manufactures the product;
- offers for sale, sells or uses the product; or
- imports the product for any of these purposes.

If the patent claims a process, then an infringement of said patent takes place when a person – without permission from the patent-holder, either uses the process or performs any of the aforementioned acts with regard to a product obtained directly by means of the process.

By virtue of the foregoing, Ecuadorian law does not consider obtaining a marketing authorisation to be an infringement of the patent. However, if a person obtains a marketing authorisation, it means that they intend to carry out any of the above-mentioned activities – thereby generating a threat of infringement that is not punishable under Ecuadorian legislation.

As mentioned previously, whenever any of the described activities are carried out, the infringer may be sanctioned. However, in cases of threat

of infringement, only precautionary measures may be ordered in order to avoid the infringement.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

In defence of patent infringement, the regulations state very clear that the right-holder is entitled to initiate both administrative and judicial actions. Thus, actions for injunctive relief may be initiated in judicial or administrative courts, as may claims for damages against infringers.

As in other jurisdictions, there is the option of requesting a compulsory licence for a drug in Ecuadorian legislation. To do so, the following requirements must be met.

- In the case of licences for use due to lack of use, the applicant must prove that they have previously tried to obtain the authorisation of the patent-holder under reasonable commercial terms and conditions.
- In the case of licences for use for reasons of public interest, the existence of reasons of public interest, emergency or national security must be declared in an executive decree or ministerial resolution.
- In the case of compulsory licences for anti-competitive practices, the decision of the competent authority in matters of defence of competition – in which existence of an anti-competitive practice is determined – must be firm.
- In the case of compulsory licences due to dependence, it is essential to justify being the holder of a second patent whose exploitation necessarily requires the use of a patent.

9.6 Proceedings for Patent Infringement

In Ecuador, patent-holders must initiate an action for patent infringement. It is rare for an exclusive licensee to initiate this type of action, given that the same rule provides that the right-holder is the one who will initiate actions in defence of its patent.

An infringement action against a patent is usually initiated through a request for administrative protection, whereby the national competent authority on IP rights will exercise inspection, monitoring and sanctioning functions to prevent and repress infringements of IP rights. A less conventional method of preventing the occurrence or continuation of the infringement of IP rights is to file a request for preventive measures before the civil judge.

In either of the two ways, the authority will verify the existence of the evidentiary elements that prove the infringement and – by means of a final act – will declare the infringement of the patent.

Ecuadorian law establishes grounds for declaring the nullity of a right. This procedure is separate from the infringement procedure, however.

In order to declare the nullity of a right, ex officio or at the request of a party, an application for nullity shall be filed and the same is made known to the owner so that he may pronounce himself on the application.

9.7 Procedures Available to a Generic Entrant

It is important to begin by noting that the authorisation of pharmaceutical products and medical devices does not have a prior verification procedure with regard to an IP right. In Ecuadorian legislation, obtaining a marketing authorisation does not constitute an infringement; therefore,

the authority does not require or perform any verification.

As regards the marketing of generic drugs in a licit manner, the legislation does not contain a licit form for their marketing. When the patent expires, other products with the same active ingredient may be lawfully marketed.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

In Ecuador, as in other countries of the Andean Community, counterfeit medicines are very common. In spite of this, there are no specific regulations on IP issues that sanction counterfeit medicines. However, in accordance with the provisions of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, it is possible to stop this type of illegal activity through the protection of trade marks or patents.

In addition to this, another mechanism contained in the Organic Code of the Social Economy of Knowledge, Creativity and Innovation is the border measures through which the customs authority seeks to alert the holders of IP rights that an unauthorised importation is taking place.

On the other hand, Ecuadorian criminal law expressly specifies that persons who produce, manufacture, commercialise, distribute, import, store or dispense counterfeit or adulterated medicines, medical devices and products for human use and consumption will be punished with a prison sentence of between five and seven years.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Ecuadorian law establishes that the owner of the trade mark is entitled to file actions against any third party that uses its trade mark in any way without prior authorisation. This provision is contained in both national and regional regulations.

Although the regulations establish that no one may use the trade mark without permission from the owner, there is no specific restriction on the importation or distribution of counterfeit pharmaceuticals or medical devices. However, owing to the prohibition of importation and commercialisation of products of a certain trade mark, it is possible to control the commercialisation of medicines and medical supplies that do not come from the holder of the trade mark.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

In Ecuador, it is possible to protect the commercial image or the design of the products through a trade mark registration. The protection granted to its owner prevents third parties from using in any way or imitating the design of the products.

Additionally, through the protection of utility models, it is possible to protect very novel packaging designs that have not been seen before in the market.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

With the entry into force of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, the protection of test data for pharmaceutical and agricultural chemical products was granted, provided that:

- they are new molecules;

- their structure is kept secret;
- they are the result of considerable effort; and
- they are required by the authority for marketing authorisation.

This test data exclusivity for pharmaceutical products does not have a distinction between chemical or biological medicines. As long as they are new molecules, they will have test data exclusivity for a period of five years in Ecuador.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the sanitary emergency, several regulations were issued to facilitate the sanitary registration of pharmaceutical products and medical devices required for the treatment of COVID-19. To date, these regulations are no longer in effect, and regulatory management of products for human use and consumption has returned to normal.

Notwithstanding the foregoing, there are two regulations that are still in force and that currently facilitate the testing and importation of products relevant to COVID-19 or similar situations that may arise in the future.

Firstly, the purpose of the "Technical Sanitary Regulations for the Approval of Clinical Trials and Certification of Products for Human Use and Consumption and Their Establishments During Sanitary Emergencies or Emergency Situations (National Or International)" is to establish guidelines for the approval process of clinical trials of products under investigation, the certification of products for human use and consumption, and establishments subject to sanitary control and surveillance under the competence of ARCSA during national or international emergencies or emergency situations, as well as the criteria for their control and sanitary surveillance.

On the other hand, the purpose of the "Substitute Technical Regulation to Authorise the Importation by Exception and Importation by Donation of Medicines, Biological Products, Medical Devices and Biochemical and Diagnostic Reagents" is to establish the requirements and guidelines to authorise the importation by exception of drugs, biological products, medical devices and biochemical and diagnostic reagents that have not obtained the corresponding Ecuadorian sanitary registration in cases of emergency in the National Health System, states of national emergency and international sanitary emergency, and other cases determined by ARCSA and declared by the competent national and international agency.

This regulation also determines the requirements and guidelines for authorising the importation by donation of medicines, biological products, medical devices and biochemical and diagnostic reagents that may or may not have Ecuadorian sanitary registration in the respective cases.

As regards the management of the pandemic, this regulation maintains in force the unique final disposition establishing that – until the products manufactured for the prevention, treatment or counteraction of COVID-19 have sanitary registration in the country of origin – the ARCSA will accept as equivalent to the sanitary registration, the Emergency Use Authorisation issued in the country of the product's origin or by a country whose National Regulatory Agency (ARN) is recognised as High Health Surveillance by the Panamerican Health Organization (*Organización Panamericana de la Salud/Organización Mundial de la Salud*, or OMS/OPS).

11.2 Special Measures Relating to Clinical Trials

In general, the procedures for the execution of clinical studies did not undergo any changes as result of COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In Ecuador, there is no specific regulation to grant emergency marketing licences.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

As a general rule, automatic renewal or temporary extensions of GMP certificates are not allowed. However, the Technical Standard on Business Process Management (BPM) has generated some exceptions.

For foreign laboratories, a specific provision was issued enabling an extension of the BPM code granted by ARCSA until the renewal in the country of origin is approved for a maximum term of one year. This provision will come into effect on 13 June 2023.

For national laboratories, the BPM certification renewal process shall be initiated at least six months prior to the expiration date of the certificate – without prejudice to the initiation of the respective legal actions for the expiration of the certificate during the renewal process.

In exceptional cases, where the establishment submits the renewal application within the aforementioned timeframe and the certificate expires during such process, an extension of the BPM certificate validity will be granted until its renewal – as long as the establishment has not generated alerts or complaints for quality problems duly confirmed or has not created non-conformities that affect the quality of the product in the initial inspection for renewal of the certification.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

During the public health emergency, ARCSA was instructed to update the regulations regarding the national production of medicines and medical devices necessary for the emergency and, at the same time, to focus attention on the ongoing regulatory processes.

In view of this, the sanitary regulations were reformed and Resolution No ARCSA-DE-016-2020-LDCL was issued for the purpose of authorising the importation by exception of medicines, biological products, medical devices and biochemical and diagnostic reagents that have not obtained a sanitary registration in Ecuador in cases of sanitary emergency declared by act of public power.

All imports from abroad, regardless of their destination in Ecuador, must obtain the respective authorisation from ARCSA as a necessary requirement for their acquisition and customs clearance.

The processes for obtaining authorisation for the importation of medicines, medical devices and other products were simplified. During the process of approval of clinical trials or obtaining sanitary registrations, for example, the omission of the apostille of the necessary technical–legal documents was allowed.

The established regulation resolved that ARCSA could prioritise at any time the review of the applications of products and establishments, as long as they are within the framework of a sanitary emergency or national emergency situation.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The pandemic created the need for several regulatory changes – not only in terms of the way products, medicines and supplies were procured, but also in the way health services were provided.

During the public health emergency, several programmes were implemented to encourage digital transformation in the provision of health services in the public and private sector. However, they were implemented temporarily and with regulations that did not have sufficient depth.

Currently, these digital mechanisms are only used in the case of electronic medical records and electronic prescriptions. Telemedicine has been practically eliminated, however.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

By Resolution of 20 March 2020, the Committee on Education, Culture and Science of the National Assembly requested the Executive Branch to include the adoption of administrative and technical mechanisms for the establishment of compulsory licences in the declaration of emergency. This was in order to ensure access to medicines and diagnostic kits, as well as any other patented product or process necessary to combat the pandemic.

In such a public health emergency scenario, a compulsory licence may be granted for reasons of public interest. Although the compulsory licence may be granted immediately, the rights of the licensee will not be set aside and the corresponding licence fee must be paid.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Although no liability exemptions have been established, ARCSA issued Resolution No ARCSA-DE-009-2020-LDCL for the registration of products authorised for use in the sanitary emergency. This aimed to establish guidelines for the certification process and criteria for the control and surveillance of such products.

It was determined that the issuance of the registration of these products would be a temporary authorisation for their commercialisation and use only for the duration of the public health emergency. Similarly, in the case of COVID-19 tests, authorisations would only be issued to establishments to perform reverse transcription polymerase chain reaction (RT-PCR) tests and rapid antigen detection tests.

ARCSA may suspend or cancel the product at any time, if it is proven that the product or its manufacturer does not comply with the requirements or conditions established in the law or if the product represents a health risk.

11.9 Requisition or Conversion of Manufacturing Sites

Regulatory changes were implemented in many countries to accelerate the production and approval of medical devices and drugs needed to treat patients with COVID-19. This established accelerated approval processes for medical products and allowed manufacturers to rapidly change their production lines in order to meet the growing demand for critical medical supplies.

By way of an example, Executive Decree 1017 of 16 March 2020 established the National Health Emergency, which allowed extraordinary measures to be taken in order to prevent the spread

of COVID-19. Such measures included the regulation and control of the production, marketing and distribution of essential goods and services to ensure the quality and safety of products manufactured with these new facility changes and thus ensure the health of the country's population.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

During the COVID-19 pandemic, there were several changes related to the public procurement system that were intended to facilitate the supply and procurement processes for medicines and supplies required for the management of the pandemic.

Several of these changes have been maintained despite the fact that the emergency situation has been overcome. Two provisions stand out, in particular.

- Circular No SERCOP-SERCOP-2020-0014-C of 26 March 2020, issued by the National Public Procurement Service, enabled and reminded the contracting entities of their obligation to have an electronic signature. This provision was based on the Law of Electronic Commerce, Signatures and Data Messages, which indicates that the electronic signature has the same validity as the handwritten signature (Article 14), as well as rules contained in the Law for the Optimisation and Efficiency of Administrative Procedures that impose an obligation on the public sector entities to "implement mechanisms, preferably electronic, for the management of administrative procedures, such as electronic signature and any other that makes the Public Administration more efficient".
- In relation to the use of electronic signature, Circular No SERCOP-SERCOP-2020-0022-C was also issued, through which SERCOP issued several provisions to the highest authorities of contracting entities regarding the implementation of the use of electronic signature. This was previously provided for in External Resolution No RE-SERCOP-2020-106.

GERMANY

Law and Practice

Contributed by:
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Contents

Baker McKenzie was founded in 1949 and is one of the world's largest and most effective law firms, with more than 12,000 employees across 74 offices. The German offices seek to play their part in fulfilling the global vision of the firm's two founders – Russell Baker and John McKenzie. Over 200 lawyers, spread across Berlin, Dusseldorf, Frankfurt/Main and Munich, can represent clients' interests, not only in Germany, but also beyond its borders, combining comprehensive expertise with long-standing experience. As one of Germany's leading law firms, Baker McKenzie advises national and international companies and institutions on all aspects of commercial and tax law. In so doing, the firm concentrates on understanding the economic background to the work, while remaining focused on helping clients realise their business goals.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals for human use are governed by the German Drug Act (*Arzneimittelgesetz*, AMG), which primarily implements the Directive on the Community code relating to medicinal products for human use (Directive 2001/83/EC). In addition, several important German regulations govern the manufacture and distribution of pharmaceuticals and the pricing of prescription-only pharmaceuticals. Since 28 January 2022, pharmaceuticals for veterinary use have been governed by the Regulation on veterinary medicinal products (Regulation (EU) 2019/6), which is complemented by the new German Veterinary Drug Act (*Tierarzneimittelgesetz*, TAMG).

Since 26 May 2021, medical devices have been governed by the Regulation on medical devices (Regulation (EU) 2017/745, MDR), which is complemented by the German Medical Device Law Implementation Act (*Medizinprodukterecht-Durchführungsgesetz*, MPDG) as well as several further implementing German regulations. Since 26 May 2022, in vitro diagnostics have been governed by the Regulation on in vitro diagnostic medical devices (Regulation (EU) 2017/746, IVDR), which is also complemented by the same German Medical Device Law Implementation Act.

Regulatory oversight of both pharmaceuticals and medical devices is divided between federal authorities and state level authorities.

With respect to pharmaceuticals, the federal regulatory authorities BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte*) and PEI (*Paul-Ehrlich-Institut*) are responsible for issuing national marketing authorisations (MAs), approving clinical trials, and for pharmacovigilance. The PEI assumes these responsibilities for biological pharmaceuticals, such as vaccines and advanced therapy medicinal products (ATMP), while the BfArM is competent for all other pharmaceuticals (centralised MAs are issued by the EU Commission based on the evaluation of the European Medicines Agency (EMA)). The state level authorities are responsible for issuing manufacturing, wholesale distribution and import licences, and for overseeing, ascertaining

through inspections and enforcing compliance with applicable pharmaceutical laws.

With respect to medical devices, the BfArM is responsible for classification decisions, clinical trial approvals and vigilance, whereas the state level authorities are responsible for general oversight, inspections and enforcement.

The BfArM and the PEI are independent federal authorities within the portfolio of the Federal Ministry of Health and subject to its oversight; the Federal Ministry of Health has the authority to issue directives to the BfArM and the PEI. The same applies mutatis mutandis to state level authorities.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Enforceable decisions by regulatory bodies qualify as administrative acts which can be challenged by the addressee (or by a third party having standing) by lodging an objection with the regulatory body which has issued the administrative act. By default, the objection has suspensory effect and impedes enforcement of the challenged administrative act. However, the regulatory body can order the immediate execution of the administrative act, notwithstanding the pending objection. In such a case, the addressee of the administrative act (or a third party having standing) can submit a request to the competent administrative court to (re-) establish the suspensory effect of the objection, which, if successful, precludes enforcement until a final decision is obtained; either the objection is sustained by the regulatory body, or otherwise, upon filing a lawsuit against the administrative act and the unsuccessful objection proceeding, the administrative act is either confirmed or lifted by the administrative courts.

Objections against administrative acts, as well as requests for the (re-)establishment of suspensory effect and lawsuits, must be lodged in writing and within one month of notification of the decision to be challenged.

The aforementioned procedure applies to pharmaceuticals and medical devices as well as to other regulated products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals may qualify as prescription-only, pharmacy-only, and freely sellable pharmaceuticals. Prescription-only medicinal products qualify at the same time also as pharmacy-only and may not be advertised to the public and, like pharmacy-only pharmaceuticals, only be dispensed by pharmacies (including online/mail-order pharmacies).

The same three-pronged distinction applies to medical devices. However, unlike pharmaceuticals, most medical devices are freely sellable and not qualified as prescription-only or pharmacy-only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Since 31 January 2022, clinical trials with pharmaceuticals have been governed by the Regulation on clinical trials on medicinal products for human use (Regulation (EU) No 536/2014, CTR) and new complementing provisions in the AMG. However, in certain scenarios, ongoing clinical trials with pharmaceuticals may continue to be conducted under the legacy national AMG rules during a three-year transition period which expires on 30 January 2025 (see **2.2 Procedure**

for Securing Authorisation to Undertake a Clinical Trial).

Since May 2021, clinical trials with medical devices have been governed by the MDR and the German MPDG. The same governance applies for clinical trials with in vitro diagnostics since 26 May 2022.

Clinical trials require prior authorisation by the federal regulatory authority BfArM (or by the PEI in case of biological pharmaceuticals such as vaccines, ATMPs and certain IVDs) and (as part or prerequisite thereof) a positive opinion by the competent ethics committee. The focus of the authorisation procedure before the federal regulatory authority is the quality, efficacy/performance and safety of the investigational pharmaceutical or medical device. The focus of the review by the ethics committee is the ethical and scientific justification of the clinical trial, in particular taking into account the rights of the trial participants.

Non-interventional clinical studies are excluded from the scope of the aforementioned regulations, but may, under the applicable state laws and regulations, require involvement of the ethics committee of the local physicians' association.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

For clinical trials with pharmaceuticals under the CTR, the sponsor must, since 31 January 2023, submit an application dossier electronically through the newly established Clinical Trials Information System (CTIS), which is the single-entry point for the submission of clinical trials under the CTR (https://euclinicaltrials.eu/). Since 31 January 2023, clinical trials can no longer be commenced under the legacy AMG rules.

The application through CTIS will cover both the scientific review of the clinical trial by the competent federal regulatory authority (the BfArM or the PEI) as well as the ethical review by the competent ethics committee.

The applications for authorisation of clinical trials with medical devices by the BfArM, as well as for the prerequisite positive opinion by the competent ethics committee, shall be submitted electronically through the German Medical Devices Information and Database System (DMIDS) portal. The new application procedure established under the MDR and the IVDR is not yet applicable because the necessary new European Database on Medical Devices (Eudamed) is not yet fully functional.

The competent federal regulatory authority (and, if applicable, the ethics committee) shall acknowledge receipt within 10 days and, in the case of formal deficiencies, request their remediation within 10 days (14 days under the legacy AMG rules).

The assessment of formally completed applications for clinical trial authorisations shall be issued by the competent federal regulatory authority within 45 days from the validation of the application (different timelines apply under legacy AMG rules). Up to five days after the assessment phase, the decision on whether the clinical trial can be conducted shall be submitted. The relevant authority or ethics committee may request additional information from the applicant; until the receipt of any such information, the clock is stopped.

Subsequent significant changes to the approved clinical trial may only be implemented after prior approval by the federal regulatory authority (and/or the competent ethics committee, if applica-

ble), depending on the subject matter of the change.

Clinical trial authorisations, as well as favourable ethics committee opinions, can be suspended or revoked if the conditions for approval of the clinical trial are no longer met.

2.3 Public Availability of the Conduct of a Clinical Trial

For pharmaceuticals, information on approved clinical trials performed under the legacy AMG rules are publicly accessible under the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/) as well as under the German Drug Information Portal of the federal government (www.pharmnet-bund.de/static/en/). For clinical trials approved under the CTR, information is available on the CTIS platform (https://euclinicaltrials.eu/).

Sponsors of clinical trials with pharmaceuticals must submit to the CTIS, within one year (or within six months for clinical trials governed by legacy AMG rules) of completion, a report of the clinical trial results, which is then published on the aforementioned databases.

In accordance with its Policy 0070, the EMA already publishes clinical data which pharmaceutical companies have submitted to support their centralised MA applications under https://clinicaldata.ema.europa.eu/web/cdp.

Information on clinical trials with medical devices is currently not made available in free public databases. However, the MDR and the IVDR provide for the transparency of clinical trial information through the Eudamed database. The European Commission has set the second quarter of 2024 as the delivery date for a fully functional version of Eudamed. The obligations of sponsors of clinical trials with medical devices to submit clinical trial results will come into force six months after publication of the Commission notice that the clinical investigations and performance studies module of Eudamed database has achieved full functionality.

2.4 Restriction on Using Online Tools to Support Clinical Trials

At the present time, there are no German regulations on the use of online tools to support clinical trials. However, in the light of experiences made with hybrid clinical trial set-ups borne out of necessity during the COVID-19-related lockdowns and the emerging discussion on decentralised or entirely site-less clinical trials, guidance in this field can be expected in the future. Generally, any use of clinical trials must comply with data protection requirements under the General Data Protection Regulation (GDPR) and applicable implementing and complementing German laws at federal and state level.

2.5 Use of Data Resulting From the Clinical Trials

The clinical trial data directly generated in the trial – whether in “raw” form, as maintained at the clinical trial site, or in pseudonymised form, as subsequently transferred from the clinical trial centre to the sponsor – are considered “special categories of personal data”. Their processing is conditioned to higher requirements set out in Article 9 (2) of the GDPR. Only anonymised data do not fall under the requirements of the GDPR, but anonymised clinical data are of limited use and the requirements for anonymisation are set at a high level. German law requires that clinical trial participants not only provide their informed consent to their participation in the clinical trial, but also provide their consent to the processing of their data by signing informed consents as approved by the competent ethics committee in the clinical trial authorisation procedure.

A transfer of clinical data which falls under the GDPR (ie, non-anonymised data) is generally only possible if covered by the informed consent of the trial participants. Whether – in the absence of express informed consent by the trial participants – the transfer of such data can also be justified by the purposes of scientific research under Article 9 (2) lit. j of the GDPR is being discussed, but has not yet been definitively decided and will depend on the specific situation.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal data of trial subjects would need to comply with the requirements set out in the GDPR. Notably, the trial participants need to be informed about the use and storage of their data in such a database, and the database must meet applicable data security requirements. To the extent that the database is operated by a third party, that third party must itself comply with the GDPR. To the extent that the database is hosted outside the EU, or data are otherwise transferred outside the EU, the rules and European Court of Justice (CJEU) case law regarding the transfer of personal data out of the EU must be complied with.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

German law defines pharmaceuticals as substances or preparations made from substances which are intended to treat, mitigate or prevent diseases, or to restore, correct or modify physiological functions, through a pharmacological, immunological or metabolic effect, or to make a medical diagnosis. Medical devices are defined as products – including devices, instruments, in vitro diagnostics, software, but also substances – which are intended for a medical use, but which achieve their principal intended action in or on the human body by means other than pharmacological, immunological or metabolic means.

Accordingly, the key criteria for classifying borderline products as either pharmaceutical or medical devices relates to (i) identifying the principal intended purpose, and (ii) analysing whether such purpose is achieved by pharmacological, immunological or metabolic means. Guidance on the interpretation of these terms has been published by the Medical Devices Coordination Group (MDCG), an EU expert body established under the MDR. This MDCG Guidance 2022-5 carries substantial weight and is available in its most current revision of April 2022 here: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en. Further guidance with specific examples can be found in the so-called "Borderline Manual" (current Version 2 of December 2022), also prepared by MDCG.

The responsibility for classifying a product appropriately lies with its manufacturer. If a product is granted an MA as a pharmaceutical, it will be considered as a pharmaceutical as long as the MA is in force. Inversely, however, CE-marking a product after conformity assessment in accordance with medical device law does not ensure that the implied classification as a medical device will be upheld if challenged by regulators or by competitors in court. Nevertheless, a manufacturer or the state supervisory authorities can apply to the BfArM for a binding decision as to whether the product in question qualifies as a medical device. The BfArM, in turn, may refer

any such request to the European Commission for a decision by way of implementing the acts pursuant to Article 4 of the MDR.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

German law does not in principle provide for different MA procedures for biological medicinal products (unlike, eg, the USA). However, the requirements regarding the contents of the dossier are different from those for biological medicinal products, owing to the importance of the manufacturing process of the biological medicinal product. Similarly, the MAs of biosimilars require substantially more documentation than MAs for generics of non-biological originator medicines.

Procedurally, MAs for biological medicinal products – provided they are not authorised by the EU Commission under an EU-wide centralised MA – are granted by the PEI rather than the BfArM (see **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices**).

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

MAs are issued for an initial period of five years. If renewed upon request, at least nine months prior to the expiry of its initial term, the MA remains valid for an unlimited period of time. The MA may, upon renewal, be limited again for a five-year-period only if the initial five-year period did not provide sufficient real-life data to guarantee the safety of the medicinal product.

An MA can be suspended or revoked if legal requirements for the MA, eg, the safety, efficacy and quality, are not met or are no longer met. Furthermore, an MA can be revoked under the "sunset clause" if the authorised pharmaceutical is not placed on the market within three years of the issuance of the MA or if the marketing of a pharmaceutical placed in the market is suspended for three successive years.

For medical devices, certificates issued by notified bodies which support the CE-marking of the medical device by the manufacturer have a validity of up to five years. Certificates issued by notified bodies can be reduced in scope, suspended or revoked by the notified body if the requirements for issuance of the certificate are not met or are no longer met.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

An MA for a pharmaceutical for human use can be obtained by the following means.

- In the centralised procedure through an application to the European Medicines Agency (EMA), with a view to obtaining a centralised MA valid in the entire EU/EEA. The EMA shall give an opinion on the application within 210 days and the opinion is the basis for the decision by the European Commission to grant the centralised MA.
- In the national procedure through an application to the BfArM (or to the PEI for biological pharmaceuticals), with a view to obtaining a national MA valid in Germany. The statutory timeframe for issuing the MA is seven months upon receipt of a completed application. Where a national MA is to be applied for in several member states (decentralised procedure, DCP), the reference member state will draw up a draft assessment report within 120 days, and each member state shall take a decision within 90 days of receipt of these drafts. Where a national MA for the medicine has already been issued in another member

state, that member state shall submit within 90 days an up-to-date assessment of the approved assessment to the German authority, which shall take a decision on the application based on the other state's assessment within another 90 days (mutual recognition procedure, MRP).

Variations to MAs for pharmaceuticals are submitted electronically to the competent regulatory authority (the EMA, the BfArM, or the PEI). Depending on their impact to the safety, quality and efficacy of the product, variations are classified as IA, IB or II. The former only require a notification, the latter prior approval.

Centralised MAs can be transferred following the procedure set out in Regulation (EC) No 2141/96. MAs issued by German authorities are transferred by contractual agreement between the current holder and future holder, and the new MAH is subsequently notified to the competent federal regulatory authority (the BfArM or the PEI).

For medical devices, the CE mark may be affixed to the device once the manufacturer has conducted a conformity assessment. Depending on the risk-classification of the medical device, the conformity assessment requires the involvement of a notified body and the issuance of the certification by that notified body. A transfer of the CE mark is not possible legally; rather, the new manufacturer of the medical device must obtain and meet all the requirements necessary to CE-mark the medical device under their own name.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Pharmaceuticals which require an MA but are not authorised (yet) may only be supplied to patients in the following scenarios.

- Clinical trials.
- Compassionate-use programmes for patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The pharmaceutical concerned must either be the subject of a pending marketing-authorisation application or must be undergoing clinical trials. In Germany, pharmaceuticals supplied under a compassionate-use programme may only be supplied free of charge.
- A named-patient programme: upon prescription for a specific patient, pharmacies may import and dispense to that patient a limited quantity of medicinal products which are authorised in the country of export, but not in Germany if no comparable medicines are available in Germany. A named-patient programme does not need to be authorised or notified to a regulatory authority.

German medical device law does not provide for compassionate-use programmes or named-patient exceptions for medical devices which need to bear a CE mark. However, the BfArM may, upon request in individual cases, authorise the use of non-CE-marked devices under Section 7, MPDG (see Article 59, MDR) if their use is in the interest of public health or patient safety or health.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

For pharmaceuticals, the MAHs must discharge several ongoing obligations, including the following:

- to keep the dossier of the product up to date and notify, or submit variations to, the competent regulatory authority if the particulars set out in the MA change;
- to set up, maintain and audit a pharmacovigilance system, appoint a qualified person for pharmacovigilance (*Stufenplanbeauftragter*), maintain a pharmacovigilance master file, operate a risk-management system for the pharmaceuticals, document and report suspected adverse reactions, monitor scientific literature for safety signals, prepare and submit periodic safety-update reports;
- to appoint an information officer (*Informationsbeauftragter*) who is responsible for ensuring that the product labelling, package-insert leaflets, and summary of product characteristics, as well as all promotional material, is in line with the terms of the MA; and
- to take out and maintain product liability insurance which fully covers the specific statutory no-fault liability of the MAH under the AMG.

Similarly, manufacturers of medical devices, ie, who are indicated as the manufacturer in the labelling, are subject to a number of obligations under the MDR/IVDR, including the following.

- To keep the technical documentation of the device up to date.
- To appoint a person responsible for regulatory compliance (PRRC).
- To maintain and provide unique device-identifier (UDI) information to improve the traceability of medical devices.
- To comply with technovigilance reporting obligations, conduct post-market clinical follow-up (PMCF) activities, prepare post-market surveillance (PMS) reports or regular periodic safety update reports (PSUR), and prepare trend reports on safety signals. Further ongoing obligations for post-market surveillance can be derived from the manufacturer's quality system, which typically implements the requirements of the harmonised technical standard ISO 13485:2016.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

While the EMA does publish a list of "medicines under evaluation", the German federal regulators do not proactively publish pending MA applications under review. Details about approved pharmaceuticals are available in the public section of the database "AMIce" (*Arzneimittel-Informationssystem*).

Requests for information about pending, granted or rejected MA applications can be submitted to the BfArM or the PEI under the German Freedom of Information Act (*Informationsfreiheitsgesetz*, IFG). However, to the extent that the requested information contains personal data, is protected by intellectual property rights or constitutes confidential business information, that information will be redacted or will not be disclosed. The authority will typically ask the MAH whether they consent to the requested disclosure and will allow for comment on the proposed redactions. Generally, the German regulatory authorities are more protective of the MAH's information than the EMA.

As medical devices are, under current medical-device law, not subject to a governmental approval process, any information about medical devices undergoing conformity assessment remains with the manufacturer and the notified body who, as private parties, are not subject to the Freedom of Information Act. For medical devices placed on the market in Germany and notified to the BfArM, a limited set of information is available on the DMIDS database (accessible through bfarm.de). Under the MDR and the IVDR, more information will become publicly available through the Eudamed database, which is currently only accessible to regulatory authorities.

3.8 Rules Against Illegal Medicines and/or Medical Devices

With respect to pharmaceuticals, the EU Falsified Medicines Directive (Directive 2011/62/EU) has been implemented into German drug law on the following basis.

- To prevent falsified prescription-only medicines entering the supply chain, prescription-only medicines must bear an anti-tampering device (eg, a sealing strip) which allows verification that the pack has not been opened, and a unique identifier to verify the authenticity of the pack (serialisation); the details are set forth in the Delegated Regulation (EU) 2016/161.
- The import and distribution of falsified pharmaceuticals in Germany is expressly prohibited and is subject to penal sanctions. The regulatory authorities are authorised to take enforcement action against falsified medicines, including seizure.
- MAHs, wholesale distributors, and pharmacies are subject to increased control and notification obligations to identify and report falsified medicines.

Under the MDR and the IVDR, importers and distributors of medical devices have the obligation to inform the competent authorities of suspected falsified devices. The authorities may, where necessary to protect the public health, confiscate, destroy or otherwise render inoperable any such falsified devices.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The Federal Ministry of Finances and the customs authorities are competent for enforcing German drug law with respect to pharmaceuticals imported from (or exported to) non-EU countries. The customs authorities will verify upon import the relevant import documentation, including whether a certificate attesting that the manufacture in the country of export complies with good manufacturing practices. If in doubt, the German customs authorities will liaise with the German regulatory authorities. German customs authorities regularly report on the numbers and types of intercepted counterfeit pharmaceuticals.

Similarly, the German customs authorities are competent for enforcing compliance of imported medical devices with the applicable law, in accordance with Regulation (EC) No 765/2008. When determining further action, the German customs authorities will liaise with the competent German regulatory surveillance authorities if a medical device:

- displays characteristics which give cause to believe that the device presents a serious health or safety risk;
- is not accompanied by the required documentation or not marked as required; or
- has a CE mark that has been affixed to the device in a false or misleading manner.

In addition to the foregoing, border measures can be based on IP rights (see **10.1 Counterfeit Pharmaceuticals and Medical Devices**).

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacture of pharmaceuticals (which includes also packaging, labelling and final release of the finished product) is subject to a manufacturing authorisation.

The authorisation is granted by the competent authority of the federal state in which the manufacturing site is located. In order to obtain a manufacturing authorisation, the applicant must:

- appoint a Qualified Person (QP), as well as a Head of Production and a Head of Quality Control, each of whom must be appropriately qualified; the QP must also be experienced and reliable, to be evidenced through a clean criminal record certificate;
- have other appropriately qualified and trained personnel to conduct the manufacturing activities;
- have the appropriate premises for performing the manufacturing activities; and
- set up and maintain a quality system, consisting of standard operating procedures, which covers the manufacturing activities, and have the staff trained to its content.

The manufacturing licence will only be issued after a successful on-site inspection of the manufacturing premises by the regulatory authority. The statutory timeframe for issuing a manufacturing licence is three months from the submission of a complete application. However, follow-up requests by the authority or deficiencies identified in the inspection will stop the clock.

The manufacturing authorisation is granted for a specific site and typically for specific manufacturing activities and types of medicines, sometimes covering only individually specified medicinal products. It is issued for an unlimited time but remains subject to regular Good Manufacturing Practice (GMP) inspections by the competent authority.

The manufacture of medical devices is not subject to a governmental authorisation. The quality of the manufacturing processes is regulated indirectly through the conformity assessment of the respective device and the manufacturer's quality system which supports the conformity assessment.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

The wholesale distribution of pharmaceuticals is subject to a wholesale distribution licence (WDL). Wholesale distribution is not limited to the physical handling and storage of pharmaceuticals. A WDL is also needed for procuring, selling and supplying pharmaceuticals, even when the physical handling and logistics are outsourced to a third party. However, a manufacturer does not need a WDL for supplying and distributing pharmaceuticals which it has manufactured; any such supply and distribution is covered by the manufacturing licence.

The WDL is granted by the competent authority of the federal state in which the wholesale distribution site is located. In order to obtain a WDL, the applicant must:

- appoint a Responsible Person for wholesale distribution (RP), who must be appropriately qualified, experienced and reliable, the latter to be evidenced through a clean criminal record certificate;
- have other appropriately qualified and trained personnel to conduct the wholesale distribution activities, as necessary;
- have the appropriate premises for performing the wholesale distribution activities; and
- set up and maintain a quality system, consisting of standard operating procedures, which covers the manufacturing activities, and have the staff trained to its content – this quality system shall in particular ensure that medicines are only sourced from, and supplied to, entities which are authorised to supply or procure such medicines, that all procurement and supply of pharmaceuticals is properly documented, and that recalls can be implemented.

The WDL will only be issued after a successful on-site inspection of the wholesale distribution site by the regulatory authority. The statutory timeframe for issuing a WDL is three months from the submission of a complete application. However, follow-up requests by the authority or deficiencies identified in the inspection will stop the clock.

As with a manufacturing authorisation, the WDL is granted for a specific site, for specific distribution activities and for specific types of medicines (including or excluding, eg, blood products, controlled substances, or temperature-controlled products). It is issued for an unlimited time, but remains subject to regular GDP inspections by the competent authority.

The distribution of medical devices is not subject to a governmental authorisation. However, under the MDR/IVDR, distributors are subject to certain obligations to ensure that only compliant medical devices are made available on the market (see Article 14, MDR/IVDR).

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals is governed by the AMG, notably its Sections 72 et seq.

The import of medical devices and in vitro diagnostics is regulated in the MDR and IVDR, respectively, by assigning regulatory responsibilities and duties to the importer where the manufacturer is not established in the EU and has not assigned an authorised EU representative (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**).

6.2 Importer of Record of Pharmaceutical and Medical Devices

In order to import from outside the EU and EEA member states into Germany or to export from Germany outside the EU/EEA, an operator is

required to have an EORI-number (EU-wide applicable customs registration number). Applying for a customs credit (deferred payment) and possibly providing a customs guarantee may allow the applicant to benefit from simplified customs operations (eg, electronic customs declarations, payment of duties online, simplified procedures). In addition, an operator may choose to apply for the status of Authorised Economic Operator (AEO), which should entail a pre-approval for most customs authorisations.

With respect to regulatory requirements, see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Pharmaceuticals may only be imported from outside the EU and the EEA member states (Norway, Iceland and Liechtenstein) into Germany if an MA for any such pharmaceutical is in place and if the importer holds an import authorisation. The issuance, scope and resulting obligations of an import authorisation are analogous to a manufacturing authorisation (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**). Exemptions from the requirements of an MA and an import authorisation requirement apply, inter alia, to:

- pharmaceuticals for the importer's own scientific use (except for clinical trials);
- pharmaceuticals imported in small quantities by the MAH or an authorised manufacturer as samples or for analytical purposes;
- pharmaceuticals imported by an authorised manufacturer for further processing;
- pharmaceuticals imported by an MAH, authorised manufacturer or wholesale distributor intended for further shipment into other EU member states;
- pharmaceuticals imported in small quantities for personal use;
- samples imported for use by regulatory authorities; and
- imports by pharmacies in connection with a "named-patient programme" (see **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations**).

The import of medical devices from outside the EU and the EEA member states into Germany does not require a governmental authorisation. However, the imported medical devices must be lawfully CE-marked, based on a complete conformity assessment, and the importer will bear the regulatory responsibility for the device if the manufacturer is based outside the EU/EEA and has not appointed an authorised representative. Under the MDR/IVDR, the importer is subject to additional obligations to ensure that only compliant medical devices are imported and made available on the market (see Article 13, MDR/IVDR).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The applicable non-tariff regulations depend on whether an imported product qualifies as a pharmaceutical, a medical device or another type of product. This in turn depends on whether that product meets the statutory product definition under the AMG or the applicable medical device regulations (for details, see **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices** and **3.1 Product Classification: Pharmaceutical or Medical Devices**).

6.5 Trade Blocs and Free Trade Agreements

Germany is a member of the EU and thus participates in the free trade arrangements concluded by the EU; it is also a member of the World Trade Organization (WTO).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Pharmaceuticals

The AMG, notably its Section 78, and the German Drug Pricing Regulation (*Arzneimittelpreisverordnung*, AMPreisV) set out whether pharmaceuticals are subject to price controls and, if so, also set out the price margins of wholesalers and pharmacies. Generally, only prescription-only pharmaceuticals which are dispensed in pharmacies are subject to price controls and fixed margins. Non-prescription pharmaceuticals, as well as prescription-only pharmaceuticals dispensed directly to hospitals, are exempt from the general statutory price controls.

Under German constitutional law, the pharmaceutical company is free to set its sales price. However, the public health insurance funds are not obliged to reimburse such prices in full. Rather, for pharmaceuticals which are subject to price control under the German AMG and German AMPreisV, the German Social Code V (*Sozialgesetzbuch V*, SGB V), which regulates the public health service and public health insurance system that covers approximately 90% of the German population, provides for several price-control mechanisms.

Early benefit assessment and reimbursement price negotiations (AMNOG)

As of 1 January 2011, the so-called AMNOG Act has introduced a price-control mechanism for pharmaceuticals with a new active substance. Reimbursement prices for such innovative pharmaceuticals are negotiated between the MAH and the Central Federal Association of Health Insurance Funds (*GKV-Spitzenverband*) on the basis of a so-called "benefit assessment". Recently, the Act to Stabilise the Financing of the Public Health Insurance (*GKV-FinStG*) has, as of 12 November 2022, materially tightened the AMNOG rules with an effort to curb public prescription-drug spending.

The process has two consecutive preparatory phases of six months each.

- Phase 1 (months one to six since product launch in Germany): upon the launch of the medicine on the German market, the MAH must submit a dossier demonstrating (through clinical evidence) the additional therapeutic benefit of the new medicinal product in comparison to the so-called appropriate comparator therapy, ie current standard treatment. Orphan drugs enjoy certain exemptions from this requirement if the annual outpatient turnover in Germany does not exceed EUR30 million (before the *GKV-FinStG* : EUR50 million). Based on the assessment of the data in the submitted dossier, the Federal Joint Committee of the German public health insurance system (*Gemeinsamer Bundesausschuss*, GBA) determines the scope and degree of the additional therapeutic benefit of the new medicine.
- Phase 2 (7–12 months since product launch in Germany): the additional therapeutic benefit determined by the GBA is a key factor for subsequent reimbursement price negotiations

between the MAH and *GKV-Spitzenverband* during the 7–12 months since the launch. The *GKV-FinStG* has emphasised the prejudicial nature of the additional therapeutic benefit assessment on the negotiable reimbursement price by establishing several mandatory price ceilings linked to certain assessment outcomes: for instance, if no additional therapeutic benefit is found and the comparator therapy is still patent-protected, the negotiated reimbursement price for the new medicinal product must result in annual therapy cost that is at least 10% lower than the patent-protected comparator therapy, effectively penalising the new medicinal product. The agreed reimbursement price will apply retroactively for all patients in Germany (including those privately insured) from the 7th month of the market launch onwards (before the *GKV-FinStG* : only from the 13th month onwards). If the MAH and *GKV-Spitzenverband* fail to agree on a reimbursement price for the new medicine, a reimbursement price will be unilaterally set by an arbitration board, with retroactive effect to the seventh month since the market launch.

In the first year of the marketing, and until the reimbursement price kicks in at the beginning of the seventh month since the market launch, the new medicinal product will by default be reimbursed at the price set by the MAH.

Reimbursement price caps for established therapeutic classes

The GBA can establish therapeutic classes of pharmaceuticals that cover a group of pharmaceuticals of similar or comparable active substance and comparable therapeutic effect. For each class, the GBA will set, and review annually, reimbursement price caps, which generally lie in the lower third of the range between the lowest price and the highest price of all pharmaceuticals in that class. Public health insurances will only reimburse these pharmaceuticals up to the cap; if the MAH sets a higher price, the patient will need to pay the difference. This price control primarily, but not exclusively, affects generics.

Statutory rebates

MAHs must reimburse a statutory rebate of 7%, temporarily raised to 12% for the 2023 calendar year by the *GKV-FinStG*, (for patent-protected pharmaceuticals) and 16% (for generics) to public health insurance funds. Statutory rebates do not apply for pharmaceuticals in established therapeutic classes subject to the reimbursement price caps.

Price freeze

Since 1 August 2010, MAHs must pay back to public health insurance funds any increase in price beyond the price effective on 1 August 2009. Since 1 August 2018, the reference price level is adjusted annually for inflation. The price freeze does not apply where a reimbursement price is set based on the early benefit assessment or capped for an established therapeutic class.

The prices for pharmaceuticals which are not covered by Section 78 of the AMG and AMPreisV, mainly non-reimbursable medicines, can be set or negotiated freely.

Medical Devices

German medical device law does not provide for price controls. German public healthcare law, in turn, does not provide for a common reimbursement and pricing mechanism for all medical devices. Rather:

- where medical devices are part of the outpatient medical therapy (eg, ophthalmic medi-

cal devices which can be implanted in an outpatient setting), the healthcare-provider is generally reimbursed for the purchase price by the public health insurance fund; however, regional collective agreements may provide for particular reimbursement requirements and price caps; and
- medical devices prescribed by a healthcare provider which serve to secure the medical therapy, or mitigate or compensate the effects of injuries, are qualified as auxiliary devices (*Hilfsmittel*). Suppliers of auxiliary devices must meet pre-qualification requirements and enter into supply agreements with public health insurance funds in order to be entitled to supply, and be reimbursed for, auxiliary devices to insured patients. Furthermore, auxiliary devices may be grouped in established therapeutic classes similarly to pharmaceuticals, with a view to capping the reimbursement price.

7.2 Price Levels of Pharmaceutical or Medical Devices

The actual sales price in other European countries shall be taken into account in the AMNOG reimbursement price negotiations for innovative pharmaceuticals (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

90% of the German population is enrolled in the statutory health system. These patients have a right to be provided with all treatments, including pharmaceuticals and medical devices, which are medically necessary, sufficient and cost-effective. This means that the coverage of pharmaceuticals is generally limited to prescription-only medicines, and the cost is controlled through various statutory price-control mechanisms (see **7.1 Price Control for Pharmaceuticals and Medical Devices**) and by tenders of the statutory health insurance funds.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The additional benefit of novel pharmaceuticals by comparison to the standard therapy is a key factor in negotiating the reimbursement price (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians are subject to various mechanisms to ensure that their prescribing of pharmaceuticals is cost-efficient. Physicians who prescribe excessively may be required to pay damages to the public healthcare system.

In order to curb pharmaceutical spending, pharmacies must observe several substitution rules designed to increase the dispensing of generics or cheaper parallel-imported pharmaceuticals instead of originator products. A pharmacist who fails to comply with those substitution rules must pay back to the public healthcare system the full price of the dispensed product, without the option to offset the theoretical cost of the cheaper alternative that should have been dispensed under the substitution rules.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps may qualify as medical devices if the app meets the definition of a medical device (see **3.1 Product Classification: Pharmaceutical or Medical Devices**). The MDCG Guidance 2019-11 on the qualification and classification of software offers additional criteria to operational-

ise the general medical-device definition for software. A key criterion within the five-step decision tree proposed by the MDCG Guidance is whether the app performs actions on data for a specific patient which go beyond mere storage, archival, lossless compression, communication or simple search. A test is whether the app creates or modifies medical information through its own algorithm.

Many medical apps which were classified as risk class I before the MDR may classify as class IIa or higher under the MDR. As a result, their recertification under the MDR will require the involvement of a notified body (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices**). Until (re-)certification under the MDR, such apps may continue to be marketed under their pre-MDR certification until 31 December 2028 subject to several conditions, including that their design and intended purpose are not significantly changed.

If a medical app qualifies as a medical device of class I or IIa, that medical app can qualify as a Digital Health Application (DiGA) and be eligible for prescription by physicians and reimbursement by the public health insurance system ("app on prescription"). This reimbursement mechanism for medical apps was introduced in late 2019 and is the first statutory reimbursement mechanism for medical apps in the world. In order to be included in the DiGA Directory of reimbursable apps, the manufacturer of the DiGA must submit an application to the BfArM, showing that:

- the main function and medical purpose of the DiGA is based on digital technologies and functions;
- beyond security and functionality (evidenced through the CE mark), quality, data protection, data security and inter-operability requirements are met; and
- the use of the DiGA provides positive care effects (medical benefit, structural and procedural improvements).

If positive care effects are not excluded, but supporting data is not yet available, DiGAs can be temporarily admitted to the DiGA Directory for up to 12 months to generate that data. Once the data is available, the reimbursement price for the DiGA will be negotiated in a process which is comparable to the AMNOG procedure for novel pharmaceuticals (see **7.1 Price Control for Pharmaceuticals and Medical Devices**). In 2021, the DiGA concept was extended to Digital Nursing Apps (DiPA), such as fall prevention apps or personalised memory games for people with dementia.

8.2 Rules for Telemedicine

German doctors may provide telemedicine services where face-to-face patient contact is not medically required. In 2019, the anachronistic prohibitions to advertise for such telemedicine services and to dispense medicines prescribed through a telemedicine service have been lifted. However, the promotion of telemedicine services remains challenging because new case law only allows the promotion of telemedicine services to the extent that it is proven that the promoted service complies with generally accepted professional standards.

In the public healthcare system, the telemedicine services which are reimbursed to the doctors are currently limited, but growing. The collective agreement between *GKV-Spitzenverband* and the doctors' head association sets out requirements on patient authentication, data privacy

and quality requirements for the telemedicine service-provider that must be complied with in the public healthcare system.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the online promotion and/or advertising of medicines and medical devices. Rather, companies promoting their medicines or medical devices online must comply with all applicable requirements, including advertising limitations set forth in the Health Product Advertising Act (*Heilmittelwerbegesetz*, HWG), pharmacovigilance obligations, and data privacy and telecommunications laws.

8.4 Electronic Prescriptions

From a regulatory perspective, German drug law (the German Drug Prescription Regulation, AMVV) and German medical-device law (the German Medical Device Dispensing Regulation, MPAV) already allow prescriptions to be issued electronically and be signed by electronic qualified signature. Pharmacy law also already allows pharmacists to accept electronic signatures.

From a reimbursement perspective, though, the public healthcare system has so far not provided for the processing and invoicing for reimbursement of electronic prescriptions. In 2021, the first test phase for submitting electronic prescriptions has launched, and electronic prescriptions may be used by service providers meeting the necessary technical requirements. The date for the nationwide roll-out of the electronic prescription has been determined for mid-2023.

8.5 Online Sales of Medicines and Medical Devices

Medicines and medical devices may be sold online. German pharmacies may also sell both prescription-only and pharmacy-only medicines online if:

- the pharmacist also holds a mail-order pharmacy permit (*Versandhandelserlaubnis*); and
- the mail-order business is conducted "out of the pharmacy" in addition to the retail pharmacy business.

Mail-order pharmacy activities without running a "bricks-and-mortar" pharmacy are not permitted in Germany.

In addition to German pharmacies, several Dutch online pharmacies located at the Dutch/German border supply the German market, leveraging the free movement of goods within the EU.

8.6 Electronic Health Records

In the public health system, which covers approximately 90% of the German population, the electronic patient file (ePA) is currently being rolled out and is expected to increase in functionality by 2023. The Federal Ministry is currently drafting an act providing for an opt-out procedure to enhance the amount of users. The ePA is regulated in the Social Code V (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

As electronic health records qualify as "special categories of personal data" under the GDPR, the considerations on clinical trial data in **2.5 Use of Resulting Data from the Clinical Trials** apply mutatis mutandis to electronic health records.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Germany, the Patent Act contains the relevant provisions for patents.

There is a huge variety of general patent law issues, which can become relevant for pharmaceutical and medical device products, ranging from the determination of the widest possible scope when applying for a patent to a potential infringement under the doctrine of equivalents in infringement proceedings. In addition, the specific provisions regarding a second and subsequent medical use, as well as the extension of the patent term by way of a supplementary protection certificate set out in **9.3 Patent Term Extension for Pharmaceuticals**, often play an important role. Not strictly resulting from patent law provisions, yet of great relevance in patent strategies and litigation, agreements between originators and generic entrants may also be considered as anti-competitive.

There are no specific patentability requirements for pharmaceuticals or medical devices as such. Even though methods for treatment by surgery or therapy and diagnostic methods are not patentable, the use of substances in these methods is explicitly not covered and thus patentable. Further restrictions regarding patentability relate to processes for cloning human beings and for modifying the germinal genetic identity of human beings.

9.2 Second and Subsequent Medical Uses

A second or subsequent medical use is patentable if the medical indication is new. Therefore, the type of application or the area of use must not be previously known.

However, generally, it is not sufficient to modify the dosage regime even if this improves the effectiveness of the drug. Notwithstanding, the discovery of the use for new patient populations is patentable if the new patient group can be clearly distinguished from the previously known group.

The preparation and use of the drug for the claimed (second or subsequent) use constitutes patent infringement regarding the (new) patent. Preparation for such use can result from instructions for use delivered with the drug. Nevertheless, the drug can be used in a non-infringing manner for the previously known purpose, provided that this application is not protected (anymore). If there is a prior product patent with broad claims, the patent covering a second or subsequent use may be a dependent invention.

9.3 Patent Term Extension for Pharmaceuticals

The patent holder of an authorised medicinal product can apply for a supplementary protection certificate (SPC) within six months from the grant of the MA. The SPC can extend the protection term by the time that elapsed between the application for the patent and the MA, reduced by five years. This potential extension is limited to five years, plus six months in cases with completed studies in compliance with an agreed paediatric investigation plan. For each medicinal product, only one SPC can be granted, and the product must be covered by a first MA.

Generally, the certificate confers the same rights as the basic patent, with certain limitations regarding the intended export of the products.

Any third party can bring an action for declaration of invalidity of the certificate before the German Federal Patent Court, according to Section 81 of the German Patent Act.

9.4 Pharmaceutical or Medical Device Patent Infringement

As for any product patent, infringing actions include the manufacturing, offering, placing on the market or use of a product, as well as importing or possessing it for these purposes. Advertising a product may also infringe a patent, even if the advertising only relates to subsequent distribution after the lapsing of the patent.

In order to get injunctive relief, the infringement must be (at least) imminent. The application for an MA is not considered to fulfil the requirement of imminent infringement.

In the case of a medical product which has been authorised more than a year before the term of the patent, but which has not been brought on to the market since, the Higher Regional Court of Düsseldorf found that the grant of the authorisation was generally not sufficient to show that infringement was imminent. Thus, the Court rejected imminent infringement, provided that the authorisation would not be withdrawn if it were not used until the end of the patent term.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The German Patent Act provides for an experimental use exemption and, in particular, for the "Roche-Bolar" exemption, which allows the generic entrant to proceed with the application for an MA before the expiry of the patent. The exemption covers all actions which are necessary in order to receive the MA.

Furthermore, there is a (theoretical) option for compulsory licences based on Section 24 of the German Patent Act. Even though this option is not strictly limited to pharmaceuticals or medical devices, the only case in which such a compulsory licence has been granted by the Federal Patent Court (upheld by the Federal Court of Justice) was related to a pharmaceutical product (an anti-retroviral HIV/AIDS medicinal product called "Isentress"). The interested licensee must apply for the grant of the compulsory licence and demonstrate:

- that they failed to receive a licence in compliance with reasonable and common business practices after having tried to receive that licence over a reasonable period of time; and
- that the public interest requires the granting of a compulsory licence.

9.6 Proceedings for Patent Infringement

Typically, the patent holder and the exclusive licensee can bring proceedings for patent infringement. The action can include claims for injunctive relief, rendering of accounts, recall and destruction of infringing products as well as damages.

The typical procedure starts at one of the most commonly used regional courts for patent litigation, which are Düsseldorf, Mannheim and Munich. The first-instance decision, which is provisionally enforceable, will be reached after 8–15 months, depending on the court. This decision can be appealed before the Higher Regional Court.

These actions can be requested as preliminary measures, in which case the courts would generally require that the patent in suit has survived an inter partes validity attack. However, this requirement is often not applied to preliminary

measures against generic entrants, thus preliminary injunctions can be granted. In spring 2021, the regional court of Munich requested a preliminary ruling of the CJEU on whether the general requirement of inter partes validity proceedings in order to grant a preliminary injunction is compliant with the IP Enforcement Directive.

Since Germany has a bifurcated patent system, invalidity is not available as a defence in infringement proceedings on the merits. The alleged infringer must bring a separate nullity action before the Federal Patent Court to invalidate the patent. This nullity action usually takes more than two years, resulting in a so-called "injunction gap" between the (provisionally) enforceable infringement decision containing injunctive relief and the potential declaration of nullity of the patent in suit. A legislative reform in summer 2021 tightened procedural timelines to close this injunction cap: the statement of defence against a nullity action must now be filed within two months, and since spring 2022 the German Federal Patent Court shall provide a "qualified notice" containing its preliminary assessment of a pending nullity action within six months from filing the action.

9.7 Procedures Available to a Generic Entrant

Even though German courts tend to be strict when granting preliminary injunctions if the patent has not been confirmed in inter partes validity proceedings, they often make an exception for cases against generic entrants. Therefore, if a generic entrant wishes to enter the market before the expiry of the originator's patent, they could file a nullity action before the Federal Patent Court in order to make sure that the potentially infringed patent will be invalidated before market entry. However, this option is very expensive and time-consuming.

There is no patent linkage system in place. Patent law and the laws governing the MA of a generic drug are separate in Germany.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Other than using patent law, an IP rights-holder can take action against counterfeit pharmaceuticals and medical devices primarily based on trade mark law.

Trade mark infringement grants the rights-holder various remedies, including claims against the counterfeiter to cease and desist infringing the trade mark, claims for damages and siphoning off the profits, and claims for destruction of the infringing products. In order to prevent counterfeit medicines from being imported, the rights-holder can also, under Regulation (EU) No 608/2013, request the customs authorities to detain products suspected of infringing the holder's trade marks for further determination. Furthermore, trade mark infringement can be criminally sanctioned and expose the counterfeiter to imprisonment of up to three years or to monetary fines.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Pharmaceuticals may not use names which are misleading, particularly regarding the efficacy and safety of the product (Section 8, AMG). Similarly, the MDR and the IVDR prohibit in their Article 7 the use of any trade mark, name or text in the labelling, instructions claims, marketing and promotion which may mislead the patient regarding the device's intended purpose, safety or performance.

Specifically for pharmaceuticals, the regulatory authorities have issued guidelines on the acceptability of names or human medicinal products. For pharmaceuticals to be authorised centrally by the EU Commission, the guideline by the EMA applies. For pharmaceuticals to be approved nationally, the guideline by the BfArM and the PEI applies. Both guidelines set out further requirements and recommendations for developing an invented name for the pharmaceutical. The German guideline also addresses under which conditions one brand name can be used as an umbrella brand for several products of a product family.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress and design of pharmaceuticals, medical devices and their packaging may be protected by design rights and by copyright, potentially also by trade marks. This protection will depend on whether the trade dress or design in question meets the criteria for any such protection. Registering design rights may present a relatively inexpensive way to protect the design of pharmaceuticals and particularly medical devices. Furthermore, the Act against Unfair Trade Practices (UWG) may afford the product-owner claims against competitors which pass off their products as the original products.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

For pharmaceuticals, the data provided by the MAH in support of the MA application is protected by regulatory data exclusivity for eight years following the granting of the MA. For this eight-year period, other applicants may not cross-refer to the original clinical and pre-clinical data in support of an MA application for a generic copy of the pharmaceutical.

Furthermore, a generic product for which an MA has been granted through reference to the originator MA data may only be placed on the market after ten years following the granting of the original MA. If, during the first eight years, a new therapeutic indication has been added to the original MA which brings a major clinical advantage in comparison to existing therapies, the marketing exclusivity can be extended by up to one more year to 11 years (so-called "8+2+1" rule). These rules apply equally to chemical drugs and biologics. This marketing exclusivity period may be reduced, or conditioned on additional requirements, in the future as part of the EU's announced revision of its general pharmaceutical legislation.

For medical devices, no data-exclusivity rules apply because medical devices do not require an MA.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

On the basis of the amended German Protection Infection Act, the BfArM has been granted authority to grant exemptions from various requirements of German drug law. This includes, where necessary, granting permissions to distribute medicines (i) with non-compliant labelling, (ii) which have been manufactured not in full compliance with GMP, or (iii) which are past their expiry date, granting exemptions from requirements applicable to clinical trials, MA applications, import of medicines, and compassionate-use programmes. This authority is set to expire on 31 December 2023.

With respect to medical devices, based on the Commission Recommendation 2020/403, special temporary regimes were in place until late summer 2020, allowing for the placing on the market of face masks which were not CE-marked, and enforcement against non-compliant face masks was limited to those presenting a health hazard. Since face masks are no longer in short supply, regulatory enforcement against non-CE-marked face masks has increased (see also the updated Commission Recommendation (EU) 2021/1433).

11.2 Special Measures Relating to Clinical Trials

The EMA issued guidance on the management of clinical trials during the COVID-19 pandemic, to which the BfArM issued complementing guidance. The EMA guidance provided that, subject to a number of specific circumstances, patients participating in clinical trials may exceptionally have investigational medicines delivered to their homes, with that delivery to be carried out by the trial sites or hospital pharmacies or, exceptionally, through distributors.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In 2022, importers and manufacturers of face masks requested to the BfArM that they be exempted from performing a full conformity assessment for non-CE-marked imported masks under the legacy medical devices rules applicable before 26 May 2021 (see currently applicable Article 59, MDR), and be permitted to rely on a fast-track assessment by certain notified bodies. Since face masks are no longer in short supply, this pathway is no longer permitted.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Generally, GMP certificates for manufacturing and importing sites in the EEA have been automatically extended until the end of 2023.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In March 2020, the German government issued a temporary decree imposing an export ban on certain personal protective equipment such as protective masks. Subsequently, the enforcement of the regulations applicable to face masks imported into the EU and Germany was temporarily halted but has resumed since (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

11.6 Drivers for Digital Health Innovation Due to COVID-19

The German healthcare system is undergoing a concerted digitalisation effort, including the wider use of telemedicine, which had been initiated before and independently of COVID-19. According to public polls, however, COVID-19 has sparked both more doctors to provide, and more patients to use, telemedicine services.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The German government has not announced any intention to issue compulsory licences for COVID-19-related treatments or vaccines. However, the German Infection Protection Act states that the Federal Ministry of Health is entitled to issue an order according to which an invention is to be used in the interest of the public welfare (Section 13, German Patent Act).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced for COVID-19 treatments or vaccines. The general liability rules for pharmaceuticals apply.

11.9 Requisition or Conversion of Manufacturing Sites

No manufacturing sites in Germany have been requisitioned or converted due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The general rules governing public procurement have not been changed due to COVID-19. Based on the amendments to the German Infection Protection Act in response to the COVID-19 pandemic, the federal government can promulgate regulations allowing the government to take measures for procuring and stockpiling drugs and other necessary products in case of an epidemic situation of national scope announced by the German Parliament. In May 2020, the German Parliament passed a regulation permitting the central procurement of certain medical products including pharmaceuticals, medical devices, laboratory diagnostics by the Federal Ministry of Health. The regulation expires on 31 December 2023. A number of tenders suggest that public purchases are increasingly placing stronger emphasis on more local manufacture and supply chain resilience.

INDIA

Law and Practice

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Contents

Obhan & Associates is a professionally managed law firm with a well-established practice in the areas of IP and corporate law. The firm was established in 2007 and has offices in Delhi and Pune. Obhan & Associates has been recognised for its expertise in patent, trade mark, copyright and design protection. The firm's corporate practice offers a broad range of transactional and advisory services to institutions and entrepreneurs, as well as to public and private companies. The firm has a well-balanced domestic and international clientele and represents a cross-section of industries, including fast-moving consumer goods, mechanical engineering, hardware and electronics, life sciences, pharmaceuticals, software, apparel, packaging and retail, process engineering, fashion brands, automobiles and parts, paints and chemicals, magazines and publications, and textiles. Obhan & Associates' life sciences and pharmaceuticals team has six experienced patent agents and lawyers who serve a varied client base that includes individual inventors, universities and national and international corporations.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The key pieces of legislation and regulation governing pharmaceuticals and medical devices are as follows.

- The Drugs and Cosmetics Act 1940 (the "DC Act") and the Drugs and Cosmetic Rules 1945 (the "DC Rules") regulate the manufacturing, importation, sale and distribution of pharmaceuticals in India.
- The Medical Device Rules 2017 (the "MD Rules") (as amended from time to time under the DC Act) – along with the DC Rules – regulate the importation, manufacture, sale and distribution of all medical devices. Furthermore, the medical device is required to conform to the standards laid down by the Bureau of Indian Standards Act 1985 or as may be issued by the Ministry of Health and Family Welfare (MoHFW) from time to time. Where no relevant standard for a medical device has been laid down, it is required to conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electrotechnical Commission (or any other pharmacopeial standards). If the standards have not been specified under any of the aforementioned two bodies, the device is required to conform to the validated manufacturer's standards.
- The New Drugs and Clinical Trials Rules 2019 (the "CT Rules") (as amended from time to time under the DC Act) regulate clinical trials, bio-equivalence studies, bio-availability studies and the Ethics Committee (EC) for new drugs and investigational new drugs for human use.
- The Narcotic Drugs and Psychotropic Substances Act 1985 (the "NDPS Act") regulates the production/manufacturing/cultivating, possessing, selling, purchasing, transporting, storing and/or consuming of any narcotic drug or psychotropic substance.
- The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 – along with the DMR Rules 1977 (as amended from time to time) – regulates the advertisement of medicinal products.
- The Uniform Code of Pharmaceuticals Marketing Practices issued by the Department of Pharmaceuticals (DoP) also provides directions on suitable promotional materials for medicinal products.
- The Code for Self-Regulation in Advertising issued by the Advertising Standards Council of India, a non-statutory body, regulates the publishing of advertisements in India – including those for medicinal products.
- The Consumer Protection Act 2019 prohibits false advertising by misrepresentations or false allurements.
- The Medicinal and Toilet Preparations (Excise Duties) Act 1956 provides for the levy and collection of duties of excise on medicinal products.
- The Essential Commodities Act 1955 and the Drugs (Prices Control) Order 2013 (DPCO) thereunder regulate the price of drugs and medical devices specified in the National List of Essential Medicines (NLEM).
- The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells 1989 (the "1989 Rules"), issued under the Environment (Protection) Act 1986, regulate hazardous micro-organisms/genetically engineered organisms or cells.

- The Foreign Trade (Development and Regulation) Act 1992 (the "FTDR Act") and the rules thereunder provide for the development and regulation of foreign trade.
- The Biodiversity Act 2002 (the "BD Act") and the rules thereunder provide a mechanism for benefit-sharing arising from the use of traditional biological resources and knowledge.
- On 8 July 2022, the MoHFW notified draft of New Drugs, Medical Devices and Cosmetic Bill 2022 for public consultation. The objective of the bill is to amend and consolidate the law in relation to:
  (a) the import, manufacture, distribution and sale of drugs, medical devices and cosmetics to ensure their quality, safety, efficacy, performance;
  (b) clinical trials of new drugs; and
  (c) clinical investigation of medical devices.

In addition to the foregoing, there are specific guidelines for various issues – for example, the conduct of clinical trials, market authorisation of biosimilars, ribosomal DNA (rDNA) research, ethics, and the privacy of healthcare-related data.

Regulatory Bodies/Committees/Authorities
The key regulatory authorities in respect of drugs and medical devices are as follows.

- The Central Drugs Standard Control Organisation (CDSCO) headed by the Drugs Controller General of India (DCGI) is responsible for the implementation of the DC Act and the rules thereunder. It exercises regulatory control over the importation of drugs, the approval of new drugs and clinical trials, and meetings of the Drugs Consultative Committee and the Drugs Technical Advisory Board (DTAB). It also acts as a Central Licensing Authority (CLA) and co-ordinates the activities of state drug control organisations (SDCOs).
- The SDCO of a particular state regulates the manufacture, sale and distribution of drugs, medical devices and cosmetics at the state level. It monitors the quality of drugs, cosmetics and medical devices in the concerned state. It also acts as a state licensing authority (SLA).
- Various authorities and regulatory bodies are responsible for implementing the provisions of the NDPS Act as follows:
  (a) the Narcotics Control Bureau (NCB)'s functions include drug law enforcement and the receipt and monitoring of returns regarding controlled substances under the NDPS (Regulation of Controlled Substances) Order 1993;
  (b) the Central Bureau of Narcotics (CBN)'s functions include licensing and supervision of the cultivation of the opium poppy, licensing the manufacture of narcotic drugs, and controlling the importation and exportation of narcotic drugs and psychotropic substances (and precursors); and
  (c) state governments' functions include:
    (i) control on sale, use, consumption and movement of narcotic drugs, usually through the state excise department; and
    (ii) framing rules with regard to permission and regulation of the cultivation of any cannabis plant and the production, manufacture, possession, transport, import and export inter-state, sale, consumption or use of cannabis (excluding charas).
- The Indian Council of Medical Research (ICMR) is the apex body for the formulation, co-ordination and promotion of biomedical research.
- The DoP regulates various issues related to pricing and the availability of medicines at affordable prices, R&D, protection of IP rights,

and international commitments involving the pharmaceutical sector that require the integration of work with other ministries.
- The National Pharmaceutical Pricing Authority (NPPA) is responsible for monitoring, fixing and revising the prices of drugs and medical devices, as well as enforcement of the provisions of the Drugs (Prices Control) Order 2013.
- The Review Committee on Genetic Manipulation (RCGM) is responsible for authorising the conduct of R&D, the exchange of genetically engineered cell banks for R&D, and the review of data up to pre-clinical evaluation.
- The Genetic Engineering Appraisal Committee (GEAC) reviews applications and approval of activities where the final drug product contains genetically modified organisms/living modified organisms.
- The Department of Biotechnology (DBT) is responsible for administrating development and commercialisation in the field of modern biology and biotechnology.
- The State Biotechnology Co-ordination Committee (SBCC) is responsible for inspecting, investigating and taking punitive action in the case of violations of statutory provisions through the State Pollution Control Board (SPCB) or the Directorate of Health, etc.
- The District Level Biotechnology Committee (DLC) is responsible at the district level for monitoring the safety regulations in installations engaged in the use of GM organisms/hazardous micro-organisms and their applications within such environments.
- The Institutional Biosafety Committee (IBC) is the nodal point for the implementation of the biosafety guidelines and the interactions within an institution.
- Gazetted officers are authorised by the state governments to enforce drug advertising regulations.
- The Bureau of Indian Standards (BIS) is responsible for the harmonious development of the standardisation, marking, and quality certification of goods, as well as matters connected therewith or incidental thereto.
- The Pharmaceuticals Export Promotion Council of India (Pharmexcil) promotes pharmaceutical exports from India. All the exporters of pharmaceutical products must have a valid registration-cum-membership certificate issued by Pharmexcil.
- The Directorate General of Foreign Trade is involved in the regulation and promotion of foreign trade under the FTDR Act.
- The National Biodiversity Authority and state biodiversity boards are the main regulatory bodies under the BD Act.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Any person who is aggrieved by any order passed by the CLA or the SLA may file an appeal to the central government or the state government respectively within the stipulated period. The respective government may make necessary orders following an inquiry and after hearing the appellant.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices are regulated according to their categories. The DC Rules provide for the classification of drugs in various schedules. Each schedule has a guideline for labelling, storing, selling, displaying and prescribing a listed drug. The schedules are as follows:

- Schedule C – biological and immunological products, antibiotics, ophthalmic preparations, and all products for parenteral use;

- Schedule C(I) – drugs of biological origin (namely alkaloids, hormones, vitamins, and antibiotics for oral use);
- Schedule G – drugs that can be administered only under the supervision of a registered medical practitioner;
- Schedule H – drugs that are required to be dispensed on the prescription of a registered medical practitioner;
- Schedule H1 – drugs including antibiotics, habit-forming drugs, and a few anti-tuberculosis medicines;
- Schedule K – OTC drugs; and
- Schedule X – psychotropic drugs that must be dispensed on the prescription of a Registered Medical Practitioner (RMP). A special retail licence is required for selling these drugs.

Similarly, the MD Rules provide for a risk-based classification of all medical devices. Medical devices, except in vitro diagnostic medical devices, are classified according to Part I of the First Schedule, as follows:

- low risk – Class A;
- low-to-moderate risk – Class B;
- moderate-to-high risk – Class C; and
- high risk – Class D.

In vitro diagnostic medical devices are classified according to Part II of the First Schedule, as follows:

- low risk – Class A;
- low-to-moderate risk – Class B;
- moderate-to-high risk – Class C; and
- high risk – Class D.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The CDSCO, via the CLA, regulates the clinical trials of drugs and medical devices. A clinical trial is required to be conducted in accordance with the Good Clinical Practice Guidelines issued by the CDSCO.

The CT Rules regulate clinical trials, bio-equivalence studies, bio-availability studies and investigations into new drugs for human use. The DC Rules regulate clinical trials for veterinary drugs.

The MD Rules regulate the clinical investigation of medical devices and the clinical performance evaluations of new in vitro diagnostic medical devices. The EC for clinical investigations of medical devices is established in accordance with the DC Rules.

The National Guidelines for Gene Therapy Product Development and Clinical trials 2019 (the "GTP Guidelines") provide guidance for conducting clinical trials in areas pertaining to gene therapy.

The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2019 and the National Ethical Guidelines for Biomedical Research Involving Children (collectively, the "Ethical Guidelines") provide general guidance for conducting clinical trials involving adults and children ethically.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Detailed clinical trials – or investigations or performance studies (as the case may be) – must be conducted in order to obtain market authorisation for any of the following.

- New drug – a "new drug" is considered "new" for a period of four years from the date of its first approval and can be:
  (a) a drug that has neither been used in India to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof nor recognised as effective and safe by the CLA for the proposed claims – and, as such, any use of which has been with the permission of the CLA;
  (b) a drug that has already been approved by the CLA for certain claims and is now proposed to be marketed with modified or new claims – namely, indications, dosage, dosage form (including sustained-release dosage form) and route of administration;
  (c) a fixed-dose combination of two or more drugs that have already been individually approved for certain claims and are now proposed to be combined for the first time in a fixed ratio (or if the ratio of ingredients in an already marketed combination is proposed to be changed) with certain claims – namely, indications dosage, dosage form (including sustained-release dosage form) and route of administration;
  (d) a vaccine, rDNA-derived product, living modified organism, monoclonal antibody, cell or stem cell-derived product, gene therapeutic product or xenografts intended to be used as a drug;
  (e) a modified or sustained-release form of a drug; or
  (f) a novel drug delivery system of any drug approved by the CLA.
- Investigational new drug – a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country.
- Investigational medical device – a device that does not have a predicate device or a device that, after being authorised for marketing, claims for a new intended use or a new population or for a new material or a major design change.
- New in vitro diagnostic medical device – any in vitro diagnostic medical device covered under the MD Rules that does not have the CLA's approval for manufacture for sale or for importation and is being tested for the relevant analyte or other parameter related thereto in order to establish its performance.

An online application for conducting a clinical trial can be filed in a prescribed format, together with all the necessary documents and information. The CLA is required to evaluate the application within the prescribed time. An application for drugs discovered, researched and manufactured in India must be evaluated within 30 days. If the CLA does not respond within 30 days to the application for drugs developed in India, the applicant may conclude that permission to conduct the trial has been granted.

The clinical trial can be initiated only once the trial protocol and other related documents have been approved by the EC. If the EC rejects the protocol, the details of the same should be submitted to the CLA before seeking approval of another EC for conducting the clinical trial at the same site. The CLA is informed about the approval granted by the EC within the stipulated time of the grant of such approval. The CLA may grant permission to conduct the clinical trial or reject the application for reasons to be recorded in writing. The permission to initiate a clinical trial remains valid for two years from the date of its grant.

The MD Rules discuss two types of clinical investigations: a pilot study and a pivotal study. A pilot study is an exploratory study that is used

to acquire specific essential information about a medical device before beginning the pivotal clinical investigation. A pivotal study is a confirmatory study to support the evaluation of the safety and effectiveness of the medical device for its intended use. For an investigational medical device developed in India, the applicant is required to conduct pilot and pivotal studies in India.

On 14 October 2022, the MoHFW issued the New Drugs and Clinical Trials (Third Amendment) Rules 2022 to further amend the CT Rules. The new rules provide for the deemed approval or permission or registration (as the case may be) for various activities such as:

- the registration of EC;
- permission to conduct clinical trials; permission to conduct bioavailability or bioequivalence studies for the new drug or investigational new drug;
- permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence studies or test and analysis;
- permission to manufacture unapproved active pharmaceutical ingredients – or to manufacture the pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence studies – if no communication has been received from the CLA after filing the necessary request or application.

Furthermore, said deemed approval or permission or registration shall be deemed to be legally valid for all purposes.

Waiver of the Requirement for a Local Clinical Trial in Certain Cases of New or Investigational Drugs

The CLA, with approval from the central government, may waive the requirement for a local clinical trial for the approval of a new drug already approved in other countries in the following cases.

- The new drug is approved and marketed in countries specified under the CT Rules and no unexpected serious adverse events have been reported, where:
  - (a) the applicant has given an undertaking in writing to conduct a Phase IV clinical trial to establish the safety and effectiveness of such new drug as per the design approved by the CLA; and
  - (b) there is no evidence or probability (based on existing knowledge) of difference in the Indian population with regard to:
    - (i) the enzymes or gene involved in the metabolism of the new drug; or
    - (ii) any factor affecting the pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug.
- The importation of a new drug for which the CLA had already granted permission to conduct a global clinical trial, which is ongoing in India, where:
  - (a) this new drug has been approved for marketing in a country specified under the CT Rules in the meantime;
  - (b) the applicant has given an undertaking in writing to conduct a Phase IV clinical trial to establish the safety and effectiveness of such new drug as per the design approved by the CLA; and
  - (c) there is no evidence or probability (based on existing knowledge) of difference in the Indian population with regard to:

(i) the enzymes or gene involved in the metabolism of the new drug; or
(ii) any factor affecting the pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug.

- Furthermore, the requirements may be relaxed, abbreviated, omitted or deferred in the case of life-threatening or serious disease conditions, or rare diseases, and for drugs intended to be used for:
- diseases that are particularly relevant to the Indian health scenario;
- an unmet medical need in India;
- a disaster; or
- a special defence use.

The CLA may relax the requirement of local Phase IV clinical trials where:

- the new drug is an orphan drug; or
- the new drug is indicated for:
  (a) life-threatening or serious diseases;
  (b) diseases with special relevance to the Indian health scenario;
  (c) a condition that has an unmet need in India;
  (d) rare diseases for which drugs are not available (or are available at a high cost).

Waiver of the Requirement of Pivotal Studies in Certain Cases of New or Investigational Medical Devices

A pivotal clinical study is not required to be conducted for investigational medical devices classified under Class A of the MD Rules. However, in exceptional cases, the CLA may – for reasons to be recorded in writing – mandate conducting a pivotal clinical study of such devices (depending on the nature of the medical device).

For investigational medical devices developed and studied in a country other than India, the applicant is required to submit the details of the pilot clinical investigation or relevant clinical study data generated outside India along with the application. The CLA may grant permission to repeat a pilot study or to conduct a pivotal clinical investigation only.

Clinical investigation may not be required in the case of investigational medical devices approved for at least two years in the USA, the UK, Australia, Canada or Japan – provided certain conditions are met.

2.3 Public Availability of the Conduct of a Clinical Trial

It is mandatory to register clinical trials prospectively in the ICMR's Clinical Trials Registry – India (ICMR-CTRI), which is a free online platform.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Trials registered on the ICMR-CTRI are publicly available and free to search.

2.5 Use of Data Resulting From the Clinical Trials

The CT Rules and the MD Rules require the investigator of a clinical trial to give an undertaking that they will maintain the confidentiality of the identities of all the participants and ensure the security of the clinical trial data. The Ethical Guidelines set out the principle of ensuring the privacy and confidentiality of the participants of the clinical trials.

2.6 Databases Containing Personal or Sensitive Data

The Information Technology Act 2000 as amended by the IT (Amendment) Act 2008 (the "IT Act") and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011 (the "IT

Rules") regulate the collection, storage and processing of personal data. The IT rules define the sensitive personal data or information (SPDI) of a person, which includes physical, physiological, mental health conditions and medical records and history. SPDI also includes medical records and health data recorded by fitness trackers.

On 7 December 2022, the Ministry of Electronics and Information Technology released a draft bill titled "the Digital Personal Data Protection Bill 2022" for public consultation. The bill is concerned with the processing of digital personal data within India. Under the bill, the digital personal data includes digital data collected online or offline. The provisions of the bill also apply to the digital data processed outside India. The bill sets out the rights and duties of citizens and the obligations of the Data Fiduciary. The obligations of the Data Fiduciary include maintaining the accuracy of data, keeping data secure, and deleting data after its purpose is fulfilled.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Please see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

All types of biologics, including biosimilars, are classed as "new drugs" under the DC Rules and the CT Rules. The applicant is required to conduct the following studies in respect of all types of biologics:

- pre-clinical studies;
- clinical studies; and
- post-market surveillance.

In addition, comparative data of the pre-clinical studies and clinical studies of biosimilars and reference biologics are required to be submitted for a biosimilar.

The following regulations and guidelines are also specifically relevant to the approval of biologics:

- the 1989 Rules;
- the Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India 2016, which lay down the regulatory pathway for a similar biologic;
- the Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment 2017, which provide guidance on handling hazardous biological material, recombinant nucleic acid molecules and cells, organisms, and viruses containing such molecules;
- the GTP Guidelines, which aim to guide and enable the stakeholders to comprehend and comply with the regulatory requirements for research and development of gene therapy products in India, as well as provide basic guidance for research involving human participants (including clinical trials) that pertains to the broad area of gene therapy;
- the Guidance Document for Industry: Submission of Stability Data and Related Documents for Review and Expert Opinion for Granting Post-Approval Changes in Shelf Life of Recombinant Biotherapeutic Products and Therapeutic Monoclonal Antibodies, which was published by the National Institute of Biologicals in 2016 and provides recommendations to holders of marketing authorisations for recombinant technology-based products who intend to make post-approval changes

in the shelf life of such products in accordance with CDSCO Guidance Document No PAC/1108 Version 1.1; and
- the Guidelines and Handbook for Institutional Biosafety Committee (IBSC).

In addition to the CDSCO, the approval of biologics is overseen by the RCGM, IBSC and GEAC.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

An original licence or a renewed licence for the manufacture for sale or distribution of drugs, unless suspended or cancelled, is valid for five years from the date on which it is granted or renewed. If the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry (after payment of an additional fee), the licence continues to be in force until orders are passed on the application.

An importation licence for a drug, unless suspended or cancelled, remains valid for three years from the date of its issue. If an application for a fresh licence is made three months before the expiry of the existing licence, the current licence is deemed to continue in force until orders are passed on the application.

The licence for manufacture, distribution, sale, importation and exportation of medical devices granted under the MD Rules remains valid unless suspended, cancelled or surrendered. The licensee is required to pay a prescribed fee every five years to prevent the cancellation of the licence.

If the licensee fails to comply with any of the stipulated conditions prescribed under the regulations, the CLA may suspend or cancel the licence by an order in writing – stating the reasons therein – after giving an opportunity to show cause why such an order should not be passed.

On 11 February 2020, the MoHFW introduced a new definition of a medical device, thereby bringing all devices under the purview of the MD Rules. On the same day, the MoHFW issued another notification requiring the registration of such newly notified medical devices on the online portal of the CDSCO according to the timeline specified therein.

On 16 March 2022, the DoP issued a draft Uniform Code for Medical Devices Marketing Practices. The draft is proposed to be a voluntary code for the marketing of medical devices specifically. The draft provides standards for the promotion, marketing and sale of medical devices, whereby the distribution of gifts or benefits to healthcare professionals is prohibited.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

An application for market authorisation of a drug or a medical device may be filed online. In the case of a new drug or an investigational new drug/medical device or a new in vitro diagnostic medical device, the application must be accompanied by detailed clinical trial data. Applications for other types of drugs must be accompanied by bio-equivalence and bio-availability studies.

On 31 December 2021, the MoHFW issued the Medical Devices (Amendment) Rules 2021, which require every medical device approved for manufacture for sale or distribution, or for importation, to bear a unique device identification in the manner as specified in said order. The rule will come into effect on a date notified by the central government.

On 24 August 2022, the MoHFW notified the Drugs (Seventh Amendment) Rules 2022 for enabling the parallel submission of applications for marketing approvals and manufacturing licences for new drugs in India.

On 30 September 2022, the MoHFW notified the Medical Devices (Fifth Amendment) Rules 2022, which amend the MD Rules. As per the amended rules, any person who intends to sell (or offer for sale), stock, exhibit or distribute any medical device (including in vitro diagnostic medical devices) is required to obtain a registration certificate from the SLA concerned. The rules also lay down the conditions for the registration certificate.

On 14 October 2022, the MoHFW notified the Medical Devices (Sixth Amendment) Rules 2022, which further amend the MD Rules in order to:

- provide for registration of all Class A medical device manufacturers through an identified online portal; and
- exempt Class A non-measuring and non-sterile medical devices from requiring an importation licence.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The DC Act and the DC Rules provide for limited access to drugs or medical devices, the importation of which is otherwise not allowed.

Small quantities of a new drug or investigational medical device may be imported for the treatment of patients suffering from life-threatening diseases (or diseases causing serious permanent disability or a disease requiring therapies for unmet medical needs) by a medical officer of a government hospital or an autonomous medical institution providing tertiary care – if duly certified by the medical superintendent of the government hospital or head of the autonomous medical institution (subject to specific conditions).

Small quantities of a drug or a medical device – the importation of which is otherwise prohibited – may be imported for personal use subject to specific conditions. Furthermore, the importation of small quantities of a drug or a medical device donated to a charitable hospital for the treatment of patients free of cost may be allowed by the CLA.

On 5 June 2020, the central government – in consultation with the DTAB – issued draft New Drugs and Clinical Trials (Amendment) Rules 2020 for compassionate use of any new unapproved drug for the treatment of patients by hospitals and medical institutions. However, there has not been any further development in this respect.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The holder of the market authorisation for a new drug, an investigational new drug or an investigational medical device is under an obligation to conduct post-market surveillance or Phase IV clinical trials. The holder is required to submit a Periodic Safety Update Report as prescribed.

The DC Rules and the MD Rules mandate maintenance of records pertaining to sales, manufacture, batches, master formula, packing and processing, distribution, investigation, testing, and remedial action taken for drugs and medical devices.

The DC Rules and the MD Rules include provisions for product recall (drugs or medical devices) by the manufacturer, importer or authorised agent (as the case may be). The CDSCO has issued detailed Guidelines on the Recall and Rapid Alert System for Drugs for both voluntary and statutory recall.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties cannot access any information regarding pending applications for marketing authorisations for drugs and medical devices.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Adulterated, misbranded, spurious or illegally distributed drugs and medical devices are regulated under the DC Act, the DC Rules and the MD Rules (as the case may be). The manufacture for sale or distribution, selling, stocking, exhibiting or offering for sale or distribution of such drugs and medical devices is a penal offence punishable with imprisonment and/or fines of varying degrees based on the seriousness of the offence.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The Customs Act 1960 (the "Customs Act"), along with the Intellectual Property Rights (Imported Goods) and the Enforcement Amendment Rules 2018 (the "IPREA Rules"), prohibits the importation of goods that infringe on intellectual property (except patents). The Customs Act empowers the customs authority to confiscate goods subject to the conditions and procedures specified under the IPREA Rules. The owner of the IP right is required to record their IP right at the Indian Customs IP Rights Recordation Portal. The owner also has to sign a bond with the customs authority undertaking to pay the costs of retention/destruction of the infringing goods and to indemnify the customs office.

Furthermore, Customs can – on its own initiative – suspend the clearance of the imported goods if there is prima facie evidence or reasonable grounds to believe that the goods are infringing IPRs. In such a scenario, the rights-holder or its agent must comply with the requirements of the recordal within five days – otherwise the goods may be released.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacturing plants of drugs and medical devices are subjected to authorisation. The CDSCO is the main regulatory body for granting the authorisation. The manufacture of any drug – or Class A and Class B medical device – is subject to the grant of a licence by the SLA. The manufacturing of Class C and Class D medical devices is subject to the grant of a licence by the CLA.

The DC Rules lay down the requirement of factory premises, plant and equipment for manufacturing, depending on the type of drug. These rules lay down the requirement for the location, building condition (as per the Factories Act 1948 (63 of 1948)), water treatment system, the disposal of sewage and effluents (as per the Environment Pollution Control Board), and biomedical waste (as per the Biomedical Waste (Management and Handling) Rules 1996).

The MD Rules lay down requirements for the manufacturing of medical devices for sale and distribution. These rules also stipulate a Quality Management System that a manufacturer is required to use. The MD Rules lay down requirements for the safety and performance of medical devices.

The licence remains valid if a licence retention fee is paid, before expiry, every five years from the date of its issue – unless it is suspended or cancelled by the licensing authority.

The manufacturer of the new medical devices is required to obtain a registration number under the MD Rules for the manufacturing of medical devices.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in the wholesale of drugs and medical devices are subject to authorisation by the SLA. An application for obtaining a wholesale licence to sell, stock, exhibit, offer for sale, or distribute a drug or a medical device may be filed online. The licence is issued based on the category of the drug or medical device in question. A licence issued remains valid if the licensee deposits a licence retention fee, before expiry, every five years from the date of its issue – unless it is suspended or cancelled by the licensing authority.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The DC Act and the DC Rules primarily regulate the importation and exportation of drugs in India along with other regulations. The importation and exportation of medical devices are regulated by the MD Rules along with the DC Act. The CLA grants the licence for importation or exportation subject to other relevant regulation(s).

6.2 Importer of Record of Pharmaceutical and Medical Devices

There are no specific requirements or qualifications required for a person to act as an importer of record.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of drugs and medical devices in India is subject to prior authorisations from the CLA. Limited access to unauthorised drugs and medical devices is allowed in specific circumstances with specific conditions (see **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations**). The importer of the new medical device is required to obtain a registration number under the MD Rules for importing medical devices (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The importation of drugs and medical devices into India is primarily regulated by the CDSCO

under the DC Act, the DC Rules and the MD Rules (as the case may be), along with other regulations. The DC Act and the MD Rules also stipulate labelling requirements for imported drugs and medical devices. By way of an example, the importation of the following is prohibited:

- any patented or proprietary medicine, unless there is displayed – in the prescribed manner on the label or container thereof – the true formula or list of active ingredients contained in it (together with the quantities thereof); and
- any drug that – by means of any statement, design or device accompanying it (or by any other means) – purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect (as may be prescribed).

Furthermore, the central government has powers to prohibit the importation of drugs and medical devices in the name of public interest.

6.5 Trade Blocs and Free Trade Agreements

India is a party to several regional and bilateral trade agreements, such as those with the UAE and various African and Asian countries. These trade agreements facilitate trade of various goods, including pharmaceuticals and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The DPCO controls the price of drugs and medical devices listed in the NLEM, which is updated from time to time based on the recommendation of the MoHFW. The NPPA is the regulatory body that regulates and monitors the price of drugs and medical devices in India.

The DPCO provides a formula for calculating the ceiling price and the maximum retail price (MRP) of the listed drugs and medical devices. In extraordinary circumstances, the government may fix the ceiling price or the retail price of any drug or medical device in the public interest. Also, if the ceiling price or the retail price of the drug is already fixed and notified, the government may allow an increase or decrease in the same.

The DPCO sets out conditions that the manufacturers, dealers and distributors are required to follow for listed drugs and medical devices. Furthermore, the DPCO stipulates that the government monitors the MRP of all drugs and medical device (including non-listed drugs and medical devices) and ensures that no manufacturer increases the MRP of a drug by more than 10% during the preceding 12 months.

7.2 Price Levels of Pharmaceutical or Medical Devices

According to the NPPA Policy 2012, the key principles for the regulation of a drug price are:

- the essentiality of drugs;
- the control of formulation prices only; and
- market-based pricing.

The DPCO provides that – at least initially – the source of market-based data will be the data available with IMS Health (a pharmaceuticals market data specialising company) and, if the government deems it necessary, it may validate such data by appropriate survey or evaluation.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The government funds and operates several healthcare/insurance schemes for reimbursement of the costs of pharmaceuticals and medical devices for people from weaker economic backgrounds and government employees – for example, the Ayushman Bharat National Health Protection Mission and the Central Government Health Scheme.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The government has created an institutional arrangement called the Health Technology Assessment in India (HTAIn) under the Department of Health Research. HTAIn is responsible for collating and, where needed, generating evidence related to the clinical effectiveness, cost-effectiveness and safety of medicines, devices and health programmes using the health technology assessment approach.

Under HTAIn, the Indian National Cost database aims to provide a one-stop shop for cost information for healthcare decision-making in India.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The prescription of drugs by a physician or a medical practitioner is regulated by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (amended 2016) (the "IMC Regulations"), which stipulate that:

- a physician must write their name and designation in full – along with registration particulars – in their prescription letterhead;
- every physician should prescribe drugs with generic names legibly and preferably in capital letters, and they shall ensure a rational prescription and use of drugs;
- the attending physician may prescribe medicine at any time for the patient, whereas the consultant may prescribe only in the case of an emergency or as an expert when called for; and
- the prescription should also make clear if the physician dispensed any medicine.

Furthermore, the DC Rules stipulate that the prescription must be in writing, as well as signed and dated.

The Pharmacy Act 1948 prohibits a person other than a registered pharmacist from the compounding, preparing, mixing or dispensing of any medicine prescribed by a medical practitioner.

8. Digital Healthcare

8.1 Rules for Medical Apps

According to the new definition of a medical device under the MD Rules, any software or app used with an instrument or an article for diagnosis, prevention or monitoring of diseases/disorders may be classified as a medical device (see **3.1 Product Classification: Pharmaceutical or Medical Devices** and **8.2 Rules for Telemedicine**).

8.2 Rules for Telemedicine

The IMC Regulations regulate telemedicine and provide guidelines for technology platforms such as mobile apps and websites enabling telemedicine. Among other things, these guidelines:

- provide information on various aspects of telemedicine, including information on technology platforms and tools available to RMPs,

and how to integrate these technologies to provide healthcare;
- spell out how technology and transmission of voice, data, images and information should be used in conjunction with other clinical standards, protocols, policies and procedures for the provision of care; and
- cover norms and standards for the RMP to consult patients via telemedicine.

Furthermore, they require RMPs to obtain the patient's consent and maintain the records/documents for the period as prescribed from time to time. An RMP can provide medical attention through a mobile device.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the promotion and/or advertising of medicines and medical devices through online portals, company web pages and social networks. See **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices**.

8.4 Electronic Prescriptions

Electronic prescriptions are regulated and allowed in India. According to the IMC Regulations 2020, RMPs providing teleconsultation can send an e-prescription or a digital copy of a signed prescription to the patient via email or any messaging platform. This entails the same professional accountability as a traditional in-person consultation.

There are certain limitations on prescribing medicines on consultation via telemedicine, depending upon the type of consultation and mode of consultation. The regulations also provide categories of medicines that can be prescribed via telemedicine that are notified from time to time. Pharmacies can only dispense prescription drugs upon the production of a valid prescription. Under the IT Act, whereby the law requires a document to be signed, it would be deemed legal only if digitally signed.

8.5 Online Sales of Medicines and Medical Devices

There are currently no specific rules that govern online sales of drugs and medical devices. Specific rules for the regulation of e-pharmacies are expected to be issued in the near future.

8.6 Electronic Health Records

The Electronic Health Record Standards for India 2016, issued by the MoHFW, provide for standardisation and homogeneity – and interoperability in the capture, storage, transmission and use – of healthcare information across various health IT systems.

The IT Act, the IT Rules, and the Information Technology (Intermediaries Guidelines) Rules 2011 govern the protection of data. On 24 August 2017, a nine-judge bench of the Supreme Court ruled that the right to privacy is a fundamental right for Indian citizens under Article 21 of the Indian Constitution.

The IT Rules provide guidelines that must be followed by a body corporate while collecting, storing and transferring information. Obtaining consent from the person providing the information is one of the most important requirements of the IT Rules. The person must be aware of the following:

- that the information is being collected;
- its purpose and intended recipients; and
- the names and addresses of the agencies collecting and retaining the information.

The body corporate (or any person on its behalf) holding SPDI must not retain that information for longer than is required. The disclosure of SPDI by the body corporate to any third party requires prior consent from the provider of such information.

In August 2020, the National Digital Health Mission (NDHM) was launched by the central government. The objective of the NDHM is to digitise India's healthcare ecosystem. It also aims to provide a health ID to all medical practitioners, clinical establishments and patients.

In December 2020, the central government approved the Health Data Management Policy (HDMP) of the NDHM. Among other things, the HDMP provides the framework for the creation of health IDs. Under the HDMP, the patient has complete ownership of the health data. It also provides a framework for the use of this data.

On 11 February 2022, the National Health Authority – under the Ayushman Bharat Digital Mission (ABDM) – announced integration with Aarogya Setu. Under the ABDM, a user can generate a 14-digit unique Ayushman Bharat Health Account (ABHA) number. The ABHA number can be used to:

- link their existing and new medical records (including doctor prescriptions, lab reports and hospital records);
- share these records with registered health professionals and health service providers; and
- access other digital health services while maintaining a common pool of medical history.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patents are regulated in India under the Patents Act 1990 and the Patents Rules 2003 (the "Patents Rules"). The most common issue encountered by patent applicants is patentability of the subject matter for which a patent is sought. Apart from being novel, inventive and useful, the subject matter must not fall within a list of inventions specifically excluded from patentability. Specific exclusions with regard to pharmaceuticals and medical devices are:

- an invention that could be contrary to public order or morality;
- any living thing or non-living substance occurring in nature;
- mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance;
- the mere discovery of any new property or new use for a known substance;
- mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;
- a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- mere arrangement or re-arrangement or duplication of known devices, each functioning independently of one another in a known way;
- any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings – or any

process for a similar treatment of animals – in order to render them free of disease or to increase their economic value (or that of their products);
- mathematical methods, business methods, computer programmes per se and algorithms;
- plants and animals in whole or any part thereof; and
- traditional knowledge.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are not patentable in India. Use, per se, is not patentable in India.

9.3 Patent Term Extension for Pharmaceuticals

There are no mechanisms for patent term extension in India.

9.4 Pharmaceutical or Medical Device Patent Infringement

When performed with the consent of the patentee, the following acts constitute an infringement of a patent:

- making, using, offering for sale, selling, or importing for those purposes a patented product in India; and
- using a patented process, and using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The Patents Act provides for the following defences to patent infringement:

- use of a patented invention on foreign vessels or aircraft temporarily or accidentally within the territory of India;
- making, constructing, using, selling or importing a patented invention solely for use reasonably related to the development and submission of information required under any law that regulates the manufacture, construction, use, sale or importation of any product in India or any other country;
- importation of patented products by any person who is duly authorised under law to produce and sell or distribute the product;
- importation or manufacture of a patented product or a product made by a patented process by (or on behalf of) the government for its own use;
- use or manufacture of a patented product or a product made by a patent process – or use of a patent process – merely for experimentation or research (or for imparting instructions to pupils); and
- importation of the patented medicine or patented drug by the government for distribution in:
  (a) any dispensary, hospital or other medical institution maintained by (or on behalf of) the government; or
  (b) any other dispensary, hospital or other medical institution that the central government, having regard to public service, specifies by notification in the Official Gazette.

Furthermore, in any suit for infringement of a patent, every ground on which it may be revoked is available as a ground for defence.

Compulsory Licences

The Patents Act provides for a compulsory licence in the following circumstances.

- At any time after the expiry of three years from the date of grant of the patent, any interested person makes an application to the Indian Patent Office for a grant of a compulsory licence on any of the following grounds:
  (a) that the reasonable requirements of the public with regard to the patent invention had not been satisfied;
  (b) that the patented invention is not available to the public at a reasonably affordable price; or
  (c) that the patented invention is not used in the territory of India.
- If the central government is satisfied – in a national emergency or in circumstances of extreme urgency, or in the case of public non-commercial use – that it is necessary to grant a compulsory licence, then it may make a declaration to that effect by notification.
- The compulsory licence is required in order to manufacture and export the patented pharmaceutical products to any country that lacks the necessary manufacturing capacity in the pharmaceutical sector to address public health problems – provided the licence has been granted by such country or such country has, by notification or otherwise, allowed the importation of the patented drug from India.

9.6 Proceedings for Patent Infringement

A proceeding for patent infringement can be brought by a patentee or a holder of an exclusive licence. Furthermore, the holder of a compulsory licence is entitled to call upon the patentee to bring such proceedings. If the patentee refuses or neglects to do so within two months of being called upon, they may institute proceedings in their own name – thereby making the patentee a defendant.

The court may grant a relief that includes an injunction and, on the request of the plaintiff, damages or an account of profits. The court may also order the goods that are found to be infringing – and materials and implements used in the creation of the infringing goods – to be seized, forfeited or destroyed (as the court deems fit under the circumstances of the case), without payment of any compensation.

The invalidity of the suit patent is an available defence in infringement proceedings and can be invoked by filing a counterclaim by the defendant in a suit for infringement.

9.7 Procedures Available to a Generic Entrant

The generic entrant may institute a suit for a declaration that their use of a product or process would not infringe a patent if it is shown that:

- the person applied in writing to the patentee or exclusive licensee for a written acknowledgment and furnished them with full particulars in writing of the process or article in question; and
- the patentee or licensee has refused or neglected to give such an acknowledgment.

The generic entrant may also initiate opposition or revocation proceedings challenging the validity of a patent. Additionally, there is an option of obtaining a compulsory licence under specific circumstances.

There is no patent linkage in India and “clearing the way” is not a requirement for generic market entry. However, the Indian courts have introduced the concept of “clearing the way” in recent patent infringement cases. If a party intends to use a patented product or method, they must exercise due diligence. If they fail to

"clear the way", then the balance of convenience may shift in favour of the plaintiff in a court proceeding and may enable the grant of an interim injunction against the said party.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

India has no specific legislation or procedures for dealing with the counterfeiting of drug and medical devices (see **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**).

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademarks Act 1999 (the "TM Act") prohibits the registration of names of chemical elements or international non-proprietary names as trade marks in India. There are no restrictions under the TM Act on the importation and distribution of non-counterfeit, genuine pharmaceutical or medical device products from other markets, regions or countries.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Although trade dress is not specifically mentioned under the TM Act, the definition of a trade mark under the TM Act includes the "shape of goods, their packaging, and combination of colours". The aesthetics of any article or product of manufacture are protected and registered in India under the Designs Act 2000 and the Designs Rules 2001.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

There are no provisions for data exclusivity in India. Under the DC Rules, a "new drug" continues to be considered as a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia – whichever is earlier. An applicant for a new drug is required to conduct extensive testing and clinical trials for obtaining market authorisation. Therefore, an application for manufacturing generic versions of a new drug during the four-year period is required to contain clinical trial data.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The central government, the CDSCO and other bodies issued various notices and guidelines to expedite the approval of COVID-19 drugs, diagnostic kits and vaccines. Some of them are listed below.

- A special notification regarding the conduct of clinical trials to make available suitable vaccines was issued by the central government.
- The CDSCO released an office memorandum dated 26 May 2020 providing for an expedited approval process for COVID-19 vaccines. As per the memorandum:
  - (a) pre-clinical trial data generated abroad may be considered as part of an application to conduct clinical trials; and
  - (b) clinical trial data generated outside India may be used to provide an abridged pathway for a COVID-19 vaccine.
- Provisions were made for high-priority processing of applications for R&D, repurposing,

importation, manufacturing, marketing and evaluation of drugs or vaccines and diagnostic kits for COVID-19.
- Draft Regulatory Guidelines for Development of Vaccines with Special Consideration for COVID-19 Vaccines were issued by the CDSCO. The guidelines are similar in nature to recommendations and do not replace any statutory requirements. The guidelines focus on safety, immunogenicity and efficacy parameters for developing COVID-19 vaccines.
- Guidelines for validation and batch-testing of diagnostic kits were issued by the ICMR-DCGI.
- Provisions were made for the relaxation of the data requirement and requirements for the importation licence.
- Emergency approvals for Covidshield, Covaxin, Sputnik-V, the Moderna vaccine, the Janssen vaccine, Corbevax, Covovax, and iNCOVACC were granted subject to terms and conditions.
- Restricted emergency use and manufacture approvals were granted to Remdesivir and Favipiravir tablets.
- A Liberalised Pricing and Accelerated National COVID-19 Vaccination Strategy was issued by the MoHFW on 21 May 2021, with the aim of liberalising vaccine pricing and scaling up vaccine coverage.
- Revised Guidelines for Implementation of the National COVID Vaccination Programme were issued by the MoHFW on 21 June 2021.
- Restricted emergency use and manufacturing approval was granted for Tocilizumab and an antibody cocktail (Casirivimab and Imdevimab).
- Restricted emergency use approval was granted for Molnupiravir in the treatment of adult patients with COVID-19 who have a high risk of progression of the disease.
- Emergency approval was granted to Covaxin for administration to children between the age of 12 and 18 years.
- EUA Emergency approval was granted for the administration of ZyCoV-D to adults and to children from the age of 12.
- A guidance notification was issued by the CDSCO in May 2021 for the importation of foreign COVID-19 vaccines by a private entity or government-sector entity.
- In April 2021, the CDSCO issued detailed guidelines and relaxed the conditions for the entry into India of foreign-made COVID-19 vaccines approved by the US Food and Drug Administration, the European Medicines Agency, the UK Medicines and Healthcare products Regulatory Agency, the Japanese Pharmaceuticals and Medical Devices Agency or the WHO Emergency Use Listing.
- In June 2021, the NPPA capped the trade margin of oxygen concentrators, pulse oximeters, blood pressure monitoring machines, nebulisers, digital thermometers and glucometers at 70%.
- Guidelines were issued by the MoHFW on 3 January 2022 for COVID-19 vaccination of children between 15 and 18 years and for precautionary doses to healthcare workers, frontline workers and members of the population who are 60 or older with co-morbidities.

11.2 Special Measures Relating to Clinical Trials

The following special measures were issued in relation to ongoing clinical trials:

- a notice regarding the conduct of clinical trials during the COVID-19 outbreak was issued by the CDSCO in March 2020;
- the registrations of BA/BE (bioavailability/bioequivalence) study centres were extended;

- a clinical trial protocol for convalescent plasma was issued; and
- a notice was issued by the CDSCO on 25 February 2021 with regard to the launch of software for online submission of all Serious Adverse Events reports through the SUGAM portal.

Please see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The DC Act contains provisions that allow the central government to regulate, restrict, manufacture, etc, a drug in the public interest by way of notification in the Official Gazette. Please refer to **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**, **11.2 Special Measures Relating to Clinical Trials**, **11.4 Flexibility in Manufacturing Certification as a Result of COVID-19** and **11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19** for details.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The following simplifications and flexibility were introduced in relation to obtaining required certifications as a result of COVID-19:

- manufacturers of industrial oxygen were allowed to manufacture oxygen for medical use subject to conditions;
- the processing of applications to manufacture hand sanitisers was completed in three working days;
- hand sanitisers were exempted from the requirement of a sale licence;
- the validity of the WHO's Good Manufacturing Practices provisions and the Certificate of Pharmaceutical Products expiring was extended by six months from March to August 2020;
- prior permission from the CLA for manufacturing and stocking a vaccine for COVID-19 was deferred;
- the CDSCO issued various orders in 2021 relaxing the manufacturing and import licensing requirements for specified periods for all implantable medical devices, CT scan equipment, MRI equipment, defibrillators, positron emission tomography equipment, dialysis machines, x-ray machines and bone marrow cell separators;

On 18 January 2022, the MoHFW issued Drugs (Amendment) Rules 2022 stating that every active pharmaceutical ingredient (bulk drug) manufactured or imported in India must bear a quick response code on its label at each level of packaging, which stores data or information readable with a software application to facilitate tracking and tracing.

On 9 February 2022, the MoHFW issued a notification that relaxes the norms related to the manufacturing and stocking, sale or distribution of new drugs under Phase III clinical trials for the treatment of Covid-19 and related diseases in public interest, upon obtaining permission as per the CT Rules.

On 17 November 2022, the MoHFW issued the Drugs (Eighth Amendment) Rules 2022, thereby further amending the DC Rules. The Rules require that the manufacturers of drug formulation products (as specified in Schedule H2) shall print or affix on its primary packaging label – or, in case of inadequate space on the primary package label, on the secondary package label – a bar code or quick response code that stores

data or information legible with software application to facilitate authentication.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The following import/export restrictions or flexibilities were introduced in relation to medicines or medical devices due to COVID-19:

- export restrictions were imposed on 26 Active Pharmaceutical Ingredients and formulations made therefrom;
- Draft New Drugs and Clinical Trials (Amendment) Rules 2020 were issued for compassionate use of any new unapproved drug;
- the exportation of items such as surgical or medical masks, medical coveralls, medical goggles, nitrile/nitrile butadiene rubber gloves, face shields and Personal Protective Equipment coveralls was completely restricted or limited to a certain quota;
- the validity of registration certificates or licences for the importation of drugs that were due to expire was extended subject to conditions;
- special conditions under which permission for the importation of drugs with a residual shelf life of less than 60% was to be allowed/extended where specified;
- a set of regulations were issued to allow for certain norms to be relaxed in order to facilitate ease in the importation and exportation of COVID-19 vaccines through a courier;
- the submission of applications for import registration for drugs, cosmetics and medical devices with self-attested documents was allowed, subject to conditions; and
- on 18 January 2022, the CDSCO issued amended the MD Rules – thereby relaxing those for manufacturers and importers that currently do not have U13485 certification and are in the process of obtaining ISO certification.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Please see **8.5 Online Sales of Medicines and Medical Devices** and **8.6 Electronic Health Records**.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Indian government has so far not announced any intention to issue compulsory licences for treatments or vaccines related to COVID-19. As regards the rules, please refer to **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The government has no proposal to indemnify or exempt vaccine manufacturers from liability in the event of serious adverse reactions or side effects due to vaccines.

11.9 Requisition or Conversion of Manufacturing Sites

Please see **11.4 Flexibility in Manufacturing Certification as a Result of COVID-19**.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

In 2017, the central government issued Public Procurement (Preference to Make in India) [PPP-MII] Order 2017 (with subsequent revisions in 2018–20) to encourage the "Make in India" incentive and to promote the manufacturing and production of goods, services and works in India – with a view to enhancing income and employment where there is sufficient local capacity and competition. In order to implement the afore-

mentioned order, the DoP issued guidelines in relation to the procurement of medical devices in 2018. These guidelines were revised in 2021.

Similarly, in 2021, the DoP issued guidelines (in supersession of the earlier guidelines) for implementing the order in relation to the procurement of pharmaceutical formulations. There has been no change due to COVID-19.

Trends and Developments

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Obhan & Associates is a professionally managed law firm with a well-established practice in the areas of IP and corporate law. The firm was established in 2007 and has offices in Delhi and Pune. Obhan & Associates has been recognised for its expertise in patent, trade mark, copyright and design protection. The firm's corporate practice offers a broad range of transactional and advisory services to institutions and entrepreneurs, as well as to public and private companies. The firm has a well-balanced domestic and international clientele and represents a cross-section of industries, including fast-moving consumer goods, mechanical engineering, hardware and electronics, life sciences, pharmaceuticals, software, apparel, packaging and retail, process engineering, fashion brands, automobiles and parts, paints and chemicals, magazines and publications, and textiles. Obhan & Associates' life sciences and pharmaceuticals team has six experienced patent agents and lawyers who serve a varied client base that includes individual inventors, universities and national and international corporations.

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Patent Case Law Developments

After India's Intellectual Property Appellate Board (IPAB) was abolished in 2021, its jurisdiction (ie, appeals from decisions of various IP offices throughout the country) was transferred to the High Courts. Thereafter, the Delhi High Court set up an Intellectual Property Division (IPD) to deal exclusively with IP cases, while other major High Courts (Bombay, Madras and Calcutta) are reportedly in the process of creating similar divisions. By way of an example, the Madras High Court – in a writ petition filed by a litigant regarding its pending case before the IPAB – recently directed the state government of Tamil Nadu to notify its IPD.

Some of the key patent-related decisions of the Delhi High Court ("the Court") in the past 12 months are summarised under the following points.

Amending claims in Indian patent applications

Section 59 of the Patents Act 1970 ("the Act") requires that any amended claim must fall entirely within the scope of the claim as filed in the original specification. In Nippon A and L Inc vs Controller of Patents (MANU/DE/2303/2022), the original "product by process" claims were converted into a process claim, which had been rejected by the Controller under Section 59. The Court said that it was a common understanding that a product claim is broader in scope than a process claim and, therefore, the present amendment was narrower in scope and satisfied the conditions of Section 59.

What is not claimed is disclaimed

A divisional application is a further application divided out of the parent application. Under Section 16 of the Act, an applicant may file a divisional application suo moto or to remedy the objection raised by the Controller that the claims of the complete specification relate to more than one invention. A key requirement for dividing a patent application is that it must contain a plurality of invention.

In Boehringer Ingelheim International GMBH v Controller of Patents and Ors (MANU/DE/2531/2022), the Court closely examined the concept of plurality of invention and, specifically, considered whether divisional applications could be filed for claims that were not part of the claims

in the parent application. The Court concluded that "plurality of inventions" should clearly exist in the claims of the original parent application and within the scope of the parent specification. The Court observed that if the applicants were permitted to file divisional applications on the basis of disclosure in the complete specification without such inventions being claimed in parent applications, the fundamental rule of patent law that "what is not claimed is disclaimed" would be defeated.

Doctrine of equivalents

When assessing the scope of the patent claims and infringement, courts in India not only rely on the literal interpretation of the claim but also apply the principles of the "doctrine of equivalents" (DOE), purposive construction (or "pith and marrow"), and prosecution history estoppel.

Assessment of infringement

The Court in Sotefin SA v Indraprastha Cancer Society & Research Center & Ors (MANU/DE/0536/2022) held that – when it comes to assessing infringement – non-essential or trifling variations or additions to the product would not be germane, so long as the substance of the invention was found to have been copied. The doctrine of purposive construction must be applied when interpreting the claims. Further, the Court would also apply the DOE to examine whether the substituted element in the infringing product does the same work in substantially the same way to accomplish substantially the same result.

Application of the DOE in process claims

In FMC Corporation and Ors v NATCO Pharma Limited (MANU/DE/4962/2022), the Court held that DOE is applicable in the case of both product and process patents. The aforementioned triple test – ie, (i) substantially the same function, (ii) in substantially the same way and (iii) to yield the same result – is applied primarily to products or devices. However, in process claims, this test may have to be suitably adapted.

In order to claim infringement, the essential elements, the essential steps, and the manner in which the essential elements interact in each step to yield the given result in a claimed process must be substantially similar to the process in question. The variations in the two methods must be compared to ascertain whether they are minor, trifling and inessential and whether they have been introduced only to camouflage piracy.

Assessment of inventive step

Simplicity does not defeat an invention

The Court in Avery Dennison Corporation v Controller of Patents and Designs (MANU/DE/4319/2022) said the fundamental principles involved in analysing inventive step and deciding whether an invention is obvious or not are that:

- simplicity does not defeat an invention; and
- it is not permissible to analyse in hindsight.

Time gap is relevant

The Court in Avery Dennison Corporation (supra) also said that the time gap between the prior art document and the invention under consideration is one of the sure tests to determine the existence of inventive step. If a long time has passed since the prior art was published and a simple change resulted in unexpected benefits that no one had thought of in a long time, the Court would be inclined to hold that the invention is not obvious.

Elements to be considered

The Court noted in Agriboard International LLC v Deputy Controller of Patents and Designs

(MANU/DE/1055/2022) that, when rejecting an invention for lack of inventive step, the Controller must consider three elements:

- the invention disclosed in the prior art;
- the invention disclosed in the patent application under consideration; and
- the manner in which subject invention would be obvious to a person skilled in the art.

Without a discussion of these three elements, simply reaching the conclusion that the subject invention lacks inventive step would not be permissible – unless it is a case where the same is absolutely clear.

Maintainability and jurisdiction of High Courts

The Court in Reddys Laboratories Limited and Ors v Controller of Patents and Ors (MANU/DE/4389/2022) discussed the jurisdiction of the High Courts that emerged after the IPAB was abolished – specifically, with regard to the revocation of a patent and appeal against the orders of the Indian Patent Office (IPO).

Appeal against the order of the IPO

The IPO operates from four major cities (Kolkata, Delhi, Chennai and Mumbai). The Court held that appeals challenging the order or direction of the IPO would lie before the High Court with territorial jurisdiction over the IPO that covers the area from which the patent application originates and, as such, is the situs of said application.

Revocation of a patent

A petition for revocation of a patent can be filed by any interested person. The definition of "interested person" is inclusive and has been broadly interpreted by courts. It follows that a large number of persons may qualify as "interested persons". Further, the grant of a patent has an all-India effect. Persons interested in seeking the revocation of a patent could, therefore, be located anywhere in India.

The Court said that the question of jurisdiction would have to be decided on the basis of both the static effect and the dynamic effect of granting the patent. The place where the commercial interest of the applicant is affected would also be relevant in determining jurisdiction. Thus, the High Court with territorial jurisdiction in respect of revocation petitions will be decided not only on the basis of the local IPO where the patent application was filed and/or examined, but also where the cause of action for filing a revocation petition arose.

Known substance needs to be identified

Section 3(d) of the Act bars a new form of a known substance from patentability unless such new form exhibits enhanced efficacy compared with the known substance. In DS Biopharma Limited v Controller of Patents and Designs and Ors (MANU/DE/3418/2022), the Court clarified that an objection raised under Section 3(d) is not maintainable unless the alleged "known substance" is first identified by the IPO. The applicant cannot be expected to identify the known substance and then provide comparative data to show enhancement in the efficacy when contrasted with such known substance.

Applicant must not suffer for the fault or negligence of the patent agent

Responses to examination reports issued by the IPO must be filed within six months of the date of issue of the reports. An extension of three months is permissible, provided a request for the same is made before the six-month period expires.

In Bry-Air Prokon Sagl and Ors v Union of India and Ors (MANU/DE/4119/2022), responses to

examination reports were not filed in time in respect of six applications. Annuity was also not paid in respect of one patent, resulting in its lapse. Accordingly, the patent applications were deemed abandoned by the IPO. The Court found that petitioners were able to demonstrate that the patent agent was negligent. The Court also noted that there was no contributory negligence by the applicant and the applicant had a positive intent to prosecute the patent application. The applicant had also issued standing instructions to the patent agent to pay the annuity.

The Court held that the case fit the criteria for the exception of "extraordinary circumstances" where the applicant could not be allowed to suffer for the fault or negligence of the patent agent. The Court allowed similar relief in European Union v Union of India and Ors (MANU/DE/2142/2022), a case in which the facts were similar.

"Evergreening" a monopoly by serial patenting is not permissible

The case in FMC Corporation and Ors v GSP Crop Science Private Limited (MANU/DE/4480/2022) related to a patent for an intermediate used in the production of Chlorantraniliprole (CTPR). Both the product patent and the process patent expired on 13 August 2022. The Court noted that CTPR was the subject matter of at least 30 separate patent applications in India, suggesting an attempt at evergreening CTPR.

The Court said that multiple patents can be filed for different aspects of a particular product, if the tests for novelty, inventive step, and industrial applicability are satisfied and inventions are patentable. However, serial patenting in order to "evergreen" a particular monopoly is not permissible.

The Court also noted that the invention had not been worked on for more than 19 years since filing in India, which thereby raises doubt as to the industrial applicability of the patent itself. This appears to be a classic case in which the plaintiffs sought to find defendant(s) who could be sued in order to prevent the commercial launch of the CTPR product in some way after the product and process patents had expired by relying on an intermediate patent that had not been worked on, was prima facie invalid, and whose term was set to expire in a few months.

Interpretation of Section 3(i)

Section 3(i) of the Act bars from patentability "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products". In Sequenom, Inc and Anr v Controller of Patents and EMD Millipore Corporation v Assistant Controller of Patents (MANU/DEOR/158713/2022), the patent applications were refused under Section 3(i). Noting that the interpretation of the provision could have a bearing on many patent applications, the Court has appointed an amicus curiae to assist the Court in this matter.

No further objections can be raised by the Controller or Examiner in the hearing

In Perkinelmer Health Sciences Inc and Ors v Controller of Patents (MANU/DEOR/0040/2023), the Court – without discussing the merits of the case – clarified that no new objections could be raised by the IPO at the time of the hearing. The Court said that the applicant should be made aware of all grounds of objection prior to the hearing and be afforded sufficient opportunity to contest the same at the time of the hearing. The Court also ruled that raising new grounds during

a hearing is improper and violates principles of natural justice.

Other Developments

Report of Economic Advisory Council to Prime Minister

In August 2022, the Economic Advisory Council issued a working paper entitled *Why India Needs to Urgently Invest in Its Patent Ecosystem* (EAC-PM/WP/1/2022) to the Prime Minister. The paper notes that, in India, it takes about 58 months on average to dispose of a patent application – compared with about 20 months in China and 23 months in the USA. The paper suggests that the major cause of this delay is the shortage of manpower in the IPO. Other causes include:

- procedural issues such as the lack of fixed timelines for various steps (eg, no fixed timeline for filing an opposition against a patent application); and
- compliance requirements such as submitting information pertaining to processing of foreign patent applications.

The paper recommends increasing manpower in the IPO from the existing 860 to about 2,800 during the next two years. The paper also recommends fixing timelines for various steps of the process (eg, filing of pre-grant oppositions) and also suggests revised timelines for certain tasks and reducing compliance requirements.

Increase in patent filings

There has been a significant increase in patent filings in India. The filings increased by more than 50% in the last seven years. A nearly five-fold increase in the grant of patents was observed in 2021-22 as compared to 2014-15. In January to March 2022, the number of domestic patent filings surpassed the number of international patent filings in India.

Launch of Grievance Portal by IPO

In October 2022, the IPO launched a Grievance Portal whereby stakeholders can lodge their grievances/complaints, if aggrieved by officials, for unnecessary demands and for quick resolution of the issues they face during the processing of their applications. The IPO is also holding regular open conferences to address grievances or suggestions on issues related to its functioning.

Procedural developments at the IPO

With a view to expediting the disposal of patent applications, the IPO issued three public notices in January 2023 that sought to bring changes in patent application processing.

The first notice clarified that only authorised patent agents are entitled to represent their clients in respective matters before the Controller of Patents. The notice also clarified that an advocate can take part in any hearing/proceeding before the Controller – provided that the advocate is duly authorised by the applicant or the party concerned and is not a patent agent – by filing Form 26 in the advocate's favour.

The second notice notified that requests for adjournment filed without mentioning "reasonable cause" will not be entertained. The notice requires stakeholders (ie, patent agents) to specify the reasonable cause in the request for adjournment, without fail.

The third notice asserted that a combined reading of Rule 129 with the proviso to Rule 129A of the Patent Rules 2003 (as amended) ("the Rules") provides at least ten working days as the inner limit and 30 days as the outer limit for hearings and adjournments. Therefore, in matters where minor procedural issues are involved, the IPO will endeavour to offer a shorter time period. However, in substantive matters related

to analysis of prior arts, claim construction, etc, a longer period would be offered in accordance with the Act and the Rules. In accordance with the principles of natural justice, the notice also clarified that:

- a fair opportunity to defend would be given to the parties; and
- adverse action would not be taken solely based on the issued public notice.

Protection of AI-based inventions

In response to the recommendations and suggestions made by the Parliamentary Committee, the Department for Promotion of Industry and Internal Trade (DPIIT) has issued its "Action Taken Report". The Committee is of the opinion that the increase in application of AI-based tools such as Aarogya Setu and CoWin in recent times for the purpose of using and extending essential services implies a likely surge in AI-based patent filings. Hence, granting proprietary rights to AI innovators and protecting AI-driven innovations by enforcing regulations and standards in India should be the way forward. The Committee has therefore recommended that the DPIIT channelise efforts to encourage and empower AI innovators by enacting suitable legislation or modifying existing laws on IP rights to accommodate AI-based inventions.

ITALY

Law and Practice

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Contents

Studio Legale Vaiano Cataldo is based in Rome and consists of a team of 15 administrative lawyers headed by Professor Diego Vaiano and by Francesco Cataldo. The firm specialises in the legal field of life sciences, with particular regard to pharmaceutical law and medical devices, in relation to which it provides judicial and extrajudicial advice and assistance to the most important companies operating in the sector. The firm also provides legal counselling on public procurement, in particular on services and supplies, offering support at every stage of the procedure, from the study of tender deeds to the preparation of any requests for clarification or quotation documents, up to the executive phase. Where necessary, the firm offers assistance before the Regional Administrative Courts, the Council of State and the ordinary civil jurisdiction (Courts, Courts of Appeal and Court of Cassation), too. Other areas of activity where the firm can boast recognised expertise are those of the administrative licensing of public goods and services, trade and production activities, environment, construction and urban planning, public competitions, and arbitration.

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Diego Vaiano has been a member of the Rome Bar since January 1994. Within his professional activity, he practises in particular in the fields of healthcare and life sciences and is considered to be one of the leading Italian experts in pharmaceutical and medical devices law. In the last two decades, he has defended the pharmaceutical industry in some of the most challenging litigation in the sector, including in relation to the governance of pharmaceutical expenditure. He was also involved in major negotiations with the Italian Medicines Agency. He has been a member of the Farmindustria Board of Arbitrators since 2008, also acting as a consultant for Confindustria – Medical devices. He has been a Full Professor of Administrative Law at the University of Viterbo – La Tuscia since 1 November 2001. He is the author of many qualified scientific publications on administrative law.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

For medicinal products for human use, the main regulatory reference in Italy is Legislative Decree No 219/2006, issued in the implementation of Directive 2001/83/EC (Community code relating to medicinal products for human use).

The matters not directly governed by the aforementioned legislative decree – such as, for example, those relating to the National Health Service's (NHS's) drug pricing and reimbursement conditions or to the evaluation of the therapeutic equivalence between different active ingredients – find their discipline within an objectively very vast and inhomogeneous series of norms.

With regard to medical devices, the application of the European Regulations 2017/745 (MDR) and 2017/746 (IVDR) has now taken place. The application of the first of these was initially planned to start on 26 May 2020, but was subsequently extended by one year, in consideration of the COVID-19 emergency. The second Regulation, relating to in vitro medical diagnostic devices, has been in force since 26 May 2022. Until these dates, the previous Community directives (90/385/EEC, 93/42/EEC and 98/79/EC) – and the Legislative Decrees that transpose their provisions at a national level – continued to apply.

The authorities responsible for the application and verification of compliance with the aforementioned Regulations are:

- the Ministry of Health, which exercises, among others, the functions of the State with regard to protection of human health, coordination of the NHS, veterinary healthcare, as well as the supervision and monitoring of the circulation of medical devices;
- the Italian Medicines Agency (AIFA), a body with legal status under public law, which operates on the basis of the guidelines and supervision of the Ministry of Health and the Ministry of Economy and Finance, and which is assigned the function of ensuring the consistency of the pharmaceutical system, as well as the task of establishing, through negotiations with pharmaceutical companies, the price and reimbursement conditions for medicinal products.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies in pharmaceutical matters are administrative acts or measures. As such, they can be challenged within 60 days of their communication or publication, with an appeal before the Regional Administrative Courts (TARs). Sentences pronounced by the TARs are appealable before the Council of State. Decisions made at appeal level can be challenged before the Supreme Court for reasons relating to jurisdiction only.

As an alternative to the appeal to the TAR, it is possible to file an extraordinary appeal with the President of the Republic within 120 days from the date of publication of the provision.

These remedies are applied identically for the challenge of any other administrative measure and, therefore, also with regard to medical devices.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are classified in different ways, according to their reimbursement and supply status.

For the purposes of reimbursement, the AIFA classifies drugs in the following categories:

- class A – essential medicines and drugs for the treatment of chronic diseases, the cost of which is borne by the NHS;
- class H – medicines dispensed in the hospital, or in a similar facility, with costs to be borne by the NHS;
- class C – medicines not reimbursed by the NHS.

For the purposes of supply, the regimes currently provided for by the legislation are as follows:

- medicines subject to medical prescription;
- medicines subject to medical prescription to be renewed from time to time;
- medicines subject to special medical prescription;
- medicines subject to restrictive medical prescription, including:
  - (a) medicines that can be sold to the public subject to prescription by hospital healthcare professionals (HCPs) or specialists;
  - (b) medicines that can only be used in a hospital (or similar) environment;
  - (c) medicines that can only be used by specialists;
- medicines not subject to medical prescription, including:
  - (a) over-the-counter (OTC) or self-medication drugs;
  - (b) the remaining non-prescription medicines.

As far as medical devices are concerned, the national legislation follows that of the Community directives. There are, therefore, three categories of products:

- active implantable medical devices, ie, devices requiring some form of energy to function and meant to be entirely or partially implanted, by surgical or medical intervention, in the human body;
- medical devices (in general);
- in vitro medical diagnostic devices, intended for in vitro use for the examination of specimens from the human body, including donated blood and tissue.

The first two categories of medical devices are grouped into different classes, according to their

complexity and the potential risk for the patient (class I, IIa, IIb, III).

A different risk classification is instead provided for in vitro diagnostic devices.

Again, with reference to medical devices, a further classification exists, for nomenclature purposes, called CND, or national classification of medical devices. This classification was selected by the Medical Device Co-ordination Group of the European Commission as a useful basis for developing the nomenclature for the European database EUDAMED, in consideration of its peculiarities in terms of structure, purpose and usability.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulatory framework governing clinical trials of medicinal products for human use, currently in a transition phase, is the result of a progressive stratification of national and community regulations.

Among these are, in particular:

- Legislative Decree No 211/2003, which implemented Directive 2001/20/EU;
- Legislative Decree No 200/2007, which implemented the subsequent directive 2005/28/EC;
- Legislative Decree No 158/2012, which provided for the reorganisation of the Ethics Committees (independent bodies responsible for ensuring the protection of subjects enrolled in clinical trials);
- Legislative Decree No 52/2019, which provided for the reorganisation of the legislation, introducing co-ordination provisions with (EU) Regulation No 536/2014.

This latest Regulation, which will abrogate the aforementioned Directive 2001/20/EC, aims to harmonise the procedures and requirements applicable to clinical trials in the various Member States. The Regulation was published on 27 May 2014, but its application is subject to the activation of the database and the EU portal of clinical trials. These systems, after several extensions, became operative in January 2022.

For medical devices, the legislation on clinical investigations is currently contained in the Legislative Decrees which implement the Community directives in force on the subject. Furthermore, since 26 May 2021, these directives have been regulated by the new EU MDR (Articles 62 to 82 and Annex XV). Finally, Article 15 of the European Delegation Law 2019-2020 (Law 22 April 2021, No 53) provided that the Government adopts one or more legislative decrees for the reorganisation and adaptation of national legislation to the new regulation, dictating a series of principles and guiding criteria that must be followed for this purpose.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The authorisation procedure for clinical trials is divided into several phases, within which the foreseeable risks and inconveniences are carefully evaluated with respect to the expected benefit.

The bodies involved in the procedure are the following:

- the AIFA, for the issue of the authorisation;
- the Italian National Institute of Health (*Istituto Superiore di Sanità*), for the advisory opinion on Phase I studies and amendments;

- the Ethics Committees, for the opinions on the merits in the healthcare facilities where the clinical study is carried out;
- the General Managers of the healthcare units, for the stipulation of contracts;
- the EudraVigilance (European Union Drug Regulating Authorities Pharmacovigilance) network, for the reporting of adverse reactions.

As previously mentioned, the publication of EU Regulation No 536/2014 – which will be fully operational with the activation of the database and the EU portal – started a reform process, leading to the issue of Legislative Decree No 52/2019, of which, however, the implementing decrees (which will concretely redefine the procedures in force) are still pending.

The discipline relating to clinical investigations relating to medical devices is also in a transition phase.

According to the discipline dictated by the new EU MDR, in general and subject to exceptions, clinical investigations are mandatory for implantable and class III medical devices, while for other devices they are necessary only if the clinical data found in other available sources is not sufficient to prove compliance with the general safety and performance requirements.

The procedural process outlined by the new EU MDR involves the submission of an application by the sponsor of the clinical investigation. The Member State concerned is required to communicate whether the application is complete within ten days from the date of receipt. At this point, if no additional information is requested and if the application concerns a low-risk device among those mentioned in Article 70, paragraph 7, letter a) of the MDR, the sponsor can start the clinical investigation on the same date as the validation of the application, provided that no negative opinion has been expressed by the competent Ethics Committee.

For the other medical devices, however, the initiation of the investigation requires prior notification of the authorisation by the Member State.

Alongside this procedure, the Regulation governs specific procedures for the clinical investigations relating to devices already in possession of the marking (Article 74), for the clinical investigations conducted for purposes other than compliance assessment (Article 82), as well as a co-ordinated assessment procedure for clinical investigations conducted in more than one Member State (Article 78).

These procedures differ, in some respects, from that currently in force at national level, which does not require an actual application, but rather a notification to be sent to the competent ministerial direction which, for medical devices belonging to classes I, IIa and IIB (excluding implantable and long-term invasive devices), allows the relevant sponsor to start the investigation immediately, provided that it has the favourable opinion of the competent Ethics Committee.

2.3 Public Availability of the Conduct of a Clinical Trial

As of 21 July 2014, the funders of a study or clinical trial relating to medicinal products for human use are required to publish its results on the European database managed by the European Medicines Agency (EMA). Through this database, it is possible to obtain information on the objectives of the study and the main results achieved.

This obligation is reinforced in the new Regulation (EU) No 536/2014, which – as mentioned in **2.1 Regulation of Clinical Trials** – entered into force on 31 January 2022. This Regulation expressly establishes that a summary of the results of the clinical trial and an abstract presented in terms understandable to laypersons are to be made available in the EU database, regardless of the outcome of the clinical trial.

Similarly, the new EU MDR requires the sponsor to submit a report on the investigation, within one year of its conclusion, regardless of its outcome.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The guidelines for the collection of the informed consent to participation in clinical trials – drawn up by the National Co-ordination Centre of Ethics Committees – recommend that the consent collection process also include "telematic" tools, in order to facilitate a full understanding by the participant. The same guidelines clarify that "in selected situations, to be assessed on a case-by-case basis, to facilitate the participation of all potentially interested patients, interactive telematic tools can be used for the patient information process and/or for the collection of their consent".

2.5 Use of Data Resulting From the Clinical Trials

Pursuant to the GDPR (General Data Protection Regulation), data resulting from clinical trials falls within the scope of "particular categories of personal data".

As such, it can be transferred to third parties or affiliates only in compliance with the provisions of the aforementioned Regulation. Depending on the case, it may be necessary for the trial promoter to enter an agreement (possibly autonomous), with these subjects on the processing of personal data.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing particular categories of personal data should take place in compliance with the technical and organisational measures provided for by the GDPR, in particular in order to guarantee the safety of the processing and compliance with the principle of data minimisation.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The European legislation, implemented at national level, defines the characteristics that medicines and medical devices should possess to be considered as such.

The main criterion that is used to distinguish a medicine from a medical device is the method by which the product pursues its intended purpose. Unlike medicines, in fact, medical devices must exert their action through methods that are not mainly pharmacological or immunological, nor through metabolic processes.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

EU Regulation No 726/2004 requires applicants to use the centralised procedure co-ordinated by the European Medicines Agency (EMA) for the authorisation of medicinal products derived from the following biotechnological processes:

- recombinant DNA technologies;
- controlled expression of genes carrying codes for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells;
- hybridoma and monoclonal antibody-based methods.

In addition, the registration of other biological drugs, not derived from the aforementioned procedures, may be requested through national, decentralised or mutual recognition procedures. In the case of biological or biotechnological originators, the application to be submitted to the AIFA for registration purposes is that based on a complete dossier, pursuant to Article 8 of Legislative Decree No 219/2006.

The same legislation, however, provides that the dossier to be presented in these cases is supplemented by additional information, precisely indicated in the Annex to Legislative Decree No 219/2006, which is justified in consideration of the peculiarities of biological medicines and their sensitivity to changes in raw materials or production processes. These peculiarities are also reflected in the registration requirements of biosimilar medicines, which may be more demanding than those necessary for the "simplified" authorisation of generic medicines (Article 10, paragraph 7, Legislative Decree No 219/2006).

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The marketing authorisation (MA) has an initial five-year validity period. It can be renewed, at the request of the holder, with an application to be presented at least six months before the expiry date, on the basis of a new assessment of the risk/benefit ratio carried out by the AIFA. In cases in which this assessment gives a positive result, the MA is renewed with unlimited validity, unless the AIFA, for pharmacovigilance-related reasons, decides to proceed with a further five-year renewal. In the event that the risk/benefit assessment is not favourable, the interested party can submit to the AIFA an opposition to the refusal provision, on which the latter decides, within 90 days, after consulting the Italian National Institute of Health. If even this last decision is not favourable, the AIFA notifies the holder and announces with a press release that the medicine can no longer be marketed.

Once the MA has been issued, it can be revoked, suspended or modified in the cases established by Article 141 of Legislative Decree No 219/2006 (eg, when the medicine is harmful, it does not allow the effect for which it is authorised to be obtained, the risk/benefit ratio is not favourable and in the other cases indicated by the law).

In addition to the foregoing, any MA issued loses its validity if it is not followed by the effective marketing of the medicinal product on the national territory within the following three years, or if an authorised medicinal product already present on the market is no longer effectively marketed for three consecutive years. However, these provisions can be derogated from by the AIFA for public health reasons.

For medical devices, the EC Certification (or CE Statement) and the underlying compliance assessment issued by the notified bodies have a maximum validity of five years (renewable). The MDR confirmed these validity periods, and regulated a transitional regime for the marketing of certified products in compliance with the Directives currently in force.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

For medicinal products, the authorisation procedures are divided into:

- a centralised procedure, aimed at obtaining an MA valid in all EU countries, which is co-ordinated by the EMA and its Committee for Medicinal Products for Human Use (CHMP), and ends with the issuing of a decision by the European Commission;
- a mutual recognition procedure, which allows the extension to one or more EEA countries of an MA already granted by a member state;
- a decentralised procedure, which allows an MA to be obtained that is simultaneously valid in two or more EEA countries on the basis of identical documentation;
- a national procedure, which allows a valid MA to be obtained within the Italian state only.

In order to initiate the procedure, the applicant is required to submit an application for authorisation to the competent authority, attaching a dossier containing the information required by Annex I to Directive 2001/83/EC.

Once the application is received, the competent authorities analyse its compliance and verify the existence of the conditions for issuing the MA. The legislation provides for a maximum term of 210 days, starting from the date of presentation of the valid application, for the conclusion of centralised, decentralised and national procedures. The mutual recognition procedure, however, provides for a term of 180 days.

The procedures for changing the terms of an MA are governed by EU Regulation 1234/2008. These procedures are different, depending on the variation requested.

Type IA variations, which have little or no impact on the quality, safety and effectiveness of the medicinal product, can be implemented even before being notified to the competent authorities (these include, for example, administrative changes relating to the identity or address of the MA-holder or the manufacturer).

For the implementation of the other variations, however, it is necessary to wait for the completion of the silent consent (type Ib variations), or the express authorisation from the competent authorities (type II variations, relating, for example, to the addition of an indication, to the production process, etc).

With regard to medical devices, the marking procedures differ according to the relative risk class.

For the lowest risk class (class I), it is generally possible to mark the device on the basis of a declaration of compliance with the essential requirements provided for by the legislation, a declaration that can be made by the manufacturers themselves.

For the other classes of devices, and for sterile devices or devices with a measuring function, also in class I, the assessment procedure provides instead for the involvement of a notified body, from which the manufacturer is required to request the issue of a certificate of compliance.

In general, any variations to the approved device require a new approval by the notified body that issued the EU technical documentation assessment certificate, if they may affect the safety and performance of the device or the conditions of use prescribed for that device.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

When certain conditions are met, the national legislation allows free access to a drug therapy that has not yet received the AIFA's authorisation.

According to Law No 648/1996, this possibility is provided for, provided that there is no valid therapeutic alternative:

- for innovative medicines authorised in other states, but not in Italy;
- for medicinal products not yet authorised, but undergoing clinical trials;
- for medicinal products to be used for a therapeutic indication other than that authorised.

Medicines that can be used pursuant to the aforementioned Law No 648/1996 are included in a special list of the AIFA, and can be prescribed at the total expense of the NHS for all the subjects who, in the national territory, are affected by the condition identified in the provision.

Early access to the drug is also allowed under "compassionate-use" programmes, for drugs still undergoing clinical trials, in patients suffering from serious or rare diseases or whose lives are in danger, when, in the physician's judgement, there are no further valid therapeutic alternatives. Access to the investigational drug requires a favourable opinion from the Ethics Committee, subject to confirmation of the pharmaceutical company's availability to supply the drug free of charge.

Subject to the authorisation of the Ministry of Health and the favourable opinion of the Ethics Committee, the possibility of resorting to compassionate use is also provided for medical devices in exceptional cases of necessity and urgency, in the interest of protecting the health of an individual patient and in the absence of valid therapeutic alternatives.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

After the granting of the MA, the holder takes into account any scientific and technical progress, and introduces the changes necessary for the medicine to be produced and controlled according to generally accepted methods.

In addition, pursuant to Legislative Decree No 219/2006, the same holder is obliged to inform the AIFA immediately of any prohibitions or restrictions imposed by the competent authorities of any country in which the medicine is marketed, as well as any other new data that may affect the risk-benefit assessment of the same.

In terms of pharmacovigilance, the legislation requires the MAH to record suspected adverse reactions in detail, and to notify with the utmost urgency those characterised as serious.

This information must be collected and submitted by the MAH in the form of PSURs (Periodic Safety Update Reports).

Similarly, vigilance obligations are envisaged for medical-device manufacturers or their authorised representatives, starting with the immediate communication to the competent authority of all the incidents of which they have become aware and of all the corrective actions that have been undertaken to avoid or reduce the risks associated with the use of a medical device.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The AIFA has adopted a regulation for the access to documents created or held permanently by itself. The regulation provides that the Administration may limit access to a document, obscuring some of its contents, when this is necessary to protect the confidentiality of persons, groups or companies. The same regulation excludes, in principle, from the right of access the documentation concerning the production methods and the know-how on the manufacture of pharmaceutical products. In principle, the jurisprudence denies the right of third parties to access any information relating to any confidential discounts granted by pharmaceutical companies to NHS bodies in the context of pricing and reimbursement contracts stipulated with the AIFA.

The situation is different for the authorisation procedures for generic medicines. In such cases, in fact, the jurisprudence has recognised the right of access to Marketing Authorisation Applications and bio-equivalence tests by the companies that market the reference medicine, noting that the latter have an interest worthy of protection in verifying the actual equivalence between their patented medicinal products and the generic ones that are the subject of the MA Application.

For medical devices, the provisions of the general legislation on the right of access apply (Article 22 et seq, Law No 241/1990).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Directive 2011/62/EU and delegated Regulation 2016/161 have integrated the regulatory system, providing for specific provisions to oppose the inclusion of counterfeit medicines into supply chains.

In order to counteract these phenomena, it was decided, in particular, to equip the packaging of the medicines with a unique identifier and an anti-tampering device.

The application of a Unique Device Identifier (UDI), including a product and production identifier, is also required for medical devices under Article 27 of the new EU MDR. Article 94 of the same regulation requires the competent authorities of the Member States to draw up annual market surveillance activity plans and to allocate sufficient resources to carry out such activities.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

A national anti-forgery Task Force is active in Italy. The main institutions involved in this Task Force and in the drug counterfeiting issue are the AIFA, the Ministry of Health, the *Istituto Superiore di Sanità* (National Institute of Health) (ISS), the Illegal Traffic of Medicines (*Nuclei Antisofisticazioni e Sanità* – NAS) (*Carabinieri*), the Ministry of Economic Development (*Ministero dello Sviluppo Economico* – MISE) and the Customs and Monopoly Agency.

Part of the control activity carried out concerns the management of reports relating to the discovery of suspicious products at customs. Specifically, this activity takes the form of a series of checks which have the purpose of ascertaining the origin of the products and their relative composition by means of laboratory analyses.

For medical devices, customs surveillance is mainly carried out by the Maritime, Area and Border Health Offices of the Ministry of Health.

The surveillance activity is carried out through three levels of verification (documentary, identity, material), to ascertain the compliance of medical goods with the requirements and prescriptions provided for by national and community regulations.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Pursuant to Legislative Decree No 219/2006, the production of medicines and medical devices requires the authorisation of the AIFA and the Ministry of Health, respectively. The authorisation, which does not expire, is issued after an inspection aimed at ascertaining that the applicant has qualified personnel and technical-industrial means compliant with the regulations.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

The wholesale distribution of medicines is subject to authorisation by the Regions, and requires the availability of suitable premises and adequately trained personnel (Legislative Decree No 219/2006).

The legislation on medical devices does not regulate the wholesale market.

5.2 Different Classifications Applicable to Pharmaceuticals

For the classification of medicines for supply and reimbursement purposes, see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

On the basis of these classifications and the relative conditions of use, medicines can be assigned to the following distribution channels.

- Hospital distribution, for medicines used in hospital. The distribution regime applicable in these cases requires hospital pharmacies to dispense medicines to hospitalised patients, subject to direct purchase from pharmaceutical companies following the outcome of public tenders.
- Territorial distribution, for chronic medicines or even short-term therapies and for clinical situations that do not require hospitalisation. The distribution regime applicable in these cases provides that the medicine is purchased by the wholesaler, dispensed by local pharmacies and, where included in reimbursement class A, reimbursed to the subjects in question by the NHS according to the relative amounts due provided for by law.
- Direct distribution, for medicines which, although not intended for hospitalised patients, meet the criteria of differential diagnostics, of therapeutic criticality, and of periodic control by the specialist structure. These medicines are purchased and dispensed by health facilities according to the scheme illustrated above for the hospital distribution, and are delivered to patients by hospital pharmacies. However, in some regions, there are agreements entered into with the pharmacist trade associations, based on which patients can collect these drugs at some affiliated pharmacies that are authorised to supply

them. These cases fall within the "distribution on behalf of the health facility".

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of medicines are governed by Legislative Decree No 219/2006.

For medical devices, it is necessary to refer to the European directives, the national implementing legislation and the new EU MDR. Articles 13 and 60 of that regulation are specifically dedicated to import and export activities.

The competent authorities for implementing the regulation are the AIFA and the Ministry of Health.

6.2 Importer of Record of Pharmaceutical and Medical Devices

In general, the compliance with authorisation requirements and obligations similar to those envisaged for the production activity is required for subjects importing medicines.

For the parallel import of medicines registered in a Member State, for which a similar medicine exists in the Italian market, the importer must have the regional authorisation for wholesale distribution. Moreover, for each workshop that carries out the re-labelling or repackaging of the product, a production authorisation is required.

There is no specific authorisation for subjects importing medical devices. However, they are responsible for the compliance of the product marketed in the Union.

Since 26 May 2021, with the full operation of the MDR, importers of medical devices have been required to comply with the obligations set out in Article 13 of the MDR itself (eg, the obligation to verify CE marking, EU declaration of compliance, labelling, etc).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Imports of medicines must be previously authorised by the AIFA.

Notwithstanding this general rule, the importation for personal use of medicines duly authorised in a foreign country is allowed in the following cases:

- medicines for which a valid therapeutic alternative does not exist or is not accessible in Italy, upon request and under the responsibility of the attending physician; and
- medicines personally imported by the traveller upon entering the national territory, provided they are intended for personal use for a treatment not exceeding 30 days.

The import of medical devices is subject to supervision by the Maritime, Air and Border Health Offices of the Ministry of Health. The surveillance activity ends with the final issue of an import-authorisation measure, or with a non-importation measure in the case of failure to pass the controls.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The import of goods into the EU is regulated by a standardised classification system, which identi-

fies products on the basis of a tariff code. The classification is based on the harmonised system managed by the WHO (HTS, first six digits of the code), on the further subdivisions applied by the Union Combined Nomenclature (CN) and, finally, on the Community Customs Tariff (TARIC). The TARIC code, consisting of ten digits, identifies the applicable rates, any preferential duties and a whole series of other measures (temporary suspensions, quotas, ceilings, etc) specifically applicable to the product being imported.

6.5 Trade Blocs and Free Trade Agreements

The EU manages trade relations with third countries in the form of trade agreements designed to create better trade opportunities and to overcome trade barriers. Among the other agreements worth of mention here are the CETA (EU-Canada) and the JEFTA (EU-Japan); the latter entered into force on 1 February 2019, with a negotiated free trade area of more than 635 million people. The agreement includes, among others, the pharmaceutical sector, to the regulation of which a specific chapter is dedicated.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The price of medicines not reimbursed by the NHS is established by the MA-holders, and can only be changed upwards in January of each odd year.

The price of the medicines reimbursed by the NHS is defined through negotiation between the companies and the AIFA.

The criteria with which the AIFA must comply during the negotiation are established by the Decree of the Ministry of Health of 2 August 2019, published on 24 July 2020.

The discipline dictated by the decree in question provides that the negotiation is initiated by the pharmaceutical company by submitting a specific request, accompanied by the documentation listed in Article 2, paragraph 2 of the same decree.

For the conclusion of the procedure, a term of 180 days is provided for, the suspension of which is allowed for a period not exceeding 90 days.

In the case of lack of agreement, the procedure ends negatively, with the classification of the medicine in class C. In the case of a positive outcome, the procedure is finalised by an agreement between the AIFA and the pharmaceutical company defining the price and reimbursement conditions applicable to the medicine.

The negotiated price is valid for a period of 24 months, unless otherwise agreed by the parties, but the AIFA can still restart the negotiation before the deadline in the event of particular "market changes", in the case of "new evidence" on the positioning in therapy or on the estimated benefits, or if a shortage of the medicine on the Italian market occurs.

The negotiated price represents the maximum price for the sale of the drug to the NHS bodies, on which further discounts can be negotiated during the tender. In addition to this price, in the market segment of territorial distribution, VAT and the profit margins envisaged by the law in favour of pharmacists and wholesalers are added. The sum of these components thus deter-

mines the retail price of the medicine (ie, the price reimbursed to the pharmacist by the NHS), which is divided among the players in the supply chain on the basis of the following quotas: 66.65% for the manufacturing pharmaceutical companies, 6.65% for wholesalers and 26.7% for pharmacists. For the transfer of equivalent medicines referred to in Article 7, paragraph 1, of Legislative Decree No 347/2001, not originally covered by a patent or licences deriving from that patent and assigned to the territorial distribution circuit, the quota attributable to the pharmaceutical company is reduced from 66.65% to 58.65% and the corresponding percentage of eight points that is released is divided between pharmacists and wholesalers, according to market rules.

For medical devices, there are no price-negotiation procedures similar to those for medicines. Prices are set by the producers and, for the supplies to NHS bodies, they are negotiated upon the outcome of public tenders between the supplying companies and the regional purchasing centres.

7.2 Price Levels of Pharmaceutical or Medical Devices

The prices of medicines and medical devices marketed in Italy are not strictly bound to those quoted, for the same products, in other European countries and in the rest of the world. Nonetheless, Ministerial Decree of 2 August 2019 provides that the information on the "marketing, consumption and reimbursement in other countries" must be communicated by pharmaceutical companies during the negotiation of the price and reimbursement conditions of medicines, and are taken into consideration by the AIFA during the negotiation process.

A reference price system is instead envisaged in the public contracts sector, to contain the variability of the regional award prices of certain products which have a high impact in terms of cost for the NHS. Following this system, Legislative Decree No 95/2012 introduced the institution of "renegotiation" of existing contracts, which NHS bodies are required to exercise in the event of a deviation of more than 20% of the award price compared to the price of reference. In the case of failure of a renegotiation agreement, the NHS bodies have the right to withdraw from the contract without any charge. This system, however, has not so far found concrete application in the pharmaceutical sector, but in exceptional cases only.

Additional control systems of award prices, starting prices and the renegotiation of existing contracts have been provided for, in the case of medical devices, by Law No 296/2006 and by Legislative Decree No 78/2015.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Medicines are eligible for reimbursement by the NHS if they are deemed by the AIFA to be indispensable for the treatment of chronic or serious diseases, after negotiating the relative price and reimbursement conditions with the company holding the MA.

For the governance of pharmaceutical expenditure, the State makes use of various instruments, among which the most incisive is certainly the setting of an overall expenditure ceiling, equal to 15% for the year 2022, 15.15% for the year 2023 and 15.30% thereafter from the year 2024, divided into a ceiling for the pharmaceutical expenditure under agreement and a ceiling for pharmaceutical expenditure for direct purchases (drugs

purchased directly from the NHS bodies). The current legislation provides, in fact, that pharmaceutical companies must participate in the settlement of the overspending of the aforementioned ceilings to varying degrees, depending on the ceiling that has been overrun. For the direct purchases' ceiling, in particular, pharmaceutical companies must participate in the settlement for an amount equal to 50% of the relative overrun (so-called pharmaceutical pay-back), in proportion to their market-share.

While the ceiling for the pharmaceutical spending under agreement has always proved to be capacious, the one intended for direct purchases has proved to have been seriously underestimated over the years, recording, starting from 2013, overspends for increasingly greater amounts, exceeding EUR1 billion per year. The requests for pharmaceutical pay-back have been the subject of extensive litigations, which are still pending before the administrative justice bodies, and have been so for some years.

With the latest in a long series of regulatory interventions, the legislator (Article 1, para 281, Law No 234/2021) provided that, starting from 2022, the expenditure ceiling for the direct purchases expenditure will be equal to 8% for the year 2022, 8.15% for the year 2023 and 8.30% from the year 2024, with an increase compared to past values.

The legislation also provides for a ceiling and a settlement mechanism for the expenditure on medical devices. Each company contributes to the settlement in a measure equal to the percentage incidence of its turnover on the total expenditure for the purchase of medical devices to be paid by the NHS, as established by an agreement during the State-Regions Conference. However, this system has not yet found any application.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The cost-benefit analysis and the "added therapeutic value" of a medicine in relation to the therapeutic alternatives available are the evaluation criteria adopted by the AIFA when negotiating the price conditions of the medicines reimbursed by the NHS.

For medical devices, the 2016 Stability Law assigned to a "Control Room" the task of carrying out a multi-dimensional technical assessment of medical devices, based on the criteria of relevance, safety, effectiveness, economic impact and organisational impact of the devices themselves, consistent with the relevant European guidelines (EUnetHTA). The rules provide that the individual NHS bodies can no longer carry out this activity autonomously, but must resort to evaluating structures established at a regional or national level, which must in any case operate under the co-ordination and on the basis of the priorities identified by the Control Room.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

For the governance of pharmaceutical expenditure, the AIFA makes use of additional instruments related to the expenditure ceilings, that specifically affect the phases of prescription, dispensing and reimbursement of the medicines whose costs are borne by the NHS.

Among these, the so-called "AIFA Notes" are particularly important: they are a regulatory tool aimed at limiting the scope of reimbursement of certain medicines by defining the indications and/or limitations that every physician should comply with in order to be able to prescribe the

drug with costs borne by the NHS. At the time of the prescription, the doctor records the number of the Note on the prescription itself, thus certifying that the conditions provided for by that Note are met for the prescription of the medicine with costs borne by the NHS. The Notes are periodically reviewed in order to update the indications and limitations provided therein according to the new evidence available in the scientific literature.

Further regulatory instruments concern the prescription and dispensing of originator medicines and their equivalent counterparts included in the "transparency list" referred to in Article 7 of Legislative Decree No 347/2001. The following mechanisms apply to the medicines included in the list in question:

- limitation of the maximum reimbursement price by the NHS, which is reduced to the price of the cheaper equivalent drug based on the same active ingredient included in the transparency list; and
- automatic replacement of prescriptions, by virtue of which the pharmacist is obliged to dispense to the patient the aforementioned drug included in the transparency list with the lowest price, unless the treating physician has expressly added the "No Replaceability" clause to the prescription, or unless the patient has insisted in any case on obtaining the dispensing of the most expensive drug, in both cases personally paying the price difference.

Finally, there is a regional practice which tends to orient/encourage/discourage doctors' prescribing choices on the basis of measures that presume an evaluation of the therapeutic equivalence between medicines containing different active ingredients. This is the case, for example, of the decisions concerning:

- the promotion of the prescription of certain active ingredients, less expensive, in place of others; and
- the creation of tenders for the competing purchase of medicinal products based on different active ingredients.

Over the years, a practice has emerged that has seen the regions adopt decisions of this type with a certain frequency, and in no particular order, with the consequent creation of inequalities of treatment among the patients in accessing pharmaceutical care services included in the essential levels of care. To resolve the matter and ensure uniformity in the access to services, the legislator has therefore intervened on the regulatory level, establishing that the aforementioned decisions, which require an evaluation of the therapeutic equivalence between medicines containing different active ingredients, can be adopted by the regions only "on the basis of the justified and documented assessments expressed by the Italian Medicines Agency" (Article 15, paragraph 11-ter, Legislative Decree No 95/2012).

In implementing the aforementioned Article 15, paragraph 11-ter, the AIFA adopted guidelines that identified the criteria for establishing, in practice, the therapeutic equivalence between medicines based on different active ingredients.

8. Digital Healthcare

8.1 Rules for Medical Apps

In October 2019, the European Commission's Medical Devices Coordination Group published a guideline on the qualification and classification of software as medical devices. The document reaffirms the general principle according to which the purpose given by the manufacturer

to the software is the main criterion that must be used for the purposes of its qualification and classification as a medical device. Consequently, it must be considered that software used solely for research or information retrieval activities cannot be classified as medical devices. Conversely, software intended for the analysis and processing of health information for medical purposes can be qualified as medical devices, and classified in risk class IIa, or in higher classes, if the decisions to be made on the basis of the software itself can seriously impact the health status of the user.

8.2 Rules for Telemedicine

On 17 December 2020, the State-Regions Conference approved a document containing "national guidelines for the provision of telemedicine services". The guidelines govern, in detail, the telemedicine activities that can be included in the essential levels of care (in particular, televisits, medical tele-consultation, medical health tele-consultation, tele-assistance by healthcare professionals, tele-reporting), and their limits and possibilities of use, as well as the applicable rules in terms of tariffs, accountability and necessary technological standards.

8.3 Promoting and/or Advertising on an Online Platform

Advertising to the public is allowed, subject to authorisation by the Ministry of Health, for medical devices and Standard Operating Procedure (SOP)/OTC medicines. Advertising can also be carried out via the internet, but in this case it must comply with the rules established in the guidelines specifically issued by the Ministry of Health. Precisely these guidelines, however, almost absolutely prohibit the possibility of advertising medicines via social networks, with an exception only for Facebook desktop (right column) and YouTube.

8.4 Electronic Prescriptions

The outbreak of the COVID-19 pandemic has given a particular impulse to the process of dematerialisation of prescriptions.

The Ordinance of the Head of Civil Protection of 19 March 2020 introduced, for the emergency phase, alternative methods to the paper prescription, in order to reduce travel and the number of accesses to the NHS GPs' offices.

Lastly, the inter-ministerial decrees of 25 March 2020 and 30 December 2020 extended the use of electronic medical prescriptions to other types of medicines, including those not reimbursed by the NHS, while disciplining the dematerialisation of prescriptions and also the relative reminders for the post-emergency phase.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicines is governed by Legislative Decree No 17/2014 and is thereby permitted only for SOP/OTC drugs, and only in the online shops of pharmacies and parapharmacies, subject to authorisation by the region of competence and registration in the list of authorised subjects, kept by the Ministry of Health.

For medical devices, online sales are permitted under Article 6 of the new EU MDR.

8.6 Electronic Health Records

The Italian electronic health record (*Fascicolo Sanitario Elettronico* – FSE) is managed by the regions in compliance with the general rules established by Article 12 of Legislative Decree No 179/2012 and by the current legislation on the protection of personal data. The FSE (or EHR) collects all the health and social health data and digital documents generated by clinical events concerning the patient. The consultation

of the data present in the FSE can be carried out only with the consent of the patient, and always in compliance with professional secrecy.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The main regulatory reference on the subject is the industrial property code (*Codice Proprietà Industriale* – CPI). There are specific regulations which integrate the CPI for the pharmaceutical sector and which concern, among others, the release of Supplementary Protection Certificates for medicines (SPCs, EC Regulation No 469/2009) and the legal protection of biotechnological inventions (Directive 98/44/EC).

9.2 Second and Subsequent Medical Uses

The possibility of obtaining patents for second medical use is generally recognised, provided that the patentability requirements are met, and it is therefore possible to demonstrate the innovative nature of the new use compared to the previous one.

The patent coverage of the new use inevitably expires after the initial one. Consequently, in the period between the first and second deadlines, a somewhat hybrid situation arises, during which generic medicines can be marketed, but not for the second use, which is protected by the patent issued subsequently. This particular dynamic also meant that in Italy, as in many other countries, second- and subsequent-use pharmaceutical patents have been the subject of litigation.

9.3 Patent Term Extension for Pharmaceuticals

Pharmaceutical companies can apply for an SPC, which allows them to extend the duration of the basic patent. These certificates are governed by Regulation No 469/2009/EC and have a duration equal to the time elapsed between the filing of the patent application and the granting of the first European MA, minus five years. In any case, the certificate can never have a duration exceeding five years from the expiry of the basic patent.

On 1 July 2019, Regulation (EU) No 2019/933 entered into force, which amended Regulation (EC) No 469/2009, providing for some exceptions to the protection provided by the Supplementary Protection Certificate. In particular, it has been possible to produce a generic – or biosimilar – version of a medicine protected by a certificate, during its period of validity, in the following cases:

- for the purpose of exporting to a non-EU market where the protection conferred by the certificate has expired or never existed;
- for the purpose of creating, in the six months preceding the expiry of the certificate, a stock intended to be marketed in the EU immediately after the expiry of the certificate.

9.4 Pharmaceutical or Medical Device Patent Infringement

The conducts subject to violation are identified, mainly, in the production, use, marketing, sale, import of the protected product/procedure, without the consent of the relative owner. The supply – or the offer to supply – to subjects other than the right-holders the means relating to an indispensable element of the invention, necessary for its implementation, also constitutes a patent infringement.

The owner of an industrial property right can request that the injunction be ordered for any imminent violation of their right and the continuation or repetition of the violations in progress and, in particular, can request the prohibition of manufacture, marketing and use of the things constituting a violation of the law, and the order to withdraw these activities from the market.

For the coverage offered by supplementary protection certificates (SPCs) and for the exemptions provided for by Regulation No 2019/933, see **9.3 Patent Term Extension for Pharmaceuticals**.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The main defensive exceptions that can be raised in the pharmaceutical and medical devices sector are based on the classification of the contested acts as:

- acts carried out in the private sphere and for non-commercial purposes;
- acts performed on an experimental basis relating to the subject of the patented invention;
- studies and trials aimed at obtaining, even in foreign countries, a marketing authorisation for a drug and the consequent practical requirements, including the preparation and use of the pharmacologically active raw materials strictly necessary for this purpose; and
- extemporaneous, and per unit, preparation of medicines in pharmacies upon medical prescription, and the medicines thus prepared, provided that industrially manufactured active ingredients are not used.

The legal system envisages the possibility of requesting compulsory licences for the non-exclusive use of the invention, but the conditions provided for the granting of such licences are extremely restrictive and stringent (eg, in the case of failed implementation of the invention, for dependent patents, or for health emergencies according to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)).

9.6 Proceedings for Patent Infringement

The actions that can be carried out by the owner of the right or its exclusive licensee include actions to ascertain a counterfeiting, a paternity and claim action, condemning actions upon the cessation of counterfeiting and compensation for damages, typical precautionary actions governed by the CPI (eg, injunction, description, seizure, etc), other precautionary actions contemplated by the CPC and, finally, executive actions.

For its part, the other party, in addition to explaining defences and exceptions, can challenge the validity of the patent by counterclaiming.

9.7 Procedures Available to a Generic Entrant

For the purposes of the marketing of generic medicines, no preventive judicial or extra-judicial actions are required. However, generic companies have the right to promote such actions to request, for example, the assessment of the invalidity of the title, or its forfeiture.

Without prejudice to data exclusivity (see **10.4 Data Exclusivity for Pharmaceuticals and Medical Devices**), according to the Italian legislation an application for an MA for a generic medicine cannot be rejected or deferred by the AIFA for reasons relating to patent coverage. Furthermore, the authorised equivalent medicinal product cannot be classified as a drug dispensed with costs borne by the NHS with effect prior to

the expiry date of the patent or the Complementary Protection Certificate (*Certificato Complementare di Protezione* – CCP), published by the Ministry of Economic Development.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting gives rise to criminal – as well as civil – liability, integrating the criminal offences envisaged by Article 473 of the Italian Criminal Code, punished with imprisonment from six months to four years and with a fine from EUR2,500 to EUR35,000.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The verification of the commercial name of a medicinal product falls within the competence of regulatory agencies only to the extent that its use could cause a safety or public health risk.

As regards the parallel import of medicines, the principles affirmed by EU and national jurisprudence provide that the medicine imported from abroad normally retains the trade name registered in the country of origin. The latter can be changed with a name coinciding with that with which the same drug is marketed in the country of destination only in the event that:

- there are regulations or practices in the country of destination that prevent the marketing of the product with the trade mark used in the country of origin; and
- the use of the designation of origin can create a confounding risk for public health.

Conversely, the change of destination is not permitted if the replacement of the trade mark is exclusively due to the desire, on the part of the parallel importer, to achieve a commercial advantage.

Article 7 of the new EU MDR also regulates the aspects in question for medical devices, prohibiting the use of texts, names, trade marks and signs that could mislead the user with regard to the destination, safety and performance of the device.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP Protection is potentially applicable to the graphic layout or design of pharmaceutical products to the extent that they meet the requirements of the legislation for the granting of such protection (eg, novelty, lawfulness, etc).

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to Article 10 of Legislative Decree No 219/2006, the simplified application for the registration of a generic medicinal product cannot be submitted before eight years have elapsed from the issue of the first Marketing Authorisation in Europe of the reference medicinal product ("data exclusivity"). Furthermore, the generic medicine thus authorised cannot be marketed before ten years have elapsed, again starting from the first MA of the reference medicine ("market protection"). If, in the first eight years, the reference medicine has obtained an extension of its therapeutic indications, the market protection period is increased by one year.

These protection regimes are calculated independently of patent protection, and can be opposed to the marketing and registration applications of generic, biosimilar and hybrid medicines, which are similarly based on the identifi-

cation of a reference medicine and on the use of the (protected) data which supported its marketing authorisation.

The same protection regimes can also be benefited from by the holders of Marketing Authorisations relating to medicinal products containing a fixed-dose combination.

There are no similar protection regimes for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The end of the national state of emergency, and most of the special and derogatory measures authorised under it, came on 31 March 2022.

That said, over the years 2020 and 2021, the emergency legislation has provided for numerous measures aimed at addressing the extraordinary needs deriving from the COVID-19 pandemic. Among these, for the purposes that are relevant here, the following are worth mentioning:

- VAT exemption or a reduced rate of 5% for a series of instruments and products used for the containment of the COVID-19 pandemic (eg, masks, lung ventilators for intensive care);
- the possibility of administering vaccines for SARS-CoV-2 in pharmacies open to the public;
- provisions to ensure the local availability of medical devices for oxygen therapy, also on an experimental basis, through the network of service pharmacies; and
- suspension of the ordinary rules (except for the general principles stated in Article 30) dictated by the code of public contracts for the award of contracts for works, services and supplies.

11.2 Special Measures Relating to Clinical Trials

In order to improve the ability to co-ordinate and analyse the available scientific evidence, the emergency legislation authorised the AIFA to access all the data from experimental and observational clinical studies and from compassionate therapeutic-use programmes activated for COVID-19 patients.

Furthermore, for the same purposes, the Ethics Committee of the National Institute for Infectious Diseases (*Lazzaro Spallanzani*) was identified as the single national body in charge of the evaluation of clinical trials, observational studies and programmes of compassionate therapeutic use of medicines for COVID-19 patients.

Finally, the AIFA was entrusted with the task of publishing a simplified procedure for the acquisition of clinical trial applications and for the modalities of enrolment in the studies.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Article 15 of Legislative Decree No 18/2020 provides for an exceptional authorisation procedure for the production of surgical masks and PPE. Based on this procedure, manufacturers who intend to make use of this derogation send the surgical masks and PPE to the ISS and the *Istituto nazionale Assicurazione Infortuni sul Lavoro* (INAIL), respectively, self-certifying that they comply with the safety requirements established by current legislation. Within three days, the ISS and the INAIL release their decisions,

based on the self-certification and the technical documentation received from the manufacturer. From June 2021, the extraordinary authorisation procedure ceased. The certificates issued on the basis of the aforementioned procedures in any case remained valid until the end of the state of emergency, on 31 March 2022.

As regards the approval of medicinal products, the applicable legislation already provided for the possibility of granting MAs subject to specific obligations in exceptional circumstances ("conditional MA"). This procedure was actually followed by the EMA for the purpose of issuing the MAs of the currently available COVID-19 vaccines.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

In order to reduce travel and access to GPs' offices, the legislation adopted for the emergency period has extended the terms of validity of the restrictive prescriptions of class A drugs. In addition, the duration of the therapeutic plans that include the provision of aids, disposable devices and other prosthetic devices and that expire during the state of emergency was automatically extended.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In order to address any shortage of medicines, the AIFA authorised the import of foreign packs of medicines for the supplies to the NHS structures.

Furthermore, Article 66-bis of Legislative Decree No 34/2020 introduced provisions on the simplification of the procedures for the import and validation of surgical masks and PPE.

11.6 Drivers for Digital Health Innovation Due to COVID-19

See 8.2 Rules for Telemedicine.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Article 56-quater of the Decree-law 31 May 2021, No 77, has inserted a new provision in the industrial property code entitled "compulsory licence in case of national emergency". Under that provision, just in case of the declaration of a national state of emergency motivated by health reasons, to cope with proven difficulties in procuring specific medicines or medical devices deemed essential, may be granted, in compliance with international and European obligations, compulsory licences for non-exclusive, non-transferable and predominantly direct use to the supply of the internal market, of patents relevant for production purposes, which have validity bound to the continuation of the emergency period or up to a maximum of twelve months from the termination of that emergency period.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Article 3-bis of the Decree-law No 44/2021, converted, with modifications, by Law No 71/2021, introduced a provision which limits the punishment, by way of manslaughter or negligent personal injury, for acts committed in the exercise of a health profession during the epidemiological state of emergency since COVID-19. On the basis of paragraph 1 of the provision, the aforementioned crimes become punishable only in cases of gross negligence. Furthermore, the following paragraph 2 provides that, for the purposes of assessing the degree of the fault, the judge takes into account, among the factors that can exclude its severity, of the limited scientific knowledge on the pathologies deriving from the SARS-CoV-2 infection, as well as the scarcity

of human and material resources concretely available, and in addition to the lower degree of experience and technical knowledge possessed by unskilled personnel, employed to deal with the emergency.

For people damaged by the anti-SARS-CoV-2 vaccine, the Decree-law No 4 of 2022 authorised the payment by the State of the indemnities established, for the other vaccines, by the current legislation.

11.9 Requisition or Conversion of Manufacturing Sites

Article 5 of Legislative Decree No 18/2020 assigned to the extraordinary Commissioner for the management of the emergency the task of providing incentives (also non-repayable) for EUR50 million in order to support projects for the expansion or conversion of activities aimed at the production of medical devices and PPE.

The subsequent Article 6 of Legislative Decree No 18/2020 attributed to the Head of the Civil Protection Department the power to dispose, with his or her own decree, the requisition in use or ownership, from any public or private entity, of health and medical-surgical facilities, as well as movable property of any kind, necessary to deal with the aforementioned health emergency. For the owners of the assets acquired, the law provided for the recognition of a requisition indemnity calculated according to the market value of the assets as of 31 December 2019.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The emergency regulation authorised the extraordinary Commissioner to purchase PPE and other medical devices in derogation from the procurement code, also through advance payments of the entire supply.

Furthermore, with the Law Decree No 76/2020, a series of provisions of a temporary nature were introduced, aimed at achieving – pending the emergency – a simplification of the procedures regarding public contracts.

JAPAN

Law and Practice

Contributed by:
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Nagashima Ohno & Tsunematsu

Contents

Nagashima Ohno & Tsunematsu is widely regarded and recognised as one of Japan's leading international law firms, specialising in all aspects of business and commercial law. The firm represents domestic and foreign clients involved in every major industry sector, including many of the largest and most influential companies, funds and organisations in Japan. The firm has structured and negotiated many of Japan's largest and most significant corporate and finance transactions, and has extensive expertise across all of its practice areas. The pharmaceutical and healthcare team is based in the Tokyo office and consists of more than 14 lawyers, including seven partners. Key areas of the firm's practice relating to the life sciences sector include pharmaceutical and healthcare, risk and crisis management/compliance, corporate/M&A, data protection and privacy, IP, antitrust/competition, consumer law (consumer litigation), dispute resolution, and labour and employment.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceuticals Law"), together with related cabinet and ministerial orders, is the primary law that governs pharmaceuticals and medical devices.

The Ministry of Health, Labour and Welfare (MHLW) is the principal regulatory body for pharmaceuticals and medical devices. The MHLW is the national governmental body that issues most of the Pharmaceuticals Law-related ministerial orders and administrative guidelines and drafts relevant cabinet orders. Prefectural governments (ie, independent local governments such as the Tokyo Metropolitan Government) are primarily responsible for monitoring pharmaceutical and medical device marketers, manufacturers and distributors in their respective jurisdictions on behalf of the MHLW. The Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese independent administrative agency that receives financial support from the Japanese government to cover its operational costs, also plays a key role in reviewing marketing authorisation applications for new pharmaceutical and medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

If a pharmaceutical or medical device firm violates the Pharmaceuticals Law or any related regulation, the MHLW or a prefectural government may issue an administrative order to that firm. The recipient may challenge the administrative order through an administrative complaint review process provided under the Administrative Complaint Review Act. A pharmaceutical or medical device firm served with an administrative order may also commence a legal action for the revocation of the administrative order with a competent court in accordance with the Administrative Case Litigation Act. These challenge procedures are also generally applicable in cases involving issuance of administrative orders for violations of laws concerning other regulated products (eg, certain food products).

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into two classes: prescription pharmaceuticals and OTC pharmaceuticals. Prescription pharmaceuticals may only be used by doctors or used in accordance with a doctor's prescription. OTC pharmaceuticals can be purchased at drug stores or other non-licensed stores. OTC pharmaceuticals are further classified into several sub-categories and, depending on the relevant sub-category, may have certain sales restrictions – for example, a requirement that they be sold only at establishments at which a pharmacist (or other designated licensed personnel) is present.

Medical devices are categorised into three classes:

- specially controlled medical devices (classes III and IV of the Global Harmonisation Task Force (GHTF) international classification structure);
- controlled medical devices (class II of the same); and
- ordinary medical devices (class I of the same).

Depending on the relevant class of medical devices, a marketer and a distributor will need to obtain different business licences, as appropriate.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The Pharmaceuticals Law, together with the Good Clinical Practice (GCP) ministerial order issued by the MHLW, is the principal law regulating clinical trials. The MHLW and the PMDA are the main regulatory authorities that oversee clinical trials.

Japan requires all drugs to be tested through clinical trials and approved for marketing in Japan. Even new drugs that have undergone clinical trials and received marketing approval in foreign jurisdictions are required to undergo separate clinical trials in Japan in order to verify such drug's effectiveness and safety when given to Japanese individuals. Even for COVID-19 vaccines supplied to Japan, the Japanese government required that a limited number of separate clinical trials be performed in Japan based on this policy.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, an applicant (a pharmaceutical or medical device marketer) must prepare a protocol and receive approval for such protocol from an institutional review board (IRB). The applicant is also required to register the protocol with the MHLW through the PMDA. In practice, the applicant consults with the PMDA informally about its draft protocol before formally registering the protocol with the MHLW.

2.3 Public Availability of the Conduct of a Clinical Trial

The website of the National Institute of Public Health discloses certain basic information regarding clinical trials conducted in Japan, including:

- the title of the study;
- the subject material of the study;
- a brief summary of the study;
- information about the monetary sponsor, the relevant IRB, and other relevant organisations;
- contact information for the relevant parties; and
- a summary of the results.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is no apparent prohibition on using online tools to support clinical trials. However, clinical trials are generally required to be conducted by doctors or hospitals and include in-person interviews with – and written informed consents from – clinical trial subjects. Recruiting clinical trial subjects can be conducted online. That being said, under a guideline from the MHLW, only limited information may be received via online communications and additional information must be obtained through a process involving in-person interviews and written informed consents.

2.5 Use of Data Resulting From the Clinical Trials

Raw data obtained from clinical trials is considered to be sensitive data of the clinical trial subjects. Therefore, clinical trial data obtained by a doctor or hospitals (investigators) is usually compiled or converted into a form that prevents the identities of clinical trial subjects from being discoverable and only such anonymised information or data is provided to the sponsor of the clinical trial. Further, upon commencement of a clinical trial, investigators must obtain an executed informed consent letter from each trial subject regarding the use and treatment of such subject's sensitive personal data.

2.6 Databases Containing Personal or Sensitive Data

As mentioned in **2.5 Use of Data Resulting From the Clinical Trials**, it is common practice for resulting data to be anonymised and in such form the data is not regulated as strictly as sensitive data. Disclosure of original, non-anonymised data (raw data) is heavily regulated as sensitive information under the Act on the Protection of Personal Information (APPI).

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The term "pharmaceutical" is defined under the Pharmaceutical Law as:

- items listed in the Japanese Pharmacopoeia;
- items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals; or
- items that are intended to affect the structure and functioning of a human or animal's body.

However, quasi-pharmaceutical products and cosmetics are excluded from the definition of pharmaceutical.

The term "medical device" is defined under the Pharmaceutical Law as appliances, instruments or similar items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals – or intended to affect the structure or functioning of the bodies of humans or animals – and that are specified by cabinet order.

The relevant cabinet order specifying medical devices is so broadly worded that almost all medical appliances, instruments or similar items can be interpreted as being covered by it and thereby classified as a medical device. Software that is intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals can also be classified as a medical device.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market a pharmaceutical or a medical device, the initial marketer is required to obtain marketing authorisation. Key factors that are taken into account when reviewing an application for marketing authorisation or marketing certification are:

- the quality, effectiveness and safety of the pharmaceutical or medical device;
- the applicant's marketing business licence;
- the manufacturer's manufacturing business licence; and
- the manufacturer's compliance with the good manufacturing practice (GMP) regulation.

To obtain marketing authorisation for a biological pharmaceutical, certain additional requirements must be fulfilled, such as:

- a manufacturer of a biological pharmaceutical must comply with more stringent management and safety requirements; and
- packaging/packaging inserts of a biological pharmaceutical must indicate that it is a biological product.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The period of validity of a marketing authorisation is not indefinite. Depending on the type of medical product, an authorisation for a new pharmaceutical is generally subject to re-examination four to ten years after the initial authorisation. Additionally, the MHLW occasionally conducts a re-evaluation of pharmaceuticals based on the recommendation of its advisory board.

A marketing authorisation can be revoked by the MHLW and other competent authorities. A marketing authorisation can be revoked when, for example, it is found that:

- the relevant pharmaceutical does not have the efficacy or produce the effects indicated in the application; or
- the relevant pharmaceutical has no value because the harmful effects associated with such product outweigh the efficacy or beneficial effects.

Additionally, a marketing authorisation can be revoked if the responsible party has not marketed the relevant authorised pharmaceutical or medical device for three consecutive years without any reasonable justification. The MHLW may vary parts of a marketing authorisation for pharmaceuticals and medical devices if, in the MHLW's view, it is necessary to do so in light of health or hygiene considerations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

An application for marketing authorisation must be submitted to the MHLW or – in the case of certain pharmaceuticals and all medical devices (other than medical devices with a GHTF classification of class IV) – to the relevant prefectural government or a particular registered certification body. With regard to an application for a pharmaceutical or medical device that must be submitted to the MHLW, the application must be submitted through the PMDA. The MHLW's review of applications for marketing authorisation for new medicinal products is substantially outsourced to the PMDA. Once the PMDA is satisfied with the application, the application is forwarded to the MHLW, which then obtains a recommendation from the Council of Pharmaceutical and Food Sanitation before approving the application.

A marketing authorisation application must include, as an attachment, data concerning the results of clinical trials and other pertinent data – except where the application is for a medicine that is subject to a conditional early approval for market authorisation (an expedited process).

Variation of a marketing authorisation – such as a change in the therapeutic indication, formulation, posology, patient population, packaging or labelling – requires the marketing authorisation holder to complete a formal process. Depending on the materiality of the change, a variation may require approval from the relevant authority or the mere submission of a report.

It is permissible for market authorisation to be transferred from the current marketing authorisation holder to a transferee. A transferee of a marketing authorisation must notify the relevant authority of the transfer at least one month prior to the date of transfer.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The Pharmaceuticals Law provides for an exceptional procedure to allow the importation of a pharmaceutical or medical device that has received a foreign marketing authorisation for compassionate use if:

- the foreign marketing authorisation was obtained in a country with a marketing authorisation system equivalent to the system in Japan;
- immediate use of the pharmaceutical or medical device is necessary to prevent a pandemic spread of a disease that can cause death or serious harm to the health of Japanese citizens; and
- the pharmaceutical or medical device is specifically designated under an administrative order.

This special procedure was once used to import a flu vaccine produced by a foreign manufacturer. It is also used for vaccines and therapeutic drugs for COVID-19 that are produced by foreign manufacturers and supplied for use in Japan.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

After the marketing of a pharmaceutical or a medical device commences, the marketing authorisation holder is required to conduct post-marketing pharmacovigilance and technovigilance. If any issue relating to the effectiveness or safety of the marketed pharmaceutical or medical device is discovered during the post-marketing authorisation surveillance period, the marketer must conduct a pharmaceutical or medical device recall campaign, report the discovery to the PMDA, issue public notices, and take other appropriate measures to prevent patients suffering further damage or losses.

An applicant for a marketing authorisation typically must complete all clinical trials first and then submit its application with complete accompanying data. However, in the case of conditional early approval for market authorisation for an innovative product exempted for a part of its clinical trials, post-marketing phase IV clinical trials must be performed.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

In general, third parties can access information about applications for marketing authorisations by making a request under Japan's information

disclosure law. Under the Act on Access to Information Held by Administrative Organs, anyone may request the disclosure of administrative documents held by an administrative organ.

Under this law, the MHLW is essentially required to disclose an application for marketing authorisation if properly requested. However, the application may include or refer to the IP or confidential information of an applicant, and the disclosure of such information to a third party may result in serious damage to an applicant's rights and competitiveness. Therefore, disclosure of an application is usually made after the relevant sensitive information contained has been redacted or masked.

3.8 Rules Against Illegal Medicines and/or Medical Devices

To market a pharmaceutical or a medical device, the initial marketing entity must obtain marketing authorisation for the pharmaceutical or medical device under the relevant regulation. Falsification or illegal distribution of pharmaceuticals or medical devices (including distribution by a party without first having obtained marketing authorisation) are violations of this regulation. The MHLW may order the responsible party to recall all such falsified or illegal products from the market, impose administrative sanctions against such responsible party, and even refer the violation to the public prosecutor for investigation and potential prosecution for criminal sanctions.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

With regard to counterfeit pharmaceuticals and medical devices, the owner of an infringed patent or other IP right can file an application for an importation suspension of counterfeit products with the Japanese customs authorities. The IP rights-holder may also file an application for an import ban or provisional disposition order or file a lawsuit with a court in Japan seeking similar relief.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

A manufacturing business licence is required in order to manufacture pharmaceuticals in Japan. If a manufacturer of an imported product is located outside Japan, said manufacturer will be required to obtain accreditation as a foreign manufacturer. A manufacturing business licence is granted by the relevant prefectural government and such accreditation is granted by the MHLW. Once an application for a manufacturing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's manufacturing premises. The period of validity of a manufacturing business licence and an accreditation is five years.

Unlike pharmaceutical manufacturers, a medical device manufacturer – whether located in Japan or outside Japan – is only required to satisfy a prior registration (ie, registration with the MHLW as a medical device manufacturer). The registration must be renewed every five years.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

In order to market pharmaceuticals or medical devices, the initial marketing entity must hold a marketing business licence and have a marketing authorisation for each of the relevant products. A marketing business licence is granted by the relevant prefectural government. Once an application for a marketing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's office or factory.

Marketing business licences are generally valid for five years; however, the actual validity period will depend on – among other things – the type of pharmaceutical or medical device to be distributed by the applicant. Wholesalers and retailers of pharmaceuticals and medical devices are required to obtain a distribution business licence.

5.2 Different Classifications Applicable to Pharmaceuticals

There are two types of marketing business licences for pharmaceuticals: Type 1 and Type 2. Type 1 marketing business licence is required for marketing prescription pharmaceuticals. Type 2 marketing business licence is required for marketing other pharmaceuticals (ie, non-prescription ethical pharmaceuticals and OTC pharmaceuticals).

There are three types of marketing business licences for medical devices:

- Type 1 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class III or IV;
- Type 2 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class II; and
- Type 3 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class I.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The Pharmaceutical Law governs the import and export of pharmaceuticals and medical devices. Imports of pharmaceuticals and medical devices from outside Japan are, in principle, subject to the same marketing regulations applicable to products manufactured in Japan. Importers of these products are subject to requirements regarding marketing authorisation, marketing business licences and accreditation as a foreign manufacturer.

A manufacturing business licence is required for the manufacture of pharmaceuticals or medical devices that are to be exported from Japan. Although marketing authorisation is not necessary, a separate registration for manufacturing of pharmaceuticals or medical devices for export is required.

The relevant prefectural government regulates marketing business licences, whereas the MHLW regulates accreditations for foreign manufacturers.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of pharmaceuticals or medical devices must obtain a marketing business licence, except in the case of the importation of small amounts of these products by an individual for its personal use. An importer must present certificates of the marketing business licence and the marketing authorisation for each particular imported product to the relevant customs house.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importation of pharmaceuticals or medical devices is not permitted unless the importer of record possesses a marketing business licence and a marketing authorisation for each particular imported product – except where small amounts of these products are imported by an individual for their personal use. As regards permitted exceptions in the case of emergency situations, see **3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations**.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In addition to obtaining a marketing business licence and marketing authorisation, it may be necessary to change the product's packaging to conform to product description information and requirements provided under the relevant marketing authorisation when importing pharmaceuticals or medical devices. By way of an example, packaging and product labelling – and the explanatory written material provided with the products (such explanatory information is usually available online) – must be provided in Japanese and satisfy the requirements under the relevant marketing authorisation. Changing a product's packaging is considered part of the manufacturing of the product and, as such, the entity responsible for performing such changes is required to possess a manufacturing business licence.

6.5 Trade Blocs and Free Trade Agreements

As of February 2022, Japan has signed 21 Economic Partnership Agreements/Free Trade Agreements with other countries. Among others, Japan is a signatory to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP) and the Regional Comprehensive Economic Partnership (RCEP).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Prices for the majority of medical services provided and prescription pharmaceuticals sold in Japan are reimbursed by the Japanese universal healthcare system, and the substantial majority of legal residents of Japan participate in and are covered by Japan's national health insurance system. The cost of prescription pharmaceuticals to be paid through the national health insurance system corresponds to the prices for the relevant pharmaceuticals listed on the drug tariff.

Listing of a prescription pharmaceutical's price on the drug tariff is based on the Health Insurance Act and is a separate procedure from the marketing authorisation procedure provided under the Pharmaceuticals Law. The profit margin of the wholesalers, the hospitals and the pharmacies is usually the difference between the prices at which the pharmaceuticals are purchased by hospitals (such price is usually lower than the price listed on the drug tariff) and the prices at

which the products are sold by the marketer of the prescription pharmaceuticals.

7.2 Price Levels of Pharmaceutical or Medical Devices

The listing of pharmaceuticals on the drug tariff – and the price designated for each of the pharmaceuticals listed – are determined by the MHLW after reviewing the applications submitted by the market authorisation holders of such pharmaceuticals. The price of the same product in other countries is one element of background information considered when determining the listing price. The drug tariff is reviewed and updated every year.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical treatments is covered by the health insurance scheme. For the majority of Japanese residents, 70% of these costs are covered by health insurance.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The MHLW considers cost-benefit analysis as a key factor when evaluating new pharmaceuticals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Historically, Japanese hospitals prescribed and dispensed pharmaceuticals themselves. However, in an effort to address excessive pharmaceutical-related spending, the MHLW began incentivising hospitals to separate prescription and dispensing of pharmaceuticals functions so that they do not prescribe pharmaceuticals unnecessarily.

8. Digital Healthcare

8.1 Rules for Medical Apps

The parts of software in medical hardware devices used for data processing are categorised as medical devices. Depending on its function, purpose, data-processing results and other factors, an application software (or relevant parts thereof) designed to run on a smartphone, tablet or other similar device may be categorised as a medical device if it is intended for use in the diagnosis, treatment or prevention of disease in humans.

8.2 Rules for Telemedicine

As a general principle, the law essentially requires medical diagnosis to be performed by a physician through a face-to-face consultation with a patient. However, a guideline issued by the MHLW provides guidance on the permissible scope of telemedicine services and legitimises the provision of such services in cases where conducting a face-to-face consultation would be practically difficult or where such services are to be provided for a patient with a chronic – yet stable – condition.

Pursuant to an amendment of the MHLW guideline in January 2022, it is generally required that physicians using telemedicine for initial consultations with the patient are primary care physicians who are familiar with the subject patient. However, owing to the COVID-19 pandemic, this requirement has been relaxed temporarily and currently physicians may generally use telemedicine from the initial consultation.

8.3 Promoting and/or Advertising on an Online Platform

Regulations addressing the promotion or advertising of pharmaceuticals and medical devices apply equally to online promotion and advertising (eg, through online portals, company web

pages and social networking websites). An advertiser's web page containing hyperlinks to other web pages may be considered collectively as a single advertisement and, as a whole, may violate regulations concerning advertisements – even if each web page on its own would not violate these regulations.

8.4 Electronic Prescriptions

The MHLW has issued a guideline addressing electronic prescriptions, which emphasises the merits of electronic prescriptions. The issuance of electronic prescriptions through email is prohibited, given the risks associated with transmission of information electronically – for example, unintentional information disclosures or unlawful theft of information. The MHLW promotes the use of electronic prescriptions through an online management system administered by the national health insurance payer, which commenced operations in January 2023.

8.5 Online Sales of Medicines and Medical Devices

Almost all OTC pharmaceutical products are marketable online, with the exception of certain potent pharmaceuticals and OTC pharmaceuticals that were formerly classified as ethical pharmaceuticals (a classification that typically requires a prescription for products to be obtained).

8.6 Electronic Health Records

The use of electronic health records is an accepted practice in Japan and almost all large hospitals have adopted the use of electronic health records, with smaller hospitals following their lead. Health-related information generally falls within the scope of "sensitive data" as defined under the APPI and is subject to stricter regulations. A person will, in principle, not be allowed to obtain sensitive data concerning an individual unless the subject individual's consent has been obtained.

The APPI requires appropriate security measures to be implemented for the handling of personal data. A specific guideline has been published regarding:

- the use of cloud platforms in relation to medical data; and
- the security measures to be implemented for the protection of medical data stored on such cloud platforms.

The transferring and storing of sensitive data of patients in cloud platforms is generally not prohibited, provided the relevant cloud platform meets and complies with the various requirements set out in the specific guideline.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Patent Act is the primary law that applies to patents. The Patent Act allows for patent term extensions for pharmaceutical patents and, as a result, commonly encountered issues include:

- whether or not a pharmaceutical patent qualifies for a patent term extension; and
- the extent to which protections under the Patent Act continue to apply in the case of a patent term extension.

As regards the issuance of patents, there are no requirements that relate specifically or exclusively to pharmaceuticals or medical devices.

9.2 Second and Subsequent Medical Uses

The novelty of a pharmaceutical invention (a requirement for a patent to be granted for such invention) is generally judged based on the following two points:

- a compound having a specific attribute; and
- a medicinal use based on such attribute.

Accordingly, second and subsequent medical uses of a known pharmaceutical product can be granted patents if the relevant usage is considered novel and other relevant conditions and requirements are satisfied.

In this respect, medicinal use includes new dosage regimes and new or selected patient populations and therefore can be patented if considered novel. Second and subsequent patents of pharmaceutical products can be infringed if the patented invention is exploited by a third party without authorisation during the term of the patent – for example, if a patented product is sold for the patented use without authorisation from the relevant patent holder.

9.3 Patent Term Extension for Pharmaceuticals

For patented pharmaceuticals, the term of the patent can be extended upon request by the patent holder to the Japan Patent Office and fulfilment of relevant procedures. The term of the extension, which cannot exceed five years, is generally equivalent to the period of time during which the patent holder was prevented from exploiting the invention while awaiting medicinal product approval in accordance with the Pharmaceuticals Law. Patent term extensions can be challenged by third parties – for example, a third party may commence a legal proceeding with the relevant court seeking invalidation of a patent term extension registration.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement of a registered pharmaceutical or medical device patent occurs when a person exploits the patented invention during the term of the patent without the patent holder's permission. This includes, for example, the unauthorised production, usage, sale, import or export of a patented product. The Patent Act provides for injunctive relief as a remedy that can be sought where there is an imminent threat of infringement, as opposed to the occurrence of actual infringement. In order for injunctive relief to be granted by a court, the threat of infringement must be present from an objective standpoint.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Protections established by a patent do not restrict exploitation of the patented invention for experimental or research purposes. Accordingly, experimental use can be asserted as a defence to a claim of patent infringement in relation to pharmaceuticals and medical devices. The Patent Act provides for the granting of compulsory licences to patents in certain situations, including – but not limited to – patents for pharmaceutical products and medical devices. A compulsory licence can be granted by the Commissioner of the Japan Patent Office in prescribed cases, such as where a patented invention has not been exploited in Japan for three years.

9.6 Proceedings for Patent Infringement

If a patent is infringed or there is a present threat of infringement, the patent holder can seek injunctive relief through a civil court proceeding to force the infringing party to cease and desist

and to destroy infringing articles. The patent holder can also assert a monetary compensation claim in a civil court proceeding against the infringing party for damages that it incurred from the infringement.

The Patent Act includes special provisions intended to facilitate a patent holder's recovery of damages incurred by the infringement of its patent. By way of an example, under the Patent Act, a person who infringes a patent is presumed to have acted negligently in relation to the infringement. This presumption shifts the burden of proof from the patent holder to the infringing party; therefore, in order for the infringing party to prevail, it must prove that there was no negligence on its part in relation to the infringement. Invalidity of the subject patent is an available defence and can be asserted in a patent infringement litigation.

9.7 Procedures Available to a Generic Entrant

In order for the producer of a potential generic entrant to establish that the action it proposes to take is lawful under patent law, it may initiate litigation against the patent holder of the relevant brand-name pharmaceutical in order to obtain a court decision confirming the non-existence of a patent infringement claim based on the generic market entry. Obtaining a court order through this type of lawsuit is not a requirement for generic market entry under the Japanese pharmaceutical regulations. It is generally considered that the existence of a potential patent infringement claim is taken into account when undergoing the marketing authorisation examination procedure.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The Pharmaceuticals Law prohibits the sale of counterfeit drugs and medical devices. As such, violators will be subject to criminal penalties. In addition, counterfeit drugs and medical devices may infringe registered trade marks and possibly registered patents. Further, the import and export of IP-infringing goods may be illegal, and violators will be subject to criminal penalties. Criminal investigations of possible violations are typically conducted by the police. The import and export of infringing goods is policed by the Japanese customs authorities.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There are no specific restrictions on the trade marks that can be used for pharmaceuticals or medical devices under the Trade Mark Act. In general, a medicinal product brand can be registered as a trade mark. There are a number of excluded categories of marks that cannot be granted trade mark rights or protections, such as a sign that:

- is the same as, or similar to, a national flag;
- is deceptive or contrary to public policy; or
- is not legally distinguishable from:
  - (a) signs or marks used to identify widely recognised brands; or
  - (b) other trade marks that were filed earlier.

The owner of an infringed IP right, including a trade mark owner, can seek to suspend the import or export of counterfeits that infringe its IP right by filing an application for suspension with the Japanese customs authorities.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for trade dress and designs of pharmaceuticals and medical devices, as well as their packaging. Trade dress and designs can be registered and protected as trade marks under the Trade Mark Act. The Trade Mark Act stipulates a number of legal criteria to be met in order to register a trade mark, including the requirement that the relevant mark or sign is capable of distinguishing the subject goods or services from those of other manufacturers or merchants or service providers.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

There is no data exclusivity available under Japanese law for pharmaceuticals and/or medical devices. An abridged procedure for obtaining marketing authorisation for generic drugs is not available until the re-examination period for the original drug has expired. This effectively operates as a time barrier that prevents a generic drug product from receiving marketing approval until such re-examination period for the original drug has expired. The same re-examination period rules apply for chemical drugs and biologics.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The MHLW has announced that it will prioritise the review of marketing authorisation applications for medicines and medical devices to be used for the treatment of COVID-19. The MHLW will also consider measures to streamline the process by reducing and facilitating the preparation of application materials for such medicines and medical devices. Amendments were made to relevant Japanese rules in order to broadly abolish various regulatory filing requirements that mandated submission of documents in hard copy with the company seal affixed thereto.

11.2 Special Measures Relating to Clinical Trials

The MHLW has issued a guidance addressing various special measures that can be taken in relation to clinical trials in light of the COVID-19 pandemic. The MHLW guidance sets out criteria to allow for, among other things, delivery of the test drug to the test subject's residence by mail, alternatives to in-person institutional review board meetings, alternatives to on-site trial monitoring, and use of telemedicine in clinical trials.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The Pharmaceuticals Law provides for a special emergency approval process whereby the MHLW may grant exceptional approval for pharmaceuticals and medical devices developed to address an urgent need relating to the prevention of the spread of disease or other health hazards that may pose a serious threat to the lives and health of the general public, where no suitable alternative is available other than the use of such pharmaceuticals/medical devices. In order to be granted this exceptional approval, the pharmaceuticals/medical devices must either:

- be presumed to have the efficacy or effects indicated in the application (and not be presumed to have no value as pharmaceutical/medical device products, owing to harmful effects that outweigh their efficacy or effects); or
- be authorised to be marketed in a foreign country (provided the foregoing is limited to foreign countries with a marketing approval

system recognised by the MHLW as being substantially equivalent to Japan's marketing approval system in terms of assessing the quality, efficacy, and safety of the pharmaceuticals/medical devices).

The MHLW has granted marketing authorisation through the exceptional emergency approval process for Remdesivir, a medication that may be used in the treatment of the COVID-19.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

During the COVID-19 pandemic, various regulatory filing and inspection processes relating to manufacturing business licences for pharmaceuticals and medical devices were revised to allow for electronic processing. Additionally, amendments were made to relevant Japanese rules in order to broadly abolish various regulatory filing requirements that mandated submission of documents in hard copy with the company seal affixed thereto.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In March 2020, the MHLW announced that it would permit companies to import disinfectant products produced outside Japan for use within their companies to protect employees from COVID-19. This announcement was made as a measure to:

- address the significant increase in demand for disinfectants due to the COVID-19 pandemic; and
- allow Japanese companies to procure, from outside Japan, supplies of disinfectant products necessary for the continuation of their business operations.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The MHLW has taken measures to facilitate the use of telemedicine services in Japan during the COVID-19 pandemic. As mentioned in **8.2 Rules for Telemedicine**, initial consultations between physicians and patients were generally not permitted to be conducted online prior to the pandemic. However, this prohibition has been temporarily suspended and telemedicine services are broadly permitted from the initial consultation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Patent Act allows for compulsory licensing in cases where the implementation of a patented invention is especially necessary for the public interest. In such cases, a person may request the patentee to participate in consultations concerning the granting of a non-exclusive licence to use the patented invention and may further request the Minister of Economy, Trade and Industry for an order compulsorily granting a non-exclusive licence to use the invention for a specified purpose. There have been discussions on whether compulsory licences under the Patent Act should be granted to ensure a stable supply of products used for COVID-19 treatments; however, no such compulsory licence has been granted thus far.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

In December 2020, the Japanese government enacted an amendment to the Immunisation Act, thereby allowing the Japanese government to enter into contracts with vaccine manufacturers and agree to indemnify the manufacturers for losses incurred from compensating victims who sustain harm to their health after receiving the manufacturer's COVID-19 vaccine in Japan.

Based on this provision, the Japanese government has reportedly been negotiating indemnification agreements with pharmaceutical companies that are to supply their COVID-19 vaccines to Japan.

Despite the measures put in place by the government concerning compensation to vaccine recipients who sustain health-related harm and pharmaceutical company indemnification for damages attributable to the COVID-19 vaccinations in Japan, Japanese law does not grant immunity to the pharmaceutical companies supplying the COVID-19 vaccines. Consequently, vaccine recipients are not precluded from asserting claims directly against these pharmaceutical companies for damages attributable to harm their health suffered from the vaccine.

11.9 Requisition or Conversion of Manufacturing Sites

In the event that the Japanese government declares a state of emergency in response to COVID-19, the Japanese government can designate individual manufacturers of pharmaceuticals and medical devices and require the designated manufacturers to take necessary measures to ensure continued manufacturing and sales of specified pharmaceuticals and medical devices. It is generally considered that the measures contemplated to be taken by the designated manufacturers would typically include measures necessary for ensuring the prevention of COVID-19 infection and the sufficient supply of pharmaceuticals and medical devices for COVID-19 treatment. The Japanese government declared a state of emergency from April to May 2020, from January to March 2021, and April to September 2021, respectively.

Pursuant to an amendment that is scheduled to take effect in April 2023, the Japanese government will be able to request that manufacturers promote and co-operate with the manufacturing of pharmaceuticals and medical devices if there is a shortage of product that may cause difficulty in preventing the spread of infectious disease and materially affect the lives and health of the Japanese people.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

As is the case in other countries, the Japanese government has actively sought to procure stocks of COVID-19 vaccines from various vaccine-producing pharmaceutical companies so that administration of vaccines can be implemented in Japan. According to press reports, the Japanese government has entered into agreements with Moderna and Takeda Pharmaceutical, as well as with AstraZeneca and Pfizer, for the procurement of COVID-19 vaccines.

Trends and Developments

Contributed by:
Junichi Kondo and Marina Asai
Anderson Mori & Tomotsune

Anderson Mori & Tomotsune is a large international Japanese law firm. The firm is known for its long history of advising overseas companies doing business in Japan and in cross-border transactions. The main office in Tokyo is supported by offices across Japan, China and the Southeast Asian region. Anderson Mori & Tomotsune has considerable experience in matters relating to the life sciences field, including expertise in licensing, regulatory, IP and corporate transactions such as M&A and venture investments. The firm works with increasingly diversified international and Japanese-based healthcare companies, including pharmaceutical manufacturers, medical device manufacturers, distributors and e-health providers. The team, which consists of about ten partners and 20 associates, provides comprehensive advice from set-up of a Japanese entity to all stages of the product lifecycle and helps clients to navigate a broad range of regulatory matters.

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Development of Software as Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceuticals Law") requires a marketer intending to sell a medical device in Japan to obtain authorisation or certification from – or provide notification to – the relevant governmental authority with regard to the medical device. The marketer's obligation to communicate with the authority depends on the statutory classification of the medical device, which is determined based on the risk to the human body in the event of the device's malfunction (Article 23-2-5, Section 1; Article 23-2-12, Section 1; and Article 23-2-23, Section 1 of the Pharmaceuticals Law).

Article 2, Section 4 of the Pharmaceuticals Law defines "medical devices" as devices intended either:

- to be used for the diagnosis, treatment or prevention of human diseases; or
- to affect the structure or function of the human body.

Only devices listed in Appended Table 1 of the Ordinance for Enforcement of the Pharmaceuticals Law (the "Enforcement Ordinance") are regarded as medical devices.

Classification of software as medical devices

In 2014, software for diagnosis, software for treatment and software for prevention of diseases were added to the Enforcement Ordinance. Prior to that time, software was authorised, certified or registered as part of the medical device in which it was installed. However, the addition of software to the Enforcement Ordinance enables computer software to be authorised, certified or registered independently from a medical device.

The Enforcement Ordinance explicitly excludes computer software that has almost no risk of affecting human life and health from the definition of medical devices. Additionally, the Ministry of Health, Labour and Welfare (MHLW) established a guideline that provides the following criteria in order to determine whether software constitutes a medical device:

- whether the software has an impact on the treatment and diagnosis of a disease, depending on the significance of the results obtained by the software; and

- whether there is a risk of negatively impacting an individual's life and health if the software malfunctions.

Since 2014, software has been authorised as a medical device in some cases. However, in each of those cases, the software was designed to function together with a hardware medical device. Two types of software have generally been recognised as medical devices:

- software to record, transmit, modify, or analyse the data obtained by a hardware medical device (eg, software to analyse and edit the image obtained by CT); and
- software to control and operate a hardware medical device.

However, Japanese law does not further define medical devices. Owing to the ambiguity of the term's definition, the question of whether other types of software – especially software operating on general-purpose devices such as smartphones and wearable devices – would also be regulated as medical devices is unsettled.

Regulation and marketing of software as medical devices

In November 2020, the MHLW announced a strategy to promote innovation in and expansion of the usage of software as medical devices, entitled "Digital Transformation Action Strategies in Healthcare for Software as Medical Devices" (DASH for SaMD). Under the DASH for SaMD, the MHLW established departments in both the MHLW and the Pharmaceuticals and Medical Devices Agency for handling cases concerning software as medical devices. It also began to provide consulting services for those who are considering developing and marketing software as medical devices.

Furthermore, in order to solve the ambiguity surrounding the application of the medical device regulations to software, the MHLW published the Guideline on the Regulation of Programmes as Medical Devices on 31 March 2021 – thereby providing the method of analysis and key points to determine whether a software constitutes a medical device. The MHLW has also established a database of the cases in which it has made judgments on whether a software constitutes a medical device.

A variety of software has recently been authorised as medical devices, including the following apps.

Non-smoking app

In August 2020, the MHLW authorised the CureApp SC Nicotine Addiction Treatment App with CO Checker (the "Non-smoking App") as a Class II medical device. Created by Japanese venture firm CureApp Inc, the Non-smoking App consists of:

- an application installed on a patient's smartphone (the "Patient's App");
- an application installed on a doctor's computer (the "Doctor's App"); and
- an exhaled carbon monoxide concentration measuring device (the "CO Checker").

A patient registers their information on the Patient's App, including whether the patient smoked, the strength of the patient's desire to smoke, and medications taken by the patient. The patient information, together with the results obtained from the CO Checker, is shared with the Doctor's App. The Doctor's App analyses all of the information and, as configured by the doctor, selects a message such as "drink more water" or "you are doing great" to be shown on the Patient's App as encouragement for smok-

ing cessation. The Non-smoking App is available only with a doctor's prescription.

The Non-smoking App is the first software to be authorised as a medical device in Japan that focuses on changing a patient's lifestyle as part of the smoking cessation treatment. In order to enable access to the Non-smoking App, the Patient's App is installed on the patient's smartphone – something that is an innovative feature of this software.

Another key component of the software that distinguishes it from other health-related apps is how the Non-smoking App is configured by a doctor especially for each patient, as opposed to simply providing general advice that may be applied to multiple patients. Given the custom configuration, the Non-smoking App will be provided to the patient based on a doctor's prescription – thus making it the first "prescribed" software to be treated as a medical device in Japan.

The authorisation of the Non-smoking App presented the possibility that other apps intended for treating patients through a lifestyle change could be marketed as medical devices. In December 2020, the MHLW also gave approval for treatments provided with the Non-smoking App to be covered under the public national health insurance system.

ECG app

In September 2020, the MHLW granted a Class II medical device marketing authorisation for an electrocardiogram (ECG) app created by Apple Inc (the "ECG App") for a popular general-purpose wearable device, the Apple Watch. Unlike previously authorised software, the ECG App analyses the signal obtained from the Apple Watch – rather than from a single-purpose electrocardiographic meter, which would also be subject to the Pharmaceuticals Law as a medical device.

The ECG App is innovative in that it detects symptoms of disease and suggests a physician visit. After its authorisation of the ECG App, the MHLW issued guidance entitled *Matters to Be Considered in Applying for Marketing Authorisation of a Home Use Medical Device to Detect Disease Symptom and to Suggest a Physician Visit*. In this guidance, the MHLW encourages manufacturers to take steps in order to mitigate the risk that users of such medical devices – including healthy people – will fail to visit a physician. Manufacturers are also reminded that a definitive diagnosis must be made by a physician. The guidance requires the manufacturers to add a cautionary statement to the device whereby it is made clear that the medical device is not designed to provide a definitive diagnosis and, irrespective of any suggestions from the app, the user should visit a physician if they experience any symptoms of disease.

Subsequently, in January 2021, the MHLW issued a notice that specifically warned local authorities about some characteristics of the ECG App. The notice pointed out that the ECG App is a secondary device used to detect atrial fibrillation only for a limited heart rate range and cannot detect symptoms of other cardiac dysrhythmia or atrial fibrillation outside the prescribed heart rate range. The notice also emphasised that the app is not designed to be used for a definitive diagnosis or a follow-up with a patient who has a history of cardiac dysrhythmia.

The authorisation of the ECG App indicates that there may be cases in which a device to collect the vital information and the software to analyse that collected information may be considered

separately and, as such, the software may be deemed to be a medical device even when the device is not. The regulatory authority is not yet sufficiently familiar with this novel category of software, so the review process may be prolonged and include broad discussions about each specific feature of the software.

Expansion of Online Medical Treatment

The provision of medical diagnoses over the telephone, by video or using other online tools ("online medical treatment") is becoming more common in Japan. However, the Medical Practitioners' Act prohibits doctors from providing medical care or issuing a medical certificate or prescription without examining a patient. There is therefore some controversy concerning whether an online examination may be construed as the examination required under the Medical Practitioners' Act and, as such, the extent to which an online examination is permitted.

Regulation of online medical treatment

The MHLW presented its initial view on this point in 1997 when it accepted online medical treatment as a supplement to face-to-face examination. Since then, the MHLW has updated the guidelines regarding online medical treatment – the latest of which is the "Guideline on Adequate Conduct of Online Medical Treatment" (updated in January 2022). The main requirements under those guidelines are as follows.

- Based on the diagnosis made during a face-to-face examination, the doctor may provide online medical treatment. However, this must include a description of the details of the online medical treatment, the treatment schedule, measures to take in case of changes in symptoms, and other matters.
- Online medical treatment for patients with sudden and acute illness is prohibited.
- The doctor and the patient must each clearly identify themselves to the other party.
- The online communication must include real-time visual and auditory information. Chats, photographs and recorded videos may only be used as supplementary information.
- The doctor must set up a private communication environment and use secure communication systems. Privacy risks must be explained to the patient.
- Providers of online medical treatment must take adequate security measures.

In 2019, the MHLW approved coverage of online medical treatment under the public national health insurance system by adding the following items to the insurance reimbursement payment list:

- online examination fee;
- online medical management fee;
- online home management fee; and
- psychiatric online home management fee.

Recent spread of online medical treatment

Until 2020, the MHLW required an in-person initial visit for the purposes of the Medical Practitioners' Act and the national health insurance system. In 2020, the MHLW issued the Temporary and Exceptional Measures for Medical Treatment Using Telephones and Other Communication Tools Under the Spread of the COVID-19 Infection, which temporarily permitted the online performance of a patient's initial medical examination in order to enable patients to safely receive treatment during the spread of COVID-19. In January 2022, such temporary measures were made permanent by the amendment to the Guideline on Adequate Conduct of online medical treatment under the following conditions.

- Online medical treatment given during the first consultation ("initial online examination") should be provided by a doctor who has been providing face-to-face treatment to the patient on a regular basis (the "family doctor"). Initial online examinations by doctors other than the family doctor are only permitted when:
  (a) the doctor is able to obtain sufficient medical information – from the relevant medical records, medical information sheets, health check-up results, results of medical examinations, regional medical information network, medication handbook or personal health record – to judge that online examination is possible, in light of the patient's medical condition;
  (b) the family doctor is not available for online examination and real-time communication via video allowing the doctor to understand the patient's symptoms and medical information ("pre-medical consultation") is held prior to the examination;
  (c) the patient has no family doctor and a pre-medical consultation is held; or
  (d) there is a referral from the family doctor and a pre-medical consultation is held.
- The List of Symptoms Unsuitable for the Initial Online Examination issued by the Japan Association of Medical Societies should be referred to when determining whether online treatment is suitable.
- In cases where medicines are prescribed during the initial online examination or where medicines for a new disease are prescribed following online-only examination, the List of Drugs that Require Careful Consideration for Prescription in the Initial Online Examination issued by the Japan Association of Medical Societies must be observed. Furthermore, the following prescriptions are prohibited in such cases:
  (a) prescription of narcotic drugs and psychotropic substances;
  (b) prescription of medicines that require special safety management for patients for whom the doctor does not have sufficient information about their underlying medical conditions; and
  (c) prescriptions of more than eight days' supply for patients for whom the doctor does not have sufficient information about their underlying medical conditions.

The use of online medical treatment is expected to spread under the amended guideline.

Utilisation of Health Data

There is growing interest in the utilisation of health data for business and individual wellbeing. As such, the Japanese government is setting up laws and systems to secure the protection of the rights of the data subject, as well as promoting usage of health data by businesses. There is no special law or ordinance dedicated to the utilisation of health data, however. The Act on the Protection of Personal Information (APPI), which broadly regulates the acquisition and processing of personal information, is the key regulation in this field.

Amendment to the Act on the Protection of Personal Information

Before the amendment enforced in 1 April 2022, the processing of personal information was restricted by several different national laws and local governments' ordinances. Although the rules were the same in principle, the piecemeal nature of the various laws resulted in cases where the applicable laws varied depending on the nature of the holder of the personal information. As this situation was considered undesirable, the various laws were integrated into a single act (the APPI).

Since the amendment, all personal information – ie, information that makes it possible to identify a specific individual (the provision/usage of which is restricted under the APPI) – held in the private sector, administrative agencies, local governments and independent administrative agencies is covered by the APPI.

In addition to such integration of the various laws, amendments were also made to strengthen:

- the protection of the rights of the data subjects; and
- the supervisory and enforcement powers of the competent authority for personal information-related matters (the Personal Information Protection Commission).

The following amendments, in particular, may have an effect on companies that handle health data containing personal information.

Introduction of pseudonymously processed information

For the purpose of promoting innovation, the category of "pseudonymously processed information" was introduced under the amended APPI. Pseudonymously processed information is defined as information created by processing personal information so that a specific individual cannot be identified unless the information is collated with other information (Article 2(5) of the amended APPI). There already is a category of "anonymously processed information" under the APPI; however, anonymously processed information refers to information processed so that a specific individual cannot be identified (Article 2(6) of the amended APPI). By way of an example, if personal information is de-identified by replacing the data subject's name with a number and there is a separate list matching the number and the replaced name, the de-identified information could be re-identified by using the list. It is not anonymously processed information, therefore, but pseudonymously processed information. On the other hand, if there is no such list and it is practically impossible to re-identify the specific individual of the de-identified data, such data is anonymously processed information.

Unless otherwise permitted by the law, personal information can only be used for the purpose specified in advance and – unless the data subject's consent is obtained – such purpose of use cannot be changed beyond the scope of what is considered reasonably relevant to the original purpose of use. However, such restriction on the scope of change does not apply to pseudonymously processed information (Article 41, Article 15(2) of the amended APPI). This is expected to broaden the usage of personal information by the data holder to include, for example, internal analyses for product development and business analysis.

It should be noted, however, that pseudonymously processed information cannot be provided to third parties (Article 42 of the amended APPI). It differs in this respect from anonymously processed information, which can be provided to third parties even without consent from the data subject.

Expansion of data subjects' rights

Before the amendment of the APPI, the data subject's right to request the cessation of use or erasure of their personal information was limited to cases of violations of the law. However, such right has been expanded to include cases where there is a risk of harm to the rights or legitimate interests of the data subject. The data subject's right to request disclosure of their own personal

information has also been expanded. The data subject is now able to:

- specify the method of disclosure (eg, electronic format), whereas only disclosure in written format was prescribed before the amendment; and
- require disclosure of records of transfer of their personal information to third parties.

Obligation to provide information on foreign privacy protection systems

The APPI, in principle, requires business operators to obtain consent from the data subject when providing personal information to a party in a foreign country. The amended APPI additionally imposed an obligation on a business operator to provide the relevant data subject with information on:

- the system for protection of personal information in the country to which the business operator is providing the personal information; and
- the protective measures to be taken by the recipient of the personal information.

Expansion of the scope of extraterritorial application

The application of the APPI to foreign entities/individuals was limited to certain provisions. However, since the amendment, all provisions of the amended APPI apply to a foreign entity that handle personal information of a subject located in Japan in relation to its provision of a product or service to an entity/person in Japan (Article 166 of the amended APPI). The subject of the personal information does not necessarily have to be the recipient of the product or service; however, both of them must be in Japan.

Establishment and initiation of the Next Generation Medical Infrastructure Act

Personal information that may lead to discrimination or other disadvantage of the individual – for example, information regarding race, religion, social status, medical history, criminal history – is defined as "personal information requiring special consideration". Provision/usage of such information is especially strictly restricted. Medical records typically constitute personal information requiring special consideration.

For ordinary personal information that does not require special consideration, a subject's consent for disclosure of personal information to a third party can be obtained (if some other requirements are met) through an "opt-out" procedure – ie, by informing the individual (or making it possible for the individual to acknowledge) that their personal information will be provided to a third party and giving opportunities to the individual to refuse such disclosure. However, explicit ("opt-in") consent is required to provide/use personal information requiring special consideration.

The Next Generation Medical Infrastructure Act was established in 2018 following the rising demand for utilisation of medical information. Utilisation of "big data" and "real world data" is expected to facilitate and streamline research and development of innovative pharmaceuticals and medical devices. Nevertheless, it has been difficult to accumulate medical information and build a database, given that:

- the medical information is often held by individual hospitals and entities; and
- provision/usage of the original data, which in many cases constitutes personal information, is restricted by the law.

The Next Generation Medical Infrastructure Act intends to make the accumulation of medical information easier, and to promote usage of big data for the development of medical technologies, while protecting patients' privacy and personal information.

If the medical institution holding the original data provides medical data to a data processing entity that de-identifies the data, the medical institution must obtain explicit consents from the individuals – even in cases in which personal information is de-identified before being added to a database. Consent must include consent to the transfer of personal information to a third party and purpose of transfer.

The Next Generation Medical Infrastructure Act allows medical information to be provided to entities authorised as data-processing entities that collect, de-identify and then provide medical information to third parties ("Authorised De-identified Medical Information Preparers"). When medical institutions provide a patient's data to the Authorised De-identified Medical Information Preparer, the patient's explicit consent is not required. The Authorised De-identified Medical Information Preparer collects data from a number of medical institutions, picks up and links the same patient's data from different medical institutions, adjusts the data format, and integrates the data into a database. When a third party – typically a healthcare company or a research institution – requests data, the Authorised De-identified Medical Information Preparer selects the relevant data, de-identifies it and provides an anonymised data set for a fee.

Several entities have been authorised as Authorised De-identified Medical Information Preparers and, while the current utilisation rate of the system is not high, it is expected to increase in the future.

MALAYSIA

Law and Practice

Contributed by:
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Contents

Shearn Delamore & Co. was established in 1905 and is one of the leading law firms in Malaysia. With more than 100 lawyers, the firm has the resources to run and manage the most complex projects, transactions and matters. It maintains extensive global network links with foreign law firms and multilateral agencies, including the World Law Group, the World Services Group and the Employment Law Alliance. Shearn Delamore & Co. formed an alliance with Drew & Napier LLC and Makarim & Taira S. to launch a blue-chip legal network named Drew Network Asia. The healthcare and life sciences team provides a full range of legal advice to innovative pharmaceutical, medical device and biotechnology companies and industry investors at every stage of the product life cycle, from intellectual property protections to commercial transactions and M&A. The firm's partners and lawyers have both legal and technical qualifications in the life sciences (including biochemistry, medical biochemistry and industrial biotechnology).

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices in Malaysia are governed by the following legislation and regulations:

- the Sale of Drugs Act 1952;
- the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984);
- the Dangerous Drugs Act 1952;
- the Poisons Act 1952 (PA 1952);
- the Medicines (Advertisement and Sales Act) 1956 (MASA 1956); and
- the Medical Device Act 2012 (MDA 2012).

The main regulatory bodies for pharmaceuticals and medical devices are:

- the Drug Control Authority (DCA);
- the Pharmacy Board;
- the National Pharmaceutical Regulatory Agency (NPRA);
- the Medicine Advertisement Board; and
- the Medical Device Authority (MDA).

All of the above legislation and regulatory bodies are under the purview of the Malaysian Ministry of Health (MOH).

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Appeals may be made against the decisions of the regulatory bodies in accordance with the procedure set out in the applicable act or regulations.

Under Regulation 18 of the CDCR 1984:

- any person aggrieved by the decision of the Authority or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health for Malaysia;
- all notice of appeals shall be made within 14 days from the date of notification from the Authority; and
- any decision of the Minister made on an appeal shall be final.

A person who is adversely affected by a decision, action or omission in relation to the exercise of a public duty or function shall also be entitled to make an application to the court for judicial review, pursuant to Order 53 of the Rules of Court 2012. The following remedies may be sought under the judicial review application:

- mandamus (peremptory or mandatory order);
- certiorari (quashing order);
- prohibition (prohibition order); and
- damages.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceutical products are categorised into:

- those containing the scheduled poison(s) listed in the PA 1952, which are categorised into the following different groups, which each have different registration requirements:
  - (a) Group A for products with high toxicity;
  - (b) Group B for prescription medicines;
  - (c) Group C for non-prescription medicines; and
  - (d) Group D for products for laboratory use; and
- those containing active ingredients that are not listed in the PA 1952 and that are not categorised as health supplements, natural products or cosmetics which may be freely available over the counter.

The wholesale and retail sale of pharmaceutical products are governed by Sections 15 and 16 of the PA 1952, respectively.

Medical devices are classified into Class A, B, C or D, based on the risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device, with different registration requirements and registration fees. The classification rules are based on:

- intended use;
- duration of use (transient, short-term and long-term); and
- the part of the human body (non-invasive or invasive with respect to body orifices, surgically invasive interventions, central circulatory system, central nervous system, etc).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Malaysia does not have specific legislation to regulate clinical trials or research.

Clinical trials are regulated in Malaysia by the NPRA or the MDA, and are reviewed by Institutional Review Boards/Independent Ethics Committees (IRBs/IECs) of the organisation conducting the trials. Approvals from the Medical Research & Ethics Committee (MREC) for trials are required for trials using MOH facilities.

The NPRA ensures the quality, efficacy and safety of pharmaceuticals in Malaysia prior to release in the Malaysian market, and acts as a Secretariat to the DCA.

Pursuant to the Medical Device (Exemption) Order 2016, medical devices that are intended for clinical research or performance evaluation are exempted from the registration requirement under the MDA 2012.

The National Committee for Clinical Research is a steering committee empowered to establish policies and guidelines to enhance and regulate clinical research practice in Malaysia.

The DCA is empowered to review matters related to product registration, and to approve or reject applications for the following:

- a clinical trial import licence (CTIL), which is issued for the import of any product for purposes of clinical trials; or
- a clinical trial exemption (CTX), which is the authorisation to manufacture any product(s) solely for the purpose of producing samples for clinical trials.

Guidelines

The applicable clinical trial guidelines in Malaysia are as follows:

- the Malaysian Guideline for Good Clinical Practice, Fourth Edition, which adopts the basic principles outlined by the International Committee on Harmonisation of Good Clinical Practice, but with appropriate modifications to suit local requirements, effective since January 2018;
- the Malaysian Guideline for Application for Clinical Trial Import Licence and Clinical Trial Exemption in Malaysia, edition 6.4, effective since August 2017;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition, effective since May 2016;
- the Malaysian Guidelines on the Use of Human Biological Samples for Research;

- the Guidelines for Good Clinical Practice (GCP) Inspection, Edition 2.1;
- the Malaysian Guideline for Phase I Unit Inspection and Accreditation Programme;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition;
- the Malaysian Guideline for BE Inspection, First Edition;
- the Malaysian Guideline for Safety Reporting of Investigational Products, First Edition; and
- Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia.

Directives

Directives from the Director of Pharmaceutical Services of the Pharmacy Board on the regulation of clinical trials include the following:

- all ethics committees that approve clinical trials in Malaysia must be registered with the DCA to regulate the quality, safety and efficacy of pharmaceutical products;
- all clinical trials requiring a CTIL/CTX must be registered with the National Medical Research Register (NMRR); and
- all bio-equivalence (BE) research conducted for the purpose of registering a product in Malaysia must be carried out in a BE research centre that has been listed in the NPRA's Compliance Programme.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Before commencing any clinical trial involving product(s), the investigator/sponsor/contract research organisation (CRO) must have secured the approval of the relevant IRB/IEC and the CTIL/CTX for the importation/manufacturing of the product locally for the study.

The following products will require a CTIL/CTX:

- a product, including a placebo, that is not registered with the DCA and is intended to be imported for clinical trial purposes;
- a product with a marketing authorisation when it is used or assembled (formulated or packaged) in a different way from the approved form, and when it is used for an unapproved indication or to gain further information about an approved use for clinical trial purposes;
- a traditional product with a marketing authorisation with an indication for "traditionally used" when used for unapproved indication/therapeutic claims for clinical trial purposes; and
- an unregistered product, including a placebo, that is manufactured locally for the purpose of the clinical trial.

IRBs/IECs

The committees to which the application should be submitted will depend on the location or facility where the clinical trial will be conducted.

Government health facilities under the MOH

Under the Malaysian National Institute of Health's Guidelines for Conducting Research in MOH Institutions and Facilities, all clinical trials involving MOH facilities must register with the NMRR and obtain prior approval from the MOH. The following requirements also apply:

- a government employee intending to act as an investigator for the clinical trial must sign an investigator agreement and obtain approval from the head of their department and the organisational or institutional director of the relevant government department – permission must be obtained to conduct research at the respective facilities/institutions;

- where a private institution undertakes collaborative research with the MOH, a formal letter of agreement between the related MOH institution or division and the private institution is required; and
- the NMRR will review the documents submitted – if it is satisfied with the registration application, the NMRR will forward them to the MREC for its review and approval.

Universities or private institutions

Applications are to be submitted to the respective IRB/IEC of the university or institution, which will review and approve the trial proposal as per the functions of the MREC. If the university or institution concerned does not have its own IRB/IEC, applications can be submitted to the MREC or any such committees of other universities or private institutions.

All ethics committees must be registered with the DCA.

The application to the IRB/IEC is made by the investigator – ie, the person responsible for the conduct of the trial or, where conducted by a team, the person who is the leader of the team (principal investigator), subject to the particular policies of that IRB/IEC.

Section 3.1.2 of the Guideline for Good Clinical Practice provides for the list of documentation to be submitted to the IRB/IEC for approval, which includes the following:

- trial protocol;
- written informed consent form;
- consent form updates;
- subject-recruitment procedures and other written information to be provided to subjects; and
- an investigator's brochure, which is a compilation of the clinical and non-clinical data on the trial drug relevant to its study in human subjects.

2.3 Public Availability of the Conduct of a Clinical Trial

There are no statutory requirements for clinical trials, nor for the results to be made publicly available.

Nonetheless, some organisations have voluntarily published their data – eg, Novartis provides technical results and trial summaries for patients from Phases 1 through 4 of interventional trials for innovative products within one year of trial completion, at their website (www.novctrd.com).

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials. Volunteers may be recruited through various online portals, such as clinicalresearch.my and my.gsk.com.

2.5 Use of Data Resulting From the Clinical Trials

The data resulting from the clinical trials would be considered "sensitive personal data" under Section 4 of the Personal Data Protection Act 2010 (PDPA 2010), which defines sensitive personal data as any personal data consisting of information on the physical or mental health or condition of a data subject.

Under Section 40 of the PDPA 2010, any disclosure or processing of sensitive personal data may only be made if the data subject has given their explicit consent to do so, or if any of the special circumstances set out in Section 40(1)(b) of the PDPA 2010 are satisfied.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data constitutes the "processing" of data under the PDPA 2010 and would therefore be subject to the seven Personal Data Principles, as set out in Sections 5 to 12 of the PDPA 2010:

- the General Principle;
- the Notice and Choice Principle;
- the Disclosure Principle;
- the Security Principle;
- the Retention Principle;
- the Data Integrity Principle; and
- the Access Principle.

Furthermore, a data user/processing body that falls under any of the classes under the Personal Data Protection (Class of Data Users) Order 2013 would also need to obtain a certificate of registration in accordance with Sections 12 to 20 of the PDPA 2010 prior to processing personal data.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The NPRA uses the following criteria to assist in the classification of products as either pharmaceuticals or medical devices:

- the primary intended purpose of the product;
- the primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved – a drug is based on pharmacological, immunological or metabolic action in/on the body, whereas a medical device does not achieve its primary mode of action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means;
- the active ingredient, indication and pharmaceutical dosage form (these are the main criteria for classification of the drugs); and
- the classification of the products in reference countries.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The NPRA's requirements for the registration of biologic/biopharmaceutical products conforms to the scientific guidelines and recommendations established by the World Health Organization, the European Medicines Agency and the International Conference of Harmonisation (ICH) with regards to quality, clinical effectiveness and safety.

Every biologic is regulated as a new product and is also considered "high risk"; both substance and drug-product production must comply with Good Manufacturing Practice strictly and in accordance with the ASEAN Common Technical Dossier (ACTD) format.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Registration/marketing authorisations are valid for five years or any such period as specified in the Authority database (unless they are suspended sooner or cancelled by the Authority). The renewal of a product registration should be submitted within six months prior to the expiry of the validity period of a product registration, together with the appropriate fee.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

To obtain a marketing authorisation for both pharmaceuticals and medical devices, the product must be registered with the relevant authorities.

The registration process may be summarised as follows.

Pre-submission of Application

The applicant needs to determine the category of the product – ie, whether it is a:

- new drug product;
- biologic;
- generic;
- health supplement; or
- natural product.

Method of Evaluation

There are four methods of evaluating the application:

- full evaluation;
- full evaluation (conditional registration), for a product that must be registered in at least one DCA reference agency; a conditional registration is valid for two years and may be renewed twice (with the possibility of two extensions of two years each);
- full evaluation via abbreviated and verification review, for a product that has been evaluated and approved by one reference drug regulatory agency – the verification review applies to a product that has been evaluated and approved by two reference drug regulatory agencies; and
- abridged evaluation.

The following general requirements for full evaluation are in accordance with ACTD/ASEAN Common Technical Requirements or ICH guidelines:

- Part I Administrative data and product information;
- Part II Data to support product quality (Quality Document);
- Part III Data to support product safety (Non-clinical Document); and
- Part IV Data to support product safety and efficacy (Clinical Document).

For an abridged evaluation, a bio-availability study and a bio-equivalence study are required.

Submission of Application

An application for product registration shall be submitted only via the online QUEST system, at quest3plus.bpfk.gov.my. To conduct transactions via the QUEST system, the applicant must first register membership of the QUEST system with the National Pharmaceutical Control Bureau and purchase a USB Token that contains a User Digital Certificate, which shall be installed on the applicant's computer.

Decisions of the Authority

A regulatory decision shall be made based on the outcome of the evaluation of the submitted documentation, and samples (if applicable). An application may be approved or rejected by the Authority, and the Authority decision will be sent via email/official letter to the product registration-holder.

Post-registration Process

After the product is registered, the applicant must apply for a manufacturer, import or wholesale licence. The registration status of a product shall be valid for five years or any such period as specified in the Authority database (unless

the registration is suspended or cancelled by the Authority). Upon approval for product registration by the Authority, applicants shall fulfil all commitments and conditions imposed during the approval of the product registration, and shall be responsible for the maintenance of the product in terms of quality, safety and efficacy throughout the validity period of registration. Failure to do so may result in the rejection of an application for the renewal of a product registration. The Authority shall be notified of any changes to the product's efficacy, quality and safety.

Rejected Application

Any person who is aggrieved by the decision of the Authority or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health Malaysia. The re-submission of product registration that was rejected for reasons of safety and efficacy shall not be accepted within two years after the rejection. However, if the product is registered in the reference countries, the submission of an application can be made earlier.

Variation of Marketing Authorisation

Two types of variations may be made to a marketing authorisation:

- major variation (MaV): this is a variation to a registered pharmaceutical finished product that may significantly and/or directly affect the aspects of quality, safety and efficacy and does not fall within the definition of minor variation and new registration – change-of-content of product labelling, change of batch site of sterile drug product, etc; or
- minor variation (MiV-N & MiV-PA): this is a variation to a registered pharmaceutical finished product in terms of administrative data and/or changes with minimal/no significant impact on the aspects of efficacy, quality and safety – change of product name, the specification of drug substance, etc.

Transfer of Marketing Authorisation

It is permissible to transfer the market authorisation from one marketing authorisation holder to another. The requirements for transfer are found in Directive (3)dlm.BPFK/PPP/07/25 and also on the NPRA's website at npra.gov.my. Upon the approval of the transfer of marketing authorisation, the former product registration holder shall no longer have marketing authorisation over the registered product.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The licence required to manufacture or supply a product does not apply to the dispensing of any drug for the purpose of it being used for the medical treatment of a patient or animal by a pharmacist, a fully licensed medical, dental or veterinary practitioner or a person employed in a governmental hospital or dispensary to dispense drugs.

Under Regulation 15(6) of the CDCR 1984, any person who wishes to import or manufacture any product solely for the purpose of treating any person suffering from a life-threatening illness may, upon application, be exempted from having to obtain marketing authorisation.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Product registration holders of pharmaceutical products are required to carry out pharmacovigilance. Pursuant to the CDCR 1984, product registration holders shall inform the Director of Pharmaceutical Services immediately of any

adverse reaction arising from the use of the registered product.

All product registration holders must ensure that the company has a pharmacovigilance system in place and that appropriate action is taken, when necessary.

Product registration holders are required to monitor and report any product safety issues that arise locally or internationally to the NPRA, and to comply with all safety-related directives issued by the NPRA.

The product registration may be cancelled if the product registration holder fails to inform the NPRA of any serious adverse reactions upon receipt of such reports. For further information, reference may also be made to the Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders, First Edition, which contains guidelines for the establishment of a pharmacovigilance system.

The Malaysian Adverse Drug Reactions Advisory Committee is an advisory body to the DCA to supervise pharmacovigilance activities for medicinal products registered in Malaysia.

In relation to medical devices, Section 38 of the MDA 2012 requires the holder of a marketing authorisation to monitor the safety and performance of the medical device, and to put a post-market surveillance system in place.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

All information declared in the registration form for marketing authorisations of pharmaceuticals is confidential and is not accessible to third parties.

In relation to medical devices, the applicant must apply to the MDA for any information relating to the application to be kept confidential. The grant of confidentiality is at the discretion of the Authority, and consideration will be given to the criteria stated in Section 68(3) of the MDA 2012. If confidentiality is not granted, Section 69 of the MDA 2012 stipulates that, subject to the discretion of the Authority, the public may have access to such information relating to the application.

Information relating to individuals is governed by the PDPA 2010. Any disclosure or processing of sensitive personal data may only be made if the data subject has given their explicit consent to do so. Notwithstanding the requirement for explicit consent from the data subject, Section 40 of the Act also allows the processing of sensitive personal data where:

- the processing is necessary for the following reasons:
  - (a) to exercise or perform any right or obligation that is conferred or imposed by law on the data user in connection with employment;
  - (b) in order to protect the vital interests of the data subject or another person, in a case where consent cannot be given by or on behalf of the data subject or the data user cannot reasonably be expected to obtain the consent of the data subject;
  - (c) in order to protect the vital interest of another person, in a case where consent by or on behalf of the data subject is unreasonably withheld;
  - (d) for medical purposes and the processing is undertaken by a healthcare professional;
  - (e) for any legal proceeding;
  - (f) to obtain legal advice;
  - (g) for the administration of justice;

(h) for the exercise of any functions conferred by law; or
(i) for any purpose the Minister deems fit; or
- the information contained in the personal data has been made public as a result of steps taken deliberately by the data subject.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Pharmaceutical Products

Regulations 7 and 18A of the CDCR 1984 prohibit the illegal distribution of drugs and cosmetics products.

Medical Devices

Section 5(2) of the MDA 2012 provides that any person who imports, exports or places on the market an unregistered medical device commits an offence, and shall be liable to a fine not exceeding MYR2 million or to imprisonment for a term not exceeding three years, or to both.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Issues relating to counterfeiting are dealt with under the Trademarks Act 2019, under Section 82(1) of which any person may file an application to the Registrar, stating that:

- they are the registered proprietor, or the licensee having the power to file such application;
- at a time and place specified in the application, goods infringing the registered trade mark are to be imported for the purpose of trade; and
- they object to that importation.

Upon approval by the Registrar, the importation of any infringing goods into Malaysia for the duration of the period specified in the approval shall be prohibited. An approval shall remain in force until the end of a 60-day period commencing on the day of the approval, unless withdrawn earlier by the applicant. Where goods have been seized pursuant to the application, the applicant must take action for infringement within the retention period, otherwise the goods shall be released back to the importer and the applicant may be further liable for loss or damage suffered by the importer as a result of the seizure.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Under Regulation 7(1) of the CDCR 1984, except as otherwise provided therein, no person shall manufacture, sell, supply, import, possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under the Regulations. The Director of Pharmaceutical Services grants the authorisation.

In relation to a licence application for pharmaceutical products, an online application can be made through the QUEST System by filing Borang BPFK-413: Application for Licence for Registered Products (Manufacturer's Licence, Import Licence and Wholesaler's Licence). The forms can be found at www.npra.gov.my. Once the Manufacturer's Licence is granted, the applicant can manufacture registered products in their premises and can sell by wholesale or supply the registered products.

The Manufacturer's Licence for pharmaceutical products is valid for one year, from 1 January to 31 December of the same year.

Medical Devices
All establishments (ie, manufacturer, authorised representative, importer and distributor) must apply for an establishment licence. However, only manufacturers and authorised representatives need to apply for medical device registration under Section 15 of the MDA 2012. The MDA grants the authorisation of an establishment licence.

The application for an establishment licence can be made by sending an email to MeDC@St2.0, according to the MDA's official website (portal.mda.gov.my). A flow chart of the application process is provided on the website. With the establishment licence, the manufacturer can import, export or place any registered medical device on the market.

The establishment licence is valid for three years, and an establishment can start to renew the licence one year prior to the expiry date.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in the wholesale of pharmaceutical products are subject to licensing requirements under the CDCR 1984. Any company carrying out the manufacture, import or wholesale of any registered products needs to have a Manufacturer's Licence, Import Licence or Wholesale Licence. The Licensing Unit's Centre for Compliance and Licensing is involved in issuing the relevant licence.

Licences for the wholesale of poisons are issued by the Director-General of Health, the Director of Pharmaceutical Services or the Director of Medical and Health Services of any State duly appointed in writing by the Director General of Health to be a Licensing Officer of any State or the federal territory, pursuant to Section 28 of the PA 1952.

A licence application for pharmaceutical products is made online through the QUEST system by filing Borang BPFK-413: Application for Licence for Registered Products (Manufacturer's Licence, Import Licence and Wholesaler's Licence).

Once the Wholesaler's Licence is granted, the licence holder can sell by wholesale or supply registered products from their premises. The Wholesaler's Licence for pharmaceutical products is valid for one year, from 1 January to 31 December of the same year.

Medical Devices
For medical devices, a distributor shall obtain an establishment licence to conduct its activity. The MDA grants the authorisation for establishment licences. The application for an establishment licence can be made by sending an email to MeDC@St2.0, according to the MDA's official website, at portal.mda.gov.my, which includes a flow chart of the application process.

With an establishment licence, a distributor can import, export or place any registered medical device on the market. An establishment licence for medical devices is valid for three years, and an establishment can start to renew the licence one year prior to the expiry date.

5.2 Different Classifications Applicable to Pharmaceuticals

The classifications of drugs can be found in the First Schedule of the PA 1952, where drugs are classified into the following:

- Group A Poison: high-toxicity medicines – eg, alclofenac, amidopyrine, avoparcin;
- Group B Poison: used in treatment where the doctor's diagnosis is needed to recognise the symptoms, and can be dispensed only against prescription – eg, nifedipine, olanzapine, ramipril;
- Group C Poison: used in treatment where the symptoms are easily recognised, and can be dispensed without prescription – eg, ibuprofen, piroxicam, mefenamic acid; and
- Group D Poison: chemicals for laboratory use – eg, cetyl chloride, ethylidene diacetate, methyl bromide.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The CDCR 1984 governs the import and export of pharmaceutical and medical devices. Under Regulation 7(1) of the CDCR 1984, except as otherwise provided therein, no person shall manufacture, sell, supply, import, possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under these Regulations.

Section 12 of the Customs Act 1967 further prohibits the importation and exportation of any dangerous drugs specified in Parts III, IV and V of the First Schedule thereof, unless otherwise authorised by the Minister.

Medical Devices

The MDA 2012 governs the import and export of medical devices.

At the point of entry, import regulations are applied and enforced by the Royal Malaysian Customs Department, specifically the Import Management & Enforcement Unit and the Export Management & Enforcement Unit under the Customs Division. Thereafter, they are enforced by the NPRA and the MOH.

6.2 Importer of Record of Pharmaceutical and Medical Devices

There are no specific requirements to apply for and hold an Import Licence (for the import and sale by wholesale or supply of registered products).

For a CTIL (for the import of any product for purposes of clinical trials, notwithstanding that the product is not a registered product), only an investigator or an authorised person from a locally registered pharmaceutical company/sponsor/CRO with a permanent address in Malaysia can act as an importer of record of pharmaceuticals and medical devices in the country.

An application for a CTIL/CTX containing a "poison/drug" should be made by a Poison Licence Type A holder for a pharmacist in the private sector or an Annual Retention Certificate holder for a public pharmacist. However, it should be noted that the holder of a CTIL/CTX for a particular product need not necessarily conduct the clinical trial themselves.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices is subject to prior authorisation, as stat-

ed in Regulation 7 of the CDCR 1984, Section 8 of the PA 1952 and Section 15 of the MDA 2012.

There are exemptions regarding those authorisations. Special exemptions for the importation of products that are not registered with the DCA may be granted for the treatment of life-threatening illnesses, as provided under Regulation 15 (6) of the CDCR 1984.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Licences are required prior to the importation of any poison into Malaysia, under Section 8 of the PA 1952.

The categories of licences can be found in Section 26(2)(a) of the PA 1952:

- Type A licence issued to a pharmacist to import, store and deal in all poisons generally by wholesale and retail or by wholesale only or by retail only, subject to this Act;
- Type B licence issued to any person who is deemed fit or a responsible officer of a company to import, store and sell by wholesale any such poisons (not being a Group A Poison) as may be specified in such a licence;
- Type C licence issued to any person (in this Act referred to as "a listed seller") the Licensing Officer considers to be a fit and proper person to hold such a licence, to store and sell by retail Group F Poisons only;
- Type D licence issued to any person the Licensing Officer considers to be a fit and proper person to hold such a licence, to store and sell by retail any such Part II Poisons as may be specified therein; and
- Type E licence issued to any person who, in the course of their business, uses sodium hydroxide in such a substantial quantity that the Licensing Officer deems it appropriate to issue them a licence to import, store and use sodium hydroxide.

Section 30 of the PA 1952 further states that any psychotropic substances listed in the Third Schedule of the Act cannot be imported, exported, manufactured, compounded, mixed, dispensed, sold, supplied, administered, possessed or used, unless it is in accordance with the regulations applicable under the PA 1952.

Section 12 of the Customs Act 1967 further prohibits the importation and exportation of any dangerous drugs specified in Parts III, IV and V of the First Schedule thereof, unless otherwise authorised by the Minister.

6.5 Trade Blocs and Free Trade Agreements

Malaysia has already signed and implemented seven bilateral free trade agreements (FTAs), with Japan, Pakistan, India, New Zealand, Chile, Australia and Turkey.

At the ASEAN level, Malaysia has six regional FTAs, with China, Korea, Japan, Australia, New Zealand and India, as well as the ASEAN Free Trade Agreement (AFTA).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals and medical devices are not regulated in Malaysia. Nonetheless, in the public sector, the MOH indirectly controls and reduces medicine prices with bulk purchases through concession supply and national tenders to provide accessible and affordable medicines.

7.2 Price Levels of Pharmaceutical or Medical Devices

Currently, the price level of a pharmaceutical or medical device does not depend on the prices for the same product in other countries.

In the Medicine Price Monitoring Report 2017 issued by the MOH, a comparison was made between the international reference price and the procurement price in the public and private sectors in Malaysia. Pursuant to this, there have been discussions on the introduction of drug price regulations, but no concrete actions have yet been taken.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In Malaysia, the government-based and publicly funded sectors provide health services that are tax-funded and administered by the MOH through its central, state and district offices. The policies and programmes are centrally formulated, funded and administered.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

There is no formal reimbursement system in Malaysia for pharmaceuticals or medical devices.

Although health technology assessments play a role in the formulation of drug policies in Malaysia, cost-effectiveness evidence is currently not mandatory, although it is of interest to decision-makers.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In Malaysia, the prescription and dispensing of pharmaceuticals are currently governed by the PA 1952 (Revised 1989), the Poisons Regulations 1952 and the Poisons (Psychotropic Substances) Regulations 1989.

Where any poison is sold or supplied as a dispensed medicine or as an ingredient in a dispensed medicine, the seller or supplier shall enter or cause to be entered in a Prescription Book certain information, on the day on which that poison or medicine is sold or supplied – the date of sale, the serial number of the entry, the name of the poison and the ingredients of the medicine, the quantity supplied, etc.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no specific rules that govern medical apps in Malaysia. However, the definition of medical devices under Section 2 of the MDA 2012 includes:

- any software for the purpose as specified in paras (i) to (vii) of Section 2 that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; or
- any software to be used on the human body, which the Minister may, after taking issues of public safety, public health or public risk into consideration, declare to be a medical device by an order published in the Gazette.

As such, the MDA 2012 shall apply to medical apps that are used for purposes within the definition of a medical device under the Act. The application for the registration of a medical device is, in turn, governed by Section 6 of the MDA 2012.

8.2 Rules for Telemedicine

The Telemedicine Act 1997 was introduced in 1997 but is not yet in force. Telemedicine is defined as the practice of medicine using audio, visual and data communications.

Section 3 of the Telemedicine Act provides that only a fully registered medical practitioner holding a valid practising certificate or a medical practitioner who is registered or licensed outside Malaysia and holds a certificate to practise telemedicine issued by the council and practises telemedicine from outside Malaysia through a fully registered medical practitioner holding a valid practising certificate is authorised to practise in Malaysia.

8.3 Promoting and/or Advertising on an Online Platform

Section 2 of the MASA 1956 defines an advertisement to include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound. The Guideline on Advertising of Medicines and Medicinal Products to General Public lists online advertising as an example of advertisement under the definition in Section 2.

The MASA 1956 governs any online advertising of medicines and medical devices in Malaysia. As advertising on online platforms is regulated, conditions imposed by the MASA 1956 shall be followed. Accordingly, online advertisement is subject to approval by the Medical Advertisement Board.

The Medical Device (Advertising) Regulations 2019 govern matters relating to the contents and conditions for the advertising of medical devices, and provide that approval must be obtained to advertise a registered medical device.

8.4 Electronic Prescriptions

Currently, there is no legislation on electronic prescriptions in Malaysia. There was a proposal to include electronic prescriptions via the Poisons Act (Amendment) Bill 2019.

8.5 Online Sales of Medicines and Medical Devices

Under Section 13 of the PA 1952, it is against the law to sell or supply medicine without a licence. A seller can be fined up to MYR3,000 or receive a one-year term of imprisonment for the first offence.

While the sale of medicines and medical devices online is not regulated by any specific piece of legislation, the seller must comply with the Consumer Protection (Electronic Trading Transaction) Regulations 2012.

8.6 Electronic Health Records

Health-related information is regulated as sensitive personal data, as defined in Section 4 of the PDPA 2010. Sensitive personal data includes personal data consisting of information on the physical or mental health or condition of a data subject.

The processing of such information is governed by Section 40 of the PDPA 2010, which states that sensitive personal data may only be processed if the data subject has given their explicit consent or if the processing is necessary under certain circumstances set out in the PDPA 2010.

In terms of the storing of information in cloud platforms, the Malaysian Department of Personal Data Protection issued a Personal Data Protection Standard in 2015, which states that the transfer of personal data through cloud platforms is not permitted unless written consent is obtained from an officer authorised by the top

management of the data user organisation. The transfer of personal data through cloud platforms must comply with personal data protection principles in Malaysia, and with the personal data protection laws of other countries.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patent rights in Malaysia are governed by the Patents Act 1983 (PA 1983), together with the Patents Regulations 1986.

The issue most commonly encountered by pharmaceutical and medical devices products under the legislation is patent infringement.

There is no specific patentability requirement for pharmaceuticals or medical devices.

9.2 Second and Subsequent Medical Uses

The patenting of second and subsequent medical uses is expressly permitted under Section 14(4) of the PA 1983. Inventions in relation to new dosage regimes or selected patient populations are patentable in Malaysia if they satisfy the novelty and inventiveness patentability requirements.

A patent is infringed when a product or process falling within the scope of the protection of the patent, as defined by the claims in the patent, is exploited without the patentee's consent.

9.3 Patent Term Extension for Pharmaceuticals

Section 35 of the PA 1983 states that the term of protection of a patent shall be 20 years. There is currently no provision for patent term extension in Malaysia.

9.4 Pharmaceutical or Medical Device Patent Infringement

The patentee's exclusive right to exploit a patent allows them to exclusively use the patented product or patented process and to make, import, offer for sale or sell the patented product and any product obtained directly by means of the patented process. A patent is infringed when there is any unauthorised exploitation thereof.

However, Section 37(1A) of the PA 1983 provides that "the rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs." Accordingly, applications for marketing authorisations for drugs (but not medical devices) will not infringe the patent.

A cause of action for "imminent infringement" is also available in Malaysia, as provided for under Section 59(1) of the PA 1983, which states that "The owner of the patent shall have the same right against any person who has performed acts which make it likely that an infringement will occur, which in this Part is referred to as an imminent infringement." It is arguable that an application for marketing authorisation constitutes "imminent infringement" of a subsisting patent in relation to the product.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

In Malaysia, the Bolar exemption is encapsulated in Section 37(1) of the PA 1983, which limits the rights under the patent to acts done for industrial or commercial purposes and not to acts done only for scientific research. Section 37(1A) of the PA 1983 further provides that a patentee's rights shall not extend to acts done in relation to a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority either in Malaysia or outside Malaysia that regulates the manufacture, use or sale of pharmaceutical products. As such, applications for marketing authorisations of pharmaceutical products will not infringe the patent. It should be highlighted that the applicability of Section 37(1A) of the PA 1983 is limited to pharmaceutical products; it does not cover medical devices.

Defences

The following defences to a patent infringement action are available:

- the claims of the patent allegedly infringed are invalid;
- the product complained of was not obtained by the patented process or, at any rate, not directly;
- the patentee has exhausted their rights – ie, the patented product or product obtained directly by means of the patented process was produced in Malaysia or elsewhere by or with the consent, conditional or otherwise, of the owner of the patent or of their licensee;
- the acts complained of were done privately either for purposes that are not industrial or commercial, or for scientific research relating to the subject matter of the invention;
- the acts complained of were reasonably related to the development and submission of information to the relevant authority that regulates the manufacture, use or sale of drugs (Bolar exemption);
- the acts complained of were done in connection with a foreign vessel, aircraft, spacecraft or land vehicle temporarily in Malaysia;
- the acts were done after notification in the Gazette that the patent has lapsed and before notification in the Gazette that the patent has been reinstated;
- the rights were done pursuant to a compulsory licence;
- the act was authorised by the government; and
- the "Gillette" defence, under which the alleged infringement is old or obvious – ie, what the defendant is doing differs from what was known before the date of the patent only in non-patentable variations.

Compulsory Licences

Under Section 49 of the PA 1983, an application for a compulsory licence may be made after the expiration of three years from the grant of patent or four years from the filing date of the patent application on the following grounds:

- where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason; or
- there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they do not meet the public demand without any legitimate reason.

Notwithstanding the above, a compulsory licence may be granted any time after the grant of patent in the following circumstances:

- where the patented products are sold in the domestic market at unreasonably high prices without any legitimate reason; or
- for the purposes of production of a pharmaceutical product in Malaysia and the exportation of such pharmaceutical product to an eligible importing country to deal with its public health problem.

Prior to making an application to the Patent Registrar for a compulsory licence, the applicant shall first attempt to obtain authorisation from the owner of the patent on reasonable commercial terms.

Under Section 84 of the PA 1983, the government may exploit a patented invention under a government-use licence, even without the consent of the patent owner, if there is a national emergency or where such is required by the public interest, particularly national security, nutrition, health or the development of other vital sectors of the national economy as determined by the government.

9.6 Proceedings for Patent Infringement

A patentee may bring a civil action against an infringer at the High Court. A patent infringement action generally begins by filing a writ of summons against the infringer. The procedure to be complied with for an action by writ is governed by Orders 6 and 10 of the Rules of Court 2012.

Remedies

A plaintiff in an infringement action may claim and obtain the following:

- an injunction (including a quia timet, interlocutory injunction and permanent injunction) restraining the defendant from any act of infringement or imminent infringement;
- an order for the delivery up or destruction of any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
- damages in respect of the infringement;
- alternatively, an account of the profits derived by the defendant from the infringement;
- a declaration that the patent has been infringed by the defendant and (if validity has been successfully contested) that the patent is valid;
- interest on any sum found payable; and
- further or other relief and costs.

Invalidation

A defendant in an infringement action may counterclaim for an invalidation of the patent on the following grounds:

- that it is not an invention – ie, not an idea that permits, in practice, a solution to a specific problem in the field of technology;
- that it is not patentable – the alleged invention is excluded from being patentable with reference to the following:
  - (a) discoveries, scientific theories and mathematical methods;
  - (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than manmade living micro-organisms, microbiological processes and the products of such micro-organism processes;
  - (c) schemes, rules or methods for doing business, performing purely mental acts or playing games; and
  - (d) methods for the treatment of human or animal bodies by surgery or therapy, and diagnostic methods practised on the human or animal body;

that it is contrary to public policy – ie, the performance of any act in respect of the claimed invention would be contrary to public order or morality;

- that it is not new – ie, the alleged invention has been anticipated by prior art, which is defined as everything disclosed to the public, anywhere in the world, by written publication, by oral disclosure, by use or in any other way, before the priority date of the claim;

- that there is no inventive step – the invention is obvious, having regard to what was known or used before the priority date;
- that it is not industrially applicable – the invention cannot be made or used in any of kind of industry;
- that the description or claim does not comply with the Patents Regulations 1986 – the specification is ambiguous or does not sufficiently and fairly describe the invention and the method by which it is to be performed, or does not disclose the best method known to the applicant for the patent and for which they were entitled to claim protection;
- that the drawings that are necessary for the understanding of the claimed invention have not been furnished;
- that the patentee not entitled – ie, the right to the patent does not belong to the person to whom the patent was granted; and
- that there is incomplete or incorrect information – false or incomplete information has been deliberately provided, or caused to be provided, to the Registrar when filing a request for substantive examination by the patentee or their agent.

9.7 Procedures Available to a Generic Entrant

At the pre-submission stage of the application to the NPRA, the potential generic entrant shall provide the NPRA with a declaration that it shall comply with all legal provisions in Malaysia and conform to the PA 1983, and that it shall not market, sell, offer for sale or store any registered product containing any patented active ingredient(s) for which the patent duration has yet to expire.

A potential generic entrant who qualifies as an interested person shall have the right to apply for a declaration from the court against the owner of a patent that the performance of a specific act does not constitute an infringement of the patent, provided that the act in question is not already the subject of infringement proceedings. These proceedings for a declaration of non-infringement may be instituted together with the invalidation proceedings.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Issues of counterfeits are generally dealt with under the Trademarks Act 2019. In addition to civil remedies pursuant to trade mark infringement, any person who counterfeits a registered trade mark commits an offence and would be liable to criminal sanctions as well.

Issues of counterfeiting may also infringe the intellectual property rights residing in the packaging/container of the pharmaceutical and medical device – eg, design rights under the Industrial Designs Act 1996 and copyrighted works in the literary and artistic works in the package inserts. An infringement proceeding for indus-

trial designs is by way of a civil action taken by the owner against any person who has infringed the rights conferred by the registered industrial design, as provided under Section 33 of the Industrial Designs Act 1996.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademarks Act 2019 does not impose any restrictions on trade marks that can be used for pharmaceuticals and medical devices.

In the now-repealed Trade Marks Act 1976, parallel imports were allowed on the principle of the exhaustion of rights, which is encapsulated in Sections 40(1)(d) and 40(1)(dd) and reads:

"(1) Notwithstanding anything contained in this Act, the following acts do not constitute an infringement of a trade mark:

(d) in relation to goods connected in the course of trade with the registered proprietor or a registered user of the trade mark if, as to those goods or a bulk of which they form part, the registered proprietor or the registered user in conforming to the permitted use has applied the trade mark and has not subsequently removed or obliterated it or has at any time expressly or impliedly consented to the use of the trade mark;

(dd) the use by a person of a trade mark in relation to goods or services to which the registered proprietor or registered user has at any time expressly or impliedly consented to…"

However, only Section 40(1)(dd) was retained in the new Trademarks Act 2019, in Section 55(3)(c), so it is unclear whether the previous case law discussing Sections 40(d) and 40(dd) remains applicable.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The Trademarks Act 2019 allows for the shape of goods or their packaging to be registered as a trade mark, as long as it fulfils the general requirements for registration. Therefore, a registered mark for the shape or packaging will be granted trade mark rights.

Unregistered trade dress or design for pharmaceuticals, medical devices or their packaging may be protected in Malaysia under the common law tort of passing off. To establish a claim for passing off, the following elements must be satisfied:

- the plaintiff has sufficient reputation or goodwill in the mark;
- the defendant has misrepresented to the relevant members of the trade/public, as a result of which they are misled or likely to be misled into believing that the goods are endorsed, permitted and/or licensed by the claimant or affiliated with the claimant; and
- the plaintiff has suffered or is likely to suffer damage or injury to its business or goodwill by reason of the defendant's misrepresentation.

Trade dress or design of pharmaceuticals and medical devices such as tablets may further be registered and protected under the Industrial Designs Act 1996, as they fall under the definition of "features of shape, configuration, pattern or ornament applied to an article by any industrial process or means".

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

In Malaysia, undisclosed, unpublished and non-public domain pharmaceutical test data is

protected under Directive No 2 on Data Exclusivity 2011 (the Directive), which was issued by the Director of Pharmaceutical Services under Regulation 29 of the CDCR 1984. The Directive provides data exclusivity for new chemical entities and second indications only.

The data exclusivity period runs from the date the new drug or the second indication is first registered or granted marketing authorisation and data exclusivity or test data protection in the country of origin or any country recognised by the Director of Pharmaceutical Services. The period for data exclusivity granted is determined on a case-by-case basis by the Director of Pharmaceutical Services; it shall not be more than five years for a new drug product containing a new chemical entity, and three years for the second indication of a registered drug product.

Data exclusivity is not automatically conferred upon approval of a drug: the interested party must make a separate application for data exclusivity.

An application for data exclusivity can be made via a Letter of Intent in conjunction with the application for registration of a new drug product containing a new chemical entity or the application for a second indication of a registered drug product.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Various regulatory bodies issued regulations and guidelines in relation to the commercialisation and distribution of medicines and medical devices aimed at handling COVID-19 in Malaysia. These include the following.

- The MDA's Guideline on Conditional Approval for COVID-19 Rapid Test Kit (Self-Test) established a temporary approval method for COVID-19 test kits to expedite the registration process of this medical device. Under this initiative, the requirement for the Conformity Assessment Bodies to conduct conformity assessments on medical devices is waived. Instead, a COVID-19 Expert Committee was established to assess and evaluate the test kits to ensure their compliance with the established requirements of quality for use. The conditional approval is valid for one year and may be revoked if concerns are raised about the device's safety and/or the applicant's non-compliance with the requirements of the conditional approval.
- The Guidance and Requirements on Conditional Registration for Pharmaceutical Products During Disaster issued by the NPRA provide expedited access to pharmaceutical products such as vaccines during a disaster. Under this scheme, all registration applications for pharmaceutical products that fulfil the stipulated conditions will be given priority review, in which evaluation will be completed within 70 working days instead of the standard 210 working days. Products that have been conditionally approved by any DCA reference country or the WHO will be given top priority. Pursuant to this Guidance, the standard requirements for the registration of pharmaceutical products have been relaxed. For instance, an application for pharmaceutical product registration may now be made for a pharmaceutical product that has not completed the Phase III clinical study.
- The DCA issued Decision NPRA.600-1/9/7(41), which exempted all registered

COVID-19 vaccine products from the requirement to conduct physical tests for lot release activities. Pursuant to this Decision, the requirement for the National Regulatory Authority or National Control Laboratory to evaluate an individual lot of a registered vaccine has been waived.

11.2 Special Measures Relating to Clinical Trials

During the COVID-19 pandemic, the NPRA allowed sponsors to distribute investigational products directly to trial subjects without the need for site visitation or personal contact ("Direct-to-Patients"). The sponsor shall notify this arrangement to the NPRA and document each delivery in an accountability report for regulatory inspections.

The IP accountability report shall include a comprehensive record of the standard operation procedure for delivery, the manner of delivery, the storage requirements, the subject receiving adequate training on self-administration of the investigational products, and the employees processing the subject's personal data.

When implementing the Direct-to-Patients option, the following must be observed:

- the sponsor holds a valid CTIL or CTX with an approved import quantity;
- the investigational products shall only be distributed from Malaysian sites to trial subjects;
- the delivery of the investigational products shall not raise any new safety risks;
- subjects understand and provide consent that the investigational products will be delivered directly to their homes;
- the sponsor has investigated the viability of alternative distribution via an investigator or hospital pharmacy; and
- the sponsor shall ensure the conduct of appropriate alternative safety monitoring if subjects are not able to come to the investigational site.

The NPRA has also issued a Special Directive to accept applications for CTX from local manufacturers to manufacture unregistered COVID-19 vaccine products for the purposes of conducting research and development in Malaysia involving First-in-Human (FIH) studies. It must be noted that the regulatory requirements for clinical trials remain applicable.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The NPRA issued Directive NPRA.600-1/9/13 (19), which grants conditional registration for COVID-19 vaccines supplied through the COVID-19 Vaccines Global Access (COVAX) Facility. The vaccine will be conditionally registered by the NPRA using the recognition mechanism that has been approved by the WHO Emergency Use Listing. The conditional registration of the vaccine under the COVAX Facility is for one year from the date the vaccine is registered, and can be renewed.

The MDA issued guidelines for the importation and placing in the market of medical devices during an emergency situation through special access notification. The relevant guidelines are as follows.

- The Medical Device Guidance Document (Special Access – Notification – General Requirements) allows the MDA to issue a "no restriction letter" to an applicant for the purposes of importation and placement of the special access medical device in the Malaysian market. These medical devices are exempted from registration with the MDA

and can be imported into Malaysia based on special access. The Guidance identified the following situations in which medical devices are eligible for special access:

(a) when medical devices are to be used in an emergency situation that poses an immediate risk to a patient's life or long-term health where the required medical devices are not available in Malaysia;
(b) where there is an absence of alternative treatment options or where available alternative treatments failed or were deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgement;
(c) where the medical device is needed to minimise disruption to the continued supply of a similar medical device; and
(d) where the design and/or operation of a device is likely to support or enhance the outcomes of the procedure or treatment for the patient.

- The Medical Device Guidance Document (Special Access – Requirements For Ventilator During Emergency Situation) allows an applicant to import and/or sell ventilators in the Malaysian market via a "special access notification". Pursuant to this Guidance, certain registration requirements are modified to ensure speedy approvals of such applications.
- Guideline for Registration of COVID-19 IVD Test Kits allows the MDA to grant conditional approval or special access notification to establishments to register COVID-19 test kits as medical devices.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The NPRA has introduced new guidelines to modify Good Manufacturing Practice and Good Distribution Practice inspections, to enable inspections to be carried out despite the physical restrictions caused by the COVID-19 pandemic. Instead of on-site inspection, the NPRA has implemented off-site inspection mechanisms such as remote and hybrid inspection to carry out national and foreign Good Manufacturing Practice inspections.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The Royal Malaysian Customs Department did not grant any import or export exemptions in relation to medicines or medical devices. However, the Customs Department granted an exemption from import duty and sales tax for the following:

- medical equipment, lab equipment, Personnel Protective Equipment (PPE) and COVID-19 consumables for the MOH; and
- raw materials for the manufacture of hand sanitisers such as undenatured ethyl alcohol and denatured ethyl alcohol.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The Malaysian Medical Council issued an Advisory on Virtual Consultations, which provides guidance on the provision of virtual consultations during the COVID-19 pandemic. The Advisory highlights that, while virtual consultations can only be provided in the context of an existing doctor-patient relationship, virtual consultations may also be given under limited circumstances, such as where a diagnosis can be accurately made with the patient's history and limited audiovisual observation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Malaysian government has yet to exercise its right to issue compulsory licences in rela-

tion to COVID-19-related patents. Under Section 84(1) of the PA 1983, the Minister in charge may allow a government agency or third party to use the patented invention without the patent owner's consent on the following grounds:

- if there is a national emergency or where the public interest so requires, particularly national security, nutrition, health or the development of other vital sectors of the national economy as determined by the government; or
- where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or their licensee is anti-competitive.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were issued to exclude civil liability from the use of COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

There have been no reported cases of manufacturing sites in Malaysia being requisitioned or converted to manufacturing sites for the production of COVID-19 medicines and medical devices.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Typically, public procurements of supplies valued above MYR500,000 are done through an open tender process. To address the urgent need of access to vaccines, the government has implemented a system of public procurement specifically for the procurement of COVID-19 vaccines in Malaysia. Accordingly, a Special Committee for Ensuring Access to COVID-19 Vaccine Supply was set up to assist with the procurement process.

Malaysia also participated in global initiatives such as the COVAX Facility and entered into bilateral agreements with countries in an effort to secure the public procurement of vaccines.

MEXICO

Law and Practice

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Contents

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Baker McKenzie has a healthcare and life sciences industry group that is active on matters throughout the whole life cycle of products, from research and development to manufacturing and commercialisation. It provides industry-focused and integrated advice in the fields of regulatory, data privacy, intellectual property, transactional and M&A, foreign trade, antitrust, compliance, tax and litigation. It acts for the leading players of the industry, including local and multinational companies, with key sectors including medicines, medical devices, health services, dietary supplements, cosmetics, food and beverages, cleaning products, seeds, biocides, fertilisers, biofuels, alcohol and tobacco. Lawyers are also actively involved in legal and trade associations that have a life sciences focus or working groups.

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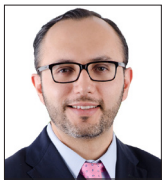

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The legal framework regulating pharmaceuticals and medical devices is largely federal in Mexico, and includes the following laws and regulations:

- the General Health Law (GHL);
- the Health Supplies Secondary Regulations (HSR);
- the Health Services Secondary Regulations;
- the Health Advertisement Secondary Regulations;
- the Clinical Research Secondary Regulations (CRSR); and
- several official Mexican standards on specific technical aspects (eg, good manufacturing practices, labelling and stability).

In Mexico, the legal and administrative nature of the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is that of an autonomous agency, under the administrative structure of the Ministry of Health (MoH). The GHL created COFEPRIS and gave it administrative, technical and operational autonomy. However, that autonomy was placed under pressure after a ministerial decree was issued in 2020, changing its ascription from the Minister directly to a Vice-Minister.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of the regulatory bodies that apply and enforce pharmaceutical and medical device regulations may be challenged through the following optional appeal proceedings:

- an initial administrative review, decided by the same authority that issued the original administrative decision;
- an annulment trial, decided by the Federal Administrative Tribunal; and
- an amparo trial, decided by a judicial body, a judge or a court, depending on the nature of the decision being challenged.

The formal requirements for challenging a decision vary depending on the nature of the decision being challenged, but generally the appeal lawsuit shall include:

- identification of the affected party;
- identification of the challenged decision;
- identification of the authority that issued the decision;
- a description of the facts; and
- the available evidence.

However, the most important element for successfully litigating regulatory decisions is to have an interdisciplinary team of lawyers and pharmaceutical chemists, so that the science and the law can be properly understood and argued in each case.

Strangely, there is still a general impression within companies that there has been no significant litigation relating to decisions taken by health regulators. However, this is not an accurate perception, as litigation has always existed in this area, particularly in relation to sanctions. There is now a lot of litigation in relation to the system of authorisations. As the regulatory system has evolved into a more complete set of legal rules, and as regulatory work is now being undertaken not only by pharmaceutical chemists but also by lawyers, companies have better understood their rights and have felt increasingly confident

to challenge regulatory decisions that affect their interests.

For a whole decade, since the creation of COFEPRIS in 2000, regulatory work was highly technical and was mainly handled by pharmaceutical chemists, both in companies and in regulatory agencies. The health law and regulation did not evolve as quickly as the science and the market. The government's regulatory decisions were frequently taken based not on existing legal rules but exclusively upon technical criteria, which led to a highly discretionary system. Although decisions were always legally vulnerable, the concern of companies was that legally challenging a decision over one product would affect other decisions pending over other products. At the same time, public affairs actions were rather successful in achieving results without the need to litigate.

Two COFEPRIS administrations (2010–18) then brought the legal framework up to date, bringing in lawyers to key positions and modernising the administrative system. This helped to trigger a trend of in-house lawyers and external counsel specialising in the field. At the same time, compliance controls tightened, forcing companies to evaluate, enforce and defend their rights and obligations on the one hand, and to put pressure on the area of public affairs on the other.

Finally, the actions of the last two COFEPRIS administrations (2018–20 and 2020–22), deliberately isolated the agency from the industry, replacing experienced examiners and reducing the number of available examiners, leading to a huge backlog that disrupted commercial operations. This created strong incentives for companies to litigate all kind of pending approval applications.

All of that combined has resulted in a significant and sustained increase in litigation, year after year, for the past decade. This led to the creation of a Specialised Chamber for Regulatory Matters within the Federal Administrative Tribunal, which heard 300 cases against COFEPRIS in 2020. Now there is significant litigation against a lack of response on renewals, modifications, rejections and inspection procedures, in addition to litigating sanction decisions. In 2022, the total number of all types of litigation cases against COFEPRIS skyrocketed to 12,000.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The GHL contains many relevant classifications for medicines, including reference and generic/biocomparable drugs, prescribed and non-prescribed drugs, standard and controlled drugs, and so on.

Medical devices are divided into three classes, according to the risk they represent to human health:

- Class I – those that are recognised in medical practice, whose safety and efficacy have been proved, and that generally are not introduced in the human body;
- Class II – those that are recognised in medical practice, that can vary in the way they are manufactured or in their concentration, and that are regularly introduced to the human body, remaining there for less than 30 days; and
- Class III – new products or those recently accepted by medical practice, or those that are introduced in the human body and remain there for more than 30 days.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulation of clinical trials includes the following key instruments:

- the GHL;
- the CRSR;
- Technical Standard NOM-012-2012-SSA3;
- the Guidelines for Good Clinical Practice published by COFEPRIS; and
- the Decree for the Operation of Ethics Committees, co-ordinated by the National Bioethics Commission.

In general, clinical trials (Phases I–IV) shall be:

- preceded and supported by pre-clinical data;
- conducted in accordance with scientific and ethical principles;
- performed with the informed consent of the participating human subjects;
- executed under a research protocol;
- overseen by a principal investigator; and
- performed in licensed health institutions.

In addition, they must obtain the relevant approvals from a Health Institution, an Ethics Committee and COFEPRIS.

Historically, the operation of Ethics Committees was largely self-regulated and based on international best practice. There was also a lack of co-ordination between COFEPRIS and the National Bioethics Commission (ConBioetica). However, the Decree for the Operation of Ethics Committees (2012) provides a clearer legal framework for Ethics Committees, establishing their structure, their objectives, the role of their members and the requirement to be registered with ConBioetica and COFEPRIS.

Notably, the Guidelines for Good Clinical Practice (2012) make a clear reference to international best practice, including standards developed by the International Conference on Harmonisation. These good clinical practices will be the basis to move towards a certification system, for which COFEPRIS has already started to conduct inspections of research sites.

The operation of contract research organisations (CROs) is not fully regulated, with references only found in the Guidelines, but there are ongoing initiatives to address this.

Other regulatory measures have been introduced to promote Mexico as a place for conducting clinical research, including the following.

- An important amendment to the Health Supplies Secondary Regulations (RIS) – Article 170 of the RIS originally required a certificate of free sale of the country of origin to be submitted as part of an application for obtaining a marketing authorisation (MA) of a drug produced abroad, which therefore made it impossible to have Mexico as the first country of registration. In 2012, however, this was changed to make it possible to submit a clinical trial report instead, provided that the Mexican population was included in the trial.
- The creation of third authorised parties for clinical research – COFEPRIS has authorised several public hospitals with extensive experience in clinical research to conduct a pre-evaluation of research protocols. If their report is positive, approval times at COFEPRIS are reduced significantly.

The same rules regulate medical devices and pharmaceuticals.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to undertake a clinical trial of a pharmaceutical or medical device is comprised of three basic steps, which are sequential and cannot be applied for in parallel:

- favourable opinion of the research protocol by the Ethics Committee of the Health Institution where the trial is to be conducted, which, according to the Decree for the Operation of Ethics Committees, must take place within 30 business days of filing;
- authorisation of the research protocol from the Director of the Health Institution where the trial is to be conducted, which must take place under its relevant internal rules; and
- approval of the research protocol from COFEPRIS, which, according to the Federal Law on Administrative Proceedings, must take place within three months of filing.

2.3 Public Availability of the Conduct of a Clinical Trial

After their protocols have been authorised by COFEPRIS, most trials are currently recorded in the National Registry of Clinical Trials (RNEC). The information contained in the RNEC is collected by COFEPRIS in collaboration with those responsible for conducting the clinical trial (sponsor, CRO or healthcare institution). The RNEC publishes an electronic database that includes only general information about the clinical trials. Although limited, this shows significant progress, as until very recently almost no local information was made publicly available. Confidential information is not included in the RNEC, nor is the health information of patients, which will be regarded as sensitive personal information under data protection laws and will be protected accordingly.

On the other hand, there is no binding provision to disclose or publish the results of clinical trials, but the Code of Ethics of CETIFARMA (the Council of Ethics and Transparency of the Pharmaceutical Industry) does contain a specific obligation for sponsors to disseminate the positive and negative results of trials, particularly the adverse events.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions regarding online clinical trial platforms. However, it would be important for the platform to comply with the regulations regarding the recruitment of and interaction with patients enrolled in a clinical trial if those functionalities are included in the platform. Additionally, this platform could involve other regulatory implications, such as the advertising of health inputs, services and privacy protection, so it is important for its content to be reviewed on a case-by-case basis.

The data resulting from the clinical trial would be considered as personal if the patients enrolled in the clinical study are identified. If the results of the clinical trial are presented without providing information or images that could lead to the identification of the patients, those results would not be considered personal data.

2.5 Use of Data Resulting From the Clinical Trials

It is permitted to transfer the data resulting from the clinical trial to a third party or an affiliate, as long as the privacy notice reveals that a transfer will occur and identifies a justifiable purpose for that transfer. When sensitive personal data is involved, the data controller must obtain express written consent for processing, through a signature, an electronic signature or any authentication mechanism established for that purpose.

2.6 Databases Containing Personal or Sensitive Data

The creation of databases that contain sensitive personal data must be justified and must follow legitimate and concrete purposes that correspond to the activities and explicit objectives of the data controller. These kinds of databases are not subject to authorisation before operations commence.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The GHL provides a general definition for pharmaceuticals. In this respect, any product that falls into such definition should be considered as a pharmaceutical. According to the GHL, a medicine is any substance or mixture of substances of natural or synthetic origin that has any therapeutic, preventative or rehabilitative properties, which is presented under any pharmaceutical form and is identified as such for its pharmacological activity and physical, chemical and biological characteristics.

On the other hand, the new definition of medical device contained in Section 3.41 of Standard NOM-241-SSA1-2021 (NOM-241) is broader: "Medical device, instrument, apparatus, utensil, machine, software, implantable product or material, diagnostic agent, material, substance or similar product, to be used, alone or in combination, directly or indirectly in human beings; with any of the following purposes of use:

(i) diagnosis, prevention, surveillance or monitoring, and/or aid in the treatment of diseases;

(ii) diagnosis, surveillance or monitoring, treatment, protection, absorption, drainage, or aid in the healing of an injury;

(iii) substitution, modification or support of the anatomy or of a physiological process;

(iv) life support;

(v) control of conception;

(vi) disinfection of medical devices;

(vii) disinfectant substances;

(viii) provision of information through an in vitro examination of samples taken from the human body, for diagnostic purposes;

(ix) devices incorporating tissues of animal and/or human origin, and/or

(x) devices used in in vitro fertilisation and assisted reproductive technologies,

as well as those whose main purpose of use is not through pharmacological, immunological or metabolic mechanisms; however, they can be assisted by these means to achieve their function. Medical devices include supplies for health in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing materials, and hygienic products."

Initially, any product that falls into that definition should be considered as a medical device.

It is also important to remember the List of Products that for its Nature, Characteristics and Uses are not Considered Medical Devices. Products

included on this list will be excluded from the regulation of medical devices.

There are other categories that are recognised in practice (eg, combination products), but these are not formally regulated through mandatory instruments.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In general, there is only one type of MA for pharmaceuticals for human health and for medical devices, which is granted by COFEPRIS. The same requirements of quality, safety and efficacy apply, regardless of whether the product is allopathic, homeopathic, herbal or a vitamin pharmaceutical.

However, there is a significant difference between the extent and scope of safety and efficacy data that would be required for an innovator product and that which would be required for a subsequent product, and the specific requirement for releasing biologic products after importation. Biotech drugs are also subject to a pre-submission regulatory meeting with the New Molecules Committee of COFEPRIS.

Please note also that a new class of approvals was introduced during the COVID-19 pandemic, albeit without a legal basis for doing so: emergency authorisations. These would have to expire once the health emergency is declared to be over.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The period of validity of any MA for pharmaceuticals and medical devices is five years. After this period, MAs may be renewed every five years. In contrast, a Recognition Letter for Orphan Drugs, the equivalent of an MA, lasts for two years only.

Also, any authorisation may be revoked by COFEPRIS at any time – for instance, when a new risk to human health is found, if an infringer repeatedly disregards safety measures or if false information is submitted. During the pandemic, MAs were cancelled for companies that failed to submit renewal application on time.

A recent change to the RIS means that the second and subsequent renewals of MAs, both for medicines and for medical devices, will only be subject to a notification, not to an authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

In general, the procedure for obtaining an MA for pharmaceuticals includes filing the MA application form at COFEPRIS, along with evidence of the following:

- the payment of governmental fees;
- a manufacturing licence or equivalent;
- notice of appointment of a qualified sanitary officer;
- draft labels;
- the information to prescribe;
- certificates of good manufacturing practices for the finished product, its active ingredients and its additives;
- the draft distinctive name;
- the quantitative and qualitative formula;
- quality information; and
- preclinical studies, including pharmacodynamics, pharmacokinetic and toxicology studies.

For products manufactured abroad, it is also necessary to file a representation letter granted to the holder.

The application to obtain an MA for medical devices must be submitted with the following:

- the payment of governmental fees;
- the technical and scientific information that proves the security and efficacy standards;
- draft labels;
- instructions;
- a general description of the manufacturing process;
- a description of the structure, materials, parts and functions;
- certificates of good manufacturing practices for the finished product;
- laboratory tests; and
- bibliographic references, if such are required.

For products manufactured abroad, it is also necessary to file the following:

- a free sale certificate;
- a representation letter issued by the manufacturer of the product;
- a certification of analysis;
- sanitary notification of the distribution warehouse; and
- notification of the sanitary official of the distribution warehouse.

Approval times are as follows:

- for pharmaceuticals that include active and therapeutic indications already registered in Mexico, the decision must be granted within 180 days;
- for pharmaceuticals whose active ingredients are not registered in Mexico but are registered and sold freely in their country of origin, a decision shall be taken within 240 days;
- for new molecules, after a prior technical meeting between applicants and the New Molecules Committee of COFEPRIS, the decision shall be taken within 180 days;
- for homeopathic, herbal and vitamin pharmaceuticals, decisions shall be taken within 45 days; and
- for biotechnological drugs, applications shall be resolved within 180 days.

These approval times can be extended if COFEPRIS requires additional information.

For Class I medical devices, the decision must be granted within 30 days; for Class II, the decision shall be taken within 35 days; and for Class III, the decision shall be taken within 60 days.

As with pharmaceuticals, these approval times can be extended if COFEPRIS requires additional information.

There is no mandatory requirement to conduct clinical trials in a paediatric population nor to obtain a waiver from this requirement in relation to individual pharmaceuticals; this is completely optional and subject to stricter requirements.

The variation of MAs can be classified as administrative or technical. Technical modifications are those relating to changes in the formulation, indication or manufacturing process. Administrative modifications include variations such as changes to the corporate name or address of the holder, or changes to the information to prescribe. An assignment of an MA is regarded as an administrative modification. Each application to modify an MA shall contain the technical and legal documentation supporting the relevant change.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

There are a limited number of cases where an unauthorised product can be imported into the country and be supplied to patients, including low-prevalence diseases, donations (eg, in natural disasters), personal use, experimental products for clinical research, and medical use.

In addition, if the relevant product is included in the List of Products that for its Nature, Characteristics and Uses are not Considered Medical Devices, it would not be considered as a medical device and consequently would not require an MA.

The MoH published two decrees, on 28 January 2020 and 22 June 2021, creating the possibility to import medicines and medical devices that do not have an MA in Mexico and to place them in the public market, provided they have an MA from certain recognised jurisdictions. For that, a number of steps must first be taken, including obtaining a prior declaration of necessity issued by multiple authorities. These decrees have also become a source of litigation.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Holders of MAs must comply with good manufacturing practices and stability, pharmacovigilance or technovigilance and labelling standards and regulations; they must also comply with the advertising regulations that apply to pharmaceuticals or medical devices. Product recall obligations have also became relevant of late.

In general, pharmaceuticals and medical devices are subject to post-approval vigilance. These obligations are developed in technical standards, which generally specify the rights and obligations for holders of MAs, distributors, research sites, health institutions, physicians and patients to monitor adverse events or incidents, and to investigate and report them. It is also necessary to have a pharmacovigilance or technovigilance unit, someone responsible for pharmacovigilance and someone responsible for technovigilance, and a pharmacovigilance or technovigilance manual.

However, Phase IV data is only required for more complex products (eg, complex biologics or biotech drugs), as decided by the New Molecules Committee.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

COFEPRIS has periodically published lists of applications, and lists of granted or rejected MAs. However, these lists are not updated regularly, and frequently contain limited information that excludes confidential information. Full access to individual files is only granted to the applicant.

Although third parties have long been able to file public information requests in relation to any file held by COFEPRIS under the mechanisms overseen by the National Institute for Access to Public Information and Data Protection (INAI), COFEPRIS historically resisted providing access to most of the files of MAs, which it regarded as being confidential in their entirety. Nevertheless, through several INAI decisions, an increasing number of data elements can now be accessed. Fortunately, COFEPRIS has now begun to populate a public database on its website that displays key data contained in the MAs for pharmaceuticals.

Confidential information is protected by several special laws, including those related to privacy, intellectual property and administrative procedures, and labour and criminal law.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Relevant legislation includes the GHL, the Federal Consumer Protection Law and the Federal Criminal Code. These legislative bills provide jurisdiction to multiple government agencies to undertake enforcement actions upon the notice of existence of falsified or illegal goods that could affect healthcare. The action that can be triggered will depend on the facts of the case and the illicit goods involved, as it could be within the legal authority of any of the above-mentioned laws.

In essence, the bills provide a legal framework to file and start complaints, through a potential infringement of the Consumer Protection Law or the GHL. These investigations shall be based on a human health risk or a consumer protection liability, rather than IP infringement. Please note that other actions – such as a damages claim for unlawful conduct that affects a company or damages its prestige and reputation – could be explored in a subsequent stage, provided that an infringement is found to have existed, and depending on the direct liability of the offender.

The actions available under these bills are not in the title-holder's control; instead, they are under the control of the relevant agency, such as COFEPRIS, the Federal Attorney General Office, the Federal Consumer Protection Agency or the Federal Police. In this regard, the title-holder/manufacturer is entitled to present a complaint for the relevant agency to start an investigation, which could be a joint investigation with law enforcement agencies, depending on the facts of the case. The agency will be in control of the investigation, while the title-holder/manufacturer can assist with the investigation and provide relevant information that will help build the case, although they will not be in control of the investigation and its outcome.

As a result, depending on the investigation's outcome, there can be injunctive relief such as seizure of illicit goods, or temporary closure of the factory or retail store. These options will be taken by the administrative agencies or the law enforcement agencies ex officio, as the title-holder is not part of the case. For these situations, it is important for the title-holder to follow the official investigation closely to ensure that the administrative agencies or law enforcement agencies liaise in due course.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

A combination of provisions found in international free trade agreements, the Mexican Industrial Property Law and Customs Law provide for the possibility of filing border measures against counterfeited pharmaceuticals and medical devices, provided a recognised IP right is at risk, which includes trade marks, patents and industrial designs. The system is operated through detection technology and databases that are built or fed by title-holders, who will be alerted to suspected goods.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

A pharmaceutical manufacturing plant is subject to a licence, and a medical device manufacturing plant is subject to submitting a notice of operation. COFEPRIS is the authority responsible for granting the manufacturing licence and receiving the notice of operation.

To obtain the manufacturing licence, a certificate of good manufacturing practices (GMP) must be obtained. For that, a COFEPRIS inspection visit to the manufacturing plant must first be requested, to review whether the plant complies with Technical Standard NOM-059-SSA1-2015 of good manufacturing practices of pharmaceuticals. If COFEPRIS determines in the inspection visit that the facility is in compliance, it would grant a certificate, which shall be included in the manufacturing licence application. Once the application is submitted, COFEPRIS shall take no more than 60 business days to grant the manufacturing licence. The activities typically approved by the manufacturing licence are the manufacture and warehousing of pharmaceuticals in the same facility. The operation licence does not have an expiry date.

The notice of operation for a medical device manufacturing plant needs only to be submitted to COFEPRIS, and becomes valid the moment it is filed. The notice of operation requires the appointment of a sanitary officer, who shall be in charge of the facility. The typical activities covered by the notice of operation are the manufacture and warehousing of medical devices in the same facility. The notice of operation does not have an expiry date. With the recent issuance of the new NOM-24 for GMP of medical devices, a GMP certificate must be obtained. This new version of NOM-241 has been a source of controversy, as it also applies to manufacturing sites dedicated exclusively to exporting, which are covered by the IMMEX (Manufacturing Industry, Maquiladora, and Export Service) Program.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

As a general rule, establishments involved in the wholesale of pharmaceuticals and/or medical devices are only required to submit a notice of operation to COFEPRIS. The notice of operation enters into effect at the moment of filing, and does not have an expiry date.

The exception to the general rule is warehouses dedicated to the wholesale of controlled pharmaceuticals (eg, psychotropic and narcotics) and/or biological products for human use, which are subject to a licence.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are divided into the following six sections in relation to their prescription status:

- Section I – prescription pharmaceuticals that can only be acquired by a special prescription or permit issued by the regulatory authority (eg, controlled substances);
- Section II – prescription pharmaceuticals that require a prescription to be collected and retained in the pharmacy as well as being registered in the pharmacy control books;

- Section III – pharmaceuticals that can only be purchased with a prescription that may not be supplied more than three times, and that must be recorded in the control book and retained in the pharmacy after the third supply;
- Section IV – pharmaceuticals that require a prescription, but that can be supplied as many times as directed by the physician (eg, antibiotics);
- Section V – non-prescription pharmaceuticals, authorised for sale only in pharmacies; and
- Section VI – pharmaceuticals that do not require a prescription and can be supplied in any establishments other than pharmacies (eg, over-the-counter products).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

A vast body of law, including secondary regulations, technical standards and administrative decrees, controls the area of foreign trade and customs law. These are not necessarily co-ordinated with the health regulation, creating frequent issues for companies in the pharma and medical devices sectors.

For instance, product classifications can differ to the extent that a product may be classified from a customs perspective as a cosmetic for importing purposes and as a medical device from a regulatory perspective for commercialisation purposes. This in turn can have a tax impact on the applicable rate of Value Added Tax.

Depending on the moment and the type of regulation to which the goods are subject, the following authorities could be involved:

- the Tax Administration Service, mainly through the General Customs Administration;
- the MoH, through COFEPRIS;
- the Ministry of Economy, mainly through the General Direction of Standards and the Federal Consumer's Protection Agency (PROFECO); and
- the Attorney General's Office.

Depending on the type of good, enforcement may also be in the remit of the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence, the Federal Commission of Telecommunications, etc.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Imports must be carried out by an individual or legal entity that is registered in the Importers' Registry, which is administered by the Tax Administration Service.

Depending on their tariff classifications, certain goods – including certain chemical products, radioactive goods, chemical precursors and essential chemical products – may be subject to registration in the Specific Sectors of the Importers' Registry. This registration is subject to additional requirements, which depend on the sector in which the importer is to be registered.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Imports of all pharmaceuticals and some medical devices are subject to the obligation of securing specific import permits.

While such imports are normally administered by the MoH through COFEPRIS, depending on the type of product they may also be subject to other types of import or export permits, including those imposed by the Ministry of Economy, the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence, the Federal Commission of Telecommunications, etc.

Among others, the following exceptions to the obligation of securing an import or export permit may apply, but only for non-commercialisation purposes:

- importing for personal use;
- importing for donations;
- importing for experimental use; or
- importing for low-prevalence diseases.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In Mexico, non-tariff regulations and restrictions – such as import permits and licences – are imposed based on the tariff classification (HTS Code) and the description of the goods to be imported or exported.

Pursuant to the Mexican Constitution, the executive power may regulate or restrict the importation or exportation of products, provided that Congress grants it such authority. The use of that authority needs to be approved by Congress at the end of each year.

Under the Foreign Trade Law, Congress grants this authority to the executive power, with the condition that, in order for a non-tariff regulation or restriction to be imposed, the corresponding decree or administrative regulation must be published in the Federal Official Gazette, and the goods subject to such regulation or restriction must be listed by tariff classification and description.

6.5 Trade Blocs and Free Trade Agreements

Mexico is an active party to the Pacific Alliance (along with Chile, Colombia and Peru). The Pacific Alliance and its framework agreement have specific provisions on regulatory co-operation and product-specific annexes, covering cosmetics, medical devices, dietary supplements and cleaning products. This has started a very promising regulatory harmonisation/convergence process in the region.

Mexico is also party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (the revised Trans-Pacific Partnership Agreement), which contains promising provisions on the regulatory co-operation side, as well as product-specific annexes.

The United States–Mexico–Canada Agreement (USMCA) entered into force in July 2020 and contains several regulatory annexes for pharmaceuticals, medical devices, chemical substances, cosmetic products and food products.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Mexico, the private and public markets for medical products have separate rules depending on whether the products are patented. However, this mainly applies to pharmaceuticals and has changed during the new federal administration.

The very general legislative bases of the dual system are contained in two laws: the GHL

(Article 31) and the Federal Economic Competition Law (Article 9). However, the rest of the rules are largely contained in separate regulatory instruments of lower hierarchy, including the Addendum to the Agreement for Drug Pricing Co-ordination signed in 2004 between the Ministry of Economy and the National Chamber of the Pharmaceutical Industry, and the technical standard for the labelling of drugs (NOM-072-SSA1-2012).

Private Market

Patented drugs for the private market are subject to a hybrid system that is largely self-regulated and voluntary. Under this system, companies compile their own information about their prices in other jurisdictions and submit that to the authority, which monitors the accuracy of the data.

The manufacturer is required to stamp the price on the label of the product at the end of the manufacturing process. PROFECO verifies that the prices at the point of sale (ie, at pharmacies) do not exceed that price.

Generic drugs, off-patent products and medical devices in general are not part of this pricing regulation, being subject to direct price competition in the market. Newly launched products are initially exempted, as explained below.

Public Market

Until very recently, patented pharmaceuticals for the public market were subject to a different process of annual negotiation. For ten years, such negotiations were held with the Co-ordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM), which was created in 2008 and gathered all major public institutions buying drugs in Mexico, as well as the Ministries of Public Administration, Finance, Economy and Health. However, the new federal administration that took office on 1 December 2018 introduced two major changes.

First, it eliminated the CCPNM, transferring the whole pricing process to the public procurement system. That change eliminated the prior distinction between pricing and acquisition, which are now defined in the same process for patented medicines.

The estimated price for generic and off-patent products was initially defined by those public institutions co-ordinating the public procurement exercise, based on their market research. However, the price would also be influenced by the discounts offered by the participating bidders, and would ultimately be determined in the acquisition award and contract.

The administration then changed the rules again, by means of issuing a new version of the Secondary Regulations for the National Compendium, which creates a National Formulary from which public health institutions must – in principle – acquire the medical products they need. The new version incorporated new provisions under which a company must provide a maximum price as part of process to add products; if the addition is approved, that maximum price will become the basis for any public acquisition mechanism.

7.2 Price Levels of Pharmaceutical or Medical Devices

Newly launched pharmaceuticals for the private market are initially exempted from the maximum retail price (MRP) system, given that in principle they would not have a comparator. The manufacturer can initially set the price, subject to a re-evaluation three months after the product launch. The review is conducted to verify wheth-

er the product exists in the international market. If this is confirmed, an MRP will be estimated. If this occurs, the price of newly launched products will be influenced by prices for the same product in other countries, but not based on a health technology assessment. The price regulations for medicines do not apply to medical devices.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Mexican system operates not through a model of reimbursement, but through a model of public procurement of drugs and medical devices.

There is a comprehensive legal regime for public procurement in Mexico, overseen by the Ministry of Public Administration in co-ordination with the purchasing entity. However, this may change during the new federal administration. In general, public procurement operates through three mechanisms:

- public bidding, with a national or international scope;
- invitation to at least three persons; and
- direct awards.

Whereas public bidding is the general rule, purchasing by invitation or direct award is allowed under certain circumstances, which are listed in the Federal Law for Procurement, Leases and Services of the Public Sector. One of the exemptions refers to cases where there are no substitute products, there is only one possible supplier or the required product is patent protected.

Accessing the public market for pharmaceuticals does not begin directly with public procurement: other key regulatory steps must first be met, given that public procurement works through product codes granted by other health authorities, in relation to a Basic Formulary and several Institutional Formularies. The process for incorporating a product to the Basic Formulary and then to Institutional Formularies takes two to four years. The decision is based largely on economic evaluation. A product can only become part of a public procurement exercise once it has been allocated a code, which in the case of medicines is assigned per active ingredient.

On 8 November 2022, the General Health Council (GHC) published a Decree that created a new Commission for the National Compendium for Medical Products, replacing the Inter-Ministerial Commission for the Basic Formulary. A new set of International Regulations for the National Compendium was then issued, on 22 November 2022, bringing several changes to the system, including one that has been a source of controversy and litigation, relating to the introduction of a new requirement. The new rules now state that an application to add a product must first obtain and submit a sponsoring letter from one of the public payors, representing an access barrier.

In 2022, after the results achieved through the collaboration agreement signed by the National Health Institute for Wellness (INSABI) and the United Nations Office for Project Services (UNOPS), it was decided that the mechanism would no longer be used as the main route to acquire medical products. Instead, a new decentralised body was created (IMSSS-Bienestar), which together with INSABI is expected to co-ordinate public acquisitions of medical products.

A lot of uncertainty continues to exist, and many stakeholders expect the public procurement system to go back to normal once this federal administration finishes its term in 2024.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Previously, the methodology was quite clear and included cost-benefit analyses. Now it is not clear. It is also not currently clear whether the new administration will be open to exploring value-based proposals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The regulatory framework links the rules of prescription and dispensing with those of substitution at the point of sale. There are two scenarios for the private and public markets.

- For the private market, the first rule is that prescribing by the active ingredient or generic name is mandatory, and that the use of the distinctive name or trade mark of the product is optional for the health professional. The second and perhaps most important rule is that if the prescription contains only the generic name, pharmacists are allowed to substitute the product. Conversely, if the product was prescribed by its distinctive name, then substitution at the point of sale is forbidden.
- For the public market, although the basic rule structure is the same, there is no reference to the option of prescribing by trade mark, which means that substitution is always allowed. At the same time, it has also become a long-held practice in the public sector to prescribe using the product code allocated in the Basic Formulary or National Compendium, which is also based on the active ingredient. There are provisions allowing prescriptions to be made under different conditions, but the respective institution would need to authorise such decisions, which is not common.

8. Digital Healthcare

8.1 Rules for Medical Apps

Until December 2021, there were no specific regulations for medical apps. However, this changed with the new version of NOM-241, and there are now specific provisions for software with health-related functionalities, including a definition of software as a medical device (SaMD). However, NOM-241 will not enter into force until 20 June 2023.

In addition, the Permanent Commission of the Pharmacopeia had announced that it would issue new rules for the risk classification of medical devices, including medical apps, as part of a new version of the Supplement on Medical Devices, but this has not yet happened. SaMD as a concept was introduced by the International Medical Device Regulators Forum.

8.2 Rules for Telemedicine

There are no special rules for telemedicine as yet; a technical regulation was drafted at one point but it was withdrawn. That failed attempt did not fully address the physician-to-patient private market interaction, covering only a clinic-to-clinic scenario, mainly to address an urban-to-rural public institution vision.

The absence of special new rules for telemedicine means that the existing rules and requirements for the provision of health services and the exercise of medicine are applicable, including the existence of a physical consulting room from which the health service is supposedly provided, and the need to be licensed in Mexico in order to practise medicine. Several draft initiatives on digital health have been submitted to the Federal Congress, all of which proposed a prior approval system for telemedicine platforms.

8.3 Promoting and/or Advertising on an Online Platform

The same legal instruments that are applicable to printed regulated advertising material apply to online content. However, additional guidance documents have been produced by the regulator, including provisions that refer to digital advertising, advertising on social networks and permits for online portals.

8.4 Electronic Prescriptions

There is still a contradiction between two key regulatory instruments. Whereas the Secondary Regulation for Medical Services was amended in 2018 to allow the prescription of medicines by electronic means, the Secondary Regulations for Medical Products still refers to a handwritten signature. The problem is that the first instrument applies to physicians and the second one applies to pharmacies. The contradiction has made pharmacies hesitate, since they are primarily bound by the unchanged instrument. However, in 2020, the Supplement for Establishments of the Mexican Pharmacopeia was amended, to allow for an e-signature. The problem was that it imposed an additional authentication measure that was not previously required, and it excluded certain groups of products from its scope. Several draft initiatives have been submitted to the Federal Congress that would align this at the law level. One of these draft initiatives was approved by the lower chamber on 27 March 2023.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicines and medical devices is closely linked to the issue of whether the retail of a product category is restricted to a particular point of sale.

In that context, there would essentially be three groups of medicines:

- those that require a prescription and can only be sold in pharmacies;
- those that do not require a prescription but have to be sold in pharmacies; and
- those that do not require a prescription and can be sold elsewhere.

In contrast, there would be two groups for medical devices:

- those that are restricted to specialised shops (ie, orthopaedic devices); and
- those that can be sold elsewhere, including pharmacies.

From there, it is important to note that there is not yet any regulation addressing the online sale of medicines; the existing rules applicable to physical pharmacies would apply.

Thus, the regulatory set-up to support the online sale of products would have to take into account the existence of a retail control for the relevant medical product and the existing rules for certain specialised retail shops.

8.6 Electronic Health Records

There are multiple legal instruments to consider, including Technical Standard NOM-004-SSA3-2012 on health records and NOM-024-SSA3-2012 on the electronic health record. However, there are still gaps in the regulation, including more flexible mechanisms to account for the electronic signature of such records.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patents are regulated by the new Federal Law for the Protection of Industrial Property (FLPIP), which entered into force on 5 November 2020, and are granted by the Mexican Institute of Industrial Property (IMPI).

In Mexico, the issues most frequently encountered by companies when trying to apply for patents include the intention of some examiners to limit the scope of protection of the subject matter as exemplified in the specification of the invention. Understanding the law and the science behind the invention is required to overcome this, which calls for in-house technical expertise.

9.2 Second and Subsequent Medical Uses

One of the critical issues with regard to pharmaceutical patents is the need to obtain patent protection for second and subsequent medical uses. Despite the fact that second uses have been accepted in Mexico, there had been no legal bases for their protection. The new FLPIP provides legal certainty for such protection, and expressly states that new uses of known compounds shall be patented as long as they comply with the other requirements established in the law.

Any activity conducted in relation to the protected second use without proper consent will constitute an infringement.

9.3 Patent Term Extension for Pharmaceuticals

Under the new FLPIP, it is now possible to adjust the validity of patents through supplementary certificates for patent applications filed as of 5 November 2020. These supplementary certificates must be requested by the patent applicant to compensate for unreasonable delays from IMPI, provided that the granting of the patent took more than five years from the date of its presentation in Mexico. The term of validity of the supplementary certificates may not exceed five years, and the validity will be one day for every two days of unreasonable delay attributable to IMPI.

Unreasonable delays will be counted from the date on which IMPI notifies the patent owner of the official action informing that the formal examination has been concluded. The periods attributable to actions or omissions of the applicant, such as delays in answering requests or extending the deadlines to respond to them, will not be taken into account when accounting for the unreasonable delay, nor will periods that are not attributable to IMPI, such as the procedure being suspended due to litigation or by acts of force majeure.

Supplementary certificates that were granted in violation of the law could be objected to by third parties.

9.4 Pharmaceutical or Medical Device Patent Infringement

The following activities constitute patent administrative infringements:

- giving the appearance that a product is patented when it is not – if the patent has lapsed or been declared invalid, the infringement will begin one year after the date of the lapse or,

where applicable, the date on which a declaration of invalidity became effective;
- manufacturing or producing products that are protected by a patent without the consent of the owner of the patent, without the appropriate licence;
- offering for sale or distributing products that are protected by patent knowing that they were manufactured or produced without the consent of the patent owner or without the appropriate licence;
- using patented processes without the consent of the patent owner or without the appropriate licence; and
- offering for sale or distributing products that are the result of the use of patented processes, knowing that these have been used without the consent of the patent owner.

It is worth noting that, in Mexico, only actual infringement is actionable; the threat of infringement is not considered by the FLPIP.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The Bolar Exemption was initially incorporated into the health regime. The HSR grant this protection to an application of a generic drug that is submitted during the last three years of a patent over an active ingredient, and to an application of a biosimilar drug that is submitted during the last eight years of a patent over the active ingredient.

The new FLPIP included a new provision that the right conferred by a patent will not produce any effect against a third party that uses, manufactures, offers for sale or imports a product with a valid patent exclusively to generate tests, information and experimental production necessary to obtain an MA of drugs for human health.

This is different to the Research Exemption found in the former industrial property regulation and maintained in the new FLPIP, which stipulates that a patent shall not have effect against any third party who, in the private or academic field, and not for commercial purposes, engages in scientific or technological research for purely experimental, testing or teaching reasons.

Under the Mexican IP regime, compulsory and emergency licences are available.

Compulsory Licences

With regard to compulsory licences, the FLPIP provides that, three years after the date of the grant of the patent or four years from the filing of the application (whichever happens first), any person may apply for the grant of a compulsory licence to use the invention when it has not been used, unless there are justified reasons for the invention not having been used. The importation of the patented product is considered as use.

However, prior to granting the first compulsory licence, IMPI shall give the patent owner the opportunity to exploit the patent within a period of one year, counted from the date the compulsory licence request was notified. If the patent is not exploited after that year, there will be a hearing, and IMPI will decide whether to grant the compulsory licence. If it decides to do so, IMPI shall specify its duration, terms and scope, as well as the royalties payable to the patent holder.

Emergency Licences

With regard to emergency licences, the FLPIP provides that, for emergency reasons or national security, and for as long as the relevant situation continues (including serious diseases designated as such by the GHC), IMPI shall publish a declaration in the Federal Official Gazette, whereby certain patents can be exploited by

means of granting a public use licence. This is for cases where the production, supply or distribution of the patented product would be prevented, hindered or made more expensive for the public if such a declaration is not made.

In the case of an emergency caused by serious diseases that may harm national security, the GHC shall make a declaration of priority treatment. Once the declaration is published in the federal Official Gazette, pharmaceutical companies may request from IMPI the right to exploit the corresponding patent. IMPI would then have 90 days to decide whether to grant the emergency licence, after hearing the parties and evaluating the circumstances.

The MoH shall establish the conditions applicable to the production, quality, duration and scope of the emergency licences, and the qualification of the technical capacity of the applicant, as well as a reasonable amount for the royalties to be paid to the patent owner.

9.6 Proceedings for Patent Infringement

The following points are worth noting in relation to important procedural considerations:

- any patentee or licensee can submit a suit against a third party for infringement (unless it is expressly forbidden from doing so in its licence agreement);
- an important available remedy is the possibility to obtain provisional injunctions; and
- another essential available remedy is to claim damages before a civil court or before IMPI under the new FLPIP, but this can only be initiated after the administrative infringement has been declared by IMPI.

The patent infringement procedure is essentially composed of two stages: first, obtaining an infringement declaration through an administrative proceeding before IMPI, and then obtaining damages directly with IMPI or before a civil court.

An invalidity defence is available in the Mexican IP regime if the patent being enforced was:

- granted in violation of the provisions on requirements and conditions for the grant of patents;
- granted in violation of the provisions of the law in force at the time the patent was granted;
- abandoned as an application during its prosecution; or
- granted by error or to someone who was not entitled to it.

In practice, invalidity is invoked by the defendant when answering the infringement complaint.

9.7 Procedures Available to a Generic Entrant

In Mexico, there are no pre-launch declaratory actions, requirements to notify a patent holder or requirements to clear the way.

Patent linkage was introduced in Mexico in 2003, through a parallel amendment of the RIS and the Secondary Regulation of the Industrial Property Law (SRIPL).

The amendment to the RIS introduced a patent linkage that excludes process patents and explicitly includes only product patents over the active ingredient. However, through litigation, protection has been extended to patents over formulation, doses and use.

The amendment to the SRIPL created a Special Edition of the Intellectual Property Gazette,

issued by IMPI, where all relevant and valid patents for active ingredients are listed.

The trigger for protection is the inclusion of a relevant patent in the Special Gazette. The extended protection mentioned was achieved through litigation aimed at the inclusion of patents over formulation, dosing and use in the Special Gazette.

At the same time, the amendment to the RIS mandates all applicants for an MA of a drug to submit full information on the status of patent protection relating to its product. Applicants must demonstrate that they are the owner or the licensee of the relevant patent, if any. For this, applicants must produce and sign a sworn oath that they do not infringe patent rights. Then, when receiving an application for a drug approval, COFEPRIS is obliged to make an internal consultation to IMPI in relation to the patents that may be directly relevant to that product.

However, the provisions are not very clear, and the ambiguities have created a system that has led to much litigation and to a situation where the burden of proof is essentially carried by users. Patent holders have to litigate inclusions and, if successful, they have to inform COFEPRIS of the results, in order to have an impact on the drug approval system.

At the end of 2020, IMPI implemented electronic tools to make it easier to consult information on patents, with the aim of improving transparency. Through these tools, it is possible to consult:

- the list of patents that will expire in the next ten years;
- a search tool for patents associated with allopathic drugs; and
- IMPI's responses to COFEPRIS on patent linkage issues.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Assuming that a patent infringement action has already been initiated, there are a couple of additional measures that can be taken to obtain extra protection against the counterfeit of protected pharmaceuticals and/or medical devices. One of these measures is the seizure of the infringing goods, both in actual commerce and in customs. Alternatively, the confiscation of packaging, stationery, advertisements and similar objects that might be used to infringe the protected rights is also possible, as well as the seizure of instruments used for the manufacture and commercialisation of those infringing products, according to the Mexican IP Law.

Criminal procedures can be triggered against the following:

- the reoccurrence of a patent infringement;
- the intentional falsification of a protected trade mark;
- the production, storage, transportation, importation, distribution or commercialisation of goods that bear a counterfeited trade mark; or
- the intentional supply of raw materials used for the manufacture of the previously mentioned goods.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Once the trade mark registration has been obtained from IMPI, no direct restrictions can be actioned against the use of those rights, unless

a prior annulment declaration has been issued by the proper authority. However, limitations on the use of a trade mark can be caused by infringement actions against unfair competition practices or trade dress violations. In addition, parallel importation restrictions could affect the use of brands, but only when the owner of the trade mark abroad is not the same as the one in Mexico, or when both parties do not belong to the same corporate structure. Since prior use rights are recognised under the Mexican IP Law, restrictions on the exclusive use of a protected trade mark could be updated as well, as prior users are not regarded as infringers.

Antitrust, consumer welfare and sanitary restrictions could also affect the use of trade marks, although they do not jeopardise the validity of the IP registration. For instance, the name of a pharmaceutical product could first be protected by a registered trade mark, but eventually not be allowed by COFEPRIS to be used as the distinctive name for the approved medicine, due to the different approval criteria (eg, the health law regime forbids names that contain the same three letters in a word, or generally any reference to organs and diseases on the respective product's name).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Under the new FLPIP, trade dress (plurality of operative elements, image elements, including size, colour, design, packaging or any other elements that distinguish products or services) can be protected in Mexico as a trade mark. In addition, trade dress had been protected in the former law and continues to be protected by the FLPIP through infringement actions against any individual who uses signs, operative elements and image combinations that are employed to identify goods or services that are confusingly similar to previously registered ones, given that such usage deceives consumers, making them believe a commercial relation exists between the owner of the rights and the unauthorised user.

Protection for the design of pharmaceuticals and medical devices, as well as their packaging, can be achieved through the registration of a trade mark (design, 3D or trade dress), copyrights, unfair competition and/or an industrial design (ornamentation arrangements in 2D and 3D).

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to the Mexican IP Law, data exclusivity for pharmaceuticals (only) is protected under the terms of the international treaties to which Mexico is a party (eg, the USMCA). The protection is granted for at least five years from the date of the approval, but the regulator, as a matter of policy, has only recognised such protection for new chemical entities, excluding orphan drugs, biologics and biotech drugs. However, the protection for these can be obtained through litigation.

Although the first USMCA text adopted in 2018 contained stronger provisions on data exclusivity, the final amended protocol of 2019 eliminated them, leaving the protection essentially as it was before.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The federal government did not generally seek to facilitate the import and commercialisation of any medicine or medical device required in

the private sector to combat COVID-19, focusing only on public acquisitions of medicines and medical devices. On 27 March 2020, the government issued a decree in which it exempted medicines and medical devices acquired by the federal government from public tenders and import permits.

Instead of facilitating existing procedures, it created new authorisations and emergency approvals, which did not exist before and still lack any legal bases.

11.2 Special Measures Relating to Clinical Trials

COFEPRIS did not issue any measure to facilitate the continuation of clinical trials. Instead, it issued a communication on 21 April 2020 in which it reiterated that any change to the approved conditions described in a research protocol would require the approval of an Ethics Committee and COFEPRIS.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Although emergency authorisations do not exist in the regulatory framework in Mexico, the federal government issued many of these during the pandemic, including for:

- diagnostic tests performed at labs;
- ventilators;
- sanitisation services;
- vaccines; and
- medicines.

The scope of these authorisations is largely unknown, as there is no transparency or publicly known database in their regard.

Apparently, certain restrictions have been incorporated in some of these emergency authorisations – eg, in the authorisation of the medicine Remdesivir, the indication of which was apparently limited to "use in specialised hospitals". However, since this form of authorisation does not exist in the legal framework, any restriction could be challenged.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

COFEPRIS published an informal announcement on its website on 8 July 2020, in which it indicated that GMP certificates could be extended for six months under certain conditions. The extension would apply if the product had not been subject to:

- complaints in Mexico;
- sanitary alerts issued abroad; or
- safety measures in Mexico (eg, suspension of activities).

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

On 27 March 2020, a presidential decree was issued in relation to any medicine or medical device related to COVID-19, allowing for:

- its public acquisition without public tenders; and
- its importing without any administrative requirement.

11.6 Drivers for Digital Health Innovation Due to COVID-19

No specific regulation was issued to facilitate telemedicine, although some local governments created limited programmes for remotely monitoring the conditions of patients. However, no new instrument was issued to clarify any of the pending issues, such as the existence of contradictory secondary regulations in relation to e-prescriptions.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The federal government did not announce any intention to issue compulsory licences for COVID-19-related products. However, in February 2021, during a formal visit to Mexico, the President of Argentina announced Argnetina's intention to request the countries of the G20 to declare COVID-19 vaccines as "global goods", which the Mexican President endorsed. Nevertheless, no further legal step was advanced in this regard.

If the federal government decides to pursue that avenue, it would have to comply with the FLPIP, Article 153 of which establisheds the conditions for issuing a compulsory licence in the event of emergencies, when not doing so would impede, hinder or make more expensive the availability of medicines.

The aforementioned provision creates a procedure where the GHC first issues a declaration of serious disease of priority attention. Interested companies can then apply for licences to IMPI, which will make a decision in no later than 90 days, after receiving the opinion of the GHC. The MoH will then define the manufacturing and quality requirements for the product, as well as the scope, timeframe and royalties for the compulsory licence, which shall be non-exclusive and non-transferable.

The federal government has declared that, since March 2020, COVID-19 constituted a serious disease of priority attention. However, this was a verbatim replication of the similar declaration made regarding the 2009 AH1N1 pandemic, rather than an announcement of its intention to issue compulsory licences.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No special provisions were introduced over product liability of COVID-19 vaccines.

11.9 Requisition or Conversion of Manufacturing Sites

In contrast to health services, where there was indeed an official programme to convert public hospitals into COVID-19 care facilities, there was no equivalent intention in relation to the manufacturing of pharmaceuticals or medical devices.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There have been profound changes to the system for public procurement of medicines and medical devices since the new federal administration took office in 2018, including changes to large centralised purchases, which for many years had been managed by the Mexican Institute of Social Security. The administration first transferred the responsibility to the Ministry of Finance; when that failed, it signed a collaboration agreement and transferred it to UNOPS, which so far has also failed. However, those changes pre-dated the pandemic.

Trends and Developments

Contributed by:
Juan Luis Serrano-Leets
Sánchez DeVanny

Sánchez DeVanny is a Mexican legal consulting firm with international expertise, which specialises in providing holistic and innovative solutions to resolve clients' needs and understands their industries from the inside out. The firm practises law with social responsibility – by exercising legal practice with transparency, ethics and inclusion – and forms lasting relationships with clients that go beyond a simple contract for temporary services. Sánchez Devanny has served clients who have placed their trust in the talent and experience of the firm's lawyers since its foundation in 1996. The team combines experience with creativity in order to build solutions for clients, because it is easier to innovate successfully when there is an understanding of how to do things correctly.

Author

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IMSS Bienestar Becomes Main Healthcare Provider for Unemployed People

A new division of the Mexican Institute of Social Security (*Instituto Mexicano del Seguro Social*, or IMSS) was created in March 2022 as part of a major reform to the Mexican healthcare system. The IMSS formerly provided healthcare services to employed persons in the private sector and was thus the largest provider in the country. The National Wellbeing Institute (*Instituto Nacional de Salud para el Bienestar*, or INSABI) provided services to persons who were not formally employed and to those not covered by another form of insurance through a combination of federal and state-run facilities.

As a consequence of this reform, states can voluntarily decide to federalise their healthcare system and allow IMSS Bienestar to run their facilities. As of February 2022, the states of Tlaxcala, Nayarit and Colima became the first to adhere to this new system. INSABI will likely still be involved in purchasing processes.

Ministry of Health Recognises Fast-Track Approvals for Drugs/Devices Approved in Other Jurisdictions

Mexico has issued several official guidelines recognising that requirements imposed by certain foreign agencies to approve pharmaceutical products and medical devices are equivalent to those established under national laws and regulations.

These guidelines include the recognition of approvals by:

- the World Health Organization (WHO) prequalification programme;
- Swissmed;
- the US Food and Drug Administration;
- the European Medicines Agency;
- Health Canada;
- the Australian Therapeutic Goods Administration; and
- WHO/Pan American Health Organization reference regulatory agencies.

Although some of these guidelines have existed for many years, their use had not been widespread – mainly because they offered no clear advantage for applicants with regard to regulatory timelines. Specifically, products submitted for approval under these guidelines would be studied on a "first-in, first-out", along with all other submissions.

This situation changed – at least on paper – in November 2020, when the Ministry of Health enabled a significant reduction in regulatory timelines by establishing:

- a term of five working days to issue product marketing authorisations filed under equivalency agreements;
- a term of three working days to issue requirements to the applicant, if the information was not complete; and
- a tacit affirmative response, meaning that the approvals would be considered as granted if the terms expire.

Despite this notification, the Mexican Regulatory Agency (*Comisión Federal para la Protección contra Riesgos Sanitarios*, or COFEPRIS) has not observed the shortened deadlines. Marketing authorisations have not been issued for what has now been more than a year and the regulator has publicly recognised that it is facing a severe backlog.

As a way to counter the inactivity of COFEPRIS, and at the request of one of Sánchez Devanny's clients in the pharmaceutical industry, the firm's

life sciences team prepared a regulatory/litigation strategy. In the corresponding trial, the team secured favourable injunctions and a favourable judgment. In the final decision, the court ordered COFEPRIS to issue the marketing authorisation. This decision is likely to have broader effects, given that several applications for fast-track approvals for drugs and devices have been backlogged.

New Rules Regarding Term Extension for Product Marketing Authorisations

On 24 January 2022, COFEPRIS published a notice in the Official Gazette establishing new rules for the digital filing of applications to extend the terms of drug and device marketing authorisations.

According to the official website, the prior procedure (involving paper filings every five years) caused severe backlogs and – in some cases – lack of products in the market, as associated processes (eg, import permits) were delayed while the extension was being considered.

Two main rules apply:

- the first term extension will be subject to a reduced term of 120 days (versus the original term of 150 days); and
- subsequent term extensions will be decided automatically, upon filing complete documentation.

Judicial Challenges Regarding Failure to Observe Tacit Affirmative Response Terms in Regulations

In Mexico, the Regulations for Health Supplies contain several petitions before COFEPRIS that are subject to tacit affirmative responses – meaning that if the corresponding deadline expires without a resolution from the Agency, the petition is legally understood as granted. However, COFEPRIS has historically refused to recognise these provisions in several instances – most notably, in cases pertaining to the modification of conditions for approved marketing authorisations and term extensions.

There have been cases where – days or months after the deadline to decide on a file expires – COFEPRIS has issued communications requesting additional technical documentation or even outright refused petitions and instead issued orders to recall products from the Mexican market.

Some companies have filed judicial challenges against these determinations. In cases filed by Sánchez Devanny, the firm has secured injunctions and final decisions reverting recall orders and ordering COFEPRIS to recognise that – owing to the lapsing of the corresponding legal term – the petitions are considered granted.

Injunctions Denied Regarding Front Labelling Requirements for Products Containing Caffeine/Sweeteners or Considered High in Calories, Sugar or Salt

On 27 March 2020, a modification to Official Norm NOM-051-SCFI/SSA1-2010 was published in the Official Gazette, thereby ordering companies selling food and drinks to adhere to a front labelling system that includes highly visible warnings against products classed as high in sugar, salt or calories or those containing caffeine/sweeteners. These modifications also banned the use of cartoons or famous athletes in the labelling or promotion of relevant products.

This prompted judicial challenges by several companies – most notably, the Coca-Cola Export Corporation, which asked for injunctions to prevent it from having to adhere to this new

system until the constitutionality of the underlying provisions was studied by the court. The injunctions were denied and, on appeal, the Fourth Circuit Court confirmed the refusal and published a non-binding jurisprudence precedent on 10 December 2021.

The Court determined that the state must inform society of risk situations, especially when associated to the human right to health. Given that Mexico has some of the highest obesity rates in the world, the Court also considered the particular impact on this right if the injunctions were granted.

Legal Challenges Continue as COFEPRIS Ratifies Position Against E-cigarettes

COFEPRIS has historically banned authorisations for e-cigarettes and vapers. However, these devices are commonly sold online or in physical stores in Mexico and several legal challenges have been filed against the prohibitions.

On 5 November 2021, COFEPRIS and the National Commission Against Addictions jointly issued a sanitary alert. In the document – and with the clear intention of targeting the legal precedents on the matter – the agencies explain: "There are three categories of tobacco products that are novel and emerging: (i) Electronic Systems to Administer Nicotine (SEAN), (ii) Similar Systems without Nicotine (SSSN) and (iii) Alternative Nicotine Consumption Systems (SACN). The first two are known as electronic cigarettes (E-cig), vapers or vaporisers; the third are known as heated tobacco products (PTC). They are all health hazards, derived from their carcinogenic components, toxic substances and aerosol emissions."

The warning goes on to explain:

- the associated health risks of these devices;
- that the efficacy of these devices as an alternative to smoking has not been proven; and
- that there are no authorisations for any of these products.

There is also an invitation to the general public to file actions before COFEPRIS if there is any evidence of sales of these devices.

This position by the regulators is not supported by available non-binding judicial precedents. When cases of this nature have been studied, the courts have generally sided with plaintiffs – especially when the products intended for market contain heated tobacco.

Litigation on the matter will continue and likely extend to actions by the customs authorities, as several devices of this nature are imported.

Litigation Regarding Patent Term Extensions in Response to a Pharmaceutical Patent Trial

According to Article 23 of the Mexican Industrial Property Law, which was in force until 5 November 2020, all patents in Mexico were granted a life term of 20 years from the date of filing (whether Patent Co-operation Treaty or domestic filings). This article was in agreement with Article 1709 (Section 12) of NAFTA, which established that "each party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant" and that a "party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes".

In December 2018, Bayer Healthcare LLC filed a brief before the Mexican Institute of Industrial Property (IMPI), requesting an extension to the term of patent No 238942 – covering the pharmaceutical compound sorafenib (used as an

active ingredient in the oncology drug Nexavar®) – from 12 January 2020 to 26 July 2023. Among other points, it argued that a proper interpretation of NAFTA should allow for the broader benefit between the two alternatives.

This petition was denied by IMPI. In the first stage of appeal, a district court confirmed the refusal by considering in part that there was no administrative delay in the process of grant that would support the broader term between the two alternatives provided by NAFTA. The appeal to this decision was remanded to the Supreme Court.

Even though the denial of a term extension by the district court was in agreement with all the precedents to date, the Supreme Court found in a decision approved on 14 October 2020 that the overall patent prosecution process of six years from the Patent Co-operation Treaty filing date unduly affected the patent owner by limiting the opportunity to secure this broader benefit. As such, the Supreme Court ordered the Mexican Patent Office to extend the term to 17 years from the date of grant (which adds up to 23 years from the date of filing).

Although this decision is not binding, it has caused several companies (mostly in the pharmaceutical space) to file similar term extension applications. According to public records, these petitions have been denied by IMPI. Patent owners have filed constitutional actions, banking on the same logic defined by the Supreme Court in the Bayer case.

Pending Linkage Rules Regarding Analysis of Patent Rights Before Issuing Marketing Authorisations

The Federal Law for Protection of Industrial Property established in a transitory article that IMPI and COFEPRIS would issue new rules to co-ordinate linkage review. Under the current system, a review is conducted between the agencies, without allowing either party to provide input. The applicant is then informed if the product is deemed to invade a patent in force.

It is possible that these new rules will adopt some of the aspects of the US Orange Book system, such as:

- a linkage gazette tied to approved products (as opposed to containing any patent covering a pharmaceutical product);
- a system allowing for claims of invalidity (and a specific timeframe for suspension of study of a marketing authorisation if infringement is claimed); and
- first generic market exclusivity.

NIGERIA

Law and Practice

Contributed by:
Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye
Jackson, Etti & Edu

Contents

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Jackson, Etti & Edu (JEE) is a leading full-service commercial law firm with a sector focus, including on the health and pharmaceutical sector. With more than 25 years' experience and several awards for excellence, JEE consistently renders legal services to Nigerian, pan-African, and international clients from diverse jurisdictions – as evidenced by the firm's presence in Lagos, Abuja, Accra, Harare and Yaoundé. JEE's lawyers have gained extensive expertise in advising and acting for clients on a wide range of subject matter pertaining to the healthcare sector, including financing, business regulatory compliance, ethics for health professionals, debt recovery, litigation, arbitration and ADR – as well as health law advocacy and reviews of laws in this sector. The firm consists of 14 partners, 60 fee earners and more than 50 paralegals and support staff. The size of JEE's dedicated commercial team is indicative of the firm's rich human resource base and its Chapteracity to effectively and efficiently help clients achieve their goals.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The key pieces of legislation and regulation that govern pharmaceuticals are:

- the Food and Drugs Act (Chapter F32) LFN 2010;
- the National Agency for Food and Drug Administration and Control (NAFDAC) Act Chapter (N1) LFN 2010;
- the Food, Drug and Related Products (Registration) Act (Chapter F.33) 2010; and
- the Pharmacy Council of Nigeria (Establishment) Act 2022.

Both the Food and Drugs Act (Chapter F32) LFN 2010 and the Food, Drug and Related Products (Registration) Act (Chapter F.33) 2010 regulate the manufacture, sale, advertisement and distribution of drugs in Nigeria. Meanwhile, the National Agency for Food and Drug Administration and Control (NAFDAC) Act Chapter (N1) LFN 2010 establishes the main regulatory agency (ie, NAFDAC) responsible for issuing marketing authorisations and product registrations for sale and distribution of imported and locally manufactured pharmaceuticals in Nigeria.

The Pharmacy Council of Nigeria (Establishment) Act 2022 regulates the sale and distribution of pharmaceutical products in Nigeria, however. It seeks to control the supply chain of pharmaceuticals and ensure the registration and regulation of premises where pharmaceuticals are sold and distributed, whether such sales are on a large-scale basis or for retail. The Pharmacy Council of Nigeria (Establishment) Act 2022 also establishes the Pharmacy Council of Nigeria (PCN), which is the regulatory agency responsible for the control and supervision of pharmacists, as well as the premises used for manufacture, distribution, and sale of pharmaceutical products in Nigeria.

To reinforce their regulatory oversight, both the PCN and NAFDAC have issued guidelines and regulations on the distribution, advertisement and importation of pharmaceutical products. These regulations include:

- Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria;
- Guidelines for Pre-Registration Inspection of Pharmaceutical Manufacturing Facilities in Nigeria;
- Good Distribution Practice for Pharmaceutical Products Regulations 2021;
- NAFDAC Guidelines for Contract Manufacturing of Finished Pharmaceutical Products in Nigeria;
- Drug and Related Products Labelling Regulations 2021; and
- Online Pharmacy Regulations 2020.

The legislation and regulation governing pharmaceuticals also govern medical devices. Thus, the PCN and NAFDAC are major regulators when it comes to medical devices. However, in addition to these regulators, legislation and regulation set up the Standards Organisation of Nigeria (SON), the Federal Competition and Consumer Protection Commission, and the Nigerian Nuclear Regulatory Authority (NNRA) under the Standards Organisations of Nigeria Act 2015, the Federal Competition and Consumer Protection Act 2018 and the Nuclear Safety and Radiation Protection Act 1995 respectively.

Although the SON is responsible for regulating the standards of medical devices, the Federal

Competition and Consumer Protection Act 2018 seeks to protect the consumer from exposures from manufacturers. The National NNRA, however, regulates the use, installation and operation of medical devices that have radiation. This would include x-ray machines and MRI machines.

It is, however, crucial to note that NAFDAC remain the main regulatory authority for medical devices. To this end, NAFDAC has issued regulations and guidelines to control the distribution, sale, and distribution of medical devices. This would include:

- Drug and Related Products Advertisement Regulations 2021;
- Guidelines for Registration of Medical Devices Made in Nigeria;
- NAFDAC Guidelines for Registration of Imported Medical Devices in Nigeria;
- NAFDAC Guidelines for the Renewal of Certificate of Registration License for Imported Medical Devices; and
- Guidelines for Advertisement of NAFDAC Regulated Products.

The regulatory bodies that enforce pharmaceuticals and medical devices laws and regulations are as follows.

- NAFDAC is the statutory body that administers the NAFDAC Act and enforces its objectives. The NAFDAC regulates and controls the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs, medical devices, pharmaceuticals, and chemicals.
- The PCN is the statutory entity responsible for the control and supervision of pharmacists as well as the premises used for manufacture, distribution, and sale of pharmaceutical products in Nigeria.
- The SON is the statutory body responsible for standardising and regulating the quality of products in Nigeria, including medical products. The SON also oversees the standard of goods imported and distributed in Nigeria.

The SON, the PCN and NAFDAC are all semi-autonomous regulatory entities, given that they are supervised by the Nigerian federal government through the Federal Ministry of Health and the Federal Ministry of Trade and Investment.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Filing a Complaint

A party who is dissatisfied with the decision of a regulatory body is entitled to petition the same regulatory body for a review of its decision. It is not unusual for decisions by the major regulatory bodies that enforce pharmaceutical and medical device regulation – especially agencies such as the PCN and NADFAC – to be contested or challenged. The following procedure is generally used to challenge decisions by such regulatory bodies.

Petition or appeal to the regulatory body to review decision

First, an attempt should be made to seek a reconsideration of the regulatory body's decision, outlining grounds for such petition or appeal. There is a statutory time limit of three months for challenging decisions of regulatory bodies; therefore, this petition or letter must be issued to the regulatory body within this timeline in order to avoid a situation where a party's right to challenge an unfavourable decision is limited and exhausted by operation of law.

Pre-action notice to the relevant regulatory body

Most regulatory bodies that enforce pharmaceutical and medical devices regulations require a party challenging their decision to issue a pre-action notice as a precondition to the commencement of a court action or to seek judicial review. One such example can be found in the NAFDAC Act, which provides that a pre-action notice (or a written notice of intention to commence a suit) must be issued one month prior to the commencement of the suit. There is also a one-month timeframe in which to submit a pre-action notice where a decision by the PCN is to be challenged.

Court action for judicial review of the regulatory body's decision

After taking the above-mentioned steps mentioned, a party is entitled to proceed to court in order to challenge the decision of the regulatory body. It is crucial to note that the court action must be filed within three months of the date of the decision of the regulatory body, or else the matter will be considered statute-barred.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are different categories in place for medical devices and pharmaceuticals and this is reflected in the laws and regulations in force.

Categories of Pharmaceuticals

Pharmaceuticals are not specifically categorised in Nigeria. Although the NAFDAC regulates all types of drugs, the NAFDAC Drug and Related Products Advertisement Regulation makes separate provisions for the labelling and advertising of prescription medication. Such provisions differ from those for OTC medication.

Categories of Medical Devices

With regard to medical devices, NAFDAC has adopted the Global Harmonization Task Force (GHTF)'s guidelines – known as the Principles of Medical Devices Classification – for the international classification of medical devices. These classes include:

- Class A for low risk (eg, cholesterol, uric acid test system, surgical instruments, bandages, surgical cameras).
- Class B for low-to-moderate risk (eg, surgical lamp, surgical mask, electric hospital bed).
- Class C for moderate-to-high risk (eg, condom, x-ray unit, syringe, contact lens).
- Class D for high risk (eg, pacemaker, defibrillator, HIV blood donor screening, stent, intraocular lens).

The higher the risk, the more stringent the regulatory requirements for such class will be.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Nigeria, clinical trials for pharmaceutical products and medical devices are regulated under the Clinical Trial Regulations 2021, with NAFDAC as the supervising agency. NAFDAC is empowered to review protocols and grant authorisation of clinical trials before they are conducted.

However, the National Health Research Ethics Committee (NHREC) and the Institutional Review Board (IRB) are statutorily expected to provide ethical opinion, which is a precondition for the grant of NAFDAC's approval of such clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to conduct clinical trials for pharmaceutical products and medical devices is governed by Clinical Trial Regulations 2021, the Good Clinical Practice Guidelines 2020, as well as the Guidelines for Clinical Investigation for Medicinal Products in the Paediatric Population.

The requirements for applying for approval to undertake a clinical trial are as follows:

- Application form – every organisation that wishes to undertake a clinical trial must fill out and submit an application form, along with supporting documents and a completed checklist, containing details of the study, the organisation conducting the trial, the technical details of the pharmaceutical or medical device being tested, as well as other relevant details.
- Protocol – certain protocols are required under the regulation, including investigation of approved trial sites and facilities used for clinical trial, processing of data of trial participants (patient information leaflet), signed declaration by the sponsor or principal investigator and co-investigators and persons of interest, informed consent of participants, and proof of indemnity or insurance certificate.
- Ethics Committee approval – after observing protocol measures, the Ethics Committee is set up only for specific matters that ensure the risks to the participants are equally managed. The Ethics Committee operates under a valid certificate issued by the NHREC and it is prescribed that members of the Ethics Committee do not have any interest in the trial.
- Registration – upon completion of the application form and submission of other supporting documents and observance of protocol measures, the applicant for clinical trial will then be registered with the Nigerian Clinical Trial Registry (NCTR), or the Pan-African Clinical Trial Registry (PACTR) and the evidence must be submitted to NAFDAC.

2.3 Public Availability of the Conduct of a Clinical Trial

Information on clinical trials is accessible to the public; therefore, their status may be ascertainable.

Clinical trial applications filed in Nigeria both for pharmaceuticals and medical devices can be accessed through NAFDAC's Electronic Clinical Trial Application Platform. Along with the NHREC and the Federal Ministry of Health, NAFDAC also maintains the NCTR, which is accessible to the public. This registry provides information in ongoing as well as completed trials.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is presently no restriction for using online tools to support clinical trials. for using online tools to support clinical trials under Nigerian legislation have not been updated.

However, in practice, NAFDAC and NHREC have associated online platforms used as a database for clinical trials, which they update with new information on the investigations and upload information peculiar to the trial.

2.5 Use of Data Resulting From the Clinical Trials

Data resulting from clinical trials may not be considered as personal data under Nigerian law.

Per the provisions of Section 5(10) of the Clinical Trial Regulations 2021, rights of the participant

to physical and mental integrity, privacy, and personal data during the clinical trial are protected. The protection of the participant's data is at the frontier of the clinical trial such that the resulting data and other information made publicly available do not contain any information concerning participants that may be considered personal data.

Where the resulting data includes details that might identify the participants, it is classed as personal data. As such, it can only be published on obtaining the informed consent of the participant to use their personal data.

Transference of Data to a Third Party

In the same vein, such resulting data may be transferred to a third party or affiliate in accordance with the laws that protect such data.

Pursuant to Section 7(6) of the Clinical Trial Regulations 2021, any transfer of ownership of the content of the clinical trial must be documented and the new owner is to assume the responsibilities set out in the regulations. Likewise, Article 3.1(7)(f) of the Nigeria Data Protection Regulation (NDPR) 2019 provides that – prior to collecting personal data from a data subject (in this case, from the participant in the trial) – the data controller (in this case, the person/organisation that is running the study) must inform the data subject of:

- the fact that the data controller intends to transfer personal data to a third party or another country or an international organisation; and
- the existence or absence of an adequacy decision by the National Information Technology Development Agency (NITDA), which indicates whether another country satisfactorily protects personal data.

Data resulting from clinical trials containing sensitive data may not be shared on the associated platform with third parties unless the participant consented to the use and transfer of their personal data.

2.6 Databases Containing Personal or Sensitive Data

By law, the creation of a database containing personal or sensitive data is subject to further protective requirements. Such a database must comply with the Clinical Trial Regulations 2021, as well as the provisions of the NDPR aimed at the protection of sensitive data of the data subject collected on a database.

A requirement of law, for instance, under Article 2.1(1)(l) of the NDPR is that personal data (applicable to the participant's information used in the trial is collected and processed where consented to by the data subject (the participant in the study) – provided that further processing may be done for archiving, scientific research, or statistical purposes for public interest. Therefore, participants are required to consent to their personal data being uploaded onto a public data base. Section 3 (9) of the Clinical Trial Regulations specifies that the confidentiality of records that could identify subjects must be protected in order to respect their privacy.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

In the determination and classification of pharmaceuticals and medical devices, the NAFDAC Act prescribed a number of specific requirements or criteria.

The NAFDAC Act defines a "drug" as any substance of vegetable, animal or mineral origin (or any preparation or admixture thereof) that is manufactured, sold, or advertised for use in:

- the diagnosis, treatment, mitigation or prevention of any disease, disorder or abnormal physical state (or the symptom thereof) in humans or animals;
- restoring, correcting or modifying organic functions in humans or animals;
- disinfection or the control of vermin, insects or pests; and
- contraception.

On the other hand, a medical device is defined as "any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof" in humans or animals.

Therefore, products that fall within the scope of these definitions would be assessed and placed in such categories, if considered to be either pharmaceuticals or medical devices.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In Nigeria there are no specific obligations provided for granting marketing licences for biologic medicinal products. As such, the general obligations under the Guidelines must be adhered to.

However, it is to be noted that the National Control Laboratory for Vaccines and Other Biologics (NCLVB) is a specially constituted NAFDAC unit responsible for confirmation of the quality, safety, efficacy and fitness for use of vaccines, biological products, and medical diagnostic devices after analysis/evaluation. This unit may therefore recommend restriction on the marketing of specific biologics based on the review of same.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The NAFDAC Drug and Related Products Registration Regulations 2019 provides that the registration of a drug with NAFDAC will be valid for a period of five years.

Mechanisms for Renewal of Marketing Authorisation

Under the NAFDAC Drug and Related Products Registration Regulations 2019, such marketing authorisations may be renewed. The NAFDAC has published further Guidelines for Renewal of Certificate of Registration for Locally Manufactured Drug Products in Nigeria, in addition to Guidelines for Renewal of Certificate of Registration for Imported Drug Products in Nigeria. These guidelines set out the mode of renewal and cover the nature of the application and the supporting documents required – for example, annual licence/premises registration, trade mark registration, Certificate of Pharmaceutical Product (COPP–WHO Format), and notarised declaration. Similar provisions are found in the Guidelines for Renewal of Certificate of Registration for Medical Devices Made in Nigeria, as well as Guidelines for Renewal of Certificate of Registration for Imported Medical Device in Nigeria.

All the above-mentioned guidelines provide that application for renewal must be initiated no later than 30 calendar days before the date the current/valid licence is due to expire. Successful renewal applications for drugs and medical devices, whether locally manufactured or imported, will result in the issuance of a Cer-

tificate of Registration with a validity period of five years.

Circumstances in Which Marketing Authorisations May Be Revoked or Withdrawn

Pursuant to Section 7 of the Drug and Related Products Registration Regulations 2019, marketing authorisation may be revoked or withdrawn by competent authorities on the following grounds:

- where the ground of registration happens to be false;
- where the conditions of registering the drug product have been breached.
- where the standard of quality in the paperwork of the registration has been contravened;
- where the product is ineffective for its primary purpose;
- where the premises in which the drug product or part thereof is manufactured – or kept on behalf of the Certificate of Registration Holder ("the Holder") – contravenes the provisions of current Good Manufacturing Practice (cGMP);
- where the Holder has given notice to NAFDAC in writing of any intentions to suspend product registration for a period not exceeding the validity of the certificate of registration; and
- where the registration is inchoate based on the information supplied.

The regulations further provide that, where the registration of drug product is suspended or cancelled, NAFDAC must then withdraw the drug product and cancel it from circulation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

In practice, there is a standard procedure for obtaining marketing authorisation for drugs and all regulated products. Pursuant to the Drugs and Related Products (Registration) Regulations 2019, a drug cannot be imported, distributed, or sold without being registered by NAFDAC.

According to the regulations, a marketing authorisation may be granted through a single application process, as follows.

- The applicant must submit an application form, along with relevant documents as prescribed by NAFDAC. This is submitted with a clear description of the product applied for that contains all technical and administrative information relating to the product. The applicant must pay the fees prescribed by NAFDAC. This may be done at any time in the course of applying for registration.
- NAFDAC may ask the applicant for further information in order to reach a decision about the application if deemed necessary. Once satisfied, NAFDAC issues a Certificate of Registration, which subsists for five years until renewal.
- NAFDAC then publishes the list of registered products on its official website, thereby notifying the registration status.

According to the Guidelines for Registration of Drug Products Made in Nigeria, the procedure for obtaining authorisation entails the following steps.

- Dossier application – the applicant must submit a dossier of the drug product for screening as a prerequisite for registration.

- Application letter – this consequently allows the applicant to submit an application for the registration of the products, which is processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal. A separate application must be made for each product and addressed to the Director General of NAFDAC. Other documents are attached with the application on the portal and the original copies will be made available on request. These documents include:
  (a) Certificate of Incorporation or any evidence of registration of the business of the applicant in Nigeria;
  (b) a legal manufacturing agreement/contract;
  (c) any evidence showing the trade mark or brand name of a drug has been registered under Class 5 in the name of the trade mark owner at the Trademarks, Patents and Designs Registry;
  (d) a copy of valid annual licence to practice of the superintendent pharmacist;
  (e) a copy of valid Premises Retention Licence for the facility;
  (f) a certificate issued by Good Manufacturing Practice (GMP) or any evidence of a successful inspection by any regulatory authority; and
  (g) an artwork or product label compliant with the Drug and Related Products Labelling Regulations.
- Product approval meeting – the Food and Drug Registration Committee (FDRC) then holds an approval meeting to determine whether the drug or product has satisfied the requirements stated.
- Issuance of Certificate of Registration – upon approval of the product, an electronic Certificate of Product Registration is issued to the applicant and subsists for a period of five years unless renewed.

Procedure for Variation of a Previously Granted Marketing Authorisation

There is a standing procedure for varying a marketing authorisation previously granted by an application to NAFDAC. According to the Drugs and Related Products (Registration) Regulations 2019, such variation can only be made where the product has been previously authorised.

The procedure for variation of a marketing authorisation that has been granted previously begins with the applicant submitting a variation application to NAFDAC with details of the changes to be carried out. This is accompanied by the prescribed fees per the request of NAFDAC. The further requirements depend solely on the type of change requested for.

Such change may be made by:

- annual notification;
- immediate notification;
- minor variation; and
- major variation.

The applicant who is deemed to hold the Certificate of Registration must not distribute the product until the variation to the authorisation has been assessed and approved by NAFDAC and the product label reflects the change where necessary. However, changes that do not adversely affect the quality of the drug may be made prior to approval by NAFDAC.

Pursuant to Section 6 of the Regulations, the applicant must seek a new application where the variations to be made fall under the following categories:

- change of the Active Pharmaceutical Ingredient (API) to a different API;
- inclusion of an additional API in a multi-component product;
- removal of one API from a multi-component product;
- change in the strength of one or more APIs;
- change from an immediate-release product to an extended or delayed-release dosage form or vice versa;
- change from a liquid to a powder for reconstitution or vice versa; and
- changes in the route of administration or other changes as prescribed by NAFDAC.

Transference of Marketing Authorisation

The position of the law on the transference of marketing authorisation is outlined in the relevant NAFDAC laws and regulations.

Pursuant to Section 2(3) of the Drugs and Related Products (Registration) Regulations 2019, once a certificate of registration has been issued, it cannot be transferred, disposed, hired or sold to a third party unless approved by NAFDAC.

Although the guidelines make no recommendation for the appropriate procedure, in practice it may be achievable by applying to NAFDAC with supporting documents.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Section 2 of the Drugs and Related Products (Registration) Regulations 2019 expressly prohibits the sale and distribution of regulated products that are not registered with NAFDAC. This implies that the product must be issued a Certificate of Registration before it can be distributed in Nigeria.

However, Section 2(2) of the referenced regulations allows exceptions and provides that NAFDAC may issue the permits to allow the supply or entry/importation of drugs for the purpose of registration (limited quantity). The exception would also be applicable for the conduct of a clinical trial, a service drug scheme, and for any use in emergency situations resulting from epidemics or disease pandemics, donation for humanitarian interventions, and so on. This exception was explored during the COVID-19 period, during which vaccines were allowed entry for humanitarian reasons owing to the pandemic.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Pharmacovigilance of Pharmaceuticals and Obligations Imposed on the Marketing Authorisation Holder

In regulating and assessing the quality of products, NAFDAC has paved the way for post-marketing surveillance/pharmacovigilance that imposes certain obligations on a Marketing Authorisation Holder (MAH).

For pharmaceutical products, the NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products outlines the recommendations and principles guiding the distribution of pharmaceutical products in Nigeria. The guidelines highlight the responsibilities of the distributor as endowed by the authorisation issued by NAFDAC.

As imposed by the guidelines, distributors or their agents can only supply pharmaceutical products to those authorised to sell or distribute such products to patients. Such authorisation must be approved and valid before the Marketing Authorisation Holder (MAH) distributes

accordingly. Likewise, the guidelines make provisions for a quality management system so that the activities carried out by the distributors and MAHs are compliant with GMP principles.

In the same vein, once MAHs have been issued with a marketing authorisation, they may be subject to post-marketing obligations to ensure that quality goods are distributed accordingly – hence pharmacovigilance of medical devices, pharmaceuticals and regulated products.

Through the Guidelines for Post-Marketing Surveillance in Nigeria, NAFDAC has made express provision for pharmacovigilance of pharmaceutical products and the necessary steps and considerations to be taken.

Under the guidelines, post marketing surveillance (PMS) planning involves international organisations, procurement organisations, NGOs, MAHs or other persons involved in the distribution of products. As with the MAHs, they must all be adequately trained in the requirements of PMS prior to commencing PMS tasks. As a prerequisite, the training must be based on written standard operating procedures (SOPs). This is mandatory, given that MAHs are obliged to comply to such post-monitoring activities.

During the PMS planning stage, among other things, the quality of the products must be considered. Likewise, the system of distributing and supplying the target medicine is sorted and reviewed to reflect the quality desired. The patient's exposure to the products is also considered and the effects thereof. The mode of carrying out the pharmacovigilance is also considered in the planning stage.

Pharmacovigilance of Medical Devices and Obligations Imposed on the Marketing Authorisation Holder

On the other hand, pharmacovigilance of medical devices is much more straightforward. The holder may be required to carry out passive and active pharmacovigilance. Passive surveillance calls for manufacturers or MAHs to submit reports to the National Pharmacovigilance Centre (NPC) on adverse events that may occur in carrying out post-monitoring activities.

Active surveillance or pharmacovigilance uses proactive measures to detect and report on adverse events resulting from medical devices authorised for distribution – for example, active follow-up of patients who subsequently used such medical devices, recording of medical events or occurrences, and so on. It may be done prospectively or retrospectively.

Circumstances in Which Obligations May Be Imposed on Marketing Authorisation Holders

There is no express provision in the guidelines regulating pharmaceutical products that allow for specific circumstances in which such obligations are imposed when granting marketing authorisations. However, MAHs and importers and distributors of medical devices are mandated to report to the NPC if certain events occur in which:

- the marketed devices may have caused death or serious injury; and
- malfunction of the marketed device may cause death or serious injury should it recur.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The status of third-party access to applications for market authorisation under NAFDAC laws is not apparent.

However, in reality, NAFDAC has executed agreements with each of its staff on the issue of confidentiality. Such agreements, which are contained in the NAFDAC Confidentiality, No Conflict of Interest, Code of Conduct Agreement Form stipulates that information obtained and treated in the course of their duties is to be treated as confidential. The agreement also mandates that "clients" of NAFDAC shall be notified ahead of any disclosure of such confidential information.

This is also mirrored in practice, where access to the records of registration and application are treated as being confidential and not easily accessible by the public.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The legislation and procedures against falsified and illegally distributed medical devices are outlined here.

First, Section (1)1 of the Food, Drugs and Related Products (Registration, etc) Act proscribes import, export, advertisement, sale, or distribution in Nigeria of unregistered drugs and devices. Section 6 of the Act also imposes a fine of NGN50,000 or imprisonment for up to two years (or both) where an individual violates this provision. However, where the offence is committed by a company, the fine is NGN100,000 and the key persons in such organisations would also be individually liable.

Furthermore, by virtue of Section 25 of the NAFDAC Act, if any person contravenes the provision of the Act, the person would be guilty of an offence and liable on conviction to the penalties specified in the regulations.

NAFDAC Drug and Related Products Advertisement Regulations 2021 provides that, if a regulated product is advertised without authorisation, the manufacturer may be liable to sanctions. Where advertised with the knowledge of an officer of the manufacturing company or any person acting in that capacity, they may be severally and jointly liable on conviction to a fine of NGN100,000. The Advertising Regulatory Council of Nigeria Act creates further penalties for broadcasting unauthorised adverts.

The Guidelines for Procurement and the Management of the Mobile Authentication Service (MAS) Scheme in Nigeria 2018 was put in place to combat against falsified medical products.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

There are a number of measures to tackle counterfeit pharmaceuticals and medical devices that are worth noting.

Primarily, the Counterfeit and Fake Drugs (Miscellaneous Provisions) Act prohibits any counterfeit or fake drugs from being distributed, imported, manufactured or sold within Nigeria. A similar provision is also found under the Food, Drugs and Related Products (Registration, etc.) Act.

In addition to the above, NAFDAC has adopted the introduction of hand-held devices used for on-the-spot detection of counterfeit medicines.

It allows law enforcement agents to conduct screening on sight to identify counterfeits.

In reality, there is significant collaborations between the Nigerian Customs Service as well as the NAFDAC in the implementation of border measure to combat fake and unregistered regulated products.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Primarily, the NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria provides that manufacturing facilities must be inspected and in compliance with GMP and an authorisation to manufacture pharmaceutical products must have been issued by NAFDAC.

NAFDAC approves the manufacture of medicines and related products before consumer use. Per its directive, Good Manufacturing Practice Guidelines for Pharmaceutical Products 2016 regulates the manufacture of these products, and NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria grants authorisation.

Furthermore, the SON has a general mandate to regulate local manufacturing in Nigeria. In furtherance of this, manufacturers of pharmaceutical products are to be authorised by this agency.

Procedure for Obtaining Authorisation of Manufacturing Plants

The NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria prescribes the following procedure that must be undertaken in order for manufacturing plants to obtain authorisation.

- Application for inspection – an application for Pre-Production Inspection should be made and submitted on the company's letter head to the director of the Drug Evaluation and Research (DER) Directorate, along with supporting documents.
- Payment for inspection – a payment invoice for the inspection is collected from the DER Directorate. The applicant may visit www.remita.net to generate a Remita invoice before printing out a copy of the invoice and paying at the nearest bank. An official receipt is issued by the Finance and Accounts Section.
- Schedule of inspection – the facility is scheduled for inspection at a convenient date, with necessary documents provided during the inspection that include:
  - (a) site master file
  - (b) current annual licence to practise of the superintendent and production pharmacists issued by the PCN;
  - (c) letters of appointment and acceptance of key officers;
  - (d) credentials of the key officers (minimum qualification should be first degree in the relevant disciplines);
  - (e) job descriptions for the key personnel;
  - (f) validation master plan for the facility;
  - (g) documentary evidence showing qualification of production and laboratory equipment;
  - (h) documentary evidence showing analytical method validation/verification;

(i) documentary evidence showing water system validation (where applicable);
(j) list of production and quality control equipment and their identification numbers; and
(k) any other relevant documents.

In addition, self-inspection is included in NAFDAC's Guidelines on Good Manufacturing Practice, so as to monitor whether the manufacturers are compliant with the principle in GMP and to make necessary corrections.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

For medical devices in Nigeria, wholesalers are held accountable for activities that relate to wholesale. Only co-ordinated wholesale centres (CWC) granted authorisation by NAFDAC may sell and distribute their products.

In the same vein, wholesalers of pharmaceuticals are restricted from selling and distributing their products in wholesale centres unless approved or granted an authorisation by the PCN, which regulates and controls pharmacies and the movement of pharmaceutical products.

Procedure for Obtaining Authorisation for Medical Devices

Wholesale centres may be granted authorisation to engage in wholesale activities in Nigeria by the guidelines and regulations on wholesale.

Since the regulations are non-specific about obtaining authorisation for wholesale distributors of medical devices, the due process for granting a marketing authorisation follows suit.

Procedure for Obtaining Authorisation for Pharmaceuticals

However, for pharmaceutical products, the guidelines posit that CWCs may be granted a permit to sell products by applying to NAFDAC.

According to the procedure stipulated, the applicant may apply for the premises of the wholesale centres to be granted an authorisation by a PCN application form for registration of premises (Form B). Such application must contain the number of premises (not less than 200 centres) and prohibit street trading within the centres.

The application is submitted to the registrar of the PCN with other documents supporting documents/information as prescribed by the PCN. Some of the documents include:

- a photocopy of the annual licence to practice/application for retention of name on the Pharmaceutical Register (Form J);
- any evidence of payment of inspection and registration fees as prescribed by the PCN;
- contract of agreement between the superintendent pharmacist and employer;
- company's Certificate of Incorporation;
- certified true copy of Article and Memorandum of Association;
- certified true copy of particulars of directors issued by Corporate Affairs Commission (CAC);
- letter of undertaking by the superintendent pharmacist;
- letter of undertaking by the managing director of the company handling the management of pharmaceuticals to the superintendent pharmacist; and
- evidence of membership of a registered and licensed pharmacist on the board of directors.

Activities Approved by the Authorisation

The activities approved by the authorisation of medical devices are such that, where granted, pharmaceuticals and medical devices may be sold within or to a country or territory.

For pharmaceuticals, the authorisation enables wholesale centres to sell medicines. However, other provisions may extend the authorisation to food vendors and banks.

Period of Validity of Marketing Authorisation for Wholesalers

There is no standing validity period applicable to wholesalers provided by the regulations. However, a marketing authorisation is valid for five years and may be renewed upon expiration.

5.2 Different Classifications Applicable to Pharmaceuticals

Although the NAFDAC Act is unclear on the classification of pharmaceuticals, some guidelines (including the Drug and Related Products Advertisement Regulations 2021) distinguish between prescription medication and OTC products.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

Laws Governing Importation and Exportation of Medical Devices

In Nigeria, Guidelines for Registration of Imported Devices in Nigeria provides for the necessary measures taken in importing medical devices. The application will pass through the following five stages.

- Submission of the application – a written application for registration of imported medical devices should be made on the company's letterhead paper to the Director-General of NAFDAC. It must indicate the name of the brand and associated product and be submitted with a separate application form for each product.
- Import permit – after screening of documents, an import permit is then issued while the products are submitted for vetting.
- Submission of products for laboratory analysis – laboratory samples are submitted with payment evidence, certificate of analysis, and evidence of submission for vetting.
- Product approval meeting – after review of the requested documents, satisfying the requirements of GMP for the production facility and laboratory analysis of product, they are then presented for approval. Product labels that are non-compliant with the restrictions will be re-sent with the compliant artworks, along with a commitment letter from the manufacturer undertaking to ensure compliance.
- Issuance of notification – the approved products are issued with a Notification of Registration or Listing, which is valid for a period of five years, while those yet to be approved receive compliance directions.

Laws Governing Importation and Exportation of Pharmaceuticals

A registered pharmacist may apply to import pharmaceuticals once they have completed the National Youth Service Corps (NYSC) programme and presented a discharge certificate to that effect.

The registration is done by a single application process. The applicant must submit an application form (Form B) to the registrar of the PCN

through the Director of Pharmaceutical Services in the state where the pharmacy is to be operated.

Alongside the application letter, the applicant must submit the following documents:

- photocopy of annual licence to practise/application for retention of name on the pharmaceutical register (Form J);
- inspection and registration fees as prescribed by the PCN;
- legal agreement between the superintendent pharmacist and employer;
- the company's Certificate of Incorporation or evidence of registration of business for a pharmacist-owned retail premises;
- certified true copy of article and memorandum of association;
- certified true copy of the particulars of directors issued by the CAC;
- photocopy of NYSC discharge or exemption certificate;
- letter of undertaking by the superintendent pharmacist;
- letter of undertaking by the managing director handling the management of pharmaceuticals to the superintendent pharmacist;
- pharmacists inter-state movement form (where applicable); and
- current annual licence of the pharmacist director.

Governmental Agencies Enforcing Import Rules

Some of the governmental agencies responsible for enforcing import rules in Nigeria include:

- NAFDAC – the key regulatory authority for drugs and medical products in Nigeria, as well as its import thereof.
- The SON – through the use of Harmonised Systems (HS) Codes for the examination of goods at the nation's entry points, the SON has been in line with international best practices aimed at reducing conflicts to the bare minimum.
- The Nigerian Customs Service – by statute, Customs are empowered to enforce custom rules, including rules of importation and any prohibition thereof through officers allocated in different units.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Only a company duly registered in Nigeria is permitted to import pharmaceutical products into Nigeria. Therefore, a foreign company seeking to import drugs into must either set up a Nigerian entity for this purpose or appoint a pharmaceutical company incorporated in Nigeria as its agent for the importation of same. The pharmaceutical company must also comply with the Pharmacy Council of Nigeria (Establishment) Act 2022.

Requirements to Act as an Importer of Record

There are a number of requirements that a company must fulfil before it can be authorised to import pharmaceutical products. These include:

- evidence of business incorporation with the CAC which show that the company is registered in Nigeria
- compliance with the provisions of the Pharmacy Council of Nigeria (Establishment) Act 2022; and
- disclosure of a suitable warehouse or storage facility where such drugs can be kept, bearing in mind the storage method prescribed for such drug.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices are subject to prior authorisation. Such regulated products cannot be imported without authorisation, according to the Drug and Related Products Registration Regulation. The application process is specified under the Guidelines for Registration of Imported Drug Products in Nigeria (Human and Veterinary Drugs) and Guidelines for Registration of Imported Drugs, as well as Guidelines for Registration of Imported Medical Devices into Nigeria.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Non-tariff restrictions are imposed upon importation of goods in Nigeria. However, existing non-tariff measures are not specific to medical devices and pharmaceuticals. The issuance of import permits has been made a prerequisite for food, drugs, and other products to be imported into Nigeria so that manufacturers and distributors alike cannot import their products without such authorisation. This applies to all entities – foreign and local – regardless of origin.

There are requirements that must be met before issuing import permits and it may be peculiar to the type of product. In order to import pharmaceuticals into Nigeria, one must apply according to the procedure provided under the Pharmacy Council of Nigeria (Establishment) Act 2022, which requires the applicant to submit an application form to the registrar with related information as prescribed by the PCN. Upon satisfying these requirements, the PCN then issues an import permit that will allow the premises to import goods.

Likewise, NAFDAC issues import permits for regulated products in Nigeria. The due process is outlined according to the Guideline for Approval to Import Products by Government Agencies, International Bodies and Multinational Organisations (including documents needed for the application). Once approved, the permit subsists until December 31st every year and may be renewed on January 1st of the following year.

In order to import laboratory and industrial chemicals into Nigeria, the Guidelines for Issuance of Permit to Import Laboratory and Industrial Chemicals prescribe the requirements and supporting documents involved in applying to NAFDAC for an import permit.

Import permits are also issued by the SON. Under the Nigeria Conformity Assessment Programme introduced by the SON, certain imported products must meet the requirements before importation into Nigeria. The SON may issue a SONCAP certificate for goods to be imported, forming a prerequisite for entry and clearance of imported goods. However, this does not extend to food, drugs, medicine, and medical devices, as the SON has other regulations that cater to those products.

Mode of Restricting Goods Imported

Goods are also prohibited from being imported according to the import prohibition list, which makes provisions for the different classes of goods and products that are not granted entry to Nigeria – thereby alerting distributors and manufacturers in this respect.

The list includes medicaments under Headings 3003 and 3004, which specify the kind of drug products prohibited (eg, penicillin/gentamycin ointments, aspirin tablets, levamisole tablets and syrups).

Likewise, the prohibition list separates some goods based on HS Codes. This is a standardised method used in identifying the traded products – ofr instance, under the list, live or dead frozen poultry have HS Codes 0105.1100-0105.9900, 0106.3100-0106.3900, 0207.1100-0207.3600 and 0210.9900.

In addition to the foregoing, some variation of a product may be exempted. By way of an example, bird eggs are prohibited from importation, with the exception of hatching eggs.

Laws and Regulations Indicating Goods Prohibited from Importation

Primarily, the Customs and Excise Management Act (CEMA) provides for an import prohibition list banning the import of different product categories, with the aim of promoting local industries and the health and safety of Nigerians. The CEMA regulates the goods imported and exported in Nigeria and enforces rules and regulations to this effect.

Besides the import prohibition list, the CEMA further restricts other goods from being imported permanently under Schedule 4 of the Act, such that Customs may enforce its authority as granted under the Act to prevent any activity inconsistent with the provisions as instilled. Some of the goods absolutely prohibited include air pistols, counterfeit or pirated materials, indecent articles or paintings, cowries, second hand clothing, and so on.

6.5 Trade Blocs and Free Trade Agreements

Nigeria is a member of the African Continental Free Trade Area (AfCFTA) and accordingly can take the benefit of the trade facilitation provisions therein. The AfCFTA, as created by the African Continental Free Trade Area Agreement on Trade Facilitation, is focused on customs and trade facilitation and aims to ensure free movement of labour, goods and services. It helps to increase profit and contributes to the development of the manufacturing sector.

Nigeria's involvement is predicted to promote business collaborations with other African countries. The Central Bank of Nigeria is heavily involved in the AfCFTA as stakeholders, unifying the vision for the trade agreement across all sectors.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Nigerian law does not expressly permit the regulation of pricing for pharmaceutical and medical devices. However, the Federal Competition and Consumer Protection Act 2018 prohibits the fixing of a minimum price for resale of goods and services, except in cases of a patent licence.

7.2 Price Levels of Pharmaceutical or Medical Devices

There are no standing provisions inferring that the price level of pharmaceuticals and medical devices is dependent on the price in foreign countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In order to mitigate cost and facilitate the accessibility of expensive pharmaceuticals and medical devices in Nigeria, the government has deployed public funds as a means of reimbursing such cost as envisaged in its laws.

For instance, the National Health Insurance Authority Act 2022 (the "NHIA Act") addresses healthcare services for Nigerians by mitigating health expenditure for children, pregnant women, physically and mentally challenged Nigerians, or other indigents under the Vulnerable Persons Scheme.

Specifically, Section 11 of the NHIA Act covers healthcare services for indigent and poor persons by the Basic Health Care Provision Fund, which is funded by the consolidated revenue fund of the federal government. This is particular to indigenes who fit the category under the Basic Health Care Provision Fund.

In addition to this, the NHIA Act also makes provisions for states in Nigeria to establish a contributory scheme to maintain health insurance for its citizens. It may be inferred from this law that the cost of medical or pharmaceutical devices incurred by a citizen will be reimbursed through the funds in the scheme. The NHIA Act was passed recently and, as such, its applicability can only be determined after a period of time.

However, the bearing of cost by the government is not exclusive to these circumstances, as it may apply:

- where the patient makes contributions to the National Health Insurance Scheme (NHIS); and
- through other health insurance schemes organised by the State – for example, Health Maintenance Organisations (HMOs).

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-benefit analysis has yet to be applied when determining the price for medical devices and pharmaceuticals in Nigeria. This is because, notwithstanding the overall legal framework in place, Nigeria is yet to make laws and legislation concerning the pricing of medical devices and pharmaceuticals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Code of Ethics for Pharmacists mandates dispensing pharmacists to refrain from dispensing drugs that may endanger the patient. A pharmacist should also not dispense drugs to a patient if they believe it is not necessary for the patient to use the drug. The code is enforced by the Pharmaceutical Society of Nigeria.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are specific rules for medical apps. The PCN's Online Pharmacy Regulations 2020 is the extant law on medical applications, and it covers the extent to which medical apps are accessed via the internet.

The Online Pharmacy Regulations 2020 did not define "medical devices" and "medical apps". However, medical devices cover a wide range of medical equipment, whether used online or offline. Thus, medical apps may be considered as medical devices. However, not all medical devices are medical apps, as not all medical devices can be accessed online.

Medical devices have been defined as any instrument that is produced or sold – whether internally and externally – for the diagnosis or treatment of a disease in humans or animals. Thus, where a medical app is used for any of the foregoing, it may be considered a medical device.

8.2 Rules for Telemedicine

According to the Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria, telemedicine is recognised in professional practice in Nigeria and seen as an opportunity to include computer and telecommunication technology in the medical profession. Telemedicine aids the process of requesting and practising medicine at a distance.

As a result of telemedicine, physicians and those who provide medical attention may do so electronically and manage patient care effectively. This is not restricted, as there is room for specialist consultation and any form of medical attention sought out through the web across various industries and fields of medicine and dentistry.

In addition, specific conditions and criteria are deemed necessary to improve telemedicine in Nigeria. Section 22 of the Code of Medical Ethics expressly provides that – in order to avoid legal action – registered practitioners bear full responsibility for ensuring they act in compliance with rules on the following matters:

- confidentiality;
- professional competence;
- legal and registration status of the specialist being consulted;
- reliability of the equipment used;
- patient management; and
- referral of patients timeously.

In the same vein, the Code of Medical Ethics emphasises specific rules to be followed when processing data electronically. Practitioners must ensure that personal information is secure. This includes any information/data stored on a database and sent or received by fax, computer, email or other electronic means. Likewise, the security of the information must be ensured before connecting to a network.

The regulations also provide that practitioners must ensure that data sent is not accessible to any party other than the intended recipient. They should also be informed about the likelihood of their emails being intercepted by internet hackers.

The same is envisaged in the NDPR, which provides for the electronic processing of patients' data to be carried out only with the consent of the patient. Article 1.3 of the NDPR sheds light on consent of the data subject (the patient in this instance) as an indication that the patient agrees to the processing of their personal data. Personal data in this context includes health-related information of the patient, which must be stored and sent with their informed consent.

Likewise, Article 2.6 of the NDPR entails that extra security measures must be taken in the electronic space to protect personal data of the patient – for example, setting up firewalls, restricting access to only authorised persons, data encryption, and other measures for handling patients' data.

8.3 Promoting and/or Advertising on an Online Platform

There are special rules guiding the advertisement of medical devices on online platforms. These rules are the NAFDAC Drug and Related Products Advertisement Regulations 2021 and the PCN's Online Pharmacy Regulations 2020.

The Drug and Related Products Advertisement Regulations 2021 provides that, after obtaining the Certificate of Registration, an application for advertisement approval must be submitted to NAFDAC. Both regulations provide that only

medicine that can be bought without a prescription can be advertised publicly, meaning that only OTC should be advertised online publicly (see **8.5 Online Sales of Medicines and Medical Devices**).

For adverts on online portals, the applicant may be required to submit the script, artwork and storyboard used in the advertisement. The same applies for any publication on radio, print, by SMS or pre-recorded messages.

Also, the Online Pharmacy Regulations 2020 makes regulations for pharmaceutical service providers who are based online. This covers all registration requirements but, specifically, makes provisions for granting licences. According to the regulations, online pharmaceutical service providers must be registered with the PCN.

Pursuant to Section 2, such licence is applied for by an application letter to the registrar of the PCN through the superintendent pharmacist in charge of online pharmaceutical services. The application is submitted with the documents/related information prescribed by the PCN. Some of these documents include:

- current annual licence of the superintendent pharmacist;
- a photocopy of the registration licence of the current premises;
- evidence of payment of fees as prescribed by the PCN;
- letter of appointment of the superintendent pharmacist;
- legal agreement between the superintendent pharmacist and employer;
- Certificate of Incorporation of the company or evidence of business name registration for pharmacist-owned retail premises;
- certified true copies of articles and memorandum of association;
- certified true copies of CAC documents showing names and particulars of directors;
- NYSC discharge or exemption certificate;
- an undertaking by the superintendent pharmacist;
- an undertaking by the managing director of the online company handling management of the business for the superintendent pharmacist; and
- policy documents including procedures and processes for all operations of the internet services.

In addition, once granted, the licence may subsist for a year such that it expires on December 31st every year and may be renewed on January 1st the following year.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed and regulated in Nigeria. Section 11 of the PCN's Online Pharmacy Regulations 2020 provides that pharmaceutical service providers may dispense prescription-only medicines (among others) electronically. Such pharmaceutical service providers are internet-based and must do so within the confines and provisions of the regulations and subsidiary legislation.

According to the regulations, a system must be put in place to ensure that the prescription orders for drugs are legitimate. Likewise, there must be a system to regulate the validity of the prescription from a professional before it is dispensed.

In addition to the foregoing, the regulations restrict prescribing drugs based on telephone or online medical consultations as it may be difficult to authenticate their validity. This extends

to restricting the quantity of prescribed drugs that can be ordered or sold online.

8.5 Online Sales of Medicines and Medical Devices

Online sale of medicines and medical devices is permitted in Nigeria, subject to the provisions of the law. The PCN's Online Pharmacy Regulations 2020 provides that, in the online sale of medicines, the following requirements must be complied with:

- policies must be in place to guarantee the legitimacy of the drugs;
- such drugs must not be sold without confirming that it was prescribed by a licensed officer;
- telephone or electronic medical consultation should be reduced; and
- the quantity of medicines to be sold or prescribed online must be reduced.

The law also makes a distinction between prescription and non-prescription drugs, whereby it provides that only non-prescription drugs should be sold or prescribed online. Prescription drugs are drugs that are considered safe and effective when used under the care and instructions of a doctor. Non-prescription drugs, such as OTC medication, can be used with or without the prescription of a doctor.

As mentioned in **8.3 Promoting and/or Advertising on an Online Platform**, pursuant to Section 12(2) of the Drug and Related Products Advertisement Regulations 2021, prescription drugs are prohibited from being advertised through television, radio or any online media. They are only advertised in scientific journals, health newsletters strictly accessed by professionals, and other means as approved by NAFDAC.

8.6 Electronic Health Records

There are no express electronic health laws in Nigeria. However, there other relevant provisions that address the subject matter. Health records, like any other records of personal or sensitive data, are regulated under the NDPR

Of course, medical personnel utilising electronic health records continue to be bound by duty of confidentiality, as well as the duty to secure medical records under the Medical and Dental Practitioners Act and The Code of Medical Ethics in Nigeria (Rules of Professional Conduct for Medical and Dental Practitioners).

Regulation of Health-Related Information as Sensitive Data

Notably, the regulation of health-related information as sensitive data depends on the importance of the data. The NDPR defines sensitive personal data as any data relating to religious or other beliefs, health, race or ethnic background, sexual orientation, and political views. Thus, health-related information is classed as sensitive data in Nigeria.

The National Health Act 2014 also provides that the health records must be kept safe by the holder in order to prevent any authorised access. This implies that health records are considered sensitive. Thus, health-related information that reveals personal data will be classed as sensitive.

Stricter Regulations for Health-Related Information

Health-related information is often subject to stricter regulations, as it qualifies as sensitive personal data. Such stricter regulations may include the need to conduct a Data Protection Impact Assessment (DPIA). According to NITDA regulations, the holder of such health-related

information may request the submission of such DPIA or mandate the appointment of a Data Protection Officer (DPO).

Special Requirements for Cloud Platforms

There are presently no special laws on the transfer and storage of sensitive data of patients on cloud platforms.

The NDPR, however, considers sensitive personal data to be of a critical nature and therefore special requirements apply. Before such personal sensitive data can be transmitted to cloud, the cloud platform must comply with the requirements for handling personal sensitive data as outlined in the NDPR (eg, collection of data, using the data for the purpose for which it was obtained, and appointment of DPO).

Transfer and Storage of Sensitive Data of Patients on Cloud Platforms

There are presently no special laws on the transfer and storage of sensitive data of patients on cloud platforms. Nevertheless, under the NDPR Regulations 2020, the data controller must ensure that the sensitive data of patients is transferred to cloud platforms and stored in line with the NDPR.

The Draft National Cloud Computing Implementation Strategy is an indication that a proper legal framework specifically designed for cloud computing will soon be established.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patent protection in the pharmaceutical and healthcare industry is not lost in thought as it is duly regulated and managed in Nigeria. The Patents and Designs Act 1971 is the legal framework for patent-related matters such as registration, procedural steps for application, and so on.

The National Office for Technology Acquisition and Promotion Act assists in the filing of patent and innovations only applicable to government-funded research, as well as in the private sector.

Nigerian legislation on patent has some shortcomings in terms of pharmaceuticals and medical devices, including that:

- there are no provisions on the infringement of second and subsequent use patents for pharmaceutical products;
- Nigerian patent laws do not provide for term extension for pharmaceuticals;
- there is no specific means of applying for a patent term extension for pharmaceuticals in Nigeria; and
- there is no requirement for pre-launch action to “clear the way” in market entry.

There are also no specific requirements for patents for pharmaceutical and medical devices in Nigeria.

9.2 Second and Subsequent Medical Uses

In Nigeria, second and subsequent medical uses of a known product are generally unpatentable in respect of product patents, as such patent

would not be considered novel. Patents are granted for either inventive activities or improvements in either products or processes. Under the Patents and Designs Act 1971, an invention results from inventive activity "if it does not obviously follow from the state of the art, either as to the method, the application, the combination of methods, or the product that it concerns, or as to the industrial result it produces". This is clearly not the case with second and subsequent medical uses of a known product.

Nonetheless, this may apply where known product is used in respect of a "novel process". Processes are also the subject matter of patents and, as such, the patentability of second medical uses of a known product may be explorable under this regime. This is yet to be tested, however.

As regards the infringement of second and subsequent patents of pharmaceutical products, there is no express provision on second patentability of drugs.

9.3 Patent Term Extension for Pharmaceuticals

Currently, the Nigerian patent laws do not provide for term extension for pharmaceuticals. The 20-year lifespan of a patent is sacrosanct, subject of course to the payment of annuity.

9.4 Pharmaceutical or Medical Device Patent Infringement

Pharmaceutical or medical device patent infringement entails the reproduction and exploitation of the subject matter of the patent. This would include making, importing, selling, or using a product or stocking the pharmaceutical or medical device for sale or use without the approval, assignment or consent of the owner of the patent right.

Seeking a marketing authorisation does not strictu sensu amount to patent infringement. However, the plaintiff may be entitled to explore a qua timet action through patent infringement action in order to prevent the issuance of such authorisation that would result in infringement.

The threat of infringement may be actionable under a qua timet action. The court may grant the patentee a quia timet injunction upon application in order to prevent such threatened infringement from occurring.

Although the Patent and Design Act 1971 does not make specific requirements for a threat of infringement in the case of imminent infringement, a party may fall back on the equitable relief of a quia timet injunction. To be entitled to such a relief, a party must prove:

- that there is threat of serious infringement;
- that potential harm will be caused if the injunction is refused;
- that irreparable harm will be caused if the injunction is not granted; and
- that the party will suffer more injury if the injunction is not granted.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

There are no specific defences to patent infringement of medical devices and pharmaceuticals. However, under the law, general defences are available to a party that has allegedly infringed a patent right, including:

- lack of novelty of the subject matter of the patent;
- prior publication of the subject matter of the patent;
- defence of previous use;

- that the subject matter of the patent is not patentable;
- ambiguity of the claims;
- insufficiency of the claim;
- inability to work the subject matter of the patent; and
- that the description of the invention or claim does not conform with the provisions of the Patent and Designs Act 1971.

Compulsory Licences for Pharmaceuticals and Medical Devices in Nigeria

There is a compulsory licensing regime under the Patent and Designs Act 1971, which allows a party to seek the compulsory licensing of patents that have not been worked to the benefit of economy.

The Patent and Designs Act 1971 provides the requirements for issuance of compulsory licenses either by the court or by an order of the Minister in the Federal Gazette. Where leave to obtain a compulsory licence is made through the court, the Patent and Designs Act 1971 provides that the applicant must show to the court that:

- the applicant has approached the patentee for a licence and is unable to secure the same within a reasonable time;
- there is a deficiency in the invention and, as such, an assurance to the court that they will rectify the deficiency;
- the patent has not been worked on as required;
- if it has been worked on, the extent of the work is not reasonable considering the nature of the product;
- the patented article has hindered the operations of patented inventions in Nigeria; and
- the refusal by the licensee has hindered industrial commercial activities in Nigeria.

Where the request for compulsory licences is made to the Minister, it is expected that the Minister will have issued a declaration stating patented products and processes that may be subject of compulsory licences and the Minister may permit importation or exploitation of the subject matter of such products.

9.6 Proceedings for Patent Infringement

Under the Patent and Designs Act 1971, the patentee may bring proceedings for patent infringement. Likewise, a patent licensee may do so in circumstances where:

- the licensee notifies the patentee of the infringement;
- the patentee refuses to act on the infringement; and
- the licensee files a copy of the notice to the patentee with the registrar.

Remedies Available for Patent Infringement

Under patent law in Nigeria, the following remedies are available to the plaintiff:

- injunctions restraining the other party from further infringement of the patent right;
- damages to compensate the owner or the inventor of the patent right;
- declaration of the patent of a plaintiff as valid where such relief is sought by the plaintiff;
- account of profits made from infringement; and
- delivery up of infringed products.

Procedure for Patent Infringement Actions

The action for infringement typically goes to trial after service of documents and processes according to a procedure that entails the following steps.

- The claimant files a writ of summons at the Registry of the Federal High Court accompanied by a statement of claim, list of witnesses, copies of document to be relied on at the trial, list of exhibits, and written statements made under oath by witnesses.
- The defendant files a statement of defence in response to the plaintiff within 30 days, along with a list of its witnesses and written testimonies, and the documents to rely on. The defendant may also file a counterclaim.
- The plaintiff may file a reply upon receipt of the defendant's filing within 14 days.
- After service of all processes, parties may explore discoveries and interrogatories in order to obtain relevant evidence and admissions from either party.
- Upon close of pleadings and interrogatories, the matter is scheduled for trial. Parties to the action give evidence and file final address, which is later adopted.
- Upon adoption, the court enters judgment within three months.

Patent Invalidity as a Defence

The invalidity of a patent may be raised as a defence by a defendant to an action for patent infringement. Such defendant is entitled to raise it in the Statement of Defence and file a separate petition for nullification of such patent. Said petition may be consolidated within the action for infringement to the extent that, if the court finds that the patent was invalid, the court action for infringement will be dismissed.

9.7 Procedures Available to a Generic Entrant

A generic product to be launched and potentially distributed would be allowed market entry in accordance with the NAFDAC Guideline on Registration Requirements to Establish Interchangeability of Generic Pharmaceutical Products. However, based on the current case law, there is no requirement for pre-launch action to "clear the way".

There is a procedure in place for obtaining marketing authorisations in Nigeria under the guidelines. However, unlike the requirement for confirmation of trade mark ownership, the rules do not require a similar confirmation that the applicant is the patent holder or duly licensed.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Other than IP laws, there are other regulations and laws in place that may be utilised to combat counterfeiting of pharmaceuticals and medical devices in Nigeria. Some of these regulations and legislations include:

- National Agency for Food and Drug Administration and Control Act 2004;
- Food Drugs and Related Products Registration Act 1993;
- Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act 2004 (Chapter 34);
- Customs and Excise Management Act 2004 (Chapter 45);
- Standards Organisation of Nigeria Act 2015; and
- Merchandise Marks Act.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Under Nigerian law, the general restrictions that apply to other products may apply to medical devices and pharmaceuticals. These restrictions include the following:

- only distinctive trade marks are registrable;
- a mark that is deceptive or scandalous, contrary to law or morality, or in any way disentitled to protection is not registrable; and
- a mark that contains some prohibited words and/or symbols (such as names of chemical substances), use of the Coat of Arms of Nigeria, or use of any emblem or title such as President or Governor without the appropriate authority.

Specifically, Section 12 of the Trade Mark Act proscribed the registration of a single chemical element or single chemical compound as a chemical or preparation.

Restrictions on Importation of Pharmaceuticals or Medical Device Products From Other Countries

Nigerian trade mark laws do not expressly prohibit parallel importation. However, it has been noted that parallel importers often violate trade mark laws with regard to disclosures as to country of origin, labelling, etc. Parallel imports are therefore dealt with for violation of such laws.

Furthermore, when a drug is to be imported into Nigeria, one of the requirements for the processing of NAFDAC registration is that an importer obtains power of attorney from the manufacturer. By requiring such power of attorney before registration for the purposes of importation, NAFDAC whittles down the likelihood of parallel importation.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The Business Facilitation and Miscellaneous Provisions Act 2022 provides that the trade dress (packaging), shape and design of a trade mark is protected. The Patent and Designs Act 1971 also protects the trade dress or trade design of a product, which may extend to a medical or pharmaceutical device.

The trade mark or patent of a pharmaceutical and medical device covers its trade dress (shape, colour and commercial look) to the extent that, once such device has been registered, it will enjoy all the trade mark protection guaranteed under the Trade Mark Act and the Patent and Designs Act.

This protection is also available under the common law of passing off. Passing off is a tort that prevents a manufacturer from misrepresenting goods or services as that of another. This avails a party even where the trade mark is not registered.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity is essential to legal practice as well as the protection of medical devices and pharmaceuticals.

Although there is no specific provision for protecting data gathered for pharmaceuticals and medical devices in Nigeria, Section 3 of the Food, Drugs and Related Products (Registration) Act provides that information disclosed while applying for registration to NAFDAC cannot be shared without the written consent of the person who supplied the information or unless instructed by NAFDAC or for the purpose of a proceeding. This applies both to medical devices and pharmaceuticals in Nigeria.

Difference Between Chemical Drugs and Biologics

There is a notable difference between chemical products and biologics.

Under Section 18 of the Chemical and Chemical Products Regulations 2020, "chemical products" refers to a substance formed by a chemical reaction to yield one or more products such as cleaning chemicals, paint, adhesives, wood preservatives and polishers, and agrochemicals.

In contrast, although NAFDAC Act does not define biologics, it refers to products derived from living cells or animal tissues – thereby differentiating them from chemical products, which are formed from chemical solutions.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

As a result of the COVID-19 pandemic, the commercialisation and distribution of medicines was handled differently. The following special regulations or guidelines were issued in relation to the commercialisation or distribution of medicines and medical devices in order to respond to the COVID-19 crisis.

- In 2020, NAFDAC released a newsletter (Vol 3, No 2) that discouraged the use of falsified chloroquine. NAFDAC also discouraged the commercialisation or distribution of unregistered hand sanitisers.
- There were also cautionary notices with regard to various drugs claimed to be used to treat COVID-19.
- The Presidential Task Force on COVID-19 also issued guidelines covering various areas, including:
  (a) expedited/emergency approvals for products;
  (b) limited GMP inspections for local facilities;
  (c) alternatives to GMP for foreign facilities when inspections could not be undertaken owing to the pandemic travel restrictions;
  (d) applications for registration of products deemed to have urgent public health impact to be processed and given conditional and limited approvals; and
  (e) encouraging the use of email and other electronic platforms when interacting with NAFDAC.

The applicability or enforcement of rules on the commercialisation and distribution of medicines in Nigeria was not relaxed. It was enforced by responsible agencies of the Nigerian federal government.

11.2 Special Measures Relating to Clinical Trials

Special measures were employed to regulate clinical trials in Nigeria. NAFDAC issued the Clinical Trial Regulations 2021 to provide clarity and purposeful measures in relation to ongoing clinical trials. With regard to specific matters, Section 3(16) made provision for investigations by NAFDAC into the trial sites and facilities to be used in order to ensure they meet the standard required under the regulations.

The regulations also catered to the rights of the participants in the trial. Section 5 provides that the investigator must inform the participant on all due processes and aspects of the trial to be conducted (including the review of the participant by the Ethics Committee) and that this must be done prior to the participant's involvement in the trial.

Special Regulations Issued in Relation to COVID-19 Treatments or Vaccines

NAFDAC issued special regulations in relation to COVID-19 treatments, including Guidance on Regulatory Preparedness for Licensing or Access to COVID-19 Vaccines 2020. This included the requirement for external review of the marketing authorisations granted to manufacturing plants – a deliberate provision that caters to COVID-19 vaccine applications. NAFDAC also released guidance notes to sponsors of clinical trials during the COVID-19 pandemic as part of the procedure.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Certain protocols were updated following the emergence of COVID-19 and other regulations were set in order to facilitate emergency approvals for medical devices and pharmaceuticals needed for the cause.

On record, NAFDAC allowed emergency approvals of pharmaceutical and medical devices via a circular dated 9 April 2020. This regulatory pathway was created specifically for COVID-19.

The pathway provides that such emergency approval must meet with the following criteria:

- previous registration and approval by the relevant regulatory authorities (eg, the European Medicine Agency);
- registration by the regulatory authority in the country of production;
- declaration of conformity; and
- validation/performance evaluation/clinical evaluation report.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

There were no specific instances where NAFDAC was flexible in granting certifications to manufacturers owing to the COVID-19 pandemic. However, NAFDAC granted the emergency conditional use of COVID-19 vaccines through Emergency Use Authorisations, which simplified the bottlenecks for authorising vaccines needed to prevent COVID-19 in people over the age of 18.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Some import restrictions were set in place for medical devices following the COVID-19 pandemic. On 24 March 2020, the federal government of Nigeria introduced an import duty waiver on medical equipment, medicines, personal protection equipment, and other medical necessities required for the treatment and management of COVID-19 in Nigeria effective from 1 March 2020 until 31 December 2020.

There were import restrictions in relation to medicines and medical devices during the COVID-19 as a result of the national and global lockdown. Nigeria could not produce medicines for export, even though most of the drugs were imported.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Digital healthcare forms an integral part of the healthcare industry and this was made more practical as a result of the COVID-19 pandemic. However, the Nigerian authorities appear not to have adopted any measures to facilitate digital health innovation or digital transformation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Notwithstanding the measures taken to adapt to the COVID-19 pandemic, the Nigerian government has not announced any intention to issue compulsory licence for Covid-19-related treatments or vaccines. However, the Nigerian Patent and Designs Act 1971 allows the Minister to issue compulsory licences for patented products declared to be important for public health. A compulsory licence may also be granted by a court upon application by an interested party/entity.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Liability exemptions regarding COVID-19 vaccines were not adopted in Nigeria.

11.9 Requisition or Conversion of Manufacturing Sites

There existing provisions for granting authorisation to manufacturing sites were adapted in response to the COVID-19 pandemic. However, no clear provisions appear to have been introduced with regard to manufacturing sites as a result of COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Following the emergence of COVID-19, changes were made to the system of public procurement of medicines and medical devices in Nigeria.

The Bureau of Public Procurement (BPP) introduced the Guidelines on the Conduct of Public Procurement Activities. According to these guidelines, an emergency procurement plan must be prepared for all projects specific to the COVID-19 pandemic and uploaded into the Nigeria Open Contracting Portal (NOCOPO), where it will be accessed by the BPP in order to qualify for funding from the federal government.

A notable change was made to the system for public procurement activities as a result of COVID-19. Instead of the previous rigorous process of placing advertisements in two national dailies and the Federal Tenders Journal, as was standard practice, the emergency procurement plans were only uploaded directly to the website.

In addition, the standard “No Objection” requirement required prior to the emergency procurement plan was no longer mandated as a result of the COVID-19 pandemic. Instead, procuring entities were allowed to respond and act on the emergencies at hand before providing a detailed report to the BPP later.

Trends and Developments

Contributed by:
Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye
Jackson, Etti & Edu

Jackson, Etti & Edu (JEE) is a leading full-service commercial law firm with a sector focus, including on the health and pharmaceutical sector. With more than 25 years' experience and several awards for excellence, JEE consistently renders legal services to Nigerian, pan-African, and international clients from diverse jurisdictions – as evidenced by the firm's presence in Lagos, Abuja, Accra, Harare and Yaoundé. JEE's lawyers have gained extensive expertise in advising and acting for clients on a wide range of subject matter pertaining to the healthcare sector, including financing, business regulatory compliance, ethics for health professionals, debt recovery, litigation, arbitration and ADR – as well as health law advocacy and reviews of laws in this sector. The firm consists of 14 partners, 60 fee earners and more than 50 paralegals and support staff. The size of JEE's dedicated commercial team is indicative of the firm's rich human resource base and its capacity to effectively and efficiently help clients achieve their goals.

Authors

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Oloruntobi Opawoye is a senior associate at Jackson, Etti & Edu and deputy head of the firm's health and pharmaceuticals sector team. Tobi succeeds in melding an in-depth knowledge of the law with diplomatic skills and nuance so that disputes reach a swift and respectful conclusion. She provides much sought-after advice to a wide range of health and pharmaceutical organisations with regard to various aspects of their businesses, including ethics, debt recovery, arbitration and IP protection, as well as enforcement, regulation and compliance. Oloruntobi is a member of the Nigerian Bar Association and provides advice to the Medical Ethics Board of a hospital chain.

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Introduction of New Healthcare Insurance Regime

In 2022, the Nigerian federal government introduced the National Health Insurance Authority Act (the "NHIA Act") to govern health insurance and make health insurance coverage mandatory for all residents in Nigeria. The NHIA Act replaces the defunct National Health Insurance Scheme Act 1999 and seeks to integrate the various state insurance schemes that have been established all over Nigeria. The new law also seeks to provide a tighter regulatory framework for governing Health Maintenance Organisations (HMOs) in Nigeria. The NHIA Act established a

new regulator (the National Health Insurance Authority), which has now replaced the defunct National Health Insurance Scheme.

Overview of the National Health Insurance Authority Act

One important positive effect of the NHIA Act would be broadening the health insurance industry in Nigeria, in view of the mandatory requirement for all residents to obtain health insurance under a State Health Insurance and Contributory Scheme. State Health Insurance and Contributory Schemes are health insurance schemes established by state governments in Nigeria.

The new law further prescribes that the National Health Insurance Authority shall establish a scheme for the employees of the Federal Civil Service and other relevant groups. This implies that the National Health Insurance Authority would be responsible for regulating the sector and organising health insurance schemes for residents not covered under the respective State Health Insurance and Contributory Scheme, especially where such persons are members of the Federal Civil Service.

The general statutory requirement for residents to obtain mandatory health insurance coverage with the State Health Insurance and Contributory Scheme would not, however, bar residents from taking supplementary healthcare coverage from private HMOs. Indeed, the NHIA Act provides that the healthcare coverage under the State Insurance and Contributory Scheme would be a basic minimum package of care in line with the guidelines for the implementation and administration of the Basic Health Care Provision Fund. The basic minimum package provides a very low coverage in the region of USD28; hence, it is anticipated that residents may adopt supplementary schemes with HMOs that provide private health insurance services in order to obtain a better coverage.

The new law also makes provision for vulnerable and indigent persons that may not have the capacity to make contributions under the mandatory scheme. The NHIA Act provides that every State and Federal Capital Territory Scheme shall provide coverage for vulnerable persons under the various schemes through the Basic Health Care Provision Fund and other sources and would not require payment of premiums for such coverage. The NHIA Act defines the persons within the vulnerable group to include "children under five, pregnant women, the aged, those who are physically and mentally challenged, and the indigent".

Despite the penetration of HMOs, which generally provide health insurance coverage in Nigeria, barely 10% of the Nigerian population has health insurance coverage. As such, the majority of Nigerians are restricted to making out-of-pocket payments for healthcare. The new NHIA Act therefore brings some hope to more than 80 million Nigerians who do not have any form of healthcare coverage. HMOs are also expected to play a greater part in the new healthcare regime by taking on a new role as third-party administrators for the various State Insurance and Contributory Schemes, in view of the logistical difficulties that are associated with administering a health insurance scheme. Given that HMOs already have systems in place in various states, integration with the state schemes is all that would be required.

In light of the additional functions granted to HMOs, it is hoped that those acting as third-party administrators to State Insurance and Contributory Schemes consider introducing healthcare insurance packages that allow residents to enjoy

various degrees of healthcare coverage that go beyond the basic minimum package, thereby enabling residents to comply with the mandatory requirement to obtain health insurance under the state scheme. This would also provide residents with an acceptable healthcare package subject to the standard or expectation of each resident.

Main players under the National Health Insurance Authority Act

The major players to emerge under the new law are:

- the National Health Insurance Authority;
- State Health Insurance and Contributory Schemes;
- HMOs;
- Mutual Health Associations (MHAs); and
- third-party administrators.

The National Health Insurance Authority is clearly the main regulator under the new regime, whereas the State Health Insurance and Contributory Schemes are saddled with the responsibility of administering their schemes and healthcare packages and ensuring that the mandatory contribution is made by residents within their respective regions in order to enforce the law. HMOs are providers of private health insurance schemes. Third-party administrators are entities that perform administrative functions on behalf of State Health Insurance and Contributory Schemes in order to facilitate the implementation of the state health scheme or functions as required by the National Health Insurance Authority. MHAs are associations that exist to represent large groups when negotiating packages with relevant insurance schemes and healthcare providers for the benefit of their own members.

New dispute resolution mechanisms

Enforcement of the NHIA Act is expected to drive more healthcare coverage and lead to investments in the sector. It is also hoped that the dispute resolution challenges faced by the sector will be reduced as the NHIA Act now provides that disputes between players should first be referred for mediation and conciliation before resorting to arbitration. In the event that arbitration fails, parties will then be expected to explore litigation in line with the Constitution of the Federal Republic of Nigeria.

Outlook

Increased demand for healthcare coverage, due to the mandatory contributions under the NHIA Act, is expected to expand health service delivery. Hopefully, this will encourage further investments in – and improve the quality of – Nigerian healthcare.

Introduction of New Pharmacy Regulatory Regime

The Nigerian government introduced a new regulatory regime under the Pharmacy of Nigeria (Establishment) Act 2022. This new law aims to bring remarkable changes to the Nigerian pharmaceutical landscape in a bid to sanitise a market that has been plagued by the free-market distribution of drugs and related exposure to counterfeiting and drug abuse.

Overview of the Pharmacy Council of Nigeria (Establishment) Act 2022

The Pharmacy Council of Nigeria (Establishment) Act 2022 has now opened the pharmaceutical business to non-pharmacists, with statutory limitations, in an attempt to drive more investments in the sector. The new law provides that a company or a foreign company shall not own or operate a chain retail or community pharmacy unless such company has a Nigerian pharmacist

or pharmacists who solely or jointly own not less than 40% of the company on its board of directors. This implies that non-pharmacists or investors can own up to 60% of a pharmaceutical-focused company in Nigeria.

The Pharmacy Council of Nigeria (Establishment) Act 2022 has now extended regulatory control to online distribution establishments, as there was previously no regulation in respect of online pharmacy practice. The new law requires any person who carries on the practice of pharmacy – whether online or on-site – to obtain certification for retention of the name of such online or physical pharmaceutical establishment. As well as providing extensive regulatory control, the new law criminalises the operation of pharmacies by persons who are unlicensed as pharmacists.

Regulatory supervision has now been entrusted to the Pharmacy Council of Nigeria (PCN). This statutory entity will be responsible for new licensing and registration regimes for pharmacists, pharmaceutical businesses and pharmaceutical premises (which include hospital premises, along with premises where manufacturing, importation, wholesale and retail are carried out) in Nigeria. The PCN will also be responsible for the discipline of any erring pharmacists and sanctioning offending pharmaceutical companies when violation occurs.

Guidelines for registration of pharmaceutical retail, distribution and importation premises

In order to register a new premises for the retail, distribution and importation of pharmaceutical products, the following documents shall be submitted to the Registrar of the PCN:

- application letter to register the premises;
- duly completed Form B (the PCN's application form for registration of premises);
- duly completed Form J (application for retention of name on the Pharmaceutical Register);
- prescribed inspection and registration fees in a bank draft payable to the PCN;
- photocopy of letter of resignation from previous employment (if applicable);
- letter of acceptance of resignation (if applicable);
- letter of appointment in the new premises where applicable;
- legal agreement between the superintendent pharmacist and their employer where applicable;
- company's certificate of incorporation (evidence of registration of business name is acceptable from pharmacist-owned retail premises);
- articles and memorandum of association (certified copy);
- particulars of directors as issued by Corporate Affairs Commission (CAC) (certified copy);
- photocopy of National Youth Service Corps (NYSC) discharge or exemption certificate (where applicable);
- letter of undertaking by the superintendent pharmacist to the effect that they have only one pharmaceutical job;
- letter of undertaking by the managing director of the company to the effect that all pharmaceutical business will be left under the direct, personal control and management of the superintendent pharmacist;
- pharmacists inter-state movement form (where applicable); and
- evidence of a pharmacist on the board of directors (ie, photocopy of the pharmacist director's annual licence to practice).

Guidelines for the registration of a pharmaceutical manufacturing premises

In the case of a pharmaceutical company that intends to engage in manufacturing, the above-mentioned requirements would also apply. However, such manufacturing entity must also provide the following documents in order to satisfy the licensing or registration requirements:

- list of products to be manufactured;
- organogram;
- list of staff qualifications and duties;
- factory lay-out;
- production flow chart;
- list of equipment in production and quality control departments;
- source and water treatment facilities
- water analysis report of raw and treated water;
- list and source of suppliers of raw materials and packaging materials;
- standard operating procedures;
- standard cleaning procedures; and
- inspection fees (bank draft for NGN30,000 payable to the PCN).

Guidelines for registration of online pharmacies or drug distribution channels

Online drug channels or pharmacies must also be licensed. Pursuant to Regulation 2 of the Online Pharmacy Regulations 2021, in order to obtain the requisite licence, an application for registration submitted to the PCN by the superintendent pharmacist should be accompanied by the following documents:

- application letter for registration of the pharmacy;
- current annual licence of the superintendent pharmacist;
- evidence of registration of the pharmacy premises;
- evidence of payment of registration fee to the PCN;
- letter of resignation from previous employment;
- letter of acceptance of resignation and appointment letter from the new pharmacy;
- a legal agreement between the superintendent pharmacist in the new premises and the owner of the pharmaceutical premises (where applicable);
- certificate of incorporation or business name certificate for pharmacist-owned retail premises;
- articles and memorandum of association;
- certified true copy of CAC documents showing the names of directors of the company;
- NYSC discharge or exemption certificate of the superintendent pharmacist;
- an undertaking by the superintendent pharmacist to be held accountable for services provided on the platform;
- an undertaking by the managing director of the pharmacy that the pharmacy will be managed by the superintendent pharmacist; and
- policy documents on procedures and processes for the operation of the internet pharmacy.

The online pharmacy is required to display the name and qualification of the superintendent pharmacist and all other personnel involved in the operation of the pharmacy. In accordance with Regulation 3 of the Online Pharmacy Regulations 2021, the physical location of the pharmacy must also be displayed online. Upon registration of the Internet-Based Pharmacy (IBP), the pharmacy will be eligible for the PCN's registered online pharmacy sites emblem (ROPSE).

Implementation Of Traceability Of Pharmaceutical Products

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is the statutory entity responsible for the regulation and control of the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents (collectively known as regulated products). In 2022, NAFDAC issued guidance on the master data attributes required to make pharmaceutical products traceable in Nigeria.

Given that the burden of regulating drug distribution, sale, use and security rests on NAFDAC, the regulatory entity developed a Five-Year Traceability Implementation plan in line with its national strategy to achieve supply chain visibility and strengthen its pharmacovigilance activities against the scourge of substandard and falsified medicines and medical devices. Traceability is expected to become fully operational in the Nigerian pharmaceutical supply chain by the end of the year 2024.

At the centre of NAFDAC's strategy on traceability is the plan to adopt a common business language that trading partners involved in the drug distribution value chain – from the manufacturer down to the dispenser – would use to identify, capture and share information about pharmaceutical products and how they move along the supply chain. In so doing, the plan is to ascertain the source, location and site(s) for drugs supplied within Nigeria.

To this end, NAFDAC has now published a list of master data attributes that marketing authorisation holders must share. "Master data attributes" have been defined in the Guidance on Master Data Attributes for Pharmaceutical Products as "attributes or characteristics of an item, entity or location that is created by the owner of that item or entity". Marketing authorisation holders would be required to share legal, function and location master data with NAFDAC, including:

- the brand name;
- generic name of the product;
- product description;
- trade item description;
- strength of the product;
- active ingredient in the product;
- global product category code;
- the anatomical therapeutic chemical or defined daily dose;
- pharmaceutical classification structure number;
- name of the manufacturer; and
- address of the manufacturer.

A good portion of this data is already provided to NAFDAC by marketing authorisation holders. However, it would appear that the collection and collation of this data is an attempt to update NAFDAC's records – especially considering that it only recently adopted a digital framework for the registration of regulated products.

Changes to Counterfeit Medical Products Legislation

The Counterfeit Medical Products, Fake Drugs and Unwholesome Processed Foods (Prohibition And Control) Bill 2021 (the "CFU Bill") was introduced in Parliament (ie, the Nigerian National Assembly) on 9 November 2021 to repeal the existing Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Provisions Act. The CFU Bill is now at third reading stage, in which a final decision will be taken by the Nigerian House of Representatives to pass the CFU Bill and refer it to a joint

parliamentary committee and the Nigerian Senate for passage.

The key changes proposed in the CFU Bill are as follows.

- Stiffer penalties for sale and distribution of unregistered and counterfeit drugs – under the CFU Bill, a person who produces, imports, or aids or abets another person to manufacture, transport and sell counterfeit medical products and fake drugs would be liable on conviction to imprisonment for life and payment of compensation to the victim of no less than NGN10 million.
- Penalty for the failure to issue a written receipt – given that dealers in counterfeit products often avoid issuance of receipts in order to avoid the existence of any documentary evidence connecting them with the sale and distribution of counterfeit drugs, the CFU Bill criminalises the failure to issue receipts with a three-year prison term and a fine of no less than NGN1 million.
- Liability of an occupier or person responsible for the management of any premises where counterfeiting activity occurs – although there is currently no liability apportionable to the owner or manager of the premises where counterfeiting activity takes place, the CFU Bill proposes punitive sanctions of a five-year prison term or a fine of NGN5 million where an occupier knows (or is likely to know) that any counterfeit medical product or fake drug is being produced or stored within their premises but fails or neglects to report such to NAFDAC.
- Forfeiture, seizure, and destruction of seized property – the CFU Bill provides that any real or personal property used for the commission of acts of counterfeiting may be liable to forfeiture.

POLAND

Law and Practice

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Tomasik Jaworski Law Firm Sp. p. (TJSP) is an independent law firm founded by lawyers with almost 20 years' experience of advising the pharmaceutical and medical devices industries in Poland. The firm offers comprehensive advice to entities operating in the pharmaceutical and medical devices market, including both local businesses and multinational companies, representing innovative and generic industry. The team provides legal assistance on all aspects of day-to-day operations, as well as strategic issues. Over the years, it has been especially active advising on regulatory matters, contracts, compliance, product liability, intellectual property, data privacy, competition law, public tenders and commercial litigation, as well as provided training for the executives and other staff of pharmaceutical companies. The firm's lawyers are often retained as experts by industry organisations in regulatory dialogue and legislative processes.

Authors

Marcin Tomasik advises businesses and organisations in regulated industries. He also specialises in compliance and unfair competition, and in administrative and criminal proceedings. Marcin is a member of the District Bar Association in Warsaw and a graduate of the Faculty of Law at the University of Warsaw and the Center for English and European Law organised in co-operation with Cambridge University. He is a lecturer in post-graduate studies on Compliance and Risk Management at the Warsaw School of Economics.

Tomasz Jaworski is attorney-at-law whose areas of expertise include pharmaceutical law, medical device law, public procurement law, litigation and administrative proceedings. He is the co-author of a commentary on the law on so-called class actions (CH Beck, 2010) and of the concept of reforming the Ukrainian drug registration system (within the framework of the EBRD project). Tomasz has also written numerous publications in the legal press, and legal reports on the pharmacy market, laboratory diagnostics and spa communities.

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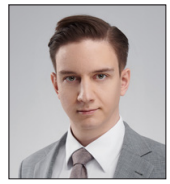

Filip Gołba advises regulated industries, primarily in the pharmaceutical, medical devices and pharmacy sectors. He represents clients before administrative courts and regulatory bodies, including the European Commission, advises on legislation, and helps to align businesses with European and national regulations. Filip previously worked in academia, teaching at the Jagiellonian University, participating in research projects funded by the National Science Center at the Departments of Legal Theory and of Constitutional Law, and authoring academic articles and chapters in commentary. He worked on reforming the Ukrainian Pharmaceutical Law (EBRD project), and has represented in proceedings concluding with key judgments shaping the Polish pharmacy market. He is a member of Bar Association in Warsaw.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Polish legislation regarding pharmaceuticals and medical devices is heavily influenced by EU legislation.

Clinical trials and the manufacturing, registration, distribution, marketing and advertising of pharmaceuticals are regulated by the Pharmaceutical Law Act of 6 September 2001 and its executive regulations. The Medical Devices Act of 7 April 2022 and its executive regulations deal with the regulation of medical devices, including the safety and quality of medical devices. Polish legislation has been adjusted to comply with the following EU Regulations relating to medical devices:

- the Medical Device Regulation (MDR); and
- the In Vitro Diagnostic Device Regulation (IVDR).

The Act on Reimbursement of Medicines, Food Products Intended for Particular Nutritional Uses and Medical Devices of 12 May 2011 regulates reimbursement from public funds; work is underway on a significant revision of the reimbursement regulations.

The key regulatory authority for medicinal products is the Pharmaceutical Inspection, which is led by the Chief Pharmaceutical Inspector and supervises the quality, manufacture, import, distribution, transport and storage of pharmaceuticals, among other matters. The Inspectorate is also responsible for overseeing the advertising of those products, and for controlling the operations of pharmacies and wholesalers.

The Pharmaceutical Inspection is also home to regional pharmaceutical inspectors, but these are formally subordinate to voivodes (regional governors in charge of governmental administration), rather than to the Chief Pharmaceutical Inspector. There are plans to amend the Pharmaceutical Law so that regional inspectors report to the Chief Pharmaceutical Inspector.

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) is the regulatory body responsible for the registration and approval of pharmaceuticals and medical devices in Poland. It is also responsible for issuing decisions regarding medical devices in relation to their classification, safety, advertising, marketing and use. The Minister of Health and the Chief Sanitary Inspector supervise the advertising of business or professional activity in which a medical device is used to provide a service.

The Ministry of Health decides on the reimbursement of pharmaceuticals and medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The procedure for challenging administrative decisions is generally similar for all regulated products, since all of the proceedings are at least partially regulated by the Administrative Procedure Code of 14 June 1960. As a rule, there is always a legal remedy.

Decisions made by local branches of the authorities can be challenged by appealing to the main authority (eg, a decision of the Regional Pharmaceutical Inspector can be appealed to the Chief Pharmaceutical Inspector), and the final decision is subject to judicial review by the Administrative Courts. In general, the administrative appeal is

free of charge and not subject to any specific formal requirements other than the explicit disagreement of the party. The judicial review is subject to a fee, which differs depending on the type of decision that is being questioned.

It is not possible to appeal against decisions made by the central authorities, such as the Chief Pharmaceutical Inspector. The party may file a motion for the decision to be reconsidered, or proceed directly to a judicial review by the Administrative Courts.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In principle, the regulations of the legislation mentioned in **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices** apply to all categories of medicines.

Medical devices and in vitro diagnostic medical devices are regulated separately.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of pharmaceuticals and medical devices are subject to similar regulations, in accordance with the relevant European regulations. Clinical trials of pharmaceuticals are regulated by the Pharmaceutical Law Act (Articles 37a to 37al), while clinical investigations/performance studies are regulated by the Medical Devices Act (Articles 31 to 38). Legislative work on the Law on Clinical Trials of Medicinal Products for Human Use is about to be completed. The new laws intend to adjust the local legal landscape to Regulation No 536/2014.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The transitional provisions of Regulation 536/2014 are currently in effect. Harmonisation of the application, evaluation and supervision processes for clinical trials in the EU is underway.

According to the Pharmaceutical Law Act, a clinical trial of a pharmaceutical may start if the President of the URPL has issued a study permit and a bioethical committee has issued a positive opinion on the study. A clinical trial can also commence if the President of the URPL has not requested supplementary information within 60 days of an application being submitted (so-called "implied consent"). The implied consent does not apply to clinical trials of pharmaceuticals for gene therapy or cell therapy, nor to trials of pharmaceuticals containing genetically modified organisms.

The authorisation is issued after the documentation submitted with the application is assessed, in accordance with the Regulation of the Minister of Health of 12 October 2018 on the specimens submitted for the clinical trial of the medicinal product and on the amount and method of payment. The application costs up to PLN8,000 (circa EUR1,700).

The President of the URPL makes a decision within no more than 60 days; this term may be extended with regard to clinical trials of pharmaceuticals for gene therapy or cell therapy, or for clinical trials of pharmaceuticals containing genetically modified organisms if expertise is necessary.

During the process, the President of the URPL may ask the sponsor to provide supplementary information necessary for issuing the permit. The

time limit within which the supplementary information should be sent cannot be longer than 90 days.

Similar rules apply to clinical trials of medical devices, which may start if the President of the URPL has issued a study permit and a bioethical committee has issued a positive opinion on the study. The application costs PLN6,000 (circa EUR1,280).

2.3 Public Availability of the Conduct of a Clinical Trial

In Polish law, there is no legal requirement for a compulsory, publicly available database of ongoing clinical trials and their results. The Employers' Association of Innovative Pharmaceutical Companies (INFARMA – member of EFPIA) represents pharmaceutical companies engaged in research and development activities in Poland, and has voluntarily established a publicly available database of ongoing clinical trials conducted by its members (ie, pharmaceutical manufacturers).

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is no specific restriction against using online tools to support clinical trials. The processing of personal data connected with clinical trials is subject to the general provisions of the Personal Data Protection Act. Sponsors and clinical investigators have to ensure that any online tools used to recruit or monitor study participants comply with the Personal Data Protection Act and other relevant data protection regulations.

2.5 Use of Data Resulting From the Clinical Trials

Data resulting from the clinical trials is considered sensitive, so written consent is required from the patient before it can be processed. The resulting data can be transferred to a third party or an affiliate, if the patient has agreed to it.

2.6 Databases Containing Personal or Sensitive Data

The Regulations of the Minister of Health on Good Clinical Practice of 2 May 2012 specify detailed requirements for the documenting and reporting of clinical trials. The creation of a database containing patient data from clinical trials requires the written consent of all participants.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The provisions of the Pharmaceutical Law Act shall apply to a product that simultaneously meets the criteria of a medicinal product and the criteria of another type of product, in particular a dietary supplement, a cosmetic product or a medical device, as defined by separate regulations.

Product qualification is carried out by the manufacturer, in accordance with the statutory definitions of a medical device and pharmaceutical. Competent authorities have the opportunity to react if there is a misclassification. However, the competences of authorities in this respect are not clearly defined or demarcated, which sometimes leads to delays in decisions.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Marketing authorisations for biologic medicines are granted in accordance with Regulation

726/2004; therefore, they are not granted by the President of the URPL.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The marketing authorisation is issued for five years and may be renewed indefinitely, at the request of the marketing authorisation holder. An application for an extension should be made at least nine months before the expiry date of the authorisation.

The President of the URPL is obliged to revoke a marketing authorisation if any of the circumstances described in Article 33 of the Pharmaceutical Law occur, including:

- an unexpected serious adverse reaction;
- the pharmaceutical does not have the declared therapeutic efficacy; or
- the risk of using it is found to be disproportionate to its therapeutic effect.

The President of the URPL can suspend a marketing authorisation when the circumstances described above do not pose a direct threat to public health.

The marketing authorisation expires if the marketing authorisation holder does not actually place the medicinal product on the market within three years of receiving the authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

The national procedure for obtaining marketing authorisation is as follows.

- The applicant for marketing authorisation should submit an application for a marketing authorisation for the medicinal product to the President of the URPL.
- The President of the URPL formally verifies the application and attached documentation.
- If formal deficiencies are found, the President of the URPL calls for the application to be supplemented within at least seven days, under pain of leaving the application unprocessed.
- If there are substantive comments on the submitted documentation, the President of the Office calls on the applicant to submit supplements and clarifications.
- Proceedings for the issuance of a marketing authorisation for a medicinal product should be completed within no more than 210 days of the application being submitted.
- If it is necessary to supplement the documents or to submit explanations, the President of the Office shall issue a decision to suspend the deadline.

The costs for obtaining a marketing authorisation depend on the nature of the medicinal product, and can be up to PLN84,000 (circa EUR20,000).

The procedure for a variation of a market authorisation is governed by Commission Regulation No 1234/2008 of 24 November 2008 and the Pharmaceutical Law Act (Article 31). The change procedure depends on the type of change. Changes are made by the President of the URPL at the request of the marketing authorisation holder.

If there is a change of marketing authorisation holder, the President of the Office shall issue a new authorisation on the basis of the application of the person assuming the rights and obligations of the existing marketing authorisation holder. The decision issued in favour of the new marketing authorisation holder shall come into

force no later than six months after it is issued. The new permit shall be issued no later than 30 days after the application is made.

The requirements that have to be satisfied before medical devices can be placed on the market are contained primarily in the MDR and the IVDR.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The following products are approved for sale without a marketing authorisation:

- magistral formulas;
- official formulas;
- radiopharmaceutical products prepared at the time of use in authorised medical entities, from authorised generators, kits, radionuclides and precursors, in accordance with the manufacturer's instructions, and radionuclides in the form of sealed radiation sources;
- blood and plasma in full composition or blood cells of human or animal origin, excluding plasma processed by an industrial process;
- pharmaceutical raw materials not intended for the preparation of prescription and pharmacy pharmaceuticals;
- immunological veterinary medicinal products made from pathogens or antigens derived from animals on a farm and intended for the treatment of animals on that farm; and
- advanced therapy medicinal products (hospital exceptions).

There are no Polish regulations relating directly to compassionate use programmes. Any medicinal products imported from abroad are allowed to be marketed without the need for authorisation if their use is necessary to save the life or health of a patient, provided that the medicinal product is authorised in the country from which it is imported and has a current marketing authorisation.

In accordance with Article 59(1) of the MDR, the competent authority (ie, the President of the URPL in Poland) may, upon duly justified request, allow the placing on the market or putting into service on the territory of the member state concerned of a specific device for which the relevant procedures referred to in the relevant provisions of the MDR have not been carried out, but the use of which is in the interest of public health or the safety or health of patients.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The following obligations may be imposed in the marketing authorisation:

- to take measures, within the framework of the risk management system for the use of the medicinal product, to ensure the safe use of the medicinal product;
- to conduct post-authorisation safety studies;
- to record or report adverse reactions;
- to use an appropriate system for the supervision of the safe use of medicinal products;
- to conduct post-authorisation efficacy studies where doubts have arisen regarding certain aspects of this medicinal product's efficacy that can only be clarified after it is placed on the market; and
- to provide information on the safety and efficacy of the medicinal product in question resulting from scientific and technical progress and the expansion of knowledge about that medicinal product.

With regard to medical devices, each manufacturer analyses all the complaints about the device, as well as cases of errors in use and

misuse. The analysis depends on risk management, ergonomics, design validation, and corrective and preventative actions. The manufacturer shall make the results of the analysis available at the request of the President of the URPL and the notified body involved in the conformity assessment of the device. The manufacturer assesses the risks associated with the devices affected by the medical incident and, based on the assessment of the risk analysis, decides whether corrective actions are necessary and to what extent. The manufacturer shall describe the corrective action in the Field Safety Corrective Action Report. The corrective action must be communicated to customers via a Field Safety Notice.

The manufacturer initiates an investigation into the reported medical incident and decides whether said incident meets the criteria for reporting to the President of the URPL.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties have access only to information on medicinal product authorisation published by the URPL (ie, the authorisation itself, the Summary of Product Characteristics, the Patient Information Leaflet and a summary of the Risk Management Plan). Other documents are available on request but only to entities that can substantiate their legal interest (eg, violation of rights), and subject to the protection of proprietary information. There are no specific regulations allowing disclosure of the process of applying for the marketing authorisation.

In the case of medical devices, it is possible to obtain public information on information contained in safety notes and certificates of conformity, and on the issuance, amendment, supplementation, suspension and withdrawal of certificates of conformity.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Pharmaceutical Law imposes an obligation on manufacturers, importers and wholesalers to notify the Chief Pharmaceutical Inspector, the President of the URPL and the relevant marketing authorisation holder of any suspected falsification of a medicinal product.

Pharmaceutical inspection authorities are authorised to withhold a medicinal product from the market, prohibit its introduction or withdraw it if said product is suspected or found to be counterfeit.

In addition, the Pharmaceutical Law states that a fine, restriction of liberty or imprisonment of up to five years can be imposed for the manufacturing, supplying or making available of a falsified medicinal product.

The Medical Devices Law states that fines can be imposed for the distribution of medical devices in violation of regulations.

In addition, in July 2017, the National Organisation for Drug Verification (KOWAL) was established to create a drug verification system and to co-operate with the European Medicines Verification Organisation. The Integrated System for Monitoring the Circulation of Medicinal Products (ZSMOPL) operates in Poland independent of EU regulations.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The Customs Service is responsible for preventing the import or release of counterfeit products.

The Customs Service is entitled to inspect and review imported goods, and may suspend the release of the goods or detain them for a period of three working days if it has sufficient grounds to suspect that goods are counterfeit products.

In order to counter the threat of counterfeit medicinal products, the Minister of Health has established a Team for Counterfeiting and Illegal Trade in Medicinal Products and Other Counterfeit Products Meeting the Criteria for a Medicinal Product. This team includes the Chief of the Customs Service.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Undertaking the business of manufacturing pharmaceuticals requires a manufacturer's licence, issued by the Chief Pharmaceutical Inspector. The manufacturing of a medicinal product is any activity leading to the creation of a medicinal product, including the purchase and receipt at the manufacturing site by the manufacturer of materials used for production and their release for subsequent manufacturing stages, including packaging or repackaging and storage and distribution of manufactured medicinal products covered by the application for a manufacturing authorisation, as well as control activities related to these activities.

An applicant for a manufacturer's licence should submit an application containing, among other things, the type and pharmaceutical form of the medicinal product, the place of manufacture of the medicinal product, and a determination of the scope of manufacture of the medicinal product.

The model application is specified in the Regulation of the Minister of Health of 29 April 2019 on the model application for a change in the authorisation to manufacture or import medicinal products.

The application fee depends on the type of medicinal product to be manufactured (sterile or non-sterile), and ranges from PLN3,300 to PLN5,500 (about EUR705 to EUR11,170).

The permit is issued for an indefinite period of time.

The manufacture of active pharmaceutical ingredients is subject to registration in the National Register of Manufacturers, Importers and Distributors of Active Pharmaceutical Ingredients.

The manufacture of medical devices does not require a special licence. The President of the URPL controls medical device manufacturers.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Undertaking the business of operating a pharmaceutical wholesaler requires a licence from the Chief Pharmaceutical Inspector.

Wholesale is any activity involving the acquisition, possession, supply or export of pharmaceuticals or veterinary drugs by holders of marketing authorisation.

An applicant for a licence should submit an application that includes:

- a definition of the scope of the wholesale business;
- the date on which the intended activity is to be undertaken;
- the name of the person responsible for the operation of the wholesale business; and
- the number of the professional licence for those who are pharmacists, or the PESEL number in the case of other individuals.

The following items should be submitted with the application:

- relevant declarations, including a declaration of the responsible person that they undertake this function as of the date the wholesale business started;
- an opinion of the competent district pharmacy chamber regarding the responsible person, if they are a member of the pharmacy chamber;
- a description of the procedures for effective withholding or withdrawal of the medicinal product or veterinary medicinal product from the market and from distributors;
- a document confirming the legal title to the premises intended for the business;
- a technical description including illustrations concerning the premises intended for the business, prepared by an authorised person; and
- an opinion on the suitability of the premises.

The model of the application is specified in the Regulation of the Minister of Health dated 29 April 2019 on the model of the application for a licence to operate a pharmaceutical wholesaler.

A wholesaler engaged in the wholesale distribution of medicines must meet the following requirements:

- having adequate facilities to carry out this activity;
- employing a qualified person;
- having a description of the procedure for the effective cessation of distribution or withdrawal of a drug from the market; and
- complying with the more specific obligations set forth in the Pharmaceutical Law.

A wholesale licence is issued for an indefinite period of time, unless the applicant has applied for a fixed-term licence. The fee for granting a licence to operate a pharmaceutical wholesaler is PLN6,756 (approximately EUR1,440).

The distribution of medical devices does not require any special licence. The President of the URPL controls distributors of medical devices.

5.2 Different Classifications Applicable to Pharmaceuticals

The Pharmaceutical Law Act divides pharmaceuticals into the following categories:

- available without prescription (OTC);
- available on prescription only (Rp);
- available on prescription only, for restricted use (Rpz);
- available on prescription only, containing narcotic drugs or psychotropic substances specified in separate regulations (Rpw); and
- for hospital use only (Lz).

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6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

In accordance with the Pharmaceutical Law, the import of medicinal products takes place only if such products are brought in from a territory outside the European Economic Area (EEA). If a medicinal product is delivered to Poland from another country within the EEA, such delivery is deemed to be wholesale of medicinal products, rather than being qualified as an import. Export and parallel import are also classified as instances of wholesale.

Similarly, the Medical Devices Act defines an importer by reference to the MDR and the IVDR, under which the importer is an entity that places a medical device from a third country on the EU market.

Articles 38 to 51a of the Pharmaceutical Law govern the import of medicinal products. The import of medical devices is regulated primarily in the MDR and the IVDR, although important provisions might be found in the Medical Devices Act as well. The main obligations for an importer are contained in Articles 13 and 16 of these two Regulations.

The Chief Pharmaceutical Inspector is a central organ of the Polish administration, which issues licences for the import of medicinal products. Importers of medical devices have to register with the President of the URPL.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Any person, natural or legal, can act as an importer of record of pharmaceuticals. However, an importer of pharmaceuticals cannot apply for a licence to run a pharmacy.

Any person, natural or legal, whose place of residence or headquarters, respectively, is in the EU can act as an importer of record of medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of medicines requires a licence from the Chief Pharmaceutical Inspector. Obtaining such a licence is compulsory even if the pharmaceuticals are only intended to be imported for the purpose of further exporting them outside the EEA. It is likewise compulsory for the import of investigational medicinal products, for example.

An application for a licence should specify which medicinal products are going to be imported. An importer can only import medicines that are covered by a licence. The Pharmaceutical Law also allows imports on the basis of an agreement with another importer.

Information on importers is publicly available in the Register of Manufacturers and Importers of Medicinal Products provided by the Chief Pharmaceutical Inspector.

Licensed importers of a medicinal product are not exempt from civil or criminal liability in relation to the use of the medicinal product.

The import of medical devices will require registration with the European Database on Medical

Devices (EUDAMED) prior to placing a device on the market. After filing with the register, the importer should apply to the President of the URPL for a single registration number. The obligation to register will not apply to custom-made devices.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Parallel import is allowed (it is an instance of wholesale trade) as required by EU law, especially the standards related to the single market. However, this requires obtaining a licence for a particular medicinal product from the President of the URPL. The licence is valid for five years, although it is possible to extend it for a further five years.

In order for the parallel import of the medicinal product to be allowed, the medicines in question have to have:

- the same active substances;
- at least the same indications up to level 3 of the Anatomical Therapeutic Chemical (ATC) code;
- the same strength;
- the same route of administration; and
- the same form or a similar form that does not result in therapeutic differences.

The medicinal product subject to parallel import has to be properly repackaged in order to satisfy all the demands of the Pharmaceutical Law. Generally, if such repackaging is necessary, it is a legal requirement and the trade mark holder cannot object to it.

6.5 Trade Blocs and Free Trade Agreements

Poland is a member state of the EU and thereby is part of the European single market comprised of all EU member states and three countries of the European Free Trade Association (EFTA) that chose to be part of the EEA: Iceland, Liechtenstein and Norway. Poland is also a member of the EU Customs Union. The EU itself is a party to an array of free trade agreements with third countries, which thus have an impact on Poland.

Poland is also a member of the World Trade Organization (WTO) and the Organisation for Economic Co-operation and Development (OECD).

Following the aggression of the Russian Federation against Ukraine in 2022, sanctions have been imposed on the import and export of certain goods to and from Russia and Belarus. Poland applies EU sanctions, and has also adopted a national law that allows the application of further sanctions on Polish entities and their related companies that deal with Russian/Belarussian entities that support the aggression. The trading of pharmaceuticals and medical devices has not been expressly excluded from these national regulations.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Generally, only the prices for publicly reimbursed medicinal products or medical devices are regulated. Key pieces of legislation in this respect are the Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices and the Act of 27 August 2004 on the Financing of Health Services by the State Fund. In accordance with the former, the following products may be publicly reimbursed:

- medicinal products, medical devices and foodstuffs intended for particular nutritional uses that have to prescribed;
- medicinal products and foodstuffs intended for particular nutritional uses available within a drug programme;
- medicinal products available within chemotherapy; and
- medicinal products and foodstuffs intended for particular nutritional uses available for use within the provision of publicly funded services other than those listed above.

OTC medicines are not publicly reimbursed, so their prices are not regulated.

If a product is reimbursed, its price is fixed unless it is procured by an entity providing publicly funded health services, in which case the official price serves as the maximum price the product may be bought for by said entity. The official prices are uniform nationwide and so are the margins: the wholesale margin is 5%, while the retail margin depends upon the price of the medicinal product, medical device or foodstuffs intended for particular nutritional uses that is the limit basis for the given limit group.

For a product to be publicly reimbursed, the marketing authorisation holder has to apply for inclusion in the public reimbursement system.

Official prices are set by the Minister of Health. The negotiations with the Economic Commission, which is an institution within the Ministry, are a key element here. The resulting prices are put on the reimbursement list, which is published on a two-monthly basis.

Medicinal products, medical devices or foodstuffs intended for particular nutritional uses are assigned to reimbursement limit groups (internal reference pricing). Medicines with the same international name or with a different international name but similar therapeutic effects and similar mechanisms of action should be classified in a single group. Medical devices or foodstuffs intended for particular nutritional uses are classified in a single group if they have the same reimbursement indications or uses and similar efficacy.

The official price of the first equivalent on the list may not be higher than 75% of the only counterpart reimbursed in a given indication. In the case of subsequent counterparts, the official price may not be higher than the price of the counterpart determining the basis of the financing limit or the cheapest counterpart if the basis for the limit in the limit group sets the drug with another active substance.

After the market exclusivity expires, the new official price cannot be higher than 75% of the product's price during the market exclusivity period.

7.2 Price Levels of Pharmaceutical or Medical Devices

The prices in other countries are legally relevant for the Minister of Health when pricing medicinal products and foodstuffs intended for particular nutritional uses that are not classified as any of the following categories of reimbursement availability:

- available in pharmacies on prescription;
- available within a drug programme; or
- available within chemotherapy.

Therefore, this broad category of reimbursement availability encompasses medicines and foodstuffs intended for particular nutritional uses used within the provision of publicly funded ser-

vices, including services provided in hospitals, in outpatient clinics, and as part of dental treatment or therapeutic rehabilitation.

The criteria that are to be taken into account by the Minister of Health when setting the official price of such products include the minimum net selling price of those products within the publicly funded system of reimbursement of particular member states of the EU or EFTA. If a given product is not publicly funded in some of these countries, then the market prices are taken into account.

Moreover, in the course of the negotiations, the Economic Commission is obliged to take into account the minimum and maximum net selling price of the product that is the subject of negotiations within the publicly funded system of reimbursement of particular member states of the EU or EFTA. If a given product is not publicly funded in some of these countries, then the market prices are taken into account. The Economic Commission can also consider rebates, discounts or price agreements in these countries.

Usually, it is expected that the price will be among the lowest in the EEA member states. An applicant must provide the prices of a product, together with information on the reimbursement status of the product (level of reimbursement, conditions, restrictions, existence of risk-charing schemes) in all EEA member states.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Polish public health funding includes reimbursement of medicinal products, medical devices and foodstuffs intended for particular nutritional uses and provided to patients in publicly funded establishments and purchased by them in pharmacies and pharmacy outlets.

The levels of reimbursement are as follows:

- 100% reimbursement (free of charge) – products with proven efficacy in the treatment of malignant cancer, psychotic disorders, mental disability and development disorders, or contagious diseases posing a special epidemic risk for the population, or products administered in drug programmes;
- lump sum (PLN3.20):
  - (a) products that must be administered for more than 30 days and whose monthly administration cost for the service recipient would, in the case of a payment level of 30% of the financing limit, exceed 5% of the minimum wage; and
  - (b) products that must be administered for no more than 30 days and whose cost for the service recipient would, in the case of a payment level of 50% of the financing limit, exceed 30% of the minimum wage for work;
- partial reimbursement – 50% of the financing limit, for products that must be administered for not more than 30 days; and
- partial reimbursement – 70% of the financing limit, for other products.

There are several ways in which medical devices are publicly funded.

- Prescribed medical devices available in pharmacies are covered by the Minister of Health's reimbursement decisions and published in its reimbursement list. This category consists of devices that do not require personalisation for every patient – eg, diagnostic strips for blood glucose monitoring and special types of dressings. The pricing of this

device group is regulated as for pharmaceuticals.
- Medical devices supplied on the instructions of an authorised healthcare professional are included in the Minister of Health's regulation, which indicates, for example, the device's public fund financing limit, the patient's own share in the limit and the criteria on which devices are granted. There are no negotiation procedures; conditions apply to every device and are set formally. This group consists of devices that require personalisation (eg, infusion sets for a personal insulin pump, lenses, prostheses, adult diapers and wheelchairs).
- Medical devices provided in an inpatient setting are financed from the public fund as part of the medical procedure and are supplied to patients free of charge. These devices are procured by hospitals and clinics in public procurements.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

During the reimbursement procedure, a health technology assessment (HTA) is provided for originators with no reimbursement equivalents. The reimbursement decision has to be made on the basis of scientific evidence. The applicant marketing authorisation holder has to prove the product's cost-effectiveness compared to the alternative therapeutic substance that is already reimbursed from public funds. The Agency for Health Technology Assessment and its advisory body, the Transparency Council, play a crucial role in the assessment process.

The Minister of Health issues an individual administrative decision on the reimbursement of a product, taking into account other medical procedures that may be applied for a given clinical condition and that may be replaced with the medicine, foodstuffs for particular nutritional uses, or medical device covered by the application. The following are also taken into account:

- the stance of the Economic Commission;
- the recommendations of the President of the Agency for Health Technology Assessment and Tariff System (AOTMiT);
- the significance of the clinical condition to which the reimbursement application relates;
- clinical and practical efficacy;
- safety;
- the relationship between health benefits and administration risk;
- the cost to health effects ratio of the previously reimbursed products compared to that covered by the application;
- price competitiveness;
- the impact on the expenses of the entity obliged to finance healthcare services from public funds and on service recipients;
- the existence of an alternative medical technology and its clinical efficacy and safety;
- the map of health needs developed by the Minister to identify priority health needs and challenges for the organisation of the healthcare system and to ensure sustainable and co-ordinated spending of public funds; and
- the threshold cost of gaining an additional quality-adjusted life year.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

While dispensing reimbursed medicinal products, medical devices or foodstuffs intended for particular nutritional uses, pharmacy staff (pharmacists and pharmacy technicians) should inform a patient about the availability of an affordable and publicly reimbursed equivalent whose retail price does not exceed the price of the prescribed product and the financing limit. In the case of medicines, the equivalent has to share its international name, dosage and

therapeutic indication with the prescribed product, and must have a pharmaceutical form that cannot give rise to therapeutic differences. The pharmacy is obliged to display this information in its premises.

Pharmacy staff are also obliged to issue an equivalent to patients who make such requests. This obligation also extends to equivalents with the same or even higher price and to equivalents that are not publicly reimbursed. In the latter case, the cost is fully payable by the patient.

The equivalent cannot be issued if the person prescribing the product indicated on the prescription that the prescribed product cannot be substituted.

These rules also apply to pharmacy outlets.

8. Digital Healthcare

8.1 Rules for Medical Apps

Apps can be classified as medical devices. There are no regulations specific to apps in Poland: EU regulations apply. The criteria for qualifying an app as a medical device are that it fulfils the definition of a medical device from the MDR/IVDR and that it has a medical purpose. An app can be independent or can be connected with another medical device.

To consider an app as a medical device, it is crucial that the manufacturer indicates its specific medical purpose. All implementing rules in Annex VIII of Regulation (EU) 2017/745 or Annex VIII of Regulation (EU) 2017/746 shall be considered.

The Polish Ministry of Health announced the start of the certification process for medical apps in the first quarter of 2023.

8.2 Rules for Telemedicine

According to the Medical Activity Act of 15 April 2011, health services may be provided via telemedicine systems. Telemedicine advice constitutes a health service that is equal to medical advice given in a traditional manner. When providing telemedicine services, it is important to remember the basic duties of a doctor: to act in accordance with the indications of current medical knowledge, available methods and means of prevention, in the diagnosis and treatment of diseases, in accordance with the principles of professional ethics and with due diligence.

In addition, the Regulation of the Minister of Health of 12 August 2020 on the organisational standard of teleportation in primary healthcare sets out the doctor's information duties and the rules for providing online consultations.

In 2022, the public payer (National Health Fund) announced that it would be entitled to cancel contracts for primary care if a clinic switches to operating mainly as telemedicine.

8.3 Promoting and/or Advertising on an Online Platform

Regulations on advertising to the public are applicable. In addition to the general rules for the advertising of medicines and medical devices, further restrictions are imposed on advertising directed to the public – eg, it may not include images of medical professionals or celebrities, it may not contain forbidden suggestive content, and it may not contain anything that encourages children to purchase medical devices.

The advertising of prescription-only medicines containing narcotics and psychotropic substances and included in the lists of reimbursable pharmaceuticals is not allowed.

Access to online platforms for healthcare professionals must be effectively protected from general public access.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed in Poland. Paper prescriptions are issued exceptionally, in strictly defined cases. The rules for issuing e-prescriptions derive from the Pharmaceutical Law and the Regulation of the Minister of Health of 23 December 2020 on prescriptions.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medical devices and non-prescription medicines are allowed, except for medicines for which dispensing is limited by the age of the patient. The terms and conditions for online sales of medicines are set forth in the Regulation of the Minister of Health of 26 March 2015 on the mail-order sale of medicinal products.

8.6 Electronic Health Records

The rules for maintaining electronic medical records are contained in the Health Care Information System Act of 28 April 2011. The Regulation of the Minister of Health of 6 April 2020 on the types, scope and models of medical records and the manner of their processing is also in force, and introduced the principle of keeping medical records in electronic form.

Health-related data is considered sensitive and is protected in accordance with the GDPR and the Data Protection Act of 10 May 2018. The use of cloud platforms is permitted, and there are no specific obligations for cloud platforms. The operation system should comply with the provisions of the Regulation and provide the required level of security.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patents and other key types of intellectual property (excluding copyright), such as trade marks, utility models and industrial designs, are regulated by the Industrial Property Law of 30 June 2000. In accordance with Article 24 of this statute, an invention must be new, have an inventive step and be suitable for industrial application in order to be patentable.

Generally, provisions regarding patents apply to pharmaceuticals and medical devices on a general basis. However, although only new inventions are generally patentable, there is an exception in Article 25.4 of the Industrial Property Law for inventions relating to substances or mixtures that are used for diagnosis and treatment. Even if such substances or mixtures are not new, applying said mixtures or substances for diagnosis or treatment purposes might be patentable if this application itself is new. Likewise, if their particular diagnostic or therapeutic application is not new, another diagnostic or therapeutic application might be new and thereby patentable.

Although products used in diagnostics or treatment (in particular, substances or mixtures) can be patented, the treatment of humans and animals by surgical or therapeutic methods and methods of diagnostics applied on humans or animals cannot.

Most disputes regarding patents revolve around the issue of the expiry of the patent for the original medicinal product and the placement of a generic product on the market by the generic manufacturer.

9.2 Second and Subsequent Medical Uses

New dosage regimes and new patient populations can justify additional patent protection under the new medical use rule established in Article 25.4 of the Industrial Property Law. Pursuant to this provision, a patent might be granted for a new (or specific) use of a substance or mixture in the methods of treatment or diagnosis if such use does not constitute the current state of the art.

Any actions regarding the use of the product for the patented use, such as manufacturing, placement on the market or offering of the product, would be considered an infringement of second and subsequent medical uses.

9.3 Patent Term Extension for Pharmaceuticals

As a rule, patents are granted for a period of 20 years. The patent term cannot generally be extended, except for pharmaceuticals, where the term can be extended by up to another five years by obtaining a supplementary protection certificate (SPC). An application for an SPC must be made within six months of the marketing authorisation being issued.

The decision to grant the SPC will be declared to have expired by the Polish Patent Office if the basic patent has expired before the end of the term for which it was granted, or if, during the term of the basic patent, the market authorisation for the product has been withdrawn or the right-holder has surrendered their supplementary protection right.

The SPC can be revoked on the following grounds:

- if it has been granted in contravention of the conditions required to obtain it; or
- if the basic patent was invalidated insofar as it was the basis for the existence of a supplementary protection right.

If the basic patent is invalidated in its entirety, the granted SPC becomes null and void by virtue of law.

9.4 Pharmaceutical or Medical Device Patent Infringement

A patent confers the exclusive right to exploit the invention, for profit or for professional purposes, throughout the territory of the Republic of Poland. Exploiting a patent holder's invention without the holder's consent for profit or for professional purposes in the following ways is considered an infringement of patent:

- making, using, offering or putting on the market a product that is the subject matter of the invention, or importing the product for such purposes; or
- employing a process that is the subject matter of the invention, as well as using, offering, putting on the market or importing for such purposes the product directly obtained by that process.

However, the Bolar exemption is expressly set out in Article 69.1.4 of the Industrial Property Law. By virtue of this provision, one does not infringe a patent if one uses the invention by making, applying, storing, depositing, offering, placing on the market, exporting or importing

in order to conduct acts which, under the law, are required for obtaining registration or authorisation, also by a third party, as a condition for allowing the marketing of certain products, including medicines, in the territory of the EEA or of another country.

The threat of infringement is actionable under Polish law. According to Article 285 of the Industrial Property Law, the holder of a patent, an SPC, a right of protection or a right in registration, or another entitled person, may demand the ceasing of infringing activities. According to the case law and doctrinal writings, the threat of infringement should be real and actual (plausible), and not merely hypothetical. The plausibility of the threat can be indicated by the nature of the actions taken (for instance, preparatory steps to produce products that violate exclusive rights).

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The following actions are not considered infringements of patent:

- using an invention for national purposes, to a necessary extent, without the exclusive right, where it is indispensable to prevent or eliminate a state of emergency relating to the vital interests of the State, particularly security or public order;
- the employing of an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching;
- the use of the invention by making, applying, storing, depositing, offering, placing on the market, exporting or importing in order to conduct acts which, under the law, are required for obtaining registration or authorisation, also by a third party, as a condition for allowing the marketing of certain products, including medicines, in the territory of the EEA or of another country (the Bolar exemption); and
- the extemporaneous preparation of a medicine in a pharmacy on a physician's prescription (the Galenic exemption).

According to Article 82 of the Industrial Property Act, a compulsory licence may be granted under the following circumstances:

- if it is necessary to prevent or eliminate a state of national emergency, particularly in the fields of defence, public order, the protection of human life and health, and the protection of the natural environment;
- if it has been established that the patent has been abused; or
- if it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) refuses to conclude a licence contract and thereby prevents the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand to receive an authorisation for the exploitation of the invention that is the subject matter of the dependent patent (a cross-licence).

A compulsory licence may be granted if the applying party is able to prove that it has previously made efforts to obtain a licence, in good faith. This requirement may be waived in the case of a compulsory licence granted for the purpose of preventing or eliminating a state of national emergency.

9.6 Proceedings for Patent Infringement

Any person holding a patent or rights stemming from a patent (such as a licence holder) can bring proceedings for patent infringement after the patent has been granted. The remedies include:

- cessation of the infringement;
- the handing over of unlawfully obtained profits; and
- compensation for damages (under general provisions of the Civil Code, including lost profits, or the equivalent of the licence fee or other relevant remuneration for the use of the invention).

Furthermore, the judgment can be made public (in a manner specified by the court) and the infringer can be ordered to publish a statement in the press. Upon a court order, any unlawfully manufactured or marketed products and materials used to produce them can be disposed of (destroyed or withdrawn from the market).

At the infringer's request, if the infringer was not culpable and the order to cease the infringement would be disproportionately harsh for the infringer, the court may order the payment of an appropriate sum of money (but only if it is also in the interest of the entitled person).

The invalidity of the patent can be used as an indirect defence that would require a motion to be filed at the Patent Office. Such a motion is possible and will be successful if a person with a legitimate interest is able to prove that the requirements for the granting of the patent were not met.

9.7 Procedures Available to a Generic Entrant

There are no specific requirements in the area of patent law for generic market entry, but also no specific procedures available to "clear the way" for generic entry. It is theoretically possible to file a declaratory action but, in practice, it would last too long to be effective. A generic entrant can perform all the necessary actions in order to obtain market authorisation while the patent is still binding. However, even if the marketing authorisation is granted, the product cannot be marketed until the patent has expired.

There is no patent linkage in Poland, and patent protection is not considered possible grounds for the refusal of a marketing authorisation under the Polish Pharmaceutical Law. The market authorisation holder (not the registration authority) is responsible for any patent infringement stemming from manufacturing or marketing the product.

However, even though the Pharmaceutical Law perceives patents as being irrelevant to the procedure of marketing authorisations, it does include data and market exclusivity rules, established in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001. After the market authorisation has been granted, the beneficiary can withhold access to the results of clinical and non-clinical studies from other entities (including generic entrants) for a period of eight years from the date the first (initial) marketing authorisation was granted in an EU or EFTA member state (data exclusivity). In addition, the generic of the referenced pharmaceutical product cannot be released onto the market until ten years have passed since the date of the initial marketing authorisation in an EU or EFTA member state (market exclusivity).

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Depending on the type and scope of the counterfeit infringement, the infringer can be held responsible on the following grounds:

- general civil responsibility for torts regulated in the Civil Code;
- violation of the Industrial Property Law (trade marks, designs);
- violation of the Act on Copyright and Related Rights;
- violation of the Unfair Competition Act; or
- violation of Regulation 608/2013 of 12 June 2013 concerning customs enforcement of IP rights.

The procedure and possible remedies differ significantly in each of these regimes.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

General rules regarding trade marks also apply to pharmaceuticals and medical devices. Any sign capable of being represented graphically can be a trade mark, as long as it possesses the attribute of distinctiveness (ie, it is capable of distinguishing the goods of one business from those of other businesses). A trade mark will not be granted for signs that were filed in bad faith, that are contrary to public order or good customs, that consist of customary elements that are present in current business practices or that may mislead consumers, especially with respect to the safety or quality of the product.

The Pharmaceutical Law contains special rules regarding the name of medicinal products, which might be an invented name that is not liable to cause confusion with the common name, or a common or scientific name that bears the trade mark or the name of the marketing authorisation holder.

The URPL issues guidelines for naming pharmaceuticals used by human beings. The latest one, including the issue of umbrella branding, was published on 24 September 2019. Despite being a soft law regulation, the guidelines have a significant impact on the practice of the Pharmaceutical Inspection.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress or design of pharmaceuticals and medical devices or their packaging can be protected as industrial designs or trade marks under the Industrial Property Law. Remedies are also available under general civil law rules and unfair competition regulations, and include cessation of the infringement, surrender of the unlawfully obtained profits and redress of the damage. In certain cases (violation of industrial property and fair competition), the judgment can be made public and the infringer can be obliged to publish a statement in the media.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Polish law follows the data and market exclusivity rules established in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. After the market authorisation has been granted, the beneficiary can withhold access to the results of clinical and non-clinical studies for a period of eight years from the date the first (initial) marketing authorisation was granted in an EU or EFTA member state (data exclusivity).

With regard to market exclusivity, irrespective of whether a marketing authorisation has been issued, the equivalent of a reference pharmaceutical product cannot be released onto the market by the marketing authorisation holder until ten years have passed since the date the initial marketing authorisation for the reference pharmaceutical was issued in an EU or EFTA member state.

If a decision is issued to add a new indication or indications that are held to bring significant clinical benefits, the ten-year period of market exclusivity can be extended by a maximum of 12 months during the first eight years after the marketing authorisation was issued for the reference pharmaceutical.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Rules on pharmaceutical prescriptions have been made more flexible. Pharmacists can now issue prescriptions even if there is no life-threatening emergency; a mere threat to health suffices.

11.2 Special Measures Relating to Clinical Trials

Measures adopted in order to adjust ongoing clinical trials to the COVID-19 pandemic primarily consisted of soft law rules.

The European Commission issued Guidance on the management of clinical trials during the COVID-19 pandemic, prepared in co-operation with the Good Clinical Practice Inspectors Working Group, the Clinical Trials Facilitation and Coordination Group (a working group of the Heads of Medicines Agency), the Clinical Trials Expert Group and, especially, the European Medicines Agency. The document includes measures to be taken in relation to ongoing trials as well as initiating new ones.

In general, it urges sponsors of ongoing trials to make changes in clinical trials based on risk assessment and to consider adopting an array of measures in their risk assessment adequacy. Sponsors should seek the approval of investigators. The well-being and best interests of the trial participants take priority in these considerations. Changes should be balanced and proportionate, and the compliance with the trial protocol should be secured to a relevant degree. Such measures include:

- the postponement of trials;
- the extension of a trial's duration;
- the postponement, limiting or even cancelling of physical visits;
- the cancelling or slowing recruitment of new participants;
- moving participants to other safer sites; and
- the closing of sites.

Initiating new trials is to be critically assessed.

Five versions of this document were issued, with the version dated 10 February 2022 being the latest.

As regards Polish law, general provisions regulating clinical trials contained in the Pharmaceutical Law include Article 37y, which allows sponsors and investigators to abandon the conduct of the clinical trial in accordance with the applicable clinical trial protocol, if there is an event that could affect the safety of participants. This particular provision is cited as being relevant for the circumstances of COVID-19 by the authori-

ties (the President of the URPL) and by guidelines from industry organisations on Good Clinical Trial Practice during COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The obvious key emergency approvals during the COVID-19 pandemic were for COVID-19 vaccines. Despite the extraordinary situation, the procedure used for that purpose was the standard procedure for conditional marketing authorisation provided for in Regulation (EC) No 726/2004, Article 14-A of which includes requirements that have to be satisfied if conditional marketing authorisation is to be issued. Further relevant rules are provided for in Commission Regulation (EC) No 507/2006.

Such conditional marketing authorisation can be granted for a medicine in order to meet unmet medical needs of patients if this medicine is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases. In standard situations, it may be granted prior to the submission of comprehensive clinical data, provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required. However, in emergency situations even comprehensive pre-clinical or pharmaceutical data is not required.

Article 14-A specifies some further conditions and imposes certain obligations on marketing authorisation holders.

Conditional marketing authorisation is valid for one year and is renewable.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

As in previous years, Good Manufacturing Practice certificates in principle have been extended until the end of 2023, including certificates for manufacturing sites and for importing sites of medicinal products and of active substances. However, for sites outside the EEA, certificates will not be extended if the relevant authority takes any steps affecting their validity.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

No new specific legislation has been adopted in this respect. However, Poland has numerous measures aimed at counteracting the illegal export of medicines and monitoring such trade.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The digitalisation of healthcare in Poland began before the COVID-19 pandemic started. One of the most significant developments was the introduction of the electronic prescription as a default form of prescription, which took place not long before the implementation of the first lockdown measures in Poland. The process of digitalisation then continued, to a significant extent in response to challenges posed by COVID-19.

The development of telemedicine is one of the examples, as it became much more dynamic after the beginning of the pandemic, as regulations were adopted to facilitate that development (although telemedicine in principle was provided for beforehand).

The key legislative development happened at the very beginning of the pandemic, when the Minister of Health chose to use its right to issue subordinate legislation determining organisational standards of healthcare in selected fields

of medicine and issued such standards for primary care. The Minister's ordinance regulated various technical issues.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Under standard Polish patent regulations, the Patent Office may grant a compulsory licence. The Industrial Property Law of 30 June 2000 allows the granting of such licence if it is necessary to prevent or remove a threat to the security of the State, particularly in the fields of defence, public order, the protection of human life and health and the protection of the environment.

However, the Polish authorities have made no publicly available declarations about a plan to use this clause or to introduce new regulations of compulsory licences tailored specifically to COVID-19-related treatments.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Legislation aimed at counteracting COVID-19 introduced liability exemptions for persons providing healthcare services.

The new regulation exempts criminal liability for a few unintentional offences: manslaughter, bodily harm and exposing a person to imminent danger of loss of life or grievous bodily harm. It provides that a healthcare professional who engages in conduct that would otherwise be classified as a criminal offence during the period of the declaration of an epidemic emergency or epidemic, while providing healthcare services in the prevention, diagnosis or treatment of COVID-19 and acting under special circumstances, does not commit a crime. The liability exemption does not apply if the effect caused by the perpetrator was the result of a grave failure to take due care, as required under the given circumstances.

11.9 Requisition or Conversion of Manufacturing Sites

The Act of 2 March 2020 on specific solutions related to the prevention, counteraction and eradication of COVID-19, other communicable diseases and emergencies caused by them introduced several legal measures enabling certain authorities to issue orders to other public bodies, as well as private entities (entrepreneurs).

These provisions are very generally worded and thus give authorities broad leeway as to the contents of orders that can be issued. Amongst other things, they can be used to convert manufacturing sites in a way deemed necessary by the authorities due to COVID-19.

The orders can be issued during a period when an epidemic emergency or an epidemic has been declared, and for up to three months after they have ended. They should be linked to countering COVID-19 and subject to immediate execution. They also do not require justification. Such orders issued by the Prime Minister and the Minister of Health may be directed at entrepreneurs. The performance of the tasks covered by the orders issued to entrepreneurs is carried out on the basis of contract and is publicly funded.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Some COVID-19-related changes to the system of public procurement were enacted in order to make it more flexible – eg, new provisions excluded the application of the provisions regulating public procurement if procured goods or services are needed for counteracting COVID-19 and there is a high likelihood of rapid and uncontrolled spread of the disease, or if the protection of public health so requires.

PORTUGAL

Law and Practice

Contributed by:
Eduardo Nogueira Pinto, Hugo Monteiro de Queirós, Eliana Bernardo and Ricardo Rocha
PLMJ

Contents

PLMJ is a law firm based in Portugal that combines a full service with bespoke legal craftsmanship. For more than 50 years, the firm has supported clients in all areas of the law, often with multidisciplinary teams, and always acting as a business partner in the most strategic decision-making processes. PLMJ has specialist lawyers that know the sectors and markets they work in well, and keep in close contact with the regulators for each sector. The firm created PLMJ Colab, a collaborative network of law firms spread across Portugal and other countries with which it has cultural and strategic ties. PLMJ Colab makes the best use of resources and provides a bespoke response to clients' international challenges. International co-operation is ensured through firms specialising in the legal systems and local cultures of Angola, Cabo Verde, China/Macau, Guinea-Bissau, Mozambique, São Tomé and Príncipe, and Timor-Leste.

The firm would like to thank Vasco Granate for his contribution to this chapter.

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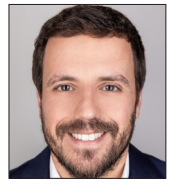

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PLMJ
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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The rules on medicines for human use come from Decree-Law 176/2006 of 30 August 2006, while the rules on medical devices come from Decree-Law 145/2009 of 17 June 2009 and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (the Medical Devices Regulation – MDR). There are also several sets of regulations implementing the decree-laws in different matters.

The regulatory body that applies and enforces pharmaceutical and medical device regulation is the INFARMED (the National Authority of Medicines and Health Products, IP). INFARMED is part of the State's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

As a rule, decisions regarding expenditure on medicines and medical devices are taken by the Minister of Health, who may delegate these decisions to INFARMED.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

INFARMED's decisions regarding medicines and medical devices may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by these decisions can react against them, mainly on the grounds of breach of the law. These means of reaction are common to decisions that affect other products (eg, food supplements), although there may be specific details.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Certain categories of medicines and medical devices are subject to specific regulation. For example:

- medicines containing psychotropic and narcotic substances are regulated by Decree-Law 15/93 of 22 January 2022, Decree-Regulation 61/94 of 12 October 1994, Law 33/2018 of 18 July 2018 and Decree-Law 8/2019 of 15 of January; and
- medical devices for in vitro diagnosis are regulated by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and Decree-Law 189/2000 of 12 August 2000.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of medicines and clinical studies of medical devices are regulated by different pieces of legislation.

Medicines

Clinical trials on medicines are regulated by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 ("Clinical Trials Regulation") and Law 21/2014 of 16 April 2014 ("Clinical Trials Law").

The entry into force of the Clinical Trials Regulation on 31 January 2022 involved the entry into force of the Clinical Trials Information System (CTIS), through which all clinical trial submission, assessment and supervision processes in

the EU are to be submitted. The Clinical Trials Regulation provides for a three-year transition period, with the following timeline:

- from 31 January 2022 to 31 January 2023, clinical trial sponsors were able to choose to submit their clinical trial applications under the Clinical Trials Directive or through the CTIS;
- from 31 January 2023, new applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS; and
- by 31 January 2025, all ongoing trials will have to be transferred to the CTIS under the Clinical Trials Regulation.

Medical Devices

The rules regarding clinical studies of medical devices are found in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and in Decree-Law 145/2009, which establishes the rules regarding the research, manufacturing, marketing, putting into use, monitoring and advertising of medical devices and their accessories. With the entry into force of the MDR, the rules of Decree-Law 145/2009 that contradict the MDR are no longer applicable; only the rules that do not contradict the MDR remain in force. The Portuguese legislation implementing the MDR is undergoing the legislative process and awaiting publication.

In Vitro Medical Devices

The legal rules applicable to in vitro medical devices are established in Decree-Law 189/2000 of 12 August and Decree-Law 145/2009.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) has been applicable since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high-risk in vitro diagnostics to 26 May 2027 for lower risk in vitro diagnostics, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

However, in January 2023 the European Commission published a draft amendment to extend transitional periods for the MDR and the IVDR.

The amending act must now go through the EU legislative process, starting with the public consultation.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicines

In the transition period up to 31 January 2023, authorisation to conduct a clinical trial of a medicine was obtained under the rules established in the Clinical Trials Law or through the CTIS, pursuant to the Clinical Trials Regulation.

If the sponsor opts for the Clinical Trials Law arrangements, the application for authorisation to conduct clinical trials must be submitted to INFARMED through the National Clinical Trials Register, together with the relevant documentation.

INFARMED will decide on the application for authorisation within 30 days, and may ask the applicant for additional information once only.

Within the period granted, the sponsor may change the content of the application for authorisation, only once, and the period will be suspended until the change is made. If the sponsor does not change the application as requested, the clinical trial may not be conducted.

INFARMED may decide on the need to obtain express authorisation to conduct trials involving the following medicines:

- those that do not have a marketing authorisation (MA) and that are listed in Annex A to Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004; and
- those which have special characteristics – ie, whose active substance or substances are biological products of human or animal origin or contain biological components of human or animal origin, or whose production requires such components.

Clinical trials involving the following medicines will require express authorisation from INFARMED:

- those for gene therapy;
- those for somatic cell therapy;
- those containing genetically modified organisms; and
- those for xenogeneic cell therapy.

If the application for authorisation is submitted under the Clinical Trials Regulation, it should be submitted through the CTIS and the sponsor of that application should propose a reporting member state, which will be responsible for the analysis of the application.

Medical Devices

Applications to conduct clinical investigations as defined in the MDR must be submitted by the sponsor to the member state(s) in which the clinical investigation is to be conducted. The application must be submitted through the electronic system referred to in the MDR, accompanied by the documents referred to in Chapter II of Annex XV of the MDR.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical trials of medicines and clinical studies of medical devices are available on the National Clinical Trials Register website at www.rnec.pt. The results of clinical trials and clinical studies of medical devices are not available in publicly accessible databases.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The methods of recruitment for clinical trials of medicines and clinical studies of medical devices must follow the legally prescribed rules. In addition to physical advertising methods, digital means can be used for this purpose. These means may also be used for monitoring purposes, provided that they do not jeopardise the purpose and safety of the trial.

2.5 Use of Data Resulting From the Clinical Trials

Data from clinical trials of medicines and clinical studies of medical devices may qualify as personal data in the sense of sensitive data. However, if the data is fully anonymised (and not merely pseudonymised), it is no longer personal data so does not fall within the category of sensitive data. Anonymisation implies that the identity of the data subject is unobtainable, in which case the data becomes anonymous.

If the resulting data is still personal data, it might be transferred to third parties or affiliates, provided such transfer complies with the requirements set out in the General Data Protection Regulation (GDPR), notably when it comes to consent and information obligations, security of the processing issues, joint-controllership or sub-processing agreements, and international data transfers. If the resulting data is anonymised data, then those GDPR requirements do not apply.

2.6 Databases Containing Personal or Sensitive Data

The requirements under the GDPR regarding the processing of health data apply with regard to the grounds for the lawfulness of processing, transparency and security measures.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Products are classified through the definition of medicine (function and/or presentation) and the definition of medical device provided in the applicable legal provisions. In the case of borderline products, the purpose intended by the manufacturer of the product in question and the mechanism through which the main desired effect is achieved are taken into consideration.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Medicines developed by means of one of the following biotechnological processes must be subjected to the centralised community procedure:

- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Medicines

In the case of medicines, the MA is valid for five years; after the first renewal, it is valid indefinitely or, if considered necessary, for a second five-year period. The renewal of the MA is subject to a specific renewal procedure.

An MA may be revoked, suspended or amended whenever there is non-compliance with the applicable legal and regulatory provisions, or with the conditions of the MA in question. This includes when it is concluded that the risk-benefit balance is unfavourable, the medicine is harmful or the manufacturing process does not comply with the applicable good practices.

Medical Devices

No authorisation is required for placing medical devices on the market. The manufacturer must submit the medical device to a conformity assessment and notify the competent authority that the medical device has been made available on the market. INFARMED may withdraw a product from the market or may suspend, restrict or subject to certain conditions the placing on the market and putting into service of a device or group of medical devices under certain conditions – namely, when the use of medical devices could compromise the health and safety of patients or other persons, or for public health reasons.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

The marketing of a medicine may follow one of these procedures:

- a national procedure, if the medicine is intended to be approved only for placing on the Portuguese market;
- a mutual recognition procedure, in which an authorisation obtained in a member state is used to apply for authorisation in a new member state;
- a decentralised procedure, when the application is submitted in several member states simultaneously and when the medicine does not have an MA in any member state; and
- a centralised procedure, managed by the European Medicines Agency (EMA), leading to an MA that is valid in all member states.

Any change in the terms of an MA must be subject to an application for a variation of the MA, including changes to the summary of product characteristics and any conditions, obligations or restrictions affecting the MA, or changes to the labelling or package leaflet in connection with changes to the summary of product characteristics.

An MA may be transferred to a new holder through the submission of a transfer application by the MA holder.

The placement of a medical device on the market does not require authorisation (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Medicines without an MA or without an MA that is valid in Portugal may be made available to patients through the exceptional use authorisation, under which they can be accessed by patients through early access programmes, which have a specific regulation issued by INFARMED.

Regarding medical devices, INFARMED may authorise the placing on the market or putting into service of a medical device for which no conformity assessment procedures have been carried out but the use of which is in the interest of public health or patient safety or health.

Compassionate use also takes place in the context of clinical trials.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The MA for a medicine may be granted subject to the subsequent conduct of additional studies or compliance with special rules regarding safety and the reporting of all incidents associated with the use of the medicine and the measures to be taken, the conduct of a post-authorisation safety or efficacy study, or the fulfilment of other obligations established by INFARMED.

After the granting of an MA, INFARMED may require its holder to conduct a post-authorisation safety study if there are doubts about the risks of the authorised medicine or if knowledge about the disease or clinical methodology indicates that previous efficacy evaluations may need to be significantly revised.

The holder of an MA is obliged to comply with the obligations provided for by law – namely, to comply with pharmacovigilance obligations and to make this or other data proving that the benefit-risk relationship of the medicine remains favourable available to INFARMED.

Manufacturers of medical devices other than investigational devices must report any field

safety corrective action to INFARMED, as well as any serious incident or any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected to have undesirable side effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

INFARMED publishes information on the status of an MA application and its assessment report on its website. It suppresses any commercially confidential information and allows access to the summary of product characteristics and the package leaflet, as well as information on the medical devices placed on the market.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Decree-Law 26/2018 of 24 April 2018 incorporated the European legislation on falsified medicines into Portuguese law. This legislation establishes the mandatory placement of safety devices on the packaging of certain medicines, which must be checked by all participants in the chain, to allow the detection of falsified or adulterated medicines in the circuit and the individual identification of packaging.

Under the regulatory framework, INFARMED must draw an annual surveillance activity plan and perform appropriate checks on the conformity characteristics and performance of medical devices, including, where appropriate, a review of documentation and physical or laboratory checks based on adequate samples.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

INFARMED established a protocol with the Tax and Customs Authority to inspect and intercept counterfeit medicines. The Legal Framework for Tax Infractions and Customs Crimes also provides for the existence of customs offences and crimes associated with the counterfeiting of goods, which may include counterfeit medicines and medical devices.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacture of medicines, experimental medicines and medical devices requires authorisation from INFARMED.

The manufacture of medicines requires the existence of facilities licensed for the purpose, and compliance with good manufacturing practices. The facilities are subject to periodic inspections by INFARMED, which certifies their compliance and issues a certificate of good manufacturing practices, which is valid for three years.

For medical devices, facilities must obtain an industrial activity licence in accordance with the applicable legislation and have an industrial activity code associated with the categories of medical devices produced in conjunction with the respective manufacturing activities performed.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Authorisation for the wholesale of medicines is issued by INFARMED and covers the activities of supplying, holding, storing or delivering medicines for processing, resale or use in medical services, healthcare facilities and pharmacies, excluding the supply to the public. It specifies the facilities from which distribution is carried out and is subject to the validity of the certificate of good distribution practices, which must be renewed every five years.

The wholesale of medical devices is subject to prior notification to INFARMED and covers the activities of supplying, holding, storing or supplying medical devices for resale or use in medical services, healthcare facilities, pharmacies and other points of sale to the public, excluding supply to the public. The application must be submitted at least 60 days before the start of the distribution activities and must include the full address of the distribution facilities. It does not have an expiration date.

5.2 Different Classifications Applicable to Pharmaceuticals

For dispensing to the public, medicines are classifiedinto prescription-only medicines (MSRMs) and non-prescription medicines (MNSRMs). The former can also be classified as renewable, special or for restricted use in specialised monitored conditions, and the latter as MNSRMs for dispensing only in pharmacies.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of medicines is regulated by Decree-Law 176/2006 of 30 August 2006 and by related legislation on good practice in transportation and distribution. For medical devices, the MDR and Decree-Law 145/2009 are applicable.

INFARMED is the entity responsible for monitoring compliance with these regulations.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Any natural or legal person duly authorised and licensed for that purpose by INFARMED can be an importer of medicines and medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of medicines and medical devices requires the economic operator to be licensed by INFARMED for that purpose. For personal use, medicines can be transported only for the necessary period, provided that they are accompanied by a medical prescription, when necessary. In the case of emergency situations or donations, INFARMED will assess each case individually.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The regulations to be considered upon importation of any products into the Portuguese terri-

tory, which is part of the customs territory of the European Union, are as follows:

- Regulation (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013, which approves the Union Customs Code;
- Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015; and
- Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015.

6.5 Trade Blocs and Free Trade Agreements

Portugal is part of the EU and the single European market, and it applies the principle of free movement of goods and services; it also has harmonised regulatory rules for medicines and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Price Control for Medicines

Non-reimbursed medicines have free pricing arrangements, but all other medicines have their prices regulated and are subject to maximum price rules or notified price rules. They cannot be sold unless the MA holder obtains a retail price (RP).

The RP of the medicine is composed of:

- the ex-factory price (EFP), which is the maximum price at the stage of production or import and has fixed rules for its determination;
- the wholesalers' and retailers' selling margins, as fixed by ministerial order;
- the tax on the sale of medicines; and
- value-added tax (VAT).

The MSRMs intended to be dispensed and used in National Health Service (NHS) establishments are also subject to maximum price rules, and their final price is composed of the EFP, the sale tax and VAT.

The prices of medicines subject to the maximum price rules are reviewed annually. The pricing rules for medicines are set out in Decree-Law 97/2015 of 1 June 2015 and regulated by several Ministerial Orders (in particular Ministerial Order 195-C/2015 of 30 June 2015 and Ministerial Order 154/2016 of 27 May 2016).

Requests for price authorisation and price revision communications follow their own procedures and are submitted to INFARMED by the MA holder.

Price Control for Medical Devices

As a rule, medical devices financed by the State have fixed maximum prices. Medical devices not financed by the State have free pricing.

The pricing rules for medical devices are set out in Decree-Law 97/2015 of 1 June 2015, and there are Ministerial Orders that define the maximum prices applicable to certain devices or groups of medical devices, which usually include the marketing margins and VAT. In these cases, the RP proposed is indicated by the manufacturer at the time of the request for reimbursement to INFARMED, which follows its own procedure.

7.2 Price Levels of Pharmaceutical or Medical Devices

Price Levels of Medicines

The price of medicines is generally set and reviewed on the basis of the prices in the refer-

ence countries with comparable GDP per capita or lowest price level, defined annually among EU countries.

The Ministerial Order 35/2023 of 26 January has defined Spain, France, Italy and Slovenia as reference countries in 2023.

Price Levels of Medical Devices
The price of medical devices does not depend on the prices applied in other countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Public financing of medicines and medical devices depends on an application to INFARMED by the MA holder or the manufacturer, respectively. This public financing may be full or partial and differs according to various factors, including pathologies or special groups of patients, therapeutic indications, prevalence of certain diseases in the population, etc; see **7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-Benefit Analyses for Medicines
State funding of medicines is, as a rule, cumulatively subject to prior technical-scientific demonstration of therapeutic innovation or equivalence for the therapeutic indications claimed, as well as demonstration of the economic advantage of the medicine. These factors are not decisive in fixing the price of medicines, because these prices tend to be fixed taking into account the prices in the reference countries – see **7.1 Price Control for Pharmaceuticals and Medical Devices** and **7.2 Price Levels of Pharmaceuticals or Medical Devices**.

Cost-Benefit Analyses for Medical Devices
A cost-benefit analysis is also carried out in the financing of medical devices by the State, considering the therapeutic innovation demonstrated for the clinical purposes claimed and the demonstration of an economic advantage – see **7.1 Price Control for Pharmaceuticals and Medical Devices**.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In order to ensure the sustainability of the NHS, the prescribing of reimbursed medicines is made using the international non-proprietary name and may only include the commercial name of the medicines in the exceptional cases listed in the law. Pharmacies are obliged to inform the patient about the medicine that, in compliance with the prescription, has the lowest price. These rules apply to reimbursed medical devices, with the necessary adaptations.

8. Digital Healthcare

8.1 Rules for Medical Apps

As software, medical apps are considered active medical devices under the MDR, with lifestyle and well-being apps being expressly excluded from the scope of the MDR. The classification criteria are provided by the MDR and supporting documents are published for this purpose by the European Commission.

8.2 Rules for Telemedicine

The rules on telemedicine are laid down in the Code of Ethics of the Portuguese Medical Association, which establishes standards for the safety and quality of the means used.

8.3 Promoting and/or Advertising on an Online Platform

The advertising of medicines and medical devices is highly regulated and there are specific regulations for each of these product categories, which are also applicable to online portals, company webpages and social networks.

8.4 Electronic Prescriptions

Electronic prescribing is the rule and has been in place for several years. Non-electronic prescriptions are exceptions and are only allowed in specific cases.

8.5 Online Sales of Medicines and Medical Devices

Regarding medicines, under certain circumstances, pharmacies and MNSRM outlets can perform home delivery of medicines, and such medicines can be ordered over the internet. Medicines cannot be delivered by post or courier.

It is possible to market medical devices online and deliver by post or courier. Admissibility must be assessed on a case-by-case basis and, in any case, the quality of the medical device must be guaranteed.

8.6 Electronic Health Records

Health-related records are regulated as health data under the GDPR, and health-related information is considered sensitive data under the GDPR. Moreover, Law 58/2019 of 8 August 2019, which ensures the implementation of the GDPR, contains specific obligations regarding professional secrecy. These obligations apply to all member of corporate bodies, employees and service providers of the controller, and to students and researchers in the field of health who have access to such data. The data subject must be notified of any access made to their personal data, and the controller must ensure that a traceability and notification mechanism is in place.

There are no special requirements for cloud platforms. Portugal does not restrict the processing of health data to its territory, so the general rules provided in Chapter V of the GDPR on international data transfers apply. It is permitted to store sensitive patient data on cloud platforms. However, regarding information security, in addition to the general requirements of the GDPR, most public bodies, including public hospitals, are obliged to comply with Council of Ministers Resolution 41/2018. This defines technical guidelines for the Public Administration on the security architecture of networks and information systems regarding personal data.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Portuguese Industrial Property Code (IPC) contains the most relevant provisions for patents, including for patent prosecution and enforcement.

Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 of 12 December 2011.

The most common issues encountered by pharmaceutical companies in Portugal relate to patent disputes between originator and generic companies under Law 62/2011. Other issues that usually arise relate to the validity of patents and supplementary protection certificates (SPCs).

There are no specific patentability requirements for medicines or medical devices per se. However, according to the IPC, processes for cloning human beings, processes for modifying the germinal genetic identity of the human being and uses of human embryos for industrial or commercial purposes are not patentable.

Methods of surgical or therapeutic treatment are also not patentable, but the products, substances or compositions used in any of these methods may be patented.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known substance or composition are regarded as patentable in Portugal, provided that any such use meets the general patentability requirements.

According to the Guidelines of the Portuguese Institute of Industrial Property, the term "use" may include new dosage regimes and new patient groups.

There is no clear guidance from the Portuguese courts as to what specific activities constitute infringement of second and subsequent patents of medicines. However, in a 2015 judgment, the Lisbon Second Instance Court decided that the patent-holder of a second medical use patent can only react against the applicant of an MA for the generic medicine if the active pharmaceutical ingredient is prepared and adopted for the specific therapeutic use that is patented. In the first instance decision of this case, the ad hoc arbitral tribunal considered that one cannot conclude that there has been an infringement of the second use patent if the generic medicine does not have the patented use as a therapeutic indication according to the granted MA.

9.3 Patent Term Extension for Pharmaceuticals

The patent-holder may obtain a patent term extension for medicines by applying for an SPC.

The application for an SPC is regulated in the IPC and is governed by Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 ("SPC Regulation"). The SPC application must be filed with the Portuguese Industrial Property Office (INPI) in Portuguese, with a copy of the first MA of the product in Portugal.

If granted, the SPC can extend the protection conferred by the basic patent for the time that has passed between the filing of the patent application and the date of grant of the MA, minus five years.

The validity of the SPC cannot exceed five years from the expiry of the basic patent, except when it concerns medicines for paediatric use, where a further six-month extension is available.

Patent term extensions via an SPC may be challenged by any interested party before the INPI if the date of the first MA indicated by the patent-holder in the SPC application is incorrect. The INPI can also amend the validity period of an SPC of its own motion when it verifies the existence of an error.

An action for the revocation of an SPC can be brought by any interested party before the Portuguese Intellectual Property Court, under the IPC.

9.4 Pharmaceutical or Medical Device Patent Infringement

Similarly to other patents, medicine or medical device patents give the patent-holder the right to prevent any third party from:

- manufacturing, offering, stocking, placing on the market or using a product that is the subject matter of the patent, or importing or possessing it, for any of the purposes previously mentioned;
- using the process that is the subject matter of the patent or, if the third party knows or should have known that the use of the process is prohibited without the consent of the patent-holder, offering to use it; and
- offering, stocking, placing on the market or using, or importing or possessing for those purposes, products obtained directly by the process that is the subject matter of the patent.

Applying for an MA does not qualify as a patent infringement action in Portugal. However, the publication of an MA for a generic medicine by INFARMED enables the patent-holder to file a special inhibitory action under Law 62/2011 for invoking incompatible patent rights. The patent-holder can also request the IP Court (or an arbitral tribunal, if arbitration is agreed between the parties), in such action, to determine precautionary measures to prevent infringement of the patent in question.

The threat of infringement is actionable to inhibit any imminent infringement.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Specific defences to patent infringement in relation to medicines and medical devices in Portugal include an experimental use exemption and, in particular, the Bolar exemption.

Compulsory licences on patents are provided for in the IPC in general terms, but there are no relevant precedents in Portugal with regard to the granting of compulsory licences. In any case, compulsory licences may be granted in Portugal in the following circumstances:

- lack or insufficient exploitation of the invention;
- dependency between patents;
- public interest;
- under EU and Portuguese Competition law; and
- under Regulation (EC) 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of medicines for export to countries with public health problems.

9.6 Proceedings for Patent Infringement

Patent infringement proceedings may be brought by the patent-holder or by the licensee. The licensee's right to bring an action depends on the specific terms of the corresponding licence agreement and on the record of the licence at the INPI.

Although patent infringement is a crime under Portuguese law, the typical procedure for patent infringement actions is a civil lawsuit at the IP Court. Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 and must also be filed at the IP Court or, upon agreement of the parties, before an institutional or ad hoc arbitral tribunal.

Civil remedies include preliminary and permanent injunctions granting the patent-holder the right to prevent any imminent infringement or to prohibit the continuation of the infringement. There is also the possibility of requesting the IP court to order the infringer to pay a periodic penalty for breach of the judgment, and to order

the destruction, recall or definitive removal of the infringing goods from the channels of commerce. Damages claims for infringement are also possible.

Invalidity is available as a defence in civil infringement proceedings on the merits, through the filing of a counterclaim for revocation of the patent or SPC.

9.7 Procedures Available to a Generic Entrant

In theory, under the Civil Procedure Code, pre-launch declaratory actions are possible for generic market entrants, although as far as is known there are no relevant precedents in Portugal in this regard. Nullity actions for the invalidation of patents or SPCs in advance of attempted market entry are also possible.

Law 62/2011 (see **9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices**) created a special action applicable to patent litigation involving generic medicines, whereby patent-holders can pursue an early assessment of prospective patent infringement, after publication of the MA applications for generic medicines. This law led to a large number of court cases and also to a large number of settlement agreements between patent-holders and generics.

Although the procedure provided for in Law 62/2011 is triggered by the publication of the MA, this procedure does not stay the grant of the MAs or their effect once granted, which means that no patent linkage effect exists.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting consists of the complete reproduction of a sign that is protected as a trade mark. The IPC provides that trade mark counterfeiting is a criminal offence, punishable with imprisonment for up to three years or a fine of up to 360 days. Civil liability also arises from trade mark counterfeiting.

Custom procedures against counterfeit medicines and medical devices are available under Regulation (EU) 608/2013 of the European Parliament and of the Council of 12 June 2013.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Besides the general requirements and impediments provided for in the IPC with respect to trade mark composition (that apply to all marks), Decree-Law 176/2006 further provides that the name of a medicine may comprise a trade mark, as long as that trade mark is not misleading with regard to the therapeutic properties and nature of the product.

Furthermore, the EU Regulations on medical devices also prohibit the use of misleading trade marks.

Under trade mark law, non-counterfeit genuine medicine or medical device products may suffer import restrictions if there is a prior registered trade mark in Portugal that prevents the use of the mark by the importer (eg, on the basis of likelihood of confusion).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection for the trade dress or design of medicines and medical devices, or their packaging, is potentially available under design rights, copyright and trade mark rights, provided they meet the legal requirements for that protection.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to an a contrario interpretation of Decree-Law 176/2006, data exclusivity for medicines (chemical drugs and biologicals) will last for at least eight years from the date of granting of the MA for the reference medicine.

Under the same Decree-Law, marketing exclusivity of the reference medicine lasts ten years from its first MA approval, or 11 years from its first MA approval if the originator obtained a new therapeutic indication within eight years of that date that brings significant clinical benefit.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, INFARMED issued guidelines to simplify the import and export of medicines, particularly regarding the import and export of medicines with controlled substances.

INFARMED also issued transitional guidelines to make the import, manufacture and distribution of medical devices faster and more efficient during the pandemic. In addition, it relaxed a number of rules that made it very time-consuming to obtain the necessary devices.

11.2 Special Measures Relating to Clinical Trials

Within the constraints imposed by the pandemic, INFARMED issued guidelines to mitigate the impact of the pandemic on clinical trials that were in progress or about to start. These measures do not specifically target clinical trials of medicines to treat COVID-19. INFARMED stressed the possibility of remote visits through technological means, ensuring the collection and recording of the information foreseen for the visit.

The EMA also implemented exceptional measures regarding the approval and documentation of medicines to treat COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The EMA has created a specific, expedited procedure for the approval of medicines, which is characterised by significantly shorter timeframes for the review and approval process.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Within the context of the COVID-19 pandemic, INFARMED has established special and temporary abbreviated procedures for the certification of medical devices that are essential to answer the needs caused by the pandemic – eg, the certification of medical devices such as surgical masks and ventilators for medical purposes.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In the context of the outbreak of the pandemic, INFARMED and other authorities issued guidance on easing import requirements for medical devices needed to contain the spread of the virus.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Telemedicine was already allowed in Portugal before the pandemic. These means were used more frequently during the pandemic period, considering the saturation of the NHS hospitals and health facilities.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

There is no intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced in existing or new provisions regarding COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

During the pandemic period, industries were turned over to the production of medical devices. Several textile industries temporarily converted their production to the production of medical devices (mainly surgical masks).

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Measures to make public procurement more flexible were adopted to ensure the immediate availability of goods and services urgently needed to respond to the pandemic. In addition, an exceptional system of public procurement, expenditure authorisation and administrative authorisation was created. In this system, the creation of exceptional arrangements for simplified direct adjustment stands out, particularly for the acquisition of medicines and medical devices.

In any case, the (almost) non-existence in 2023 of exceptional measures related to COVID-19 should be highlighted. The exceptional and temporary reimbursement regime for Rapid Antigen Tests (TRAg) for professional use prescribed in the National Health Service, which was one of the last remaining measures in force, ended on 30 September 2022.

Trends and Developments

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Sérvulo & Associados is a Portuguese full-service law firm that occupies a leading position in the Portuguese legal market. Recognised for the quality of its legal services in all relevant areas of law and strategic sectors, SÉRVULO has a highly competent multidisciplinary team of more than 100 lawyers, motivated by a single purpose: to transform academic research and accumulated knowledge into the design of sound legal solutions, thus creating added value for clients. The firm is trusted by a vast number of private and public entities, both domestic and international, in the Portuguese-speaking legal markets and in all the most significant economic sectors. Its lawyers are fully capable of facing all of the challenges that may arise at any time and in any field of law.

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Highlights

The life sciences sector has been improving at a fast pace, and the experience of the COVID-19 pandemic has had a very positive impact on the sector.

Companies continue to transform themselves and implement new measures based on digital models. Digital transformation is accelerating every part of the life sciences value chain and the way the sector deals with patients and clinical trials. Technology is also being used to store the data of companies and patients (highly sensitive data), and to accelerate companies' level of performance. Therefore, digital privacy and security must be a concern in the sector, and the digital transformation used to address this concern is seen as a challenge.

In Portugal, several important research initiatives in the sector should be highlighted due to their impact on worldwide trends – namely, those carried out by Fundação Champalimaund. Two new research centres have also been created.

In addition, ESG is expected to be a trend in the future as companies face increased trials and new global standards that should be taken into consideration.

The Unified Patent Court (UPC) will be a reality after ten years of discussions, and life sciences companies should review their portfolio of patents and IP strategy for the future, due to the several advantages of this court. The supplementary protection certificate (SPC) waiver is in place, and is being used by several blockbusters in the medicines market in Portugal.

Technology and Life Sciences

Clinical trials

The COVID-19 pandemic created the need to develop medicines and vaccines at a much faster pace than used to be the norm. Therefore, new processes and techniques were developed, which are now being applied to other drugs.

Also, with the pandemic restrictions, workarounds had to be found. Thus, remote monitoring and remote visits were top strategies for keeping clinical trials ongoing during the pandemic. This means that geography and business hours are no longer barriers to performing clinical trials, thanks to the new digital and virtual tools. Researchers have been finding ways to bring more people into trials through adaptive, decentralised and hybrid models, which leads to better results with more and more diversified subjects. This being said, many hospitals

and research institutions have started to include home-based reporting and to use tools such as telemedicine, sensor-based technologies and wearable medical devices.

In addition, adaptive trials using artificial intelligence were used to discover and compare potential treatments, which may start to be used during research and development of all kinds of medicines.

All this digitalisation of trials decreases the burden on patients as they no longer have to travel to participate; it also decreases the report subjectivity, due to the data being based on sensors and wearables instead of the sole reporting. This leads not only to there being more data, but also to it being more accurate.

Patient-centricity

The pandemic led to an increase in the importance of disease treatment for patients. Digital technologies enabled telemedicine to become broadly available, thus making treatment much faster and more cost-effective, and putting patients in charge of their own treatments.

Companies are also enhancing engagement with patients while developing new medicines, and are starting to understand that it is useful to involve patients in all phases of development, from brainstorming to launch. As time goes by, patients have been seen more than ever as an equal partner. Pharma companies are starting to reflect more of the patient's needs, building trust between companies and patients, and also providing better products that fulfil their targets' needs much better than before.

In addition, drug development is taking patients' experiences, needs and outcomes further into account, instead of the traditional parameters thought about when running clinical trials. For instance, factors like quality of life and physical and mental health are starting to be used as parameters for patients to provide feedback during clinical trials. This enhanced engagement allows companies to have access to more accurate and complete data, as it has led to the incorporation of patient experiences, resulting in better products and a life improvement for the community in general. This also leads to greater adherence to treatments, as the outcomes will consider more factors than the simple treatment of a specific symptom.

Cloud-first transformation

Many life sciences companies have been making efforts towards adopting technologies in which the main data is stored beyond their own premises, in a cloud. This transformation allows a company's workers to have access to information at any time and from anywhere, which has enabled businesses to run at a much faster and more effective pace.

It also empowers collaboration, because it allows every worker to have access to the most updated data for each document in real time. When dealing with sensitive matters like those treated in the life sciences area, and in a business field that has so many changes and constant progress, regularly updated data has been turning clouds into an important resource.

In addition, the value of working on a cloud-first basis can be maximised, with the usage of integrated information management systems, for example. This leads to more efficient usage of the available data, with faster and better outcomes.

Cybersecurity

With all the data involved in life sciences, from research and development to marketing, stock management and everything in between, and the digitalisation of this information, cybersecurity has become more and more of a concern. The risks of industrial espionage and regulatory fines are increasingly high, with data breaches becoming more common and courts being increasing open to using digital data as evidence.

Therefore, digital privacy and security have become a major concern, and have been developed through giving more information to workers, adopting zero-tolerance cybersecurity measures while developing and updating the data-managing software, and selecting what is the most critical data and who has access to that data, considering the potential impact if it is compromised.

Recent Relevant Research

The human brain

The understanding of the human brain and how it works has been a great focus of research, as it is so important to understand the whole human body, as well as human behaviour. For that reason, Fundação Champalimaund (an institution that performs research in cutting-edge areas and whose priority is to stimulate discoveries that benefit people, developing its activity in the areas of neuroscience and cancer) has been investing in research regarding this matter.

For instance, in January 2023, this foundation announced funding for a study to understand how the fruit fly brain computes and corrects trajectory errors, which has an impact on understanding the human brain with regards to physical orientation.

In February 2023, the Fundação Champalimaund and the University of Minho published a study which suggests that the brain works like a resonance chamber: ultra-fast, ultra-high-field magnetic resonance imaging performed in rats revealed that there are resonance waves in the brain that establish connections between distant brain areas, which are essential for the normal functioning of the brain. This research may create a new path to dealing with brain diseases, as it provides a better understanding of how the brain works both when healthy and when sick.

New research centres in Portugal

There has been great progress in biomedical investigation. However, although it is possible to cure cancer or diabetes in animals like rats, those diseases still cause great suffering and a lot of mortality in humans. It is believed that one of the reasons for that limited success is the lack of understanding of human biology and physiopathology on a cellular and molecular level.

Focusing on filling that gap, a new investigation centre is being developed by Nova University of Lisbon, in partnership with the Max Delbrück Centre in Berlin, run by researcher António Jacinto: the NOVA Institute for Medical Systems Biology (NIMSB). It will focus on the development of experimental models that are more similar to human tissues and organs, and with a better analysis to understand the outcome of those experiments. Fourteen new research groups will be created, in which researchers will access innovative technologies that provide unprecedented information on the generation, progression and treatment of diseases.

Following up on the digital trend, this new project foresees the usage of new technologies such as Artificial Intelligence being applied to the biomedicine and emerging multitopic meth-

odologies (ie, methods that combine genomic data with data from other modalities such as transcriptomics, epigenetics and proteomics, to measure gene expression, gene activation and protein levels). With these technologies, it is expected that the causes of diseases will be treated rather than symptoms, and that the early detection of diseases will be made possible, enhancing the chances for the patient to be cured.

Focusing more on the application of the research to hospitals and patients, another new research centre is being created inside the Portuguese Institute of Molecular Medicine – the IMM-Care – by Maria Manuel Mota, a researcher who has been researching malaria, with the main goal of stimulating clinical research for the benefit of society.

Environmental, Social and Governance (ESG)

Life sciences organisations, including those operating in Portugal, have been put under a lot of scrutiny regarding ESG policies, primarily related to employment hiring practices and manufacturing standards. Life sciences companies are accordingly expected to invest even more in ESG policies.

There is an increasing need for companies to be transparent with all stakeholders and to incorporate their perspectives into their decisions, which has the benefit of improving understanding of the consequences of a decision and minimising the risk of said decision by having support. This also increases the company's reputation. Building trust amongst the community is crucial to demonstrate the value of these companies, and that means being transparent regarding the ESG policies adopted.

Pharma companies have been focusing on making medicines more sustainable and reducing greenhouse gas emissions, particularly the emissions of supply chain companies. This is also becoming a legal obligation.

In November 2022, the European Union adopted the Corporate Sustainability Reporting Directive, which aims to strengthen the requirements of companies' reporting sustainability measures by broadening the categories of companies covered by the reporting requirements, to include qualitative and quantitative elements concerning sustainability impacts, and the extent to which sustainability issues affect development, growth and market positioning.

This directive has yet to be transposed in Portugal, but companies must start making efforts to comply with the legal rules in order to be prepared for the transposition.

Public institutions also consider this a concern. In January 2023, the Portuguese Council for Health and Environment expressed its position in favour of the creation of a global strategy to reduce the ecological footprint in the health sector, with goals such as hitting zero greenhouse gas emissions by 2035, which is important because this sector is responsible for 4.4% of such emissions.

Companies have become more concerned about social inequalities in clinical trials, as ensuring diversity expands access to better therapies, thereby building trust and promoting innovation. To this aim, strategies are being created, such as:

- the creation of research sites in non-traditional locations like community health centres

and pharmacies, to increase closeness to the communities and mutual trust;
- the establishment of relationships with the community, which might help to gather significant inputs; and
- the development of rationally and ethnically diverse pools of staff to ensure cultural competence and mindfulness of existing biases, which ensures that relevant inequalities are properly treated, thereby assuring the quality of the medicines and their adequacy to everyone.

Industrial Property in Life Sciences

The Unified Patent Court

The UPC is a major change in the European landscape and is the result of more than 20 years of attempts to create a united European patent system. If everything goes as planned, the UPC and Unitary Patent will enter into force in 2023.

Lisbon will host a local division, as well as the Patent Mediation and Arbitration Centre of the UPC. The decision-making process of this court is typically panel-based, and the expected uniformity of approach should be location-independent. Also, it is expected to integrate legal and technical expertise in its decisions. This court will be competent for all matters regarding the infringement and validity of unitary and classical European patents granted by the European Patent Office (EPO).

A European Patent with Unitary Effect will be a European patent granted in accordance with the requirements of the European Patent Convention, which, with a single application, produces effects in the territory of all member states that have signed the Agreement on a Unified Patent Court.

A challenge will arise concerning which strategies pharmaceutical companies (among others) will pursue regarding patents for reference medicines, as there are many advantages but also great risks to adhering to the European Patent with Unitary Effect and to the UPC.

SPC waiver

The time-consuming and costly research into medicines and plant protection products must be offset by additional protection for the basic patent. The SPC is the sui generis right created for this purpose. It increases the period of exclusivity of the pharmaceutical product or plant protection product covered by a patent, to compensate for the time that it has taken to get a first administrative marketing authorisation.

In 2019, the SPC Waiver Regulation entered into force, enabling other companies to export the protected product to third countries and, within the six months before the expiry of the certificate, to store or make for the purpose of storing the protected product, provided that the maker notifies the Industrial Property Authority of the relevant country and the SPC holder.

The transitional provisions for the application of the SPC waiver ended in July 2022. Since then, several notifications for either storing and/or exporting have been published in Portugal in relation to SPCs covering several blockbuster substances.

This means that this new option for generic medicine manufacturers to produce and store products before the expiry of the SPC is being used by companies, and it is a trend for the future.

It is worth noting that the articulation between the SPC and the Patent with Unitary Effect has not yet been made by the European Union.

However, changes are expected in this regard to avoid the holder of a European Patent with Unitary Effect needing to request a different SPC for every country individually.

The Use of Cannabis for Medical Purposes – Still an Opportunity in Portugal

The Portuguese legislation in force still reflects the legislature's strong concern about providing activities linked to cannabis. The discussion around the decriminalisation or legalisation of cannabis for recreational use is not over, but some developments made over the past year should be highlighted.

Such development contribute to the clarification of the regulatory steps for the cultivation of cannabis for medical purposes in Portugal.

Indeed, all drugs in Portugal require a licence from the National Authority of Medicines and Health Products, I.P. (INFARMED) before they can be launched on the market. INFARMED is an entity within the Portuguese Health Ministry that is responsible for the management, control and assessment of medicines and health products to secure general health.

Ministerial Order No 14/2022, of 5 January, amends some articles of Ministerial Order No 83/2021, of 15 April, which sets out the requirements for the instruction of applications and procedures regarding the granting of authorisations for the exercise of activities related to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances based on the cannabis plant.

The recently introduced amendment is intended to address the insufficient regulation on some issues related to the cultivation of the cannabis plant for medical and non-medical purposes. Specifically, the amendment addresses the cultivation of hemp for industrial purposes, differentiating it from the cultivation of the cannabis plant for other purposes.

Therefore, for the wholesale trade of the plant or part of the plant, or active substances based on the cannabis plant for medicinal purposes, the list of requirements has been expanded to include the following:

- the full address and geographic location by co-ordinates of the facilities;
- a licence for the use of the storage facilities;
- a plan and description of the warehouse premises and the security measures implemented;
- a technical pharmaceutical manager;
- written procedures concerning the activities performed regarding the receipt of goods, storage, expedition, transport, records of traceability of the product from its acquisition to its expedition, and the qualification of suppliers and clients;
- certification of the security manager, to be issued by the Private Security Department of the Public Security Police Force, upon proof of the security manager's training and other requirements established in the legal regime of private security, and the criminal record must be issued for the purpose of the "lawful drug/psychotropic substances market";
- the term of responsibility issued by the person in charge of security; and
- the employment contract signed between the applicant and the security officer.

Conclusion

COVID-19 has had a permanent impact on all fields of activity, especially the life sciences sector, as it was a health issue that led to major

scientifical developments and created a different way to view the life sciences field and the way companies work in the sector. It has also accelerated the importance of new digital technologies in this field of activity, allowing faster and more cost-effective ways of working and achieving scientifical progress, which has led to important breakthroughs.

As the way of viewing and dealing with life sciences is also changing, there have been many legal changes that impact this field of activity, considering issues like ESG concerns and the methods of dealing with companies' industrial property.

Life sciences is therefore an area with increasing importance in Portugal, which is attracting more investment and being subjected to many policy measures to meet the currently fast-paced world and the importance of this area to people's lives.

SERBIA

Law and Practice

Contributed by:
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BDK Advokati

Contents

BDK Advokati is a full-service commercial law firm for corporate, institutional and high net worth (HNW) clients with multiple specialisations and with offices in Serbia, Montenegro, and Bosnia and Herzegovina. The firm advises clients on deals and support, represents them in contentious situations and provides legal advice in support of their business. The firm's focus is on prime expert work and complex cross-border deals, but it is also able to work on bread-and-butter matters in an efficient manner due to institutionalised know-how and organised processes. BDK Advokati's Life Sciences and Healthcare Group has assembled lawyers with different areas of expertise of relevance to these industry sectors, and has advised leading multinational companies on commercial, competition, data protection, disputes, employment, M&A and industry regulations. Present and former clients from the industry include Aspen Pharma, Biotest AG, GlaxoSmithKline, Hoffmann-La Roche, Mylan, Hemofarm and Farmalogist.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Applicable Legislation

Pharmaceutical products in Serbia are regulated in the Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act). The sections of the Medicines Act regulating medical devices have ceased to apply and medical devices are now regulated separately in the Medical Devices Act of 2017. A considerable number of by-laws regulate in more detail different matters governed by the Medicines Act and Medical Devices Act.

Competent Bodies

Competences for implementation and enforcement of pharmaceutical and medical devices legislation are shared between three governmental bodies:

- the Agency for Medicines and Medical Devices (ALIMS), the regulatory body tasked with enforcement of pharmaceutical and medical devices legislation for pharmaceuticals for human and veterinary use. The ALIMS is an independent regulatory body established by law;
- the Ministry of Health has certain competences with respect to the area of pharmaceuticals and medical devices for human use, particularly with respect to licensing and administrative oversight; and
- the Ministry of Agriculture, Forestry and Water Management is competent for matters concerning the pharmaceutical products intended solely for veterinary use.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Right to Appeal

Decisions of the ALIMS can be challenged before the competent ministry – ie, the Ministry of Health with regard to medicines and medical devices for human use, and the Ministry of Agriculture, Forestry and Water Management with regard to medicines for veterinary use.

A party to the proceeding before the ALIMS, or any person whose rights, obligations or legal interest may be affected by the outcome of the proceedings, may submit an appeal. An appeal may also be submitted if the ALIMS fails to adopt a decision within the statutory deadline.

Appeal Procedure

A party may submit an appeal against the ALIMS's decision to the competent ministry through the ALIMS. The deadline for submitting an appeal is 15 days from adoption of the first-instance decision, or, in the case of failure to adopt a decision, within a year from the expiry of the statutory deadline. Decisions of the competent ministry upon appeal, as well as first-instance decisions of the ministries in the matters from their competence, are final and may be challenged only before the Administrative Court.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Classification of Pharmaceuticals

Pharmaceuticals are classified into pharmaceuticals for human use and those for veterinary use. Furthermore, pharmaceutical products are classified into (i) prescription-only, and (ii) over-the-counter (OTC) pharmaceuticals. The ALIMS carries out the classification in the process for issuing marketing authorisations. Prescription-only and OTC pharmaceuticals are subject to different regimes with respect to pricing, advertising, dispensing and sale.

Classification of Medical Devices

Medical devices are classified into (i) general medical devices, (ii) in vitro diagnostic medical devices, and (iii) active implantable medical devices.

General medical devices are classified according to the degree of risk for the users into:

- Class I – medical devices with a low degree of risk for the user;
- Class IIa – a low to medium degree of risk for the user;
- Class IIb – a medium to high degree of risk for the user;
- Class III – medical devices with a high degree of risk for the user.

A notified body carries out the classification of medical devices. As an exception, the manufacturer classifies class I medical devices and others as in vitro medical devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical Trials for Pharmaceuticals

The Medicines Act is the principal piece of legislation regulating clinical trials of pharmaceuticals. Additionally, the Healthcare Act of 2019 and the Rulebook on Clinical Trials for Medicines for Human Use (2022), set out detailed rules related to ethics committee approval and performance of clinical trials.

Clinical trials of pharmaceuticals are conducted in accordance with the Ministry of Health's guidelines on Good Manufacturing Practice (2017), Good Laboratory Practice (2008), and Good Clinical Practice (2017).

Clinical Trials for Medical Devices

The Medical Devices Act and the Rulebook on Clinical Trials for Medical Devices of 2018 (as amended) regulate clinical trials for medical devices.

Clinical trials of medical devices are conducted in accordance with the guidelines of the Good Clinical Practice.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical Trials Subject to Approval

Sponsors must request simultaneous authorisations for conducting a clinical trial from the

ALIMS and the Ethics Committee of Serbia, a government-appointed expert body that takes care of the provision and implementation of healthcare at the national level, in the case of:

- clinical trials for medicines which do not have a marketing authorisation or for which a different use from the one prescribed in the approved summary of product characteristics is proposed, or medical devices for which a conformity assessment has not been carried out; and
- an interventional post-marketing clinical trial, where the medicinal product is applied in accordance with the conditions prescribed in the marketing authorisation, but requires additional diagnostic procedures, as well as the monitoring procedures defined by the clinical trial protocol, or where a medical device has been subject to conformity assessment, but the clinical trial is conducted for a purpose that is absent from the conformity assessment.

Clinical Trials Subject to Notification Only

Sponsors must only notify the commencement of a trial to the ALIMS if they wish to conduct a non-interventional post-marketing clinical trial of a pharmaceutical or a medical device in accordance with an approved summary of product characteristics of a pharmaceutical for which a marketing authorisation has already been issued, or a clinical trial of a medical device for which a conformity assessment has already been carried out.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical Trials Database

Basic information on all clinical trials conducted at a given moment in Serbia are publicly available within the database kept by the ALIMS on the e-government Portal. The information includes the date and number of the relevant decision on approval of the clinical trial, the protocol number, the names of the sponsor and the client, and the title of the trial, as well as its basic description.

Publication of Clinical Trial Results

Sponsors of clinical trials do not have an obligation to make the results of clinical trials publicly available. They must submit to the ALIMS, within one year of completion of the clinical trial, the report containing detailed results, both positive and negative, obtained through the trial.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, either for recruiting or monitoring purposes. Sponsors must, however, undertake all adequate measures to provide information to, and secure the consent of, the subjects and to protect their personal data.

2.5 Use of Data Resulting From the Clinical Trials

The Serbian Data Protection Commissioner has long held that data on a patient participating in a clinical trial is personal data, as long as a specific individual can be identified from such data. The same conclusion also applies under the new Data Protection Act (2018), which is an almost verbatim copy of the GDPR.

The Commissioner has yet to express its opinion on the legal basis for the data processing concerning the resulting data, including for disclosing the data – ie, transferring them to third parties or affiliates. The Commissioner might consider that reliance on consent as the legal basis for any type of processing of data in the context of clinical trials is unavailable because consent could not be considered as freely giv-

en. Therefore, one or more of the following legal grounds for the processing could be employed:

- processing is necessary for compliance with a legal obligation to which the controller is subject;
- processing is necessary for the performance of a task carried out in the public interest; or
- processing is necessary for the purposes of the legitimate interests pursued by the controller, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

The resulting data may be transferred abroad, under the conditions similar to those from the GDPR Articles 44 et seq. Importantly, the Data Protection Act does not recognise the model clauses of the European Commission as a transfer tool eliminating the need to seek and obtain transfer authorisation. Instead, the law authorises (in Article 45(11)) the data protection authority to adopt controller-to-processor standard contractual clauses. The authority adopted these clauses in January 2020. Controller-to-controller standard contractual clauses are still missing in Serbia because the Data Protection Act in the current iteration does not authorise the data protection authority to adopt them.

2.6 Databases Containing Personal or Sensitive Data

Creation of a database with the resulting data from the clinical trials would require carrying out a data protection impact assessment, in line with the Decision of the Serbian Data Protection Commissioner on the list of categories of data processing activities for which a data protection impact assessment must be carried out.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

An assessment of whether a product should be classified as a pharmaceutical or as a medical device is carried out by the ALIMS in the process of issuing of a marketing authorisation for a pharmaceutical product or registration of a medical device. The Medicines Act and the Medical Devices Act contain the criteria for classification.

The main criterion for differentiating between pharmaceuticals and medical devices is the following: pharmaceuticals are applied to humans or animals with the intention to restore, improve or modify physiological function by pharmacological, immunological or metabolic action, or by setting up a medical diagnosis; however, medical devices do not fulfil their principal intended purpose in or on the human body by pharmacological, immunological or metabolic means, but the medical device may be assisted in its function by such means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological medicinal products must meet the same quality, safety and efficacy criteria as other medicinal products to receive marketing authorisation. Biosimilars, however, may benefit from the short-form procedure for the granting of marketing authorisation, equivalent to the one available to generic medicinal products.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Validity and Renewal of Marketing Authorisation

Marketing authorisation is valid for five years. It may be renewed based on the reassessment of the risk/benefit ratio of the medicine. If, on the basis of the available pharmacovigilance data, the ALIMS determines that a pharmaceutical is safe, it grants a permanent marketing authorisation. In the event that the ALIMS determines that the pharmaceutical product is not safe, it will refuse to grant a permanent authorisation. Instead, the ALIMS will decide on whether to renew an authorisation for an additional period of five years. A marketing authorisation may be renewed for an additional period of five years only once. If the ALIMS still has justified doubts with respect to product safety, it will terminate the already issued marketing authorisation.

Revoking of a Marketing Authorisation

The ALIMS will revoke a marketing authorisation if it determines that the product is not safe for the life and health of humans and animals. The ALIMS will revoke the marketing authorisation if:

- the medicinal product is harmful under normal conditions of use;
- the medicinal product has no therapeutic efficacy;
- the risk-benefit ratio is not favourable under typical application conditions;
- the qualitative and quantitative medicinal product composition does not match the declared composition of the medicinal product;
- the marketing authorisation was issued on the basis of incomplete or false information, or if data is not amended in accordance with the law;
- the marketing authorisation-holder no longer meets the prescribed requirements; and/or
- the medicinal product was not marketed in Serbia for three years from the date of marketing authorisation issuance or was withdrawn from the market in Serbia for three consecutive years.

The ALIMS may vary, suspend, or revoke a marketing authorisation on the basis of data on adverse drug reactions collected within the scope of its pharmacovigilance activities.

Medical Devices

If the Ministry of Health determines that a medical device constitutes an unacceptable risk to public health and/or safety, or does not meet the statutory requirements, the Ministry may order the manufacturer or its authorised representative to take all appropriate and justified preventive or corrective measures. The Ministry may also prohibit or restrict the placing of a medical device on the market, set specific requirements for the placement of a medical device on the market, or order the withdrawal of a medical device from the market.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Pharmaceuticals

The Medicines Act and a series of implementing by-laws govern the granting of a marketing authorisation. The ALIMS is the competent authority for issuing marketing authorisations. A medicinal product may be granted a marketing authorisation after undergoing pharmaceutical (pharmaceutical, chemical, and biological), pharmaco-toxicological and clinical trials and provided that it has the required quality, safety and efficacy. The ALIMS conducts a formal review of an application for marketing authorisa-

tion within 30 days. The substantive review must be completed within 210 days. If the ALIMS requests additional documents from the applicant, the deadline is paused until submission of those documents. There is also an accelerated procedure for obtaining a marketing authorisation, for a medicinal product which obtained a marketing authorisation in accordance with the EU centralised procedure, and for medicines for human use of utmost importance for public healthcare. The accelerated procedure may last no longer than 150 days from receipt of a complete application.

Medical Devices

Medical devices are not subject to marketing authorisation. Medical devices may be placed on the market or in use if they comply with essential requirements set out in the Medical Devices Act regarding conformity assessment, labelling and supporting documents, if they are properly procured, installed and maintained, and used in accordance with their purpose. A manufacturer or its representative must submit the application for registration of a medical device to the ALIMS before placing it on the market or putting it to use. The Medicines Act contains a limited list of medical devices which do not need to be registered in order to be placed on the market or put to use (ie, medical devices for approved clinical trials or research and development, custom-made devices, devices for the personal use of a patient previously treated abroad, devices imported on a temporary basis for medical fairs, and those manufactured in medical institutions for in-house use).

Variations

A request for a variation is submitted to the ALIMS. Marketing authorisation-holders are obliged to:

- report IA-type variations within 12 months from the moment of application ("do and tell" procedure);
- report IAIN variations without delay following their application for the purpose of continuous monitoring of the medicinal product;
- request the ALIMS's approval for IB-type and type-II variations before their application ("tell, wait and do" procedure); and
- submit a new request for marketing authorisation for variations related to changes of the active ingredient or changes in strength, pharmaceutical form, or manner of application of the medicine, and for variations of veterinary medicines for animals used in human alimentation.

The ALIMS conducts a formal assessment of the application within 15 days from the day the application and the substantive review within 90 days from the day when the application is deemed complete. The pharmaceutical product must be marketed in accordance with the approved variation at the latest within 12 months from the delivery of the ALIMS's act on approval of the variation.

Transfer of a Marketing Authorisation

A marketing authorisation may be transferred to a new marketing authorisation-holder at the request of the existing one submitted to the ALIMS. The ALIMS will assess whether the prospective new holder meets the requirements prescribed by the law. The ALIMS conducts a formal assessment of the application within 15 days from the day of the application and the substantive review within 60 days from the day when the application is deemed complete.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

General Conditions

An importer may submit to the ALIMS a request for importation of a pharmaceutical for which a marketing authorisation was not issued in Serbia if:

- there is no registered pharmaceutical of the same international non-proprietary name (INN), strength, pharmaceutical form, and packaging size on the market in Serbia;
- the pharmaceutical is intended for treatment of rare diseases in humans;
- it is necessary to ensure sufficient quantities and types of a pharmaceutical in the case of epidemics, natural disasters, or other emergency situations; or
- there are no sufficient quantities and types of medicines with marketing authorisation on the market in Serbia.

Compassionate Use Programme

In addition to the import of unregistered pharmaceuticals under the general conditions previously described, import is also permitted on the basis of a compassionate use programme. The purpose of such a programme is to treat specific patients or a group of patients who are afflicted by life-threatening diseases such as AIDS, cancer and other malignant or auto-immune diseases. Import is organised as a donation or humanitarian aid to a health institution, provided that such pharmaceuticals are not subject to clinical trial in Serbia at the moment of the submission of request for import, and provided that they:

- are undergoing an advanced stage (Phase III) of clinical trial procedure in an EU country or in a country with similar requirements as Serbia regarding issuance of a marketing authorisation;
- have completed a clinical trial procedure in that country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- have received a marketing authorisation in the EU centralised procedure.

Exceptionally, a patient or a group of patients who are not eligible to participate in the ongoing clinical trial for that medicinal product in Serbia may receive a donation or humanitarian aid in the form of unregistered pharmaceuticals or registered pharmaceuticals for an unregistered indication, which are at that time subject to clinical trial in Serbia.

Import of Unregistered Medical Devices

The ALIMS may also authorise the import of a medical device not registered in Serbia. This is permissible if that import is intended for a particular patient or group of patients, or comes as a donation or humanitarian aid, or the subject-matter of the import is a medical instrument for scientific research or for emergency situations. In order to be imported, these medical devices must have undergone a conformity assessment.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Pharmacovigilance of Medicinal Products

In the post-marketing phase, marketing authorisation-holders must ensure continuous monitoring of adverse drug reactions to a pharmaceutical product (pharmacovigilance), namely:

- the continued monitoring of adverse drug reactions (ADRs), and have a full-time employee with adequate qualifications responsible for pharmacovigilance;

- keep records on all suspected ADRs notified in Serbia, EU countries or any third country, and provide the ALIMS with electronic reports;
- keep records of all suspected serious ADRs reported by health or veterinary professionals, or records of ADRs that MAHs can reasonably be expected to be aware of, and to report this information promptly to the ALIMS, no later than 15 days following the receipt of information;
- submit to the ALIMS periodic drug-safety reports at six-month intervals if the marketing authorisation was conditional or under special circumstances; and
- submit periodic drug-safety reports every six months for a period of two years following the placing of the pharmaceutical on the market, then annual reports for another two years and finally submit reports at three-year intervals.

Vigilance of Medical Devices

A manufacturer of medical devices or its authorised representative must employ a person responsible for vigilance and continuously monitor the medical device on the market, with the aim of identifying any need for corrective or preventive measures.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The Agency and the competent Ministries must treat as confidential all the data in the documentation enclosed within an application for the issuance of a marketing authorisation, variation or a renewal. This obligation applies in particular in relation to trade secrets – ie, when the following cumulative conditions are met:

- the data is confidential – ie, not generally known or easily available to persons usually dealing with that kind of information;
- the data has commercial value due to its confidentiality, during the period of confidentiality; and
- an applicant for a marketing authorisation, variation, and/or renewal, under the circumstances, takes reasonable measures to keep that data confidential.

Information from the documentation submitted during the procedure of obtaining a marketing authorisation, as well as in other procedures handled by the Agency and/or relevant Ministries, may only be disclosed to third parties with the consent of the applicant, or if the data is already available to the general or professional public for the purpose of providing information necessary for use or handling of a pharmaceutical or a medical device, or required for the protection of health in humans and animals.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Pursuant to the Medicines Act and Medical Devices Act, it is prohibited to manufacture or sell counterfeit pharmaceuticals and medical devices. If any such products are detected on the market, the competent ministry will prohibit their sale and order recall at the proposal of the ALIMS.

In 2019, Serbia signed the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME).

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

If certain goods are suspected of infringing intellectual property rights, customs authorities may, upon request or ex officio, suspend the release of goods or retain the goods. Customs authorities will request that the owner of the goods and the right-holder make a declaration about the potential infringement. The right-holder may initiate court proceedings against the alleged infringer, and in that case the goods will remain confiscated until the court renders a decision, or the right-holder may give permission to the customs authorities to destroy the goods, in which case the goods will be destroyed, provided that the owner of the goods consents to, or does not oppose, the destruction.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Manufacturing of Pharmaceuticals

The manufacturing of pharmaceuticals is subject to a licence issued by the Ministry of Health to legal entities. The application for a manufacturing licence must contain information and documents regarding the location and premises of the manufacturing site, equipment, personnel, medicines to be produced, relevant procedures, as well as other information required by the law. The Ministry issues a licence for a particular manufacturing site and certain forms of pharmaceutical manufactured at that site. The licence may include an entire manufacturing process or only a part of the process. The licence is valid for an indefinite period.

Manufacturing of Medical Devices

Manufacturers of medical devices may be both legal entities and individuals. A manufacturing licence is necessary only for class I medical devices (other than Is and Im class), other in vitro diagnostic medical devices, medical devices for which no conformity assessment has been performed, those not covered by the sign of conformity, custom-made devices for a particular patient, and medical devices for clinical trials, as well as a system or a kit. The Ministry of Health issues a manufacturing licence for medical devices, which is valid for five years.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale of medicines and medical devices includes purchase, storage, distribution, imports and export. A wholesale licence is issued by the Ministry of Health for an indefinite period for pharmaceuticals, and for medical devices for a period of five years.

The exception from obtaining of a wholesale licence applies to (i) manufacturers of medicines for products from their production programme, (ii) manufacturers of medical devices with a registered seat in Serbia, who must obtain a manufacturing licence for medical devices from their production programme, and (iii) entities performing only import or export activities on behalf of and for the account of a medicines wholesale licence-holder.

Applicants for a wholesale licence must provide information and documents regarding the legal entity, location and premises, supply territory, products for which the wholesale licence

is sought, personnel, equipment, a plan for an urgent withdrawal of products from the market, as well as the other information of relevance for the issuance of the wholesale licence.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices** relating to different categories of pharmaceuticals.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of pharmaceutical and medical devices in Serbia are governed by the Medicines Act and the Medical Devices Act, respectively. Import and export constitute the wholesale of medicines and medical devices and as such are additionally regulated in the rule books governing the wholesale of medicines and medical devices.

Depending on whether the product is intended for human or veterinary use, the Ministry of Health or the Ministry of Agriculture issues a pharmaceutical wholesale licence. The ALIMS issues (i) opinions on the import of cell or tissue samples for clinical trials' procedures of medicinal products, (ii) approvals for the import of medicines for clinical trials, and (iii) approvals for the import of medicines without a marketing authorisation.

Customs officials check if all the conditions are met in each case.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of record for pharmaceuticals or medical devices may be a legal person with a relevant wholesale licence.

Furthermore, a pharmaceutical or a medical device manufacturer may import products from its production programme, raw materials and substances for production, interim products, and semi-finished products, in accordance with the manufacturing licence, medicinal products marketing authorisation, or a subcontracting agreement.

Manufacturers of medical devices with a registered seat in Serbia who do not need a manufacturing licence must obtain a wholesale licence for medical devices from their production programme.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of pharmaceuticals and medical devices is subject to a prior issuance of a medicinal product wholesale licence, subject to exceptions described under **6.2 Importer of Record of Pharmaceutical and Medical Devices**.

A legal entity that performs only the activities of the import and export may perform these activities without a medicinal product wholesale licence if it conducts the import and customs clearance activities on behalf of and for the account of a wholesale licence-holder to the site of the goods' free marketing, in accordance with the customs regulations.

Generally, only medicinal products with a valid marketing authorisation and medical devices

registered in the ALIMS's registry of medical devices may be imported. Exceptionally, the ALIMS may approve import of medicinal products without a marketing authorisation in Serbia or unregistered medical devices under conditions prescribed for compassionate-use programmes, donation or humanitarian aid, or the emergency situations described in **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations**.

Persons entering or leaving Serbia may carry medicinal products in the amount not exceeding their six-month requirement within one calendar year, for their personal usage or for an animal travelling with them, depending on the type and length of the underlying illness. They have to provide to the Customs Authority the approval of a competent Serbian ministry for bringing in or carrying out medicinal products for personal use.

The transfer of medicinal products across the border in the amount not exceeding the 15-day requirement of an individual is not subject to any approval.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Although Serbia is not yet an EU member state, nor a member of the World Trade Organization (WTO), Serbia has to a large extent harmonised its legislation with the EU acquis and WTO agreements. Therefore, non-tariff restrictions are rare and imposed only in particularly justified situations, in line with the general principles of the EU and WTO to limit the use of non-tariff restrictions.

Non-tariff regulations and restrictions are imposed based on the Harmonized Tariff Schedule (HTS) Code. The products that are subject to those restrictions (usually quotas) are listed for example in specific international agreements which Serbia has concluded.

6.5 Trade Blocs and Free Trade Agreements

Serbia is a party to the Stabilisation and Association Agreement with the EU, the Central European Free Trade Agreement, and the Agreement with EFTA, as well as a number of bilateral free-trade agreements.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals are controlled by the government only with respect to prescription-only pharmaceuticals. The government determines the criteria for the pricing of pharmaceuticals, and calculates their maximum prices at the joint proposal of the ministries competent for health and trade. The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals.

The pricing of prescription-only medicines is governed by the Medicines Act, the Decree on Criteria for Forming of Prices of Prescription-Only Pharmaceuticals for Human Use, and the Decision on Maximum Prices of Prescription-Only Pharmaceuticals for Human Use. Prescription-only pharmaceuticals for which the government did not determine the maximum wholesale price may not be placed on the market.

Once the government decides on the maximum permitted wholesale price of the pharmaceutical, marketing authorisation-holders may apply to include the pharmaceutical into the positive

reimbursement list of medicines ("Positive List"), to be prescribed and issued at the expense of the compulsory health insurance. Wholesalers of pharmaceuticals as well as pharmacies must align the prices of pharmaceuticals that they have in stock with the maximum prices determined by the government on the same day as the relevant decision on maximum prices enters into force.

However, marketing authorisation-holders are free to determine the prices of over-the-counter medicines and must only notify the Ministry before March 31st of the current year of the price for the previous year.

7.2 Price Levels of Pharmaceutical or Medical Devices

The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals based on a number of criteria. One of these criteria is price parity – ie, the comparable wholesale prices of pharmaceuticals in reference countries, namely, Slovenia, Croatia and Italy and the current wholesale price in Serbia.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

For the cost of a pharmaceutical to be reimbursed, the product must be included in the Positive List. The general criteria for adding a pharmaceutical to the List are, as follows:

- pharmaco-therapeutic justification of the pharmaceutical;
- pharmaco-economic justification of the pharmaceutical; and
- financial resources provided by the annual financial plan of the National Health Insurance Fund.

In cases when there are not sufficient resources to include in the Positive List all pharmaceuticals which comply with the general criteria, the National Health Insurance Fund further considers two special factors: (i) the existence, if any, of a managed entry agreement, and (ii) the priority for adding the pharmaceutical to the list according to the following criteria:

- the lack of a pharmaceutical from the same pharmaco-therapeutic group on the Positive List for a particular medical indication;
- the significance of a pharmaceutical for public health; and
- ethical aspects.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Within the scope of the process for inclusion of pharmaceuticals into the Positive List of pharmaceuticals to be reimbursed from the national health insurance, the Central Medicines Commission established by the National Health Insurance Fund conducts the health technology assessment of medicines when reviewing the applications for inclusion of pharmaceuticals on the List.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Dispensing and sale of pharmaceuticals is regulated only with respect to prescription-only medicines. The ALIMS decides whether a medicine is to be dispensed only on prescription in a marketing authorisation procedure. Prescriptions and dispensing of pharmaceuticals are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Healthcare professionals are obliged to observe the recommendations from Good Practice in Prescribing of Pharmaceuticals.

A pharmacy may replace the prescribed brand-name medicine with its generic equivalent only if the patient consents after being adequately informed by the pharmacist, and under the condition that the physician did not prohibit replacement on the prescription.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no special rules governing medical apps in Serbia. Medical devices are defined in the Medical Devices Act as any instrument, apparatus, appliance, software, implant, reagent, material and other product used alone or in combination, including software provided by the manufacturer for diagnostic or therapeutic purposes and which is software support that is necessary for its proper use in people intended by the manufacturer, and is used for:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of injury or disability;
- investigation, replacement or modification of the anatomy or physiological or pathological process and state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;
- control or support of conception; and
- products intended for cleaning, disinfection or sterilisation of medical devices.

Therefore, a medical app may be classified as a medical device, depending on its intended use. The ALIMS has the authority to determine if a medical app is a medical device, on a case-by-case basis.

8.2 Rules for Telemedicine

Telemedicine is not regulated in Serbia. In the context of the coronavirus health crisis, the Ministry of Health introduced an e-health portal, where patients can fill out a questionnaire with regard to their symptoms and receive instructions on the steps to take, and can enter their contact information to be contacted by a physician for an appointment.

Conditions for the introduction of a wider variety of telemedicine services should be fulfilled through the implementation of a proposed Programme of Digitalisation of the Health System of the Republic of Serbia for 2022-2026.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules applicable to online advertising. Advertising of medicines and medical devices is regulated in the Medicines Act and Medical Devices Act, respectively, while the relevant by-laws provide detailed rules.

In addition, the Serbian Association of Manufacturers of Innovative Drugs (INOVIA) adopted in 2014 the Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the INOVIA Code).

8.4 Electronic Prescriptions

Electronic prescriptions in Serbia are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Prescription of medicines is conducted through an integrated health information system in electronic form, and prescriptions in paper form may still be issued exceptionally.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines and medical devices are prohibited in Serbia.

8.6 Electronic Health Records

According to the Health Documentation and Health Records Act (2014, as amended) (HDHRA), health institutions, private practices, and other legal entities are obliged to keep health records (Article 2, para 2). The records may be kept either in paper or electronic format. Where not all the requirements for keeping the records in electronic format are met, the competent healthcare professional is obliged to keep a printed and signed copy of the electronic records in paper format.

Additionally, the HDHRA prescribes the keeping of a so-called electronic medical dossier. According to the law, the dossier is kept within the Integrated Health Information System of the Republic of Serbia (Article 49) and it contains the assembled data important for the patient's long-term health status which derives from the patient's health records and health insurance records kept in electronic format. Only competent healthcare professionals may access the dossier, immediately prior to the provision of healthcare services. Patients are entitled to opt for their electronic medical dossiers not to be kept. Patients are also entitled to access their data from the dossier. They may exercise the right to access either online or by addressing the competent healthcare professional or other authorised individual. In practice, there has been little use of electronic medical dossiers.

The Serbian Data Protection Act considers health-related information as sensitive data (Article 17 of the Act). The processing of sensitive data is permissible if the data controller may rely on a legal basis for processing of any category of personal data, sensitive or not, and additionally on a statutory exception from the general prohibition of the processing of sensitive data.

It is permitted to transfer and store sensitive data of patients on cloud platforms. The Serbian Data Protection Commissioner would typically consider a cloud platform to be a data processor. Therefore, exporters of health-related sensitive data may use as the transfer instrument the controller-to-processor standard contractual clauses which the Data Protection Commissioner issued in January 2020.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Serbia, the Patent Act (Official Gazette of the Republic of Serbia, No 99/2011, 113/2017 – other act, 95/2018, 66/2019 and 123/2021) (Patent Act) applies to all patents.

Under the Patent Act, the general patentability requirements of novelty, inventive step, and industrial application apply to all inventions, including pharmaceutical and medical device inventions.

However, there are certain exceptions to patentability of pharmaceutical inventions. A patent will not be granted in respect of methods for treatment by surgery or diagnostic methods or therapy practised directly on the human or animal body (Methods). This exception does not apply to products, in particular substances or compositions, for use in any of these methods.

9.2 Second and Subsequent Medical Uses

The Patent Act allows for the patentability of a second or subsequent medical use of a known substance or composition.

The patentability requirement of novelty does not exclude patentability of any substance or composition, comprised in the state of the art, for use in a Method, provided that its application in any Method is not comprised in the state of the art. The requirement of novelty also does not exclude patentability of that substance or composition, for any specific use in a Method, provided that such use is not comprised in the state of the art.

Provisions of the Patent Act that regulate the issue of second and subsequent medical uses are in line with the corresponding provisions of the European Patent Convention (EPC). The European Patent Office's (EPO) interpretation of these provisions is that they also apply to patent claims for treatments that draw their novelty from new dosage regimes, methods of administration, or new classes of patients (the interpretation expressed in the EPO Enlarged Board of Appeal's decision G2/08). Since the corresponding provisions of the Patent Act are modelled after the EPC, it can reasonably be expected that the Serbian Intellectual Property Office (IP Office) and courts would also allow patent claims in relation to new dosage regimes, methods of administration, or new classes of patients.

The activities that constitute infringement of second and subsequent patents of pharmaceutical products are described in **9.4 Pharmaceutical or Medical Device Patent Infringement**.

9.3 Patent Term Extension for Pharmaceuticals

The owner of a pharmaceutical patent can apply for a supplementary protection certificate (SPC).

A patent-owner can submit an SPC request to the IP Office within six months from obtaining marketing authorisation for the patented product. The SPC is valid for the period equal to the period from the date of submission of the patent application to the date of the first marketing authorisation, minus five years. The maximum duration of an SPC is five years. An SPC can be extended for six additional months if all necessary tests are completed in the European Union in accordance with an approved paediatric research plan.

SPCs obtained as of 2 July 2022 will not confer protection against the acts of (i) making of a product protected by an SPC for the purpose of export, and (ii) making, no earlier than six months before the expiry of the SPC, of a product, for the purpose of storing the product in Serbia, in order to place that product on the Serbian market after the expiry of the SPC.

Third parties can request that the IP Office declare an SPC invalid under the same conditions prescribed for declaration of patent invalidity.

9.4 Pharmaceutical or Medical Device Patent Infringement

The following activities constitute patent infringement:

- manufacturing, offering, placing on the market, using, and importing or storing for those purposes, a patented product or a product directly obtained through a patented process;
- using or offering a patented process; and

- offering or supplying products that constitute essential elements of a protected invention to parties unauthorised to use the invention, provided that the products are offered or supplied in bad faith.

An applicant, owner, or licensor of a patent may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement. Applying for marketing authorisation before a patent expires does not amount to patent infringement, since it falls within the scope of exemption mentioned in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences to patent infringement include:

- use in personal and non-commercial purposes;
- research and development activities, including activities that are necessary for obtaining an authorisation for placing medicinal products on the market (a Bolar exemption); and
- direct, individual preparation of a medicine in a pharmacy in accordance with a prescription, and placement of that medicine on the market.

Compulsory licences are available on request.

Requirements for obtaining a compulsory licence depend on the grounds on which the licence is sought (eg, insufficient use of the protected invention, inability to use another invention commercially, etc). Usually, the following will apply:

- a request for a compulsory licence can be submitted after the expiry of a period of four years from the date of filing of the patent application, or three years from the grant of the patent, whichever period expires later;
- in order to obtain the licence, the requestor must prove that he or she has previously unsuccessfully attempted to conclude a licensing agreement with the patent-owner.

These requirements will not apply if a compulsory licence is being issued because of a public emergency (eg, in the fields of health, defence and ecology) which jeopardises the survival of the state or its citizens, or in cases of public non-commercial use.

9.6 Proceedings for Patent Infringement

An applicant, patent-owner, SPC-owner, and patent licensor may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement.

Available remedies include, among others:

- determination of infringement or serious threat of infringement;
- prohibition of acts that constitute infringement or serious threat of infringement;
- compensation of damages; and
- seizure, removal from the market, or destruction of infringing products.

Infringement proceedings are initiated with a lawsuit. The defendant then submits a response to the lawsuit, after which the court schedules hearings. The defendant may at any time submit a request for determination of invalidity to the IP Office. The court would consider the invalidity proceedings a preliminary issue, and may decide to rule on this issue itself, or, more likely, to discontinue the court proceedings and wait for the IP Office's decision on invalidity.

Before, during or after the proceedings, the court may order provisional measures on request, provided that the requestor presents evidence reasonably supporting his or her claim that his or her rights have been infringed or are about to be infringed. Such provisional measures include, for example, seizure or removal from the market of infringing products, and prohibition of acts that represent infringement or serious threat of infringement.

9.7 Procedures Available to a Generic Entrant

A generic entrant has no obligation to "clear the way". However, by not "clearing the way", a generic entrant exposes itself to possible infringement proceedings, in the event that its activities amount to a serious threat of patent infringement.

The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Intellectual property right-holders may initiate civil proceedings in the case of counterfeiting. Moreover, counterfeiting is a criminal offence. Anyone can submit a criminal complaint to a public prosecutor, based on which the public prosecutor will decide whether to conduct an investigation, file an indictment, or reject the criminal complaint. Counterfeiting may also trigger misdemeanour proceedings. Customs authorities may prevent counterfeited goods from entering Serbian territory, as explained in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The IP Office will reject an application for a descriptive trade mark. According to the IP Office's Methodology in the Procedure for Trademark Registration and Procedures for Registered Trade marks (Methodology), a mark used for pharmaceuticals will be considered descriptive if:

- the mark consists exclusively of the name of the chemical substance used for production of that pharmaceutical; or
- the mark slightly deviates from the generic name of the chemical substance.

According to the Methodology, the IP Office will consult the WHO's list of international non-proprietary names (INNs). In trade-mark registration proceedings, the IP Office considers the WHO's recommendation that a verbal trade mark for a pharmaceutical should differ in at least three letters from the generic name.

The Trademark Act, enacted in 2020, lifted the prohibition on parallel imports. According to the Trademark Act, a trade-mark proprietor who has placed, or consented to placing, on the market anywhere in the world goods protected by the trade mark, cannot prohibit further circulation of such goods. However, the Medicines Act and the implementing by-laws have not yet been aligned with the amendments to the Trademark Act and do not regulate parallel import. The government has announced the plan to adopt a new Medicines Act, although no draft has yet been made publicly available. It remains to be seen whether the new law will regulate parallel imports.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

It is possible to protect a 3D shape as a trade mark. Therefore, pharmaceuticals, medical devices and their packaging may be protected, provided that they meet the requirements for trade-mark protection. However, if a mark consists exclusively of the shape or another characteristic which results from the nature of the goods, or is necessary to obtain a certain technical result, or gives substantial value to the goods, trade-mark protection cannot be granted. This restriction may be especially significant when seeking protection for 3D trade marks that relate to medical devices, tablets, etc.

A shape can also be protected as industrial design if it meets the requirements of novelty and individual character. However, protection will not be granted if the design is determined solely by the function of the product in question.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data Exclusivity for Foreign Manufacturers

Different rules on data exclusivity apply to manufacturers with and without a seat in Serbia. Originators without a seat in Serbia may benefit from a ten-year exclusivity period from the issuance of the marketing authorisation for the data submitted to obtain that marketing authorisation. Originators may not extend the exclusivity period on account of amendments to the marketing authorisation in terms of medicinal product strength, pharmaceutical form, methods of administration, packaging, or variations and claims for extension of the scope of the marketing authorisation.

Therefore, an applicant for a marketing authorisation issuance in a short-form procedure (for a generic medicinal product, generic hybrid medicinal product, or biologically similar medicinal product) may obtain a marketing authorisation after ten years from the date of issuance of the marketing authorisation for the reference product, but may apply for that marketing authorisation earlier, after at least eight years have elapsed from the date when the initial marketing authorisation had been issued in Serbia, in the European Union or in countries that have the same or similar requirements for the issuance of the authorisation.

If, during the eight years from the issuance of the marketing authorisation for the reference medicinal product, the marketing authorisation-holder for the reference medicinal product obtains a new marketing authorisation for one or more new indications that show a significant improvement in that reference medicinal product therapy, the period of ten years may be extended (cumulatively) for one more year.

Data Exclusivity for Manufacturers with a Seat in Serbia

These rules will also apply to manufacturers with a seat in Serbia from the moment of accession of Serbia in the European Union. Currently, the ten-year protection period applies only to biotechnological medicines, while for the other medicinal products the protection period is six years from the date of receiving the first marketing authorisation for the reference pharmaceutical.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In March 2020, the Customs Administration announced that legal entities, regardless of

the business activity they perform, may import masks and gloves for their employees' personal protection. However, masks and gloves imported for these purposes may not be distributed – ie, sold – to third parties.

During March, April and May of 2020, the Regulation on Special Technical Requirements, Standards and Application of Medical Devices During the Emergency Condition Due to COVID-19 Disease Caused by SARS-CoV-2 (Regulation) was in force. The Regulation allowed the procurement, putting into use and application in treatment of medicines and medical devices that were not manufactured in accordance with all prescribed standards. This relaxation applied only during the state of emergency.

11.2 Special Measures Relating to Clinical Trials

On 24 March 2021, the ALIMS issued Instructions for Clinical Trial Sponsors During the COVID-19 Pandemic. The instructions cover, among others, the following topics:

- handling the medicine in a clinical trial;
- changes in visits/transfer of respondents from one centre to another;
- informed consent of the respondents; and
- revising the monitoring plan, etc.

No special measures were issued in relation to COVID-19 treatments or vaccines.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In accordance with the provisions of the Medicines Act, pre-dating COVID-19, the ALIMS can issue a temporary marketing authorisation for the duration of an epidemic, natural disaster or state of emergency and only for a certain type and quantity of a medicine. On that basis, the government has adopted the Regulation on Temporary Marketing Authorisation for Medicine – Vaccine for Immunisation of the Population Against Infectious Disease COVID-19 (Official Gazette of the Republic of Serbia, Nos 17/2021 and 97/2021) (Regulation), providing that the ALIMS may issue a temporary marketing authorisation for a COVID-19 vaccine if one of the following applies:

- the vaccine is on the WHO's list of COVID-19 vaccines (in accordance with the WHO's Emergency Use Assessment and Listing mechanism);
- there is a bilateral agreement signed by Serbia, the applicant is a medicine manufacturer that has a manufacturing licence in Serbia, and the vaccine is not yet on the WHO's list of COVID-19 vaccines (but the listing procedure has been initiated); or
- the vaccine is registered in the country of origin, the EU, or in countries that have identical or similar requirements for the issuance of a marketing authorisation as in the countries of the EU.

Under the Regulation, the ALIMS may only issue a temporary marketing authorisation if an epidemic has been declared, the Ministry of Health has issued an order on emergency immunisation, and the relevant national bodies have determined that it is necessary to obtain a certain amount of COVID-19 vaccine urgently.

Other possible pathways applicable for emergency approvals of pharmaceuticals under the Medicines Act are for the ALIMS to issue:

- a marketing authorisation in an expedited procedure for a medicine of the greatest interest for protection of population health, primarily relating to innovation of treatment, as

well as for a medicine that has already been approved by the European Medical Evaluation Agency;
- a provisional marketing authorisation for medicines used in an emergency, or for other medicines of a greater public health interest; in a state of emergency where public health is in jeopardy, the applicant can obtain a provisional marketing authorisation without providing to the ALIMS the clinical, pharmaceutical, biological, toxicological, and other types of data that are generally required; or
- a "marketing authorisation under special circumstances" for a medicine of a particular public health interest.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No new measures were introduced due to COVID-19 to facilitate obtaining the manufacturing certifications.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

During March, April and May of 2020, the export and re-export of medicines was prohibited, except in the case where:

- medicines were manufactured in Serbia, but were not registered in Serbia – ie, the medicines were manufactured exclusively for foreign markets; and
- a foreign person shipped medicines in the transit procedure from the Serbian customs territory.

Exceptionally, the export and re-export of medicines was allowed upon the approval of the government.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The ALIMS announced during the COVID-19 crisis that, as of 20 August 2020, its activities that were previously performed in direct contact with parties were to be performed exclusively by e-mail, registered mail, or telephone. The ALIMS provided dedicated e-portal and email addresses for communication with parties.

In the context of the coronavirus health crisis, the Ministry of Health introduced an e-health portal, where patients can fill out a questionnaire regarding their symptoms and receive instructions on the steps to take. The patients can enter their contact information to be contacted by a physician for an appointment.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The government has not announced an intention to issue compulsory licences for COVID-19-related treatments or vaccines.

The general rules for issuing compulsory licences, described in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**, would also be applicable to COVID-19-related patents.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were introduced regarding COVID-19 vaccines or treatments.

In accordance with the regular liability regime, the marketing authorisation-holder is responsible for the quality, safety and efficacy of the medicine.

The manufacturer of a medicine is responsible for the process of manufacturing. If that manu-

facturer places a product batch on the market, he or she is also responsible for the quality, safety and efficacy of the medicine.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions of the Rulebook on the Conditions, Content of Documentation and Manner of Approval of Amendments to the Marketing Authorisation (2012, as amended) regulates requisition or conversion of manufacturing sites. The marketing authorisation-holder must notify the ALIMS of suspension on any manufacturing site ("Do and Tell" procedure). In the case of a modification of a manufacturing site of biological medicine active substance, the marketing authorisation-holder must apply for a new authorisation.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

No changes to the system of public procurement were introduced due to COVID-19.

SINGAPORE

Law and Practice

Contributed by:
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Contents

Drew & Napier LLC has been providing exceptional legal service since 1889 and is one of the largest full-service law firms in Singapore. The firm has three senior counsel. It is pre-eminent in dispute resolution, international arbitration, competition and antitrust, corporate insolvency and restructuring, IP (patents and trade marks), tax, and telecommunications, media and technology, and has market-leading practices in M&A, banking and finance, and capital markets. Drew & Napier has represented Singapore's leaders, top government agencies and foreign governments in landmark, high-profile cases. It is also appointed by Fortune 500 companies, multinational corporations, and local organisations. The firm is experienced in international disputes before the Singapore International Commercial Court and covers the full range of commercial litigation matters, including building and construction, constitutional law, debt recovery, defamation, fraud and white-collar crime.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The Health Products Act 2007 (HPA) is the main legislation governing pharmaceuticals, which are referred to as "therapeutic products", and medical devices.

Therapeutic products and medical devices are also regulated under the following legislation and regulations:

- the Health Products (Advertisement of Therapeutic Products) Regulations 2016;
- the Health Products (Medical Devices) Regulations 2010;
- the Health Products (Therapeutic Products) Regulations 2016;
- the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016;
- the Poisons Act 1938 and its subsidiary legislations; and
- the Sale of Drugs Act 1914 and its subsidiary legislations.

The Health Sciences Authority (HSA), a statutory body under the Ministry of Health (MOH), is the main regulatory body which administers, applies and enforces the aforementioned legislation and regulations. The HSA also publishes guidelines in its administration of the legislation and regulations. As a statutory body, the HSA has substantial independence and autonomy over its operations. Nevertheless, it generally operates in line with the policy directions set by the government.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

An appeal can be made in respect of any of the following decisions made by the HSA:

- refusal of the HSA to register a health product;
- attachment of any condition to the registration of a health product;
- decision to re-categorise or reclassify a health product;
- decision to suspend or cancel the registration of a health product;
- refusal of the HSA to issue or renew a licence or to grant any approval;
- attachment of any condition to a licence; and

- decision to suspend or revoke a licence or to cancel an approval.

Any person aggrieved by the aforementioned decisions can make an appeal in writing within the time specified in the decision notice to the Minister of Health, whose decision is final. The Minister may choose to refer the appeal to an Appeal Advisory Committee before making a decision and will have to take into consideration any report made to him or her by the Appeal Advisory Committee in making the decision.

This challenge procedure is specific to health products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Therapeutic Products

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List medicines. These categories of therapeutic products are regulated differently on the basis of the types of marketing authorisation required.

Medical Devices

The appropriate product registration requirements and evaluation route depends on the risk classification of the medical device.

Medical devices are classified into the following risk groups, based on guidance developed by the Global Harmonisation Task Force:

- Class A – low risk, (eg, wheelchairs and tongue-depressors);
- Class B – low to moderate risk (eg, hypodermic needles and suction equipment);
- Class C – moderate to high risk (eg, lung ventilators and bone-fixation plates); and
- Class D – high risk (eg, heart valves and implantable defibrillators).

In vitro diagnostic (IVD) medical devices are separately classified on the basis of their risk levels:

- Class A (IVD) – low individual risk and low public-health risk (eg, specimen receptacles);
- Class B (IVD) – moderate individual risk and/or low public-health risk (eg, vitamin B12 and pregnancy self-tests);
- Class C (IVD) – high individual risk and/or moderate public-health risk (eg, blood glucose self-tests and rubella tests); and
- Class D (IVD) – high individual risk and high public-health risk (eg, HIV blood-donor screening and HIV diagnostic kits).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of therapeutic products are specifically regulated by the HSA under the Health Products (Clinical Trials) Regulations 2016.

Clinical trials of medical devices are not regulated by the HSA. Where clinical trials of medical devices involve human biomedical research, such trials are required to comply with the requirements of the Human Biomedical Research Act 2015, which is administered by the MOH. Clinical trials of medical devices which do not involve human biomedical research are currently unregulated in Singapore.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Therapeutic Products

In order to undertake a clinical trial of a therapeutic product, regulatory approval from the

HSA and ethics approval from the relevant Institutional Review Board (IRB) must be obtained.

Applicants must first determine whether the clinical trial is subject to the requirements of a Clinical Trial Authorisation (CTA) or Clinical Trial Notification (CTN). CTAs are required for higher-risk clinical trials involving therapeutic products unregistered in Singapore or uses of registered therapeutic products which are unapproved. CTNs are required for low-risk clinical trials involving only registered therapeutic products used in accordance with their approved labels.

The clinical trial application, together with the relevant supporting documents, should be submitted by the sponsor to the HSA via its online platform, PRISM. The study may be initiated after the HSA accepts the notification of clinical trial or authorises the clinical trial.

Medical Devices

Authorisation is generally not required for clinical trials of medical devices. However, a notification must first be submitted to the Director of Medical Services before the commencement of any clinical trial of medical devices involving human biomedical research.

2.3 Public Availability of the Conduct of a Clinical Trial

Particulars of ongoing clinical trials are made publicly available online on the Clinical Trials Registry. All information in the Clinical Trials Register is maintained and updated by the local sponsors at least once every six months. The results of the trials are not made publicly available.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, as long as the use complies with the International Council for Harmonisation (ICH) E6 (R2) Good Clinical Practice Guidelines.

2.5 Use of Data Resulting From the Clinical Trials

Data from clinical trials is considered personal data under the Personal Data Protection Act 2012 (PDPA), Singapore's primary data protection legislation. While there is no express categorisation of sensitive data in Singapore, the Personal Data Protection Commission (PDPC), which administers the PDPA, has taken the position in several enforcement decisions that medical data is more sensitive in nature and requires a higher standard of protection.

Resulting data may be transferred to a third party or an affiliate if consent has been obtained from individuals involved in the clinical trials. Data transfers are required to comply with the requirements of the PDPA.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data would not be subject to requirements beyond that which is already required in the PDPA.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The classification of the health product is assessed when an application for registration is screened to determine whether it should be accepted for evaluation.

Therapeutic Products

A therapeutic product is any substance that has certain active ingredients as a constituent, is intended for use by and in humans for any of the following purposes:

- preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or any symptom thereof;
- investigating, modifying or replacing any physiological process;
- influencing, controlling or preventing conception; or
- inducing anaesthesia,

has as a constituent any of the following active ingredients:

- any chemical or botanical element, naturally occurring chemical or botanical material, or chemical product obtained by chemical change or synthesis;
- any metabolite from a micro-organism;
- any macromolecule extracted from an organism; or
- any substance derived from a biological system,

and which exerts an inherent effect, either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose.

Medical Device

A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purpose,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical devices also include the following:

- any implant for the modification or fixation of any body part;
- any injectable dermal filler or mucous membrane filler; or
- any instrument, apparatus, implement, machine or appliance intended to be used for

the removal or degradation of fat by invasive means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biologic medicinal products are generally classified as therapeutic products and are not subject to any specific obligations in relation to the granting of a marketing authorisation.

Biosimilars are "follow-on" versions of biologic medicinal products. Biosimilars are required to be submitted under a new drug application, rather than a generic drug application. The registration of biosimilar products involves a comprehensive comparability exercise, where similarity to an existing biologic medicinal product registered in Singapore in terms of physicochemical characteristics, biological activity, safety and efficacy needs to be established.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Registrations of therapeutic products and medical devices generally remain valid for a year and may be renewed by paying an annual retention fee, unless the registration is suspended by the HSA or cancelled by either the HSA or the product registrant. There is no requirement to market the health product once it is registered by the HSA. However, under the Singapore Association of Pharmaceutical Industries Code of Conduct, the first use of all promotional materials circulated to the market may not be more than two years from the date of approval. Materials used beyond this time period are required to be re-approved.

The registration of a health product may be suspended or cancelled by the HSA on the following grounds:

- the registration has been obtained by fraud or misrepresentation;
- the registrant of the health product has contravened or is contravening any provision of the HPA, any condition attached to the registration, or any other prescribed requirement;
- the formulation, composition, design specification, quality, safety or presentation of the health product has changed in such a way as to render it unsuitable to continue to be registered;
- the health product no longer complies with a prescribed requirement; or
- it is in the public interest to do so.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Therapeutic Products

Registration procedure

Pre-submission: at the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification and may also request a pre-submission meeting with the HSA where necessary to address specific submission issues.

Application submission: submission of the application form online via the HSA's portal, PRISM, and submission of the technical dossier accompanying the application, within two working days of the PRISM application submission, must be made.

Application screening: the application is screened to ensure that the application type is correct, and the technical dossier is complete. Where any changes are required or where there are deficiencies in the application, the HSA will request that the applicant take the necessary action via an Input Request. In the case

of certain major deficiencies, applicants will be requested to withdraw the application.

Application evaluation: the evaluation stage begins when the application is accepted. Evaluation queries may be issued to the applicant if clarification or additional information is required. The evaluation route applicable depends on whether the therapeutic product has received reference agency approvals.

Regulatory decision: the HSA will notify the applicant of one of the following outcomes after the application has been evaluated: approval, approvable, non-approvable or rejection.

Where the applicant receives an approvable regulatory decision, the applicant will be informed of the conditions for approval and will receive a grant of a final approval if the conditions are fulfilled within a stipulated timeframe.

Where the applicant receives a non-approvable regulatory decision, the applicant will be informed of the deficiencies leading to the non-approvable decision. The applicant may address the specified deficiencies by furnishing a response based on the original data set submitted to the HSA within the stipulated timeframe to continue with the application.

Variation procedure

Variation applications of registered therapeutic products are split into major variation applications (MAV) and minor variation applications (MIV). Each application type may be subject to different evaluation routes and different variation procedures.

As a whole, the procedure to vary a therapeutic product registration is largely similar to the registration procedure.

- At the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification and also request a pre-submission meeting with the HSA where necessary to address specific submission issues.
- Only MAV applications will be screened to ensure the correctness of the application type and completeness of the technical dossier.
- During the evaluation stage, applicants who have incorrectly selected an application type or evaluation route will be requested to make the appropriate changes. In such cases, the applicant will be required to withdraw and resubmit the application if they intend to pursue the application.

Transfer procedure

A registrant for a registered therapeutic product may be changed from one company to another.

Before the submission of a transfer application, the existing registrant should conclude all pending variation applications and payment of the annual retention fee. To make a transfer application, the existing registrant first initiates the application via the HSA's portal, transfer@prism. The new registrant will receive an email notice with a PRISM transaction number. The new registrant is then required to retrieve the draft application on transfer@prism using the transaction number and submit the completed application in PRISM within 30 calendar days of receiving the email notice.

Medical Devices

Registration procedure

The registration requirements and evaluation route for medical devices depend on their risk classification, whether they have received reference agency approvals, and their prior safe marketing history. Generally, medical devices which have not received prior reference agency

approvals will have to undergo the full evaluation route.

Medical device registration applications are submitted online via the HSA's portal, MEDICS. For applications under the full or abridged evaluation routes, the application will first be verified for eligibility and completeness before it is accepted for evaluation. In the event that the application does not qualify for the selected evaluation route, it will be re-routed accordingly. A regulatory decision is made after the HSA's evaluation of the application. Only applications that satisfy the registration requirements will be registered and listed on the Singapore Medical Device Register (SMDR). For applications under the immediate evaluation route, the medical device is registered immediately and listed on the SMDR within an hour.

Variation procedure

Registrants may be required to submit a "Change Notification" application to the HSA upon changes to the medical device registrations. A Change Notification to the HSA can be categorised into Notification, Administrative, Technical and Review changes.

Some changes may not qualify for a Change Notification and will require the submission of a new registration. These include:

- a change to the intended purpose of the registered medical device;
- a change to the risk classification of a registered medical device;
- a change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
- any addition of model(s) that do not fulfil the grouping criteria, including permissible variants, as per the GN-12 guidance documents on Grouping of Medical Devices for Product Registration; and
- any addition of medical devices with device proprietary names that are different from the registered devices into a device listing, unless permitted to be listed together under one SMDR listing based on the GN-12 guidance documents on Grouping of Medical Devices for Product Registration.

A Change Notification application is submitted to the HSA via MEDICS. The following changes must be evaluated by the HSA first, prior to implementation:

- all Technical changes;
- all Review changes; and
- Administrative changes involving changes to administrative documents and information submitted at the point of registration of the medical device.

Where the HSA determines that the Change Notification is approvable, the change to the registered device may be implemented.

All other applications (ie, all Notification changes and all other Administrative changes to device particulars which are published on the public SMDR listing) may be implemented immediately upon the receipt of the acknowledgement email from the HSA.

Transfer procedure

A transfer application can only be made to the HSA after the medical device is listed on the SMDR and there are no pending applications in the HSA's system in relation to the device.

The new registrant is responsible for making the transfer application, by emailing the application form and required supporting documents to the

HSA. The new and existing registrants will then be notified of the outcome of the application for the change in registrant.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Unregistered therapeutic products may be imported and supplied for patient's use via the Special Access Route (SAR) under certain circumstances, including the following:

- a licensed hospital or medical clinic importing the drug for use by its own doctors or dentists on patients under their care;
- a licensed retail pharmacy acting on behalf of, and in accordance with, a valid prescription issued by a registered doctor or dentist; or
- a company acting on behalf of a licensed hospital or clinic.

However, any such use of unregistered therapeutic products should only be considered for life-saving therapies, and are to be done through either a named-patient application or a buffer stock application.

Note that if the therapeutic product consists of controlled drugs or psychotropic substances, then the respective licences will also have to be obtained in order to import the product.

Unregistered medical devices may be supplied via SAR under a number of exceptions, including the following:

- for non-clinical purposes;
- for a clinical purpose in clinical research;
- for export or re-export; or
- for patients' use.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

In general, health products may be registered subject to post-approval commitments.

Therapeutic Products

Ongoing obligations of registrants of therapeutic products include:

- maintaining records of every receipt and supply of the therapeutic product;
- maintaining records of defects and adverse effects and reporting them to the HSA within certain timeframes;
- notifying the HSA before any intended recall;
- informing the HSA of any information that adversely affects the validity of any data furnished to the HSA;
- submitting benefit-risk evaluation reports periodically to the HSA;
- implementing risk-management plans; and
- informing HAS of any regulatory actions taken by other regulatory authorities, or actions taken by the company arising from significant safety issues of the therapeutic product.

The Regulatory Guidance on Post-Marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products, revised by the HSA in March 2021, sets out further guidance relating to the submission of relevant safety information during the post-marketing phase.

Medical Devices

Ongoing obligations of registrants of medical devices include:

- ensuring and maintaining objective evidence to establish that the medical device complies with safety and performance requirements;

- maintaining records of every supply of the medical device;
- maintaining records of complaint reports and of actions taken in response to these reports;
- reporting defects in the medical device or adverse effects arising from the use thereof;
- reporting information that adversely affects the validity of any data furnished to the HSA relating to the quality, safety or efficacy of the medical device;
- notifying the HSA prior to any intended recall and furnishing a report of that recall; and
- notifying the HSA prior to carrying out any field-safety correction in relation to a medical device and furnishing a report thereof.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The Health Products (Medical Devices) Regulations 2010 and Health Products (Therapeutic Products) Regulations 2016 allow the disclosure of information relating to applications for registration. Trade secrets and information of commercial value that would be, or would be likely to be, diminished by disclosure are excluded from any such disclosure.

The HSA makes publicly available, on an online database, information submitted to the HSA in support of health product registration applications for registered health products. Information relating to pending applications is currently not publicly available.

Confidentiality

Disclosure of any confidential information obtained in the administration or enforcement of the HPA is generally prohibited, except with the consent of the person from whom the information was obtained. However, the HSA may disclose any confidential information relating to the quality, safety or efficacy of a therapeutic product or medical device if the disclosure is, in the HSA's opinion, necessary to protect the health or safety of members of the public or the disclosure is to a government body.

Additionally, confidential supporting information given in relation to an innovative therapeutic product application is protected by the HSA for a period of five years after the application is received by the HSA, subject to exceptions. An innovative therapeutic product application is a therapeutic product registration application of a substance that is an ingredient in the manufacture or preparation of the therapeutic product to which the application relates and that has not been referred to as an ingredient in the manufacture or preparation of any other therapeutic product in any previous application.

3.8 Rules Against Illegal Medicines and/or Medical Devices

It is an offence under the HPA to manufacture, supply or import:

- an adulterated health product;
- a counterfeit health product;
- a health product that has been tampered with; or
- an unwholesome health product.

If found dealing with any adulterated, counterfeit or tampered health products, offenders may be subject to a fine not exceeding SGD100,000 and/or imprisonment for up to three years.

If found dealing with any unwholesome health products, offenders may be subject to a fine not exceeding SGD50,000 and/or imprisonment for up to two years.

The HSA has also compiled a non-exhaustive public database of detected and tested illegal health products in Singapore.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Border measures are available under intellectual property law for proprietors or licensees of registered trade marks. See **10.1 Counterfeit Pharmaceuticals and Medical Devices** for more information.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Manufacturers of therapeutic products and medical devices are generally required to obtain a manufacturer's licence from the HSA. The manufacture of a health product means to make, fabricate, produce or process the health product, and includes:

- any process carried out in the course of so making, fabricating, producing or processing the health product; and
- the packaging and labelling of the health product before it is supplied.

Manufacture of Therapeutic Products

To obtain a manufacturer's licence, the HSA must be satisfied that the applicant is able to comply with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products in relation to the manufacture of the therapeutic product in question. The HSA enforces these standards by conducting pre-approval and routine GMP audits to ensure conformance to the standards. The details of the audit process may be found in the Regulatory Guidance published by the HSA on Audit and Licensing of Pharmaceutical Manufacturers in December 2017.

If the therapeutic products contain controlled drugs or psychotropic substances, the respective licences will also have to be obtained.

Manufacture of Medical Devices

Applicants for a manufacturer's licence are required to provide information on their Quality Management System through the submission of an ISO 13485 certificate, the scope of which must include distribution of the categories of medical devices and the activities performed, or a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only).

A manufacturer's licence is not required for certain activities, including:

- manufacture at the request of a qualified practitioner practising at the licensed healthcare institution intended for the use of a particular patient of the licensed healthcare institution;
- manufacture by way of fitting or adjusting the medical device to meet the requirements of the end user;
- manufacture to enable the continued used of the medical device by the end user;
- secondary assembly where the company holds an importer's licence or wholesaler's licence and is able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485;
- manufacture for use in clinical research;

- manufacture of laboratory-developed tests;
- manufacture of Class A medical devices for a charitable purpose; or
- manufacture of specified dental medical devices.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments are generally required to obtain a wholesaler's licence from the HSA in order to engage in the wholesale of therapeutic products and medical devices. The wholesale of a health product includes the supply of the product:

- to a person who obtains the product for the purposes of supplying it to another person;
- to a person as a commercial sample in the normal course of a lawful trade;
- to the Singapore government where it is required for the purposes of public service or use in connection with the exercise of any statutory power;
- to a person or an institution concerned with scientific education or research requiring the health product for such a purpose;
- to a person who requires the health product for the purpose of complying with any written law with respect to the medical treatment of individuals employed by that person in any business or trade carried out;
- to a person who requires to use the health product, other than by way of administration to one or more individuals, for the purpose of business or trade; or
- by export to a party outside Singapore.

Wholesale of Therapeutic Products

To obtain a wholesaler's licence for therapeutic products, the establishment must first be audited to comply with the HSA's Good Distribution Practice standards, which are set out in the HSA's Guidance Notes on Good Distribution Practice, revised in March 2021.

Where the establishment intends to export codeine cough preparations or therapeutic products containing psychotropic substances, additional approval must first be obtained from the HSA.

Certain activities may not require a licence if the exceptions available in the Health Products (Therapeutic Products) Regulations apply.

Wholesale of Medical Devices

To be granted a wholesaler's licence for medical devices, the establishment is generally required to submit to the HSA any of the following:

- an ISO 13485 certificate, the scope of which must include distribution of the categories of medical devices and the activities performed at the facility, where applicable;
- a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only); or
- a Good Distribution Practice Standard for Medical Devices certificate issued by a certification body accredited by the Singapore Accreditation Council or a declaration of exemption thereof.

A wholesaler's licence is not required if the wholesaling is for a clinical purpose in clinical research.

The period of validity of a wholesaler's licence depends on the respective terms and conditions of the licence.

5.2 Different Classifications Applicable to Pharmaceuticals

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List Medicines. Prescription Only Medicines may only be supplied by a registered medical practitioner or pharmacist in accordance with a prescription. Pharmacy Only Medicines may be supplied by a pharmacist without a prescription and General Sale List Medicines can be freely obtained from any retailer.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of therapeutic products and medical devices are governed by the Health Products (Therapeutic Products) Regulations 2016 and the Health Products (Medical Devices) Regulations 2010 respectively. Additionally, all goods imported into Singapore are regulated under the Customs Act 1960, the Goods and Services Tax Act 1993 and the Regulation of Imports and Exports Act 1995.

The Singapore Customs applies and enforces import regulations at the point of entry and thereafter, the regulations are applied and enforced by the HSA.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Only a qualified pharmacist or a person approved by the HSA may act as the importer of record of therapeutic products. There are no specific requirements regarding the importer of record of medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

An importer's licence is required to import therapeutic products and medical devices. In general, only registered therapeutic products and medical devices may be imported.

Some exemptions from holding an importer's licence include the following:

- a healthcare institution may import an unregistered therapeutic product without a licence, on a named-patient basis with the prior approval of the HSA;
- a person may import a therapeutic product that does not contain psychotropic substances or amounts of codeine and dextromethorphan greater than that specified by the HSA without a licence for personal use with the prior approval of the HSA;
- a licensed manufacturer may import any therapeutic product or medical device if required for the purpose of carrying out the licensed manufacture of a therapeutic product or another medical device;
- medical devices may be imported without a licence for personal use subject to conditions set out by the HSA or for use in a clinical purpose in any clinical research; and
- in light of the COVID-19 situation, the HSA announced that surgical masks, particulate respirators, thermometers and protective gear for medical professionals may be imported

without a licence (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Harmonised System (HS) codes are required in Singapore in the permit declaration of goods. They are used to determine the tariffs, controls and rule of origin applicable to the relevant goods. The HS code of goods used in Singapore is an eight-digit code known as the ASEAN Harmonised Tariff Nomenclature code. The HS codes are listed in the Singapore Trade Classification, Customs and Excise Duties published by the Singapore Customs.

6.5 Trade Blocs and Free Trade Agreements

Singapore is part of the ASEAN trade bloc and is a party to Free Trade Agreements with numerous jurisdictions containing provisions on trade/regulatory facilitation, including the European Union, China and New Zealand.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In general, prices for therapeutic products and medical devices are not regulated in Singapore. However, it should be noted that public healthcare institutions in Singapore procure medicinal products in bulk by way of tender contracts through Group Procurement Offices to achieve economies of scale.

7.2 Price Levels of Pharmaceutical or Medical Devices

Price levels of therapeutic products and medical devices generally do not depend on the prices for the same product in other countries, as prices are generally not regulated in Singapore. However, this may be a factor considered in negotiations with drug companies.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Singapore government provides direct subsidies of up to 75% for subsidised medications at specialist outpatient clinics and polyclinics. Patients receive drug subsidies and assistance based on their subsidy and means-test status, and the scheme under which the drug is covered (eg, Standard Drug List, Medication Assistance Fund).

The Singapore government has also implemented the Seniors' Mobility and Enabling Fund, which provides subsidies to offset the costs of assistive devices and home healthcare items.

Additionally, the government provides multiple tiers of financing for Singapore citizens and permanent residents for their healthcare expenditure, which includes a basic health insurance plan and a medical endowment fund.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The Agency for Care Effectiveness (ACE), under the purview of the MOH, is the national health technology assessment agency in Singapore. The ACE works to lower prices of health technologies, including drugs, medical devices and medical services, by evaluating their clinical and cost-effectiveness and negotiating with companies based on their proven outcomes. The

evaluations made by the ACE also guide policy-makers in making subsidy decisions. Summaries of the rationale for subsidy decisions, as well as the key clinical and economic evidence supporting such recommendations, are published by the ACE to increase the level of transparency in decision-making.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

There are generally no regulations restricting pharmaceutical spending with regard to prescriptions by physicians and dispensing by pharmacies. However, medical practitioners are increasingly reminded to prescribe medications which are the most cost-effective for patients.

8. Digital Healthcare

8.1 Rules for Medical Apps

There is currently no specific legislation governing mobile medical applications in Singapore. Mobile medical applications may be classified as telehealth products, which includes any equipment (eg, instruments, apparatus, machines or software, including mobile phone applications) that is involved in the provision of healthcare services over physically separate environments via info-communication technologies (including mobile technology). The HSA has clarified under the Regulatory Guideline for Telehealth Products that, generally, telehealth products may be considered medical devices if they are intended to be used for medical purposes such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process.

Telehealth products that are medical devices are subject to the following medical device regulatory controls:

- product registration;
- dealer's licence requirements; and
- post-market obligations.

Separately, there is an immediate registration pathway for Standalone Medical Mobile Applications (SaMD). SaMD refers to a software and/or mobile application that is intended to function by itself and is not intended to be used to control or affect the operation of other hardware medical devices. Where the SaMD has been approved by at least one of the HSA's reference agencies for the same intended use, the submission of a product registration application with the HSA grants it immediate market access.

On the other hand, where the application is for general wellness purposes, such as for fitness tracking, then it is not regulated as a medical device. However, owners of such applications should clearly state that the application is intended for use only for general wellbeing purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose.

8.2 Rules for Telemedicine

While there is no legislation governing telemedicine, the policy stance taken in Singapore is reflected in the National Telemedicine Guidelines issued by the MOH in January 2015 and the HSA Regulatory Guidelines for Telehealth Products, which were revised in April 2019.

Registered medical practitioners may provide medical attention through a mobile device in Singapore. Such services were previously regulated under the Licensing Experimentation and Adaptation Programme (LEAP), a regulatory sandbox initiative launched by the MOH in April 2018. The MOH has since closed the sandbox for telemedicine, in February 2021.

Under the new Healthcare Services Act 2020 (HCSA), independent doctors/dentists offering teleconsultations themselves or organisations which have set up clinical and operational governance for their doctors and/or dentists to provide teleconsultation will need to be licensed. As part of the transition to the licensing framework under the HCSA, the MOH has also introduced a voluntary listing of direct telemedicine service providers. It is expected that the HCSA will take effect fully by the end of 2023.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules governing the promotion and advertisement of therapeutic products and medical devices online. The general rules regarding the advertisement of therapeutic products and medical devices apply.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed and used in Singapore by both public and private healthcare providers. Electronic prescriptions are not specifically regulated and are subject to the general legislation governing the collection of personal data and medical records under the PDPA and various healthcare-related legislation.

8.5 Online Sales of Medicines and Medical Devices

General Sale List Medicines may be sold online, subject to certain regulatory requirements. They are set out in the Medicines (General Sale List) Order 2016.

On 5 May 2020, the HSA introduced the roll-out of the e-pharmacy service. HSA-licensed retail pharmacies and wholesalers in Singapore with a good track record in handling Prescription Only Medicines and Pharmacy Only Medicines may apply for a retail pharmacy licence, or include such services in their existing retail pharmacy licence if they intend to carry out e-pharmacy operations.

In general, Class A medical devices and selected categories of unregistered Class B, C and D medical devices may be sold online.

8.6 Electronic Health Records

Electronic health records are currently not specifically regulated in Singapore and are subject to the general legislation governing the collection of personal data and medical records under the PDPA and various healthcare-related legislations.

Health-related information is not regulated as sensitive data, although the PDPC, which administers the PDPA, has taken the position in several enforcement decisions that medical data is more sensitive in nature and require a higher standard of protection.

Cloud Platforms

While there are no specific requirements for the storage of information on cloud platforms, the PDPC has published the Guide to Data Protection Practices for ICT Systems, to provide guidance for organisations using cloud platforms. Sensitive data of patients may be transferred and stored on cloud platforms. Where the cloud platforms are based outside Singapore, the PDPA requires organisations to ensure that the transferred personal data is accorded a standard of protection that is comparable with that of the PDPA.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Singapore, patents are regulated under the Patents Act 1994 (Patents Act) and its various subsidiary legislations, which include the Patents Rules. Therapeutic products are commonly patented in Singapore and there are generally no patentability requirements specific to therapeutic products or medical devices.

Issues

The Court of Appeal in Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd [2017] SGCA 45 has recently raised the issue of whether Swiss-type claims are necessary in Singapore to frame second and subsequent medical-use claims, given that purpose-limited product claims may be sufficient to protect such claims. While the Intellectual Property Office of Singapore continues to take the approach that Swiss-type claims are valid, it is not certain if this approach will change in the future to reflect the Court of Appeal's views.

As software is not patentable under the Singapore patent regime, medical devices consisting exclusively of software may not receive patent protection.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are patentable in so far as they are claimed in the form of "Swiss-type" claims. Additionally, second medical-use claims can only derive novelty from their intended use where the use is a method of treatment of the human or animal body by surgery or therapy or a method of diagnosis practised on the human or animal body. It should be noted that the Singapore patents' registry practice for using the Swiss-type claim format differs from that of the United Kingdom and Europe, which are contracting members of the Europe Patent Convention 2000.

Patentability of Claims

Second medical-use claims are typically used to protect the use of a substance or composition in the treatment of a different disease.

They are also allowable for new dosage regimes, on the condition that the claimed dosage regime is novel and inventive. However, the patents' registry recognises that, in most cases, it is generally presumed that new dosage regimes lack inventiveness, unless there is a clear technical prejudice pointing away from the claimed dosage regime.

Depending on the factual scenario, second medical-use claims may rely solely on the patient population to be treated to fulfil the requirements of novelty and inventive step, despite known associations of the claimed product and the disease to be treated. For such claims to be patentable, the new patient group must consist of a distinctly different patient population from those treated in the prior art.

Infringement

It is uncertain how the Singapore courts will apply the legislation on infringement to second and subsequent patents as, at the time of writing, there are no cases in Singapore on the infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

Under the Patents Act, the proprietor of a patent can make an application to the patents' registry to extend the terms of the patent on any of the following grounds:

- where there was an unreasonable delay by the patents' registry in granting the patent;
- where the patent was granted on the basis of any prescribed documents relating to a corresponding application or related national phase application, and there was an unreasonable delay in the issue of the corresponding patent or related national phase patent, and the patent office that granted the corresponding patent or related national phase patent has extended the term of the corresponding patent or related national phase patent on the basis of that delay; or
- where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, and there was an unreasonable curtailment of the opportunity to exploit the patent, due to the process of obtaining marketing approval for the first pharmaceutical product, which uses the substance as an active ingredient, and the patent term has not previously been extended on this ground.

Further guidance on how the aforementioned grounds are applied is set out in the Patent Rules.

Patent-term extensions may not be challenged by third parties.

9.4 Pharmaceutical or Medical Device Patent Infringement

When a person carries out any of the following acts in Singapore in relation to the invention of a patent without the consent of the proprietor's consent, it will constitute a patent infringement:

- where the invention is a product, the person makes, disposes of, offers to dispose of, uses or imports the product, or keeps it, whether for disposal or otherwise;
- where the invention is a process, he or she uses the process or offers it for use in Singapore when he or she knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent; and
- where the invention is a process, he or she disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product, whether for disposal or otherwise.

An application for marketing authorisation, in itself, will not infringe a patent. However, the HSA may refuse the application if the doing of the act for which the marketing authorisation is sought will infringe on an existing patent.

Only actual infringement is actionable under the Patents Act and a person aggrieved by groundless threats of infringement proceedings may bring an action against the person making the threats.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Relevant to pharmaceuticals and medical devices, it is a defence to patent infringement if the act:

- is done for experimental purposes relating to the subject-matter of the invention;

- consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;
- consists of the doing of any infringing act in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not made, used or sold in Singapore or exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; or
- consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, or the use of that product by or on that patient, where that product is required for use by or on that patient, the relevant authority has granted approval specifically for the import of that product for use by or on that patient, and that product was produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by him or her.

Compulsory Licence

An interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice. The court may grant the licence if:

- there is a market for the patented invention in Singapore;
- that market is not being supplied on reasonable terms; and
- the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented invention, whether directly or through a licensee, on reasonable terms.

9.6 Proceedings for Patent Infringement

The proprietor of the patent may bring proceedings for patent infringement in court and make a claim for any of the following remedies:

- an injunction restraining the defendant from any apprehended act of infringement;
- an order for the defendant to deliver up or destroy any patented product in relation to which the patent is infringed, or any article in which that product is inextricably comprised, or any material, and implement, the predominant use of which has been in the creation of the infringing product;
- damages in respect of the infringement;
- an account of the profits derived by the defendant from the infringement; and/or
- a declaration that the patent is valid and has been infringed by the defendant.

The proprietor of a patent and any other person may choose to refer to the Registrar of Patents to determine whether the other person has infringed the patent, upon mutual agreement.

The procedure for regular court proceedings apply to a patent infringement action in court. Typically, the plaintiff commences an action by filing an originating claim and serving it on the defendant. Parties will then file their respective pleadings and exchange their affidavits before setting down for trial. Patent infringement actions are heard in the General Division of the High Court and any appeals are made directly to the Court of Appeal. Separate procedures apply for references to the Registrar of Patents.

Invalidity is an available defence to patent infringement and can be invoked during the infringement proceedings at the pleadings stage.

9.7 Procedures Available to a Generic Entrant

In general, when processing applications for therapeutic product registration, the HSA will take into account patent protection.

Before making an application for a generic market entry, the applicant must first declare the existence of any patent in force in respect of the therapeutic product, and whether the applicant is the proprietor of the patent. Where a patent is in force in respect of the therapeutic product and the potential applicant is not the proprietor, the potential applicant should first obtain the consent of the patent proprietor to make the application.

Where an applicant takes the position that the patent is invalid or will not be infringed by the generic market entry, the HSA may require the applicant to serve on the proprietor a notice in the form specified by the HSA, declaring that the applicant has made an application in respect of the proprietor's patent. If the proprietor does not make a court application to restrain the generic market entry or seek a declaration that the patent is valid or will be infringed by the generic market entry within 45 days of receiving the notice, the HSA may proceed with the generic market entry application. If the proprietor is successful in its court application, a 30-month moratorium will be granted, during which the HSA will not grant marketing approval for the generic market entry.

Where the patent proprietor misses the deadline to make a court application and the applicant successfully registers the therapeutic product, the proprietor may still make an application to the HSA to cancel the registration if the proprietor has obtained a determination that:

- the doing of an act authorised by the registration infringes a patent; or
- the initial declaration made by the applicant contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application.

This was confirmed in the recent Court of Appeal case Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd [2019] SGCA 31.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

It is an offence under the Trade Marks Act 1998 to counterfeit a trade mark, falsely apply a registered trade mark to goods or services, or do any of the following in relation to goods to which a registered trade mark is falsely applied:

- import into Singapore for the purpose of trade or manufacture;
- sell or offer or expose for sale; or
- possess for the purposes of trade or manufacture.

Seizure of Infringing Goods

The proprietor or licensee of a registered trade mark in Singapore who expects infringing goods to be imported or exported may request the Singapore Customs to seize the goods by giving written notice and sufficient information to identify the goods, enable the Singapore Customs to ascertain when and where the goods are expected to be imported or exported, and satisfy the Singapore Customs that the goods are infringing goods. The requestor may also be required to

provide security for the liability or expense of seizing the goods, and their subsequent storage and disposal.

At any time after the goods have been seized, the Singapore Customs may give the requestor the name and contact details of any person connected with the import or proposed export of the seized goods and permit the requestor to inspect the seized goods. The seized goods will be released to the importer or exporter if the requestor has not instituted an infringement action in relation to the goods before the expiry of the retention period.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for therapeutic products and medical devices will not be registered if they contain or consist of their international non-proprietary name without being accompanied by any other distinctive matter due to their descriptiveness and lack of distinctive character. There are no restrictions under trade mark law to import and distribute non-counterfeit, genuine pharmaceutical or medical device products.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

While the concept of trade dress is not expressly recognised in Singapore, it is possible to register the design of therapeutic products and medical devices and their packaging, and any such registered designs can receive protection for up to 15 years. Registrable designs generally refer to the features of shape, configuration, colours, pattern or ornament applied to any article or non-physical product that give that article or non-physical product its appearance, but do not include methods or principles of construction and designs that are solely functional.

The design and packaging of therapeutic products and medical devices, including their three-dimensional shape, may also potentially be registered as trade marks or receive protection under the common law tort of passing off.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Safety and efficacy data generated in support of an innovative therapeutic product registration cannot be relied on by a subsequent similar therapeutic product to obtain registration for a period of five years after the date of the registration of the first therapeutic product. Chemical drugs and biologics are not treated differently.

There is no such registration exclusivity period for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Waiver of Import Licence Requirements for Masks, Thermometers, etc

On 31 January 2020, an exemption order was effected, following which the HSA waived the requirement for import licences for surgical masks, particulate respirators (eg, N95 masks), thermometers and protective gear for medical professionals such as gloves. Commercial importers were still required to file online notifications. However, the 2020 exemption order has been revoked from 1 September 2022 and all standard regulatory controls are now back in force.

Provisional Authorisations for COVID-19 Diagnostic Tests

As a temporary measure for the timely detection of COVID-19, the HSA had previously set up an expedited provisional authorisation process for COVID-19 diagnostic tests. However, the HSA is no longer accepting any such applications. With effect from 1 January 2022, COVID-19 test kits must undergo a fully fledged registration with the HSA, or be authorised under the Pandemic Special Access Route (PSAR), in order to be supplied in Singapore. It is also noted that from 15 March 2022, applicants who wish to supply COVID-19 antigen rapid self-test kits which use nasal swab samples only will no longer be eligible for PSAR submission and will have to apply for the full-fledged registration with HSA.

Regulatory Flexibility in Relation to Respiratory Devices

On 1 April 2020, the HSA announced a position of regulatory flexibility towards respiratory devices in view of the COVID-19 pandemic. The regulatory measures had:

- allowed the safe use of HSA-registered anaesthesia machines and positive airway pressure devices as emergency ventilators without approval;
- allowed upgrades or modifications to HSA-registered ventilators without approval as long as the changes do not affect registered performance specifications, the devices continue to meet the safety and performance requirements and the changes are notified on a six-monthly basis; and
- advised companies seeking to supply unregistered ventilators to meet local clinical needs.

However, these regulatory measures have since been discontinued. All standard regulatory controls are now back in force.

Provisional Authorisations for Respirator Decontamination Devices

On 11 June 2020, the HSA announced a provisional authorisation pathway for medical devices intended for decontaminating used respirators, in view of the increasing demand for respirators and the global supply constraints during the COVID-19 situation. However, this regulatory measure has since been discontinued. All standard regulatory controls are now back in force.

11.2 Special Measures Relating to Clinical Trials

As of February 2022, the HSA has not issued any special regulations in relation to clinical trials of COVID-19 treatments and vaccines specifically.

HSA Guidance on the Conduct of Clinical Trials

On 27 March 2020, the HSA issued a guidance on the conduct of clinical trials in relation to the COVID-19 situation, which was subsequently revised on 29 July 2020. The potential contingency measures discussed include:

- remote study visits;
- direct-to-patient services for investigational product supply;
- obtaining informed consent remotely; and
- sponsor site-monitoring visits.

Recommendations include:

- ensuring proper documentation of reasons for implementing any contingency measure and performing an impact assessment of the implemented measures on trial-participant safety, data credibility and trial integrity;
- engaging in early consultations with sponsors, investigators, IRBs and the HSA; and
- including in the Clinical Study Report the impact of COVID-19 and contingency meas-

ures on the safety and efficacy data for the clinical trial.

The guidance was revised again on 26 August 2022. A notable change from this latest revision is that the HSA will now prioritise clinical trial applications that are made to address the needs of public health emergencies such as COVID-19. The HSA may also allow for a shortened review time where appropriate. In a similar vein, the HSA will also prioritise requests made by sponsors and investigators for rapid scientific and regulatory advice on the regulatory requirements for the development of novel vaccines and therapeutics to address the public health emergency.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

New Pandemic Special Access Route (PSAR)

In 2020, the HSA introduced the PSAR, which facilitates early access to novel vaccines, medicines and medical devices which the government designates as being required for a pandemic by granting such products an interim authorisation, exempting them from the registration and licensing requirements.

The HSA will consider interim authorisation if there is reasonable quality, safety and efficacy (QSE) data suggesting that the potential benefits outweigh the known risks and there is continuing QSE data generated from ongoing studies to support the eventual transition of the interim authorisation to full registration. The HSA may cancel an interim authorisation if the evolving data suggests that the benefits no longer outweigh the risks, or if the emergency ceases.

The PSAR allows vaccines, medicines and medical devices to be evaluated based on data submitted on a rolling basis instead of full data sets, giving the HSA more time to review submitted data while companies to continue with clinical trials and development. Companies will be required to file an application to transition the status of the health product from PSAR interim authorisation to full registration, once sufficient data is available for full registration.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Other than the measures targeted at medical devices (such as diagnostic tests) for addressing COVID-19 specifically (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**), no other simplifications or flexibilities in certification requirements were formally introduced by the HSA as a result of COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Waivers were granted for import licences on masks, respirators, thermometers and protective gear, although they are now discontinued (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

The PSAR (discussed in **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**) allows, subject to conditions, the interim authorisation of vaccines, medicines and medical devices designated by the government to be exempt from the prohibition against importation without the required importer's licences and product registrations.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Financial Support for Telemedicine

On 3 April 2020, to support the safe-distancing measures to minimise activities and to reduce the risk of local transmission of COVID-19, the

Ministry of Health introduced a time-limited initiative to allow the tapping of funds from the Community Health Assist Scheme (a government scheme which provides subsidies for medical care at general practitioner clinics) and Medisave accounts (the national savings scheme which sets aside part of a person's income for medical expenses) for follow-up video consultations by approved healthcare institutions for certain chronic conditions. The list of eligible chronic conditions was subsequently expanded from seven to 20.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Power to Issue Compulsory Licences

There have been no announcements by the government regarding the compulsory licensing of COVID-19 treatments or vaccines. To the best of the available knowledge, the government has never exercised these powers.

Under the Patents Act, the government (and any authorised party) may do anything in relation to a patented invention for a public non-commercial purpose or, for or during a national emergency or other circumstances of extreme urgency, without amounting to an infringement of the patent.

In particular, the government may import any health product and do anything in relation to any imported health product that is patented, upon giving the Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights the required notification.

Restrictions and Obligations of the Power to Issue a Compulsory Licence

The government can only issue licences which are non-exclusive and non-assignable (except where the assignment is in connection with the goodwill of the business in which the patented invention is used).

The government's right to use a patented invention is similarly non-exclusive, non-assignable and limited to the supply of the patented invention, predominantly in Singapore.

The government must inform the patentee promptly of its use of the patented invention and must pay the remuneration that has been agreed, or in default of agreement, remuneration as determined by the Singapore courts. There is no requirement to pay remuneration if the patentee has already received or will receive some other remuneration.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

As far as is known, no information is publicly available as to whether liability exemptions or indemnities are applicable for COVID-19 vaccines or treatments.

Notably, the government has introduced the Vaccine Injury Financial Assistance Programme to provide a one-time goodwill financial assistance to persons who experience serious side effects from the COVID-19 vaccines. To be eligible, the individual must have received his or her COVID-19 vaccine under the National Vaccination Programme and the side effect experienced must be assessed by a doctor to be related to the individual's COVID-19 vaccination.

11.9 Requisition or Conversion of Manufacturing Sites

As far as is known, no manufacturing sites were requisitioned or converted due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

No systemic changes were made to the system of public procurement of medicines and medical devices due to COVID-19. However, according to a statement released by the Second Minister for Finance, emergency procurement procedures were invoked at the early stages of the pandemic to allow the government to source and secure essential medical supplies quickly. Instead of open sourcing, the government contracted directly with suppliers with the necessary expertise and resources and who were best able to meet the requirements within the shortest timeframe possible.

The Minister signalled that, as the situation improves and the urgency to secure supplies abates, a larger proportion of procurement will be done through the default process of open sourcing.

SOUTH AFRICA

Law and Practice

Contributed by:
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Spoor & Fisher

Contents

Spoor & Fisher is a leading intellectual property firm that specialises in intellectual property (IP) law. The firm was established in 1920 and has since grown to become one of the largest and most respected IP firms in Africa. It provides a comprehensive range of legal services related to patents, trademarks, copyright, IP litigation, commercial IP transactions and IP portfolio management. The firm has a team of experienced attorneys, patent agents and technical specialists who serve clients in various industries, including pharmaceuticals, biotechnology, telecommunications and consumer goods. Spoor & Fisher has a strong reputation for excellence in the IP field and is consistently ranked among the top IP firms in South Africa and Africa as a whole. The firm has also been recognised internationally for its work in IP, receiving numerous awards and accolades over the years.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Regulation of the South African Pharmaceutical sector is primarily governed by The Medicines and Related Substances Act 101 of 1965 ("Medicines Act"), and the published Regulations thereto. These include the General Regulations to the Medicines and Related Substances Act, published under Government Notice 859 in Government Gazette 41064 of 25 August 2017 ("General Regulations"), which deal with general issues such as the registration and supply of medicines and requirements for permits and authorisations, including for conducting clinical trials. Regulations dealing with specific issues include, for example: (i) Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 ("Transparent Pricing Regulations"); (ii) Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs), published under Government Notice 1515 in Government Gazette 40480 of 9 December 2016 ("Medical Devices Regulations"); and (iii) Regulations Relating to the Period and Manner of Appeal Against Decisions of the Medicines Control Council, published under Government Notice R906 in Government Gazette 14826 of 28 May 1993 ("Appeal Regulations").

In addition, the Minister of Health is enabled to publish Notices in the Government Gazette relating to administrative aspects in terms of the Medicines Act and several such Notices have been published.

The regulatory body charged with administering the Medicines Act is the South African Health Products Regulatory Authority (SAHPRA), which took over administration of the Medicines Act from its predecessor, the Medicines Control Council (MCC). Both the MCC and the SAHPRA have issued several guidelines relating to various aspects of registration of medicines.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative and Judicial Review

Under generally applicable administrative review provisions, an administrative action (a decision

or omission in making a decision by a person exercising a public power or function) is subject to review under certain circumstances. The grounds for review include:

- the administrator was not authorised;
- a compulsory and material requirement was not complied with;
- the action was procedurally unfair;
- the action was materially influenced by an error in law;
- the action was taken for an ulterior purpose; or
- the action was unlawful or unconstitutional.

Challenging Pharmaceutical and Medical Device Regulators

A decision by the Director-General under the Medicines Act may be challenged by an aggrieved person by making written representations to the Minister within 30 days.

Any decision by the SAHPRA may be appealed on notice to the CEO of the SAHPRA within 30 days. The CEO must attempt to resolve the matter, failing which an appeal committee will be formed. Any decision by the appeal committee is subject to judicial review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The Medicines Act provides for the regulation of pharmaceuticals, medicines, medical devices and IVDs, complementary medicines and veterinary medicines. In terms of the General Regulations, medicines, including veterinary and complementary medicines, are classified as Category A, B, C or D medicines. Medical devices are similarly classified as Class A, B, C or D devices based on an assessment of the manufacturer's or distributor's intended use, the level of risk to users, the degree of invasiveness, and the duration of use and exposure. Although differing levels of supporting data will be required, each of the above-mentioned categories is regulated, in terms of the Medicines Act, by the SAHPRA. The SAHPRA has issued guideline documents for each category that details the approach to be followed and the information required in the registration process. The Medicines Act and regulations do not make special provision for biologics, but separate guideline documents have been issued by the SAHPRA.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Non-clinical studies and clinical trials are provided for under the provisions relating to access to unregistered medicines in the Medicines Act. In terms of these provisions, the SAHPRA may authorise the sale of an unregistered medicine to a specific person or institution for the purpose of conducting clinical trials. The General Regulations to the Medicines Act set out the specific requirements for conducting clinical trials and investigations for medicines. In terms of these requirements, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee, together with the stipulated information.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In terms of the requirements set out in the Medicines Act and the General Regulations, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee and stipulated information. There are set dates approximately every six weeks for submission of clinical trial applications to the SAHPRA, with

the deadline published on its website. Once the clinical trial application is received it is screened and allocated to an evaluator within two weeks of the submission date and either rejected for being deficient or accepted for review, whereupon the evaluator reviews the study and submits its report to the clinical trials committee. Approximately six to eight weeks after the submission date, the clinical trials committee meets to discuss the report and provide its recommendation. Thereafter, the recommendation is communicated to the applicant, within ten weeks of the submission due date. In cases where the investigational product is unfamiliar, the submission may be referred to external reviewers or other committees of the SAHPRA for input and the turnaround time may be prolonged.

2.3 Public Availability of the Conduct of a Clinical Trial

It is a requirement that all new clinical trials conducted in South Africa be registered in the South African National Clinical Trials Register (SANCTR), an official registry and member of the World Health Organisation (WHO) Network of Primary Registers. The SANCTR provides a publicly searchable database including updated information on clinical trials on human participants conducted in South Africa. This information includes the purpose of the trial, details of who can participate, where the trial is located, and contact details.

The database ensures that the WHO-stipulated minimum dataset for registered trials is publicly and freely available to all users of the registry. It includes information on the questions being investigated, findings of studies, locations, funders, funding and research institutions involved. Further, principal investigators are obliged to ensure the reporting of the trial and its findings.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials, including for recruiting or monitoring purposes, provided that the data integrity and accuracy is maintained at all times.

2.5 Use of Data Resulting From the Clinical Trials

The Protection of Personal Information Act, No 4 of 2013 (POPIA) commenced on 1 July 2020, with a one-year grace period to comply. POPIA was enacted to promote the protection of personal information processed by public and private bodies and to establish minimum requirements for the processing of personal information. The Academy of Science of South Africa has published a draft POPIA Code of Conduct for Research (POPIA Research Code) for public comment. However, POPIA and the POPIA Research Code only apply to identifiable personal information, and data is not considered personal data if it has been permanently de-identified or anonymised. Thus, clinical trial data is not considered personal, provided it is permanently anonymised and can be transferred.

2.6 Databases Containing Personal or Sensitive Data

Any database containing personal or sensitive data, that is data that is not permanently anonymised, would be subject to the requirements of POPIA. In terms of POPIA, such data may only be processed in a fair and lawful manner and only with the consent of the data subject. Such data may only be processed for specific, explicitly defined and legitimate reasons and may not be processed for a secondary purpose unless that processing is compatible with the original purpose and with the consent of the subject.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The assessment process and the related criteria for determining whether or not a product should be classified as a pharmaceutical or as a medical device should start with the definitions of "medicine", "medical device", and "IVD", provided in the Act. Where a reagent is used in vitro, alone or in combination, the product will be classified as a device. The regulations also deal with a "combination device" which is a device that incorporates a substance, which if used separately, would be considered a medicine. An application for registration of a medical device must provide the particulars of the scheduled substance or biological substances contained therein, which substances will require a separate registration as a medicine. Application may also be made to transfer information pertaining to a medicine to the register for medical devices or IVDs.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

For biologic medicinal products, there are specific obligations that must be fulfilled in South Africa for granting a marketing authorisation. The SAHPRA has set out specific guidelines and requirements to ensure that biologic medicinal products are safe, effective and of high quality. These obligations include:

- conducting clinical trials;
- providing scientific data to demonstrate safety and efficacy;
- providing information on the manufacturing process and quality control measures;
- conducting post-market surveillance;
- complying with labelling and packaging requirements;
- providing updates to the SAHPRA regarding any changes to the manufacturing process; and
- complying with all relevant regulations and guidelines.

It is worth noting that the authorisation process for biologic medicinal products may be more complex and time-consuming than for other medicinal products due to the nature of these products and the need for extensive data on their safety and efficacy.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The period of validity of marketing authorisation for pharmaceuticals and medical devices varies depending on the product and its characteristics. The initial period of validity for a marketing authorisation is ordinarily five years, but this period can be shorter or longer depending on the specific product and its intended use.

Marketing authorisation can be renewed for a further period of five years if the product continues to meet the necessary requirements for safety, efficacy and quality.

The SAHPRA can revoke a marketing authorisation:

- if the product is found to be unsafe, ineffective or of poor quality;
- if the holder of the authorisation fails to comply with the conditions of the authorisation; or
- if it fails to place the product on the market within a certain time frame.

The SAHPRA can also vary, suspend or withdraw a marketing authorisation under certain circumstances, such as if new safety concerns arise or if the product is found to be in violation of any regulatory requirements. The procedures for varying, suspending or withdrawing a marketing authorisation are outlined in the Medicines and Related Substances Act (Act 101 of 1965) and its associated guidelines.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

The procedure for obtaining a marketing authorisation for pharmaceuticals and medical devices in South Africa involves submitting an application to the SAHPRA.

The application must include:

- particulars of the applicant and the prospective holder of the certificate of registration;
- data on the safety, efficacy and quality of the product;
- a copy of the manufacturing licence;
- a copy of the current GMP certificate from the regulatory authority in the country where the product is manufactured; and
- details of the labelling, and packaging.

The application is evaluated by the SAHPRA, and if all requirements are met, the marketing authorisation is granted.

The procedure for variation of a marketing authorisation involves submitting a variation application to the SAHPRA. The variation application should include all relevant data and information related to the proposed changes, such as changes in the therapeutic indication, formulation, posology, patient population, packaging and/or labelling. The SAHPRA will evaluate the variation application and determine if the changes are acceptable and whether the marketing authorisation can be amended.

It is permissible to transfer a marketing authorisation from one marketing authorisation holder to another. The transfer process involves submitting a variation application to the SAHPRA. The new marketing authorisation holder must meet all the requirements and obligations set out in the original marketing authorisation.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

In terms of Section 21 of the Medicines Act, the SAHPRA may authorise anyone to sell a specified quantity of an unregistered medicine, medical device or in vitro diagnostic to a specified person or institution for a specified period. Such approval may be withdrawn at any time by the SAHPRA. This section governs both clinical trials, as well as named-patient or compassionate use programmes.

Such application can be made online and must be made by a treating medical practitioner, who must provide details of the pharmaceutical or medical device, evidence of compliance with good manufacturing standards and reasons why a registered medicine cannot be used. Such authorisation typically lasts for six months, following which re-authorisation must be requested.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The holder of a marketing authorisation for a pharmaceutical or medical device is required to comply with ongoing obligations, including pharmacovigilance and technovigilance activi-

ties. These obligations entail monitoring, detection, assessment, understanding and prevention of adverse effects or incidents associated with the use of the product.

The holder of the marketing authorisation is required to report any suspected adverse reactions or incidents to the SAHPRA as per the prescribed requirements. The SAHPRA may also impose post-marketing obligations, including Phase IV trials, as part of the marketing authorisation, based on the evaluation of the risk-benefit profile of the product.

The holder must comply with these obligations and submit the required data to the SAHPRA within the specified timelines. Failure to comply with these obligations may result in sanctions, including revocation of the marketing authorisation.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties can access limited information regarding pending applications for marketing authorisation for pharmaceuticals and medical devices through the SAHPRA website. The information available includes the name of the product, the applicant's name, and the date the application was received. However, detailed information, such as clinical trial data or proprietary information, is not publicly available during the application process.

Once a marketing authorisation has been granted or refused, the decision and the reasons for it are made public on the SAHPRA website. Third parties can also request access to non-confidential portions of the marketing authorisation application through a formal request to the SAHPRA.

Commercially confidential information and personal information are protected under South African law. The SAHPRA may redact or withhold information that is considered commercially confidential or sensitive personal information, such as patient data or trade secrets, from the publicly available information. However, the SAHPRA is required to balance the public interest in accessing information against the protection of commercial or personal information.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Medicines Act and Health Act provide for measures against contraventions in respect of medicines and medical devices. Inspectors under the Medicines Act may enter a premises relating to medicines or medical devices at reasonable times, and may inspect or seize such medicines or devices as evidence of contravention, or take samples necessary for further testing. Officials under the Health Act may similarly enter health establishments to ensure compliance and obtain evidence of non-compliance, including search and seizure with a warrant. Various sanctions for contravention are available under the two Acts, including:

- fines;
- imprisonment;
- written warnings;
- revocation of compliance certificates; or
- referral to the National Prosecuting Authority.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Counterfeit goods, especially in relation to pharmaceutical and medical devices, represent a dire societal epidemic considering that their utility, as substandard goods, bears a strong possibility of adversely impacting the health and

quality of healthcare treatment received by the general population. In terms of the counterfeit pharmaceuticals, most of these contain inter alia no active/substandard/illegal ingredients or incorrect dosages and their ingestion – especially where necessary for the management of life-threatening diseases – can prove fatal to the end-user. In relation to medical devices, the same concerns apply: the lower quality of equipment that is used when handling someone's life is of great concern because medical devices, in their ordinary sense, will not work as intended or cost someone their life due to inadequate use/functionality. Whilst they have gained popularity for their low cost amongst the less affluent groups, it nonetheless poses a danger to enable these goods to enter the South African channels of commerce.

One of the main purposes of the Counterfeit Goods Act is to prevent the release of counterfeit goods into the channels of commerce in South Africa. The Department of Customs and Excise ("Customs") is primarily responsible for monitoring the country's borders, including its ports of entry. To enable Customs to detain and seize any suspected counterfeit goods that are imported into South Africa, it is necessary for the owner of trade marks and/or copyright to file an application with the Commissioner for the South African Revenue Service (the "Commissioner") requesting such detention and seizure. This is governed by Section 15 of the Counterfeit Goods Act and the application filed is commonly referred to as "the Section 15 application".

In order to improve the success rate of counterfeit goods identification, sufficient training is required on how to identify them. Training of customs officials to maintain up-to-date knowledge of how counterfeiters are counterfeiting medical devices and pharmaceuticals is crucial. To promote this, brand awareness seminars and training sessions are necessary and, in conjunction with the experts from the brand owners, Customs officials can understand the intricacies of the goods and differentiate between that which is genuine and that which is not. Through this, Customs officials are given a basis of knowledge in what to immediately hone in on and look for when examining cargo.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Manufacturing plants of pharmaceutical products and medical devices require a licence in terms of Section 22(C)(1)(b) of the Act. The application for registration as a manufacturer is made to the SAHPRA on the relevant Form, supported by the documentary proof specified in the general regulations. A licensed manufacturer may validly conduct all operations including purchasing, processing, production, packaging, releasing, and storage and shipment. An annual renewal fee is payable and the licence is valid for a period of five years from the date of issue. In addition to the SAHPRA manufacturer's licence, an application will also require a site licence from the Department of Health and registration as a manufacturing pharmacy with the South African Pharmacy Council.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in wholesale of pharmaceutical and medical devices also require a licence in terms of Section 22(C)(1)(b) of the Medicines Act. As with the manufacturer's licence, application for registration as a wholesaler is made to the SAHPRA on the relevant form, supported by the documentary proof specified in the General Regulations. In terms of the Regulations, a "wholesaler" is a person or entity that holds, stores, delivers or purchases medicines or scheduled substances from a manufacturer and sells into the retail sector or to any person that may lawfully possess such substances. The licence is valid for a period of five years provided annual renewal fees are paid.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceutical products are scheduled as one of Schedule 0–8 for the purposes of sale, possession or manufacture. A consolidated list of the scheduled substances is available from the SAHPRA.

Schedule 0 substances may be sold in an open shop. Schedule 1 substances may only be sold without a prescription by a certain list of qualified individuals, and may not be sold to persons under the age of 12 years except where certain requirements are met. Schedule 2 substances may be sold without a prescription. The sale of Schedule 2, 3, or 4 substances may be repeated if indicated on the prescription, but not for longer than six months. Schedule 5 substances may only be prescribed for longer than six months if certain conditions are met. The sale of Schedule 6 substances may only be repeated on a new prescription and may only be sold for a course of not more than 30 days. Schedule 5 and 6 substances may be sold for use for a period of 48 hours in emergency situations on a verbal instruction, provided a written prescription is issued with 72 hours.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The importation and exportation of pharmaceuticals and medical devices in South Africa are governed by various laws and regulations, including the Medicines and Related Substances Act, the Customs and Excise Act, and the International Trade Administration Act.

The SAHPRA is the authority responsible for regulating the importation of pharmaceuticals and medical devices into South Africa. The SAHPRA applies import regulations at the point of entry to ensure that imported products comply with South African regulatory requirements.

Other entities that are involved in enforcing import regulations in South Africa include the South African Revenue Service (SARS), which is responsible for collecting customs duties, and the Department of Health, which has the power to prohibit the importation of certain pharmaceuticals and medical devices that do not meet South African regulatory requirements.

In addition to these entities, the National Regulator for Compulsory Specifications (NRCS) is responsible for enforcing technical regulations

relating to the safety, health and environmental protection of products imported into South Africa, including medical devices. The NRCS ensures that imported products comply with relevant South African technical regulations and standards.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Any person who is a resident of South Africa, or who has a physical presence in the country, may act as the importer of record for pharmaceuticals and medical devices.

There are, however, specific requirements that must be met by the importer of record. The importer must be registered with the South African Revenue Service (SARS) as an importer and must hold a valid import licence issued by the Department of Health. The importer must also comply with all applicable regulations, including those related to labelling, packaging and storage of the products.

In addition, the importer must be able to demonstrate that the products being imported comply with all applicable regulations, including those related to safety, efficacy and quality.

It is important to note that the importer of record is responsible for ensuring that the products being imported comply with all applicable regulations and for any costs or liabilities associated with non-compliance.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importation of pharmaceuticals and medical devices into South Africa is subject to prior authorisation, and the importer must hold a valid import permit issued by the SAHPRA. Without this permit, the importation of pharmaceuticals and medical devices is prohibited.

There are however certain exemptions available in terms of the Medicines and Related Substances Act (Act 101 of 1965) and the Medical Device Regulations of 2017, which provide relief from the requirement for prior authorisation for the importation of pharmaceuticals and medical devices.

Some of these exemptions include:

- personal use exemptions;
- emergency use exemptions;
- special use exemptions;
- low-risk medical device exemptions; and
- in vitro diagnostic medical device exemptions.

It is important to note that each exemption has its own specific criteria, and the importer must comply with all applicable requirements to qualify for the exemption.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In South Africa, non-tariff regulations and restrictions (NTRs) on the importation of pharmaceuticals and medical devices are imposed by the Department of Health (DOH) and the SAHPRA under the authority of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965). The NTRs are mainly based on the regulatory category of the products and are aimed at ensuring that imported pharmaceuticals and medical devices comply with the applicable standards, specifications and regulations.

Import permits and licences are generally required for the importation of pharmaceuticals and medical devices, depending on their regu-

latory category. The specific types of products subject to NTRs upon importation are listed in the Schedules to the Medicines and Related Substances Act, 1965, which include the Schedules of Medicines, Scheduled Substances, and Scheduled Devices. The Schedules categorise products according to their regulatory requirements, including registration, notification or exemption, and the importation requirements for each category are set out in the relevant regulations.

6.5 Trade Blocs and Free Trade Agreements

South Africa is a member of several trade bloc or free trade agreements that include provisions relating to the trade in pharmaceuticals and medical devices, and/or touch on regulatory standards or include statements in support of harmonisation. Examples include the Treaty of the South African Development Community (SADC Treaty), Agreement Establishing the African Continental Free Trade Area (AfCFTA), and the SADC-EU EPA (Economic Partnership Agreement (EPA) between the SADC EPA States, of the one Part and the European Union and its Member States, of the other Part). In addition, the SAHPRA provides for, and encourages, the use of reliance-based evaluations of products registered with a recognised regulatory authority (RRA). The RRAs include the European Medicines Agency Centralised Procedure (EMA CP); European Medicines Agency Decentralised Procedure (EMA DCP); Health Canada; Medicines and Health Products Regulatory Agency; UK (MHRA); Ministry of Health, Labour and Welfare (MHLW), Japan; Swiss Agency for Therapeutic Products (Swissmedic); Therapeutic Goods Administration, Australia (TGA); and the Unites States Food and Drug Administration (US FDA).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The Medicines Act provides for a transparent pricing system and establishes a Pricing Committee tasked with overseeing the pricing of medicines and scheduled substances. The relevant regulations that govern pricing of medicines are the Regulations Relating To A Transparent Pricing System For Medicines And Scheduled Substances published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 (Pricing Regulations), as amended.

The Pricing Regulations establish a single exit price for each pharmaceutical. In terms of the Medicines Act and Pricing Regulations, no pharmacist, wholesaler, distributor or anyone permitted to sell medication may sell a medicine to anyone other than the State at a price higher than the single exit price. The Pricing Regulations provide for the charging of a dispensing fee by pharmacies; however, this is also strictly regulated.

The single exit price is made up of:

- the price determined by the manufacturer or importer;
- a logistics fee; and
- VAT.

In terms of the Pricing Regulations, the manufacturer or wholesaler must publish a schedule specifying the single exit price of a medicine or scheduled substance, as well as the logistics fee. The logistics fee is determined by agreement between a logistic services provider and the manufacturer or importer, which must be less

than the maximum logistics fee set by the Pricing Committee.

The single exit price may only be increased by the Minister of Health, on the recommendation of the Pricing Committee and taking into account several factors mentioned in the Pricing Regulations, including international pricing information, changes in foreign exchange rates and the need to ensure the availability, affordability and quality of medicines.

7.2 Price Levels of Pharmaceutical or Medical Devices

The single exit price is determined by the Pricing Committee according to a methodology that conforms with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or an equivalent thereof is sold in other countries in which the prices of medicines are regulated and published.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The WHO advocates that procurement of medicines should take place against a list of essential medicines. In South Africa, there is a distinction between the procurement and pricing reimbursement of pharmaceuticals in the public sector versus the private sector.

In the public healthcare sector, the national selection of medicines available for procurement is provided for by the National Essential Medicines List Committee (NEMLC) and on a local level by the provincial and facility-based Pharmacy and Therapeutics Committees (PTCs). The State, through the National Department of Health, prepares, advertises, adjudicates, awards and manages the national medicines tenders. In terms of the tender process, pricing is evaluated critically on the basis of global trends in active pharmaceutical ingredient (API) price increases and formulation costs.

In the private healthcare sector, there is no reimbursement from public funds and clinical decisions regarding the selection of medicines are made within each medical scheme, as implemented by medical scheme administrators. The selection of medicines for private sector schemes is dependent on the type or class of medicine. For high-volume, low-cost medicines the selection is generally based on price. Where high-cost medicines are considered for selection, these are subject to a more thorough evaluation, which includes clinical efficacy and effectiveness, cost-effectiveness and budget impact on the medical scheme.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In the private health sector, each medical scheme is allowed to use a selection process to create its own prescribed minimum benefit formulary on the basis of principles of evidence-based medicine, cost-effectiveness and affordability.

In the public health sector, the selection and pricing of medicines is subject to a tender process, the review of which includes a pharmacoeconomic analysis. However, this analysis merely informs whether a particular pharmaceutical will be procured and not necessarily the price at which it will be reimbursed.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Pricing Regulations specify the dispensing fee that may be charged with respect to the sale of any medicine. The maximum dispensing fee is calculated as a base amount plus a percentage of the single exit price of the medicine. Four cat-

egories are provided for, where the percentage of the single exit price for dispensing low-cost medicines is higher and the percentage of the single exit price for dispensing higher cost medicines is lower. The dispensing fee is reviewed annually by the Minister of Health.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps may be considered medical devices depending on their intended use and how they work. Medical apps that provide medical services for humans or animals relating to diagnosis, prevention, monitoring or treatment of diseases or injuries, or even relating to control of conception, fall within the legislative definition of a medical device in the Medicines Act. Accordingly, such medical apps are subject to the same rules and prescripts for medical devices.

8.2 Rules for Telemedicine

Regulation of Physicians and Telemedicine

Telemedicine is governed by the Health Professions Council of South Africa (HPCSA), as well as by legislation, including the Health Professions Act and National Health Act. Physicians may provide medical attention through mobile devices. Any telemedicine providers, including cross-border providers, must be registered in terms of the Health Professions Act and are subject to the ethical rules of conduct of the HPCSA. Cross-border telemedicine providers serving South African patients must be registered with the regulatory bodies in their respective countries, in addition to with the HPCSA.

Telemedicine Guidelines

The HPCSA guidelines provide that "Telehealth should preferably be practised in circumstances where there is an already established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using Telehealth provided that such consultations are done in the best clinical interest of patients".

8.3 Promoting and/or Advertising on an Online Platform

Promotion or advertisement of medicines or medical devices on online media, including web pages or social media, is governed by the same regulations for any other form of promoting or advertising of such health products. Further, electronic promotion is not permitted unless, on first contact with a person, an option to opt out of further electronic communication is provided clearly and the decision in respect thereof is subsequently respected by the promoter. A comprehensive set of rules is applicable to advertising of medicines and medical devices, and is not set out here in detail. However, some of the provisions include that:

- scheduled medicines may only be advertised if registered;
- advertisements must be complete, clear and accurate, and not misleading in any form;
- advertisements may not disparage competitor products; and
- advertisements may not be set out in a manner relating to trademarks or otherwise that leads to the deception or confusion of consumers or practitioners as to the origin of the products.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed in South Africa for schedule 1, 2, 3 and 4 medicines. The HPCSA guidelines provide that prescriptions must be issued under a practitioner's personal and original signature, which includes electronic signatures that meet the prescribed require-

ments. For schedule 1 to 4 medicines the prescriptions may be computer generated, but for schedule 5 to 8 medicines the prescriptions may be handwritten only and accordingly cannot be issued electronically.

The guidelines of the Digital Healthcare Association require that electronic scripts must be sent directly a patient's pharmacy of choice, and not to the patient to forward to the pharmacy.

Lastly, it is not an acceptable standard of care for prescriptions issued via telemedical services to be based solely on an online questionnaire.

8.5 Online Sales of Medicines and Medical Devices

The online sales of medicines and medical devices is generally governed by the same regulations for other forms of sale. There are no provisions prohibiting the online sale of medicines and medical devices, and accordingly such sale is permitted.

8.6 Electronic Health Records

Electronic Records and Health-Related Information

Electronic records are regulated generally by the Electronic Communications and Transactions Act (ECTA), and therefore include electronic health records.

Health-related information specifically is included in the definition of "personal information", which is governed in terms of the POPIA, in terms of which strict provisions are made for the lawful processing of personal information. Health-related information may strictly not be processed except by healthcare professionals or institutions, including insurance companies and medical schemes, as well as various other bodies under specific circumstances. The POPIA provides for the strict integrity, security and confidentiality of personal information.

The HPCSA guidelines also provide that arrangements must be made for proper security of electronic health records, including storage and transmission thereof. Passwords must be required for the access of health records in electronic format.

Cloud Platforms

There are not provisions in healthcare legislation specific to cloud platforms. Notwithstanding this, subject to the provisions of the ECTA and POPIA, and other measures put in place such as those of the HPCSA, regarding personal information, confidentiality and security, it would be permissible to transfer and store health-related data of patients on cloud platforms. Should a cloud platform be hosted outside of South Africa, the transfer of health-related information to a foreign country must be authorised, either by legislation or by the relevant regulatory body.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The South African Patents Act governs patents in South Africa. Under the Act, a patent provides the patent holder with the exclusive right to prevent others from making, using, exercising, disposing of, or offering to dispose of the invention within South Africa, without their consent.

In practice, one common issue faced by pharmaceutical and medical device products under the Act is the question of whether a particular invention is patentable subject matter. Section

25(2) of the Act sets out certain exclusions from patentability, such as methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods.

Another issue that may arise is the question of whether an invention is new and inventive. To be patentable, an invention must be new and inventive, which means it must not have been previously disclosed or made available to the public and must not be obvious to a person skilled in the art.

In addition to the general requirements for patentability, pharmaceuticals and medical devices may also be subject to specific patentability requirements. For example, Section 27(1) of the Act requires that an invention in the pharmaceutical field must involve a new chemical entity or a new use of a known chemical compound, and that the invention must be capable of being used in trade or industry.

9.2 Second and Subsequent Medical Uses

In South Africa, second and subsequent medical uses of a known product may be regarded as patentable subject matter. The South African Patents Act does not explicitly exclude second and subsequent medical uses from patentability. Therefore, claims directed to such uses may be patentable, provided that the relevant patentability criteria are met, including novelty, inventive step and industrial applicability. Additionally, in terms of decided South African case law a claim directed to a first medical use should be drafted in the "for use type" claim format and a claim directed to a second medical use should be drafted in the "Swiss-type" claim format.

In relation to new dosage regimes and new or selected patient populations, such inventions may also be patentable subject matter, on condition that they meet the relevant patentability criteria.

Infringement of a second and subsequent patent of a pharmaceutical product may occur where an infringing party exploits the patented invention without the permission of the patent owner. This may include activities such as manufacturing, importing, offering for sale, selling or using the patented invention. The scope of the patent and the alleged infringing activity will be assessed by the courts in order to determine whether infringement has occurred.

9.3 Patent Term Extension for Pharmaceuticals

South African law does not make provision for, or include any mechanism whereby the term of a patent can be extended in any way. In fact, Section 69A of the Patents Act (a so-called Bolar provision) provides that certain non-commercial scale acts which are reasonably related to the obtaining, development and submission of regulatory information required under law will not be considered patent infringement. The proviso to this section is that no product may be stockpiled in anticipation of the first sale upon patent expiry.

9.4 Pharmaceutical or Medical Device Patent Infringement

A pharmaceutical or medical device patent may be infringed by unauthorised:

- making;
- use;
- exercise;
- disposition (eg, sale);
- offering to dispose (eg, advertisement); or
- importation.

Applying for marketing authorisation in itself does not constitute patent infringement. It may in certain instances, along with other factors, contribute to an apprehension that the applicant may launch an infringing product once marketing authorisation has been obtained, which may form one of the grounds for applying for an interim interdict (injunction), pending the outcome of a final action. Such an application, by its very nature, requires urgency, and amongst other things, it must be shown that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted and ultimate relief is eventually granted.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences to Patent Infringement

Specific defences to patent infringement in relation to pharmaceuticals and medical devices include Bolar-type defences. Acts conducted for the purpose of acquiring regulatory approval do not constitute patent infringement. However, the acts must be conducted in good faith, on a non-commercial scale and solely for the purposes reasonably related to obtaining regulatory approval.

Compulsory Licences

Compulsory licences of patents, including those relating to pharmaceutical products and medical devices, are provided for in South African patent law. Application may be made for a compulsory licence on two grounds:

- where the working of a patent without the infringement of a prior patent is dependent on obtaining a licence under the prior patent; and
- where patent rights are abused.

Patent rights are considered abused if:

- the patented invention is not worked to an adequate extent after a certain period subsequent to the application or grant of the patent, without satisfactory reason;
- the demand for the patented article is not adequately met;
- the trade or industry or agriculture is prejudiced by the refusal of the patentee to grant a licence reasonably or at all, and it is in the public interest that a licence be granted; or
- the demand for the patented article is met by importation, but at excessive prices

9.6 Proceedings for Patent Infringement

Who May Institute Proceedings?

Patent infringement proceedings may be brought by the patentee, or in certain instances by a licensee under a licence of right, where the patentee refuses to institute proceedings after being called upon by the licensee to do so.

Relief

A successful plaintiff may obtain an interdict, delivery up, damages or a reasonable royalty instead of damages, and may recover legal costs.

Procedure

Patent infringement proceedings are typically instituted by way of action, commenced by issuing a combined summons, together with a particulars of claim. The defendant has an opportunity to defend the action, and will be required to deliver a plea to the particulars of claim, and a counterclaim, if any. The plaintiff is afforded an opportunity to replicate to the defendant's plea, and plea to the counterclaim, following which the defendant may replicate to the plea in reconvention. This is followed by discovery and expert summaries, and any other interlocutory

proceedings, and thereafter a trial date may be allocated.

Invalidity is available as a defence in an infringement action, and is instituted by way of counterclaim.

9.7 Procedures Available to a Generic Entrant

South African patent law makes provision for a declaration as to non-infringement should an applicant wish the courts to adjudicate on the question of whether or not there is or will be patent infringement. "Clearing the way" is not a requirement for generic market entry (ie, for obtaining marketing authorisation). The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection; ie, no provision is made in South African law for patent linkage.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting refers to the intentional and illegal production, or mislabelling, of goods regarding their identity and origin in order to appear as genuine and deceive customers into buying them. The pharmaceutical industry is worth almost USD1 trillion in sales annually, but the World Health Organisation (WHO) estimates that counterfeit medicines constitute more than 50% of the global drug market; a sizeable portion is experienced in developing countries. The groups distributing counterfeit medicines thrive mostly in countries where there are weak anti-counterfeiting laws; the legal actions are ineffective; and the pharmaceutical regulatory agencies are not efficient through being underfunded or understaffed. A similar trend is demonstrated with medical devices whereby, in 2010, the WHO revealed that 8% of the medical devices in circulation were known to be fake, but this is likely be an underestimate and also likely to be a much larger figure now.

There are three main sources of counterfeits entering channels of commerce: (i) national production; (ii) imported products which enter via the country's ports and borders; and (iii) independent manufacturers who produce counterfeit products. The first source refers to the manufacturing of counterfeit products in the domestic market and can be a consequence of outsourcing manufacturing to non-reputable manufacturers; the second pertains to the importation of fake items through the country's ports and borders; and the third relates to independent manufacturers producing counterfeit goods.

The similarity between these two industries, especially within the realm of counterfeits, is that they enter the market through the supply chain. With medical devices, criminals can invade the ecosystem through sneaking counterfeit medical devices into local hubs and, due to the complexity of the healthcare supply chain and the equipment involved with that industry, it becomes attractive for counterfeiters to bring their products in at a fraction of the price. In respect of pharmaceuticals, a study conducted on the supply chain of counterfeit medicine also demonstrated that the distribution side of the business concerns non-reputable doctors and pharmacies who seek to purchase stock for a lower price than the genuine product, whereas another case identified the counterfeit goods being imported.

A burgeoning concern is the proliferation of counterfeit medical devices and pharmaceuticals becoming available online. E-commerce

has grown into a key channel for counterfeiters to reach larger audiences and the advertising of pharmaceuticals and medical devices – which are ordinarily expensive – are attractive to the less affluent, especially since e-commerce circumvents the geographical border and enables them to obtain these goods. Counterfeiters have adopted strategies where they can receive stock by a supplier only when they have an order and can thus act as a front selling directly to the consumer but not holding any of the counterfeit goods in their possession. Corroborating this issue is the ability to leave little or no record to trace back to the end-user and, with the lack of a regulatory environment/oversight mechanism on these transactions, the sale of these goods is likely to continue.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trade Marks Act 194 of 1993 (the "Trade Marks Act") was enacted to improve on the protection of trade marks and illuminate the intellectual property landscape in terms of what is permissible to be registered and the rights granted thereto. The Trade Marks Act permits a variety of different representations of a mark to be registered, and this is inclusive of shapes. However, Section 10 of the Trade Marks Act specifically provides for instances where the registration of a trade mark may be refused and, when it comes to registering a shape, pharmaceutical companies have encountered difficulties with this endeavour. One particular hurdle to overcome is the registrability of the shape of a medical pill because, regardless of the extensiveness and consistency of use, this is not a registrable trade mark. For a shape mark to be registered, it must overcome Section 10(5) of the Trade Marks Act, which stipulates that a mark which consists exclusively of the shape of the goods, where such a shape is necessary to obtain a specific result, may not be registered. In Beecham Group Plc v Triomed (Pty) Limited, it was held that the unique shape of a medical tablet, which was designed to make swallowing easier, is not registerable as a trade mark. Therefore, a pharmaceutical manufacturer cannot trademark the shape of the tablets that they use, nor the container utilised, thereby making them susceptible to counterfeits of their products being created.

Another hurdle to surmount is Section 10(11) of the Trade Marks Act which allows for a refusal to register a shape, container for goods, configuration, colour or pattern of goods where the registration of the mark will limit the development of an industry. The issue resides in the "colour depletion doctrine", which limits the number of colours available to an industry and forces the owners of the brand to operate within such parameters. This undoubtedly results in many of the same colour schemes for trade marks being utilised by the many entities in the industry and curtails, to a degree, the ability of the proprietor to act.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Trade Dress

In South Africa, instances of trade dress infringement are enforced by way of the "passing-off" course of action. This is a common law remedy which was defined in Capital Estates v Holiday Inns as a representation by a person that their business is that of another, or associate thereof, to the extent that members of the public may be confused into believing that one business is that of another. To be successful with a passing-off claim, it must be proven that:

- there was a reputation existing in the mark;

- there is evidence of misrepresentation by the other mark to the extent that there exists a likelihood of confusion or deception; and
- that there was damage, assuming that misrepresentation was established.

The Supreme Court of Appeal case of Koni Multinational Brands (Pty) Ltd v Beiersdorf AG examined these factors in relation to two personal care items and concluded that, on the basis of inter alia shape, product type, colour and reputation, the products were deceptively confusing, and such parameters would likely also be canvassed when considering the trade dress of pharmaceuticals or medical devices. However, it is worth considering the dissenting judgment which, whilst only persuasive, had a valid point in finding from leading literature on the topic that the public will tend to focus primarily on the brand name of any other product, as supposed to the entire get up. This lends itself to the conclusion that a competitor utilising a different and distinguishable brand name from another is likely to avoid a finding of passing-off.

Designs

IP protection is also available for the design of pharmaceuticals (for example tablets), medical devices or their packaging, in the form of design registrations. In addition to being new and original, or new and not commonplace, the articles to which the design applies must also be intended to be multiplied by an industrial process.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

South African law does not provide for any form of data exclusivity for pharmaceuticals or medical devices. No provision is made for Orphan Drug or similar status. In fact, the South African regulatory landscape favours early market entry and includes provisions for the more affordable supply of medicines. In addition to Section 69A referred to above, the Act provides a system for the potential parallel importation, under certain circumstances, of medicines registered in South Africa but imported by a person other than the holder of the registration certificate, and that such importation will not be considered patent infringement.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

South Africa did not enact any special rules or regulations to aid the commercialisation or distribution of medicines and medical devices during the COVID-19 pandemic, nor were any rules relaxed. However, the SAHPRA did make use of the relevant provision in the Act which allows them to authorise the sale of unregistered medicines, medical devices and IVDs. The SAHPRA also partnered with other leading regulatory agencies during this time to ensure the availability of the medicines and devices required to respond to the pandemic. The SAHPRA made use of the provisions to allow for the supply of unregistered medicines to approve the use of several vaccines, ivermectin, and medical devices. Several of the vaccines initially approved under this process have now undergone full registration.

11.2 Special Measures Relating to Clinical Trials

The SAHPRA issued special guidelines relating to the inspection of clinical trial sites and other on-site inspections. In particular, in order to ensure safe on-site inspection of sites for compliance with Good Clinical Practice guidelines, the SAHPRA provided for remote virtual inspec-

tion of such sites, as well as the following of strict protocols for on-site inspection.

Furthermore, for ongoing trials, the SAHPRA issued a communication to all investigators requiring them to consider the circumstances of the trial and modify the study conduct accordingly, including amending patient monitoring standard operating procedures, providing for virtual safety assessments and where possible, alternative delivery methods.

In addition, the SAHPRA provided for expedited review of COVID-19-related clinical trial applications, with a review timeline of 7-10 working days. The SAHPRA also provided for rolling review of COVID-19 vaccine applications.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

South Africa had regulatory pathways applicable for emergency approvals of pharmaceuticals or medical devices prior to the COVID-19 pandemic. The SAHPRA had provisions for expedited review of applications for registration of medicines and medical devices in cases of emergency, such as epidemics or pandemics. Under these provisions, the SAHPRA could waive certain requirements for the registration of medicines and medical devices and fast-track the review process to ensure availability of essential medical products in emergency situations. The expedited review was applicable for products already approved by certain international regulatory authorities, or in cases of new products for which there was a strong scientific rationale and evidence of safety and efficacy.

In response to the COVID-19 pandemic, the SAHPRA implemented an expedited regulatory process to enable faster approvals for COVID-19-related products. The expedited process allows for the accelerated evaluation of applications for registration or emergency use authorisations of COVID-19 diagnostics, therapeutics and vaccines. Applicants must submit a complete dossier for evaluation, and the SAHPRA will prioritise the evaluation of these dossiers. The authority may also waive certain requirements, such as the need for local clinical data, depending on the product's nature and urgency. However, safety and efficacy requirements are still maintained, and products authorised through this pathway must meet these requirements before being allowed on the market.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

SAHPRA introduced certain flexibilities relating to manufacturing certifications for pharmaceutical and medical device manufacturers during the pandemic to ensure that production of essential products could continue. SAHPRA provided for the extension of validity period of GXP certificates, and introduced remote GXP inspections of manufacturing facilities to reduce the need for in-person inspections during the pandemic.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

South Africa implemented various import/export restrictions and flexibilities in relation to medicines and medical devices due to the COVID-19 pandemic. In March 2020, the South African government issued regulations restricting the export of certain medical supplies, including personal protective equipment (PPE) and ventilators, to ensure that these supplies remained available in the country during the pandemic.

The South African government also implemented measures to expedite the importation and registration of essential medical products and devices, including COVID-19 diagnostic tests

and vaccines. In addition, the SAHPRA introduced several expedited review processes for COVID-19-related products to facilitate quicker regulatory approval of medicines and medical devices. These processes included:

- expedited review of clinical trial applications;
- expedited review of applications for the use of unregistered medical products in the course of an emergency situation;
- COVID-19 emergency use authorisations; and
- fast-track registration of COVID-19 vaccines.

These expedited review processes were put in place to respond to the urgent public health needs created by the COVID-19 pandemic.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Numerous systems were introduced or improved upon to facilitate digital healthcare solutions during and subsequent to the COVID-19 pandemic:

- introductions of mobile health apps, or more features in respect of existing apps;
- developments in telemedicine;
- WhatsApp and SMS-based systems; and
- utilisation of various social media platforms.

These solutions provided access to medical assistance virtually, improved communications, assisted in screening and monitoring of diseases, bettering electronic prescriptions and ensuring compliance with medicines or treatments, or were used simply for educational or awareness campaigns.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

In 2020, South Africa joined with India in petitioning the World Trade Organisation (WTO) to temporarily suspend intellectual property rights in order to ensure accessibility of COVID-19 vaccines and other new technologies for poorer countries. In 2022 the WTO adopted a limited waiver for COVID-19 vaccines and initiated discussions on a potential extension of the waiver to cover the production and supply of COVID-19 diagnostics and therapeutics.

Although the South African Patents Act provides for compulsory licences in certain instances, no such licences have been applied for in respect of COVID-19 vaccines or therapeutics to date. The requirements for the issue of a compulsory licence in South Africa are set out in the Patents Act.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

In order to secure a supply of COVID-19 vaccines, the South African government had to exempt vaccine manufacturers from liability. The mechanism for exempting manufacturers from liability was introduced under the regulations promulgated in terms of the Disaster Management Act, 2002. In an amendment to the regulations published on 22 April 2021, government introduced the COVID-19 Vaccine Injury No-Fault Compensation Scheme. In terms of the published regulations the scheme will only come to an end upon publication of a notice to that effect in the Government Gazette, after the period for submitting claims has expired, and all claims have been finalised.

11.9 Requisition or Conversion of Manufacturing Sites

There were no special provisions relating to the requisition or conversion of manufacturing sites in South Africa in response to the pandemic. However, the South African government did introduce measures aimed at encouraging the local production of pharmaceuticals and other

medical supplies during the pandemic. The establishment of a dedicated fund, the COVID-19 Solidarity Fund, assisted with funding for companies to repurpose their existing facilities to manufacture certain essential medical supplies. SAHPRA also produced updated guidelines specifically directed at the licensing of personal protection products such as masks and sanitisers. Some examples of successful efforts to increase local production include the National Ventilator Project (NVP) between the Department of Trade and Industry (DTI) and The Council for Scientific and Industrial Research (CSIR), and an agreement between a local pharmaceutical manufacturer, Aspen Pharmacare, and Johnson & Johnson to manufacture COVID-19 vaccines in South Africa.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

On 15 March 2020, the president of the Republic of South Africa, President Cyril Ramaphosa, declared a national state of disaster in South Africa following the WHO declaring that the COVID-19 outbreak was considered a pandemic. The pronouncement of a state of disaster allowed for emergency procurement of certain named classes of goods (including personal protective equipment, digital thermometers, sanitisers and disinfectants, and body bags) in terms of the Disaster Management Act and an instruction from National Treasury. The national state of disaster as it relates to COVID-19 has since been lifted.

SOUTH KOREA

Law and Practice

Contributed by:
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Lee & Ko

Contents

Lee & Ko has become one of Korea's premier full-service law firms, widely recognised for its leadership and outstanding success in every area of legal practice. As has been confirmed in numerous reviews conducted by Korea's major media outlets, as well as ratings produced by international law firm rating services, Lee & Ko enjoys one of the highest levels of client satisfaction and a particularly excellent reputation for the quality of the firm's legal services. Lee & Ko's healthcare practice group of more than 70 professionals focuses on providing legal services expertly tailored to meet the needs of clients with specific concerns around healthcare and related matters, including pharma, bio, medical devices, food and beverage products, medical data with AI application, genome analysis, DTC, tobacco and cosmetics.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing pharmaceuticals in Korea is the Pharmaceutical Affairs Act (PAA), while the Medical Devices Act and the In-Vitro Medical Devices Act (collectively, MDA) regulate medical devices, in both cases, together with related presidential decrees and regulations and guidelines promulgated by the Office of the Prime Minister and the Ministry of Food and Drug Safety (MFDS).

The Ministry of Health and Welfare (MHW) and the MFDS (which is overseen by the MHW) are the main regulatory bodies in relation to pharmaceuticals and medical devices, and they are responsible for issuing and enforcing most of the regulations, guidelines and administrative orders for pharmaceuticals and medical devices. Local governments (such as the Seoul Metropolitan government) also monitor pharmaceutical and medical device entities within their jurisdiction.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative orders issued by the MFDS, MHW or local governments to entities in violation of the PAA or MDA may be challenged via an administrative appeal to the competent administrative appeals commission under the Administrative Appeals Act, or via administrative litigation to the competent court under the Administrative Litigation Act. In most cases, either action will request that the competent commission or court revoke or declare null the administrative order. Rulings rendered by an administrative appeal commission may also be appealed to the competent court.

In general, these challenge procedures are applicable to other regulated products, such as food products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into over-the-counter (OTC) drugs and prescription drugs. In principle, all pharmaceuticals must be delivered to patients by licensed pharmacists at pharmacies, except in some cases such as delivery of pharmaceuticals to patients by doctors within medical institutions. While prescription drugs require a prescription from physicians, OTC drugs can be supplied to consumers without a prescription. Additionally, the MHW has designated certain OTC drugs as emergency drugs to treat light symptoms in urgent situations at patients' discretion, and such OTC drugs may be sold at 24-hour convenience stores by non-pharmacists after such stores' registration with the local government.

Medical devices are classified into Classes I to IV, based on their intended use and the risk level associated with the device. Class I devices present the lowest risk, while Class IV devices are considered the highest risk and are subject to the greatest scrutiny. While medical devices may only be marketed after obtaining the relevant licence from the MFDS, certain types of medical devices designated under the MDA can be sold without such a licence. For example, glucometers that are included in, or combined with, mobile phones or household appliances, condoms, personal pregnancy diagnosis kits, and electronic thermometers can be sold without a marketing licence.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The PAA, the MDA, the Bioethics and Safety Act (BSA) and relevant regulations govern clinical trials of medicinal products and medical devices, and the MFDS oversees approval for clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, the relevant clinical trial protocol must be reviewed and approved by an institutional review board (IRB) of the MFDS. The materials required to be submitted by the sponsor for clinical trial approval include the following:

- for medicinal products, the clinical trial protocol, development plan, investigator's brochure, material on manufacturing and quality of the investigational drug, preclinical trial data, materials on medical institution conducting the clinical trial, institute analysing the clinical trial sample, and the investigator and Contract Research Organisation (CRO), policies and forms regarding the clinical trial subjects, etc; and
- for medical devices, the clinical trial protocol, materials proving that the clinical trial medical device is being manufactured in accordance with the facility, manufacturing and quality management system standards, purpose of use, working principle and technical documents to verify performance and safety.

Once approved, clinical trials must be conducted in accordance with the protocol and standards regarding good clinical practice for medicinal products and medical devices, as applicable.

2.3 Public Availability of the Conduct of a Clinical Trial

All clinical trials are registered with the MFDS. Basic information regarding clinical trials such as sponsor information, information on the clinical trial including its title, purpose and use, information of drug used, plan for clinical trial, method to arrange the participants subject to experimental group or control group, the status of the clinical trial (eg, on-going, completed), method to administer and evaluate the clinical test (eg, primary and secondary end point), and subject inclusion and exclusion criteria can be searched at the medicinal products comprehensive information system, which is a website of the MFDS (www.mfds.go.kr/eng/index.do).

2.4 Restriction on Using Online Tools to Support Clinical Trials

No restriction exists on using online tools to support clinical trials. However, it is generally required that clinical trials are to be conducted by doctors or hospitals with in-person interviews, and written informed consents from clinical trial subjects. Recruitment of clinical trial subjects can be conducted online.

The protocols allowing provisional "untact" medical care (a term coined by a research team in Korea for non-face-to-face contact) under Article 49-3 of Infectious Disease Control and Prevention Act may apply to clinical trials, whereby the treatment for, and monitoring of, patients during clinical tests may be changed into untact treatment and monitoring.

2.5 Use of Data Resulting From the Clinical Trials

The data from the clinical trials is considered as personal and sensitive data and the institutions conducting clinical trials are subject to the Personal Information Protection Act (PIPA)

for handling and protecting information such as collection, use, provision, etc, of personal information. In addition, unless permitted to directly access the personal information, information with respect to the participant's identity or sponsor's intellectual property, etc, shall not be disclosed to third parties. Further, in order to protect the clinical trial subjects' identity, unique identity numbers need to be assigned to subjects instead of their name.

When obtaining consent on the clinical trial from its subjects, the medical institution conducting the clinical trial must explain that the records of subjects' personal information will be kept confidential, stipulate the same in writing, and make it clear that such personal information shall be maintained confidential even if results of the clinical trial become publicly available. It further needs to inform that the records relating to clinical trial including the subjects' medical record can be accessed by the sponsor's monitoring agent or inspector through an institutional review board (IRB) of the medical institution above, and that the MFDS may also access and review such information and relevant materials.

2.6 Databases Containing Personal or Sensitive Data

In addition to the requirements described in **2.5 Use of Data Resulting From the Clinical Trials**, according to clinical trial management standards, such database needs to have a security system which prevents unauthorised persons from accessing the information, and matters as prescribed by the chief of MFDS for proper management of electronic records must be complied with. The sponsor also has to use identifier code for clinical trial subjects.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Under Article 2 of the PAA, "drugs" are defined as those other than quasi-drugs, among the articles listed in the Korean Pharmacopoeia, or articles, other than appliances, machinery or equipment, used for the purposes of diagnosis, treatment, alleviation, care or prevention of diseases of human beings or animals, or used for the purpose of exerting pharmacological effects upon the structure or functions of humans or animals.

A "medical device" is defined under the MDA as an instrument, machine, apparatus, material, software or any other similar product specified in the following:

- a product used for the purpose of diagnosing, curing, alleviating, treating or preventing a disease;
- a product used for the purpose of diagnosing, curing, alleviating or correcting an injury or impairment;
- a product used for the purpose of testing, replacing or transforming a structure or function; and/or
- a product used for the control of conception.

Sometimes, it is difficult to distinguish medical devices from personal healthcare products even when considering the purpose of use and the risk to the human body. In such case, guidance or administrative interpretation from the MFDS may be requested.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market biological drugs in Korea, the initial marketer is required to obtain marketing approval, the same as that for chemical drugs. Key factors to consider when reviewing an application for market approval are:

- data on origin or discovery and development process;
- data on structure and physicochemical properties;
- data on stability;
- toxicological data;
- data on pharmacological mechanism;
- data on clinical trial results; and
- data on domestic and overseas usage and approval status.

For some biologics such as the botulinum toxin, additional strict requirements on use, transfer, etc, apply. Meanwhile, unlike generic drugs, a bioequivalence test does not replace data on stability and efficacy in order to obtain market approval for biosimilars.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Under the PAA, market approval for pharmaceuticals is valid for five years, and renewal is required after five years. For renewal, safety data, domestic manufacturing/import data, and a GMP compliance certificate must be submitted to the MFDS at least six months before the expiration date. If the market approval holder does not file the application for renewal or fail to meet the requirements, the market approval is cancelled.

In the case of medical devices, no renewal system existed previously, but since 8 October 2020, market approval for medical devices is to be valid for five years from the market approval date. Similar to pharmaceuticals, for medical devices, data proving that safety and efficacy has continued to be the same since market approval was initially granted, and data on production/import performance, etc, must be submitted for renewal at least 180 days before the expiration date.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Data proving safety and efficacy, such as clinical trial results, must be submitted to the MFDS for obtaining market approval. In some cases such as generic drugs or incrementally modified drugs, however, safety and efficacy data can be replaced with bioequivalence test result data.

The procedure for assessing market approval on medical devices varies depending on the risk they pose to human bodies. In the case of high-risk medical devices (Class III/IV), higher level of scrutiny will apply such as requesting and reviewing more data, including clinical data proving the efficacy and safety, compared to low-risk medical devices (Class I/II) where various data such as clinical trial data is exempted.

In the event that the indications for drugs or medical devices are changed after market approval, it is possible to file an approval for change, and the procedure is similar to the procedure for new market approval.

It is also possible to transfer a market approval from one market approval holder to another.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

In Korea, even if no market approval has been obtained, investigational drugs can, after relevant clinical trials are implemented and approved, be used as part of a compassionate use programme. The compassionate use programme is permitted only in cases where a patient has:

- a serious or urgent life-threatening condition; or
- no other alternative treatment methods in a condition that warrants urgent treatment.

In addition, certain orphan drugs and drugs for the treatment of rare diseases which are directly imported and distributed by the Korea Orphan & Essential Drug Center (KOEDC), and drugs which MFDS admitted for urgent introduction for treatment of patients following MFDS or MOHW's request are exempted from obtaining import approval.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Pharmaceuticals and medical devices are subject to PMS during the following re-examination periods, starting from the date of issuance of the market approval:

- new drugs – six years;
- pre-approved prescription drugs with a new indication – four years; and
- new medical devices – four to seven years.

Approved pharmaceuticals or medical devices may be subject to re-evaluation if the MFDS finds it necessary to re-evaluate the safety and efficacy of approved pharmaceuticals or a medical device. To re-evaluate, the MFDS reviews not only documents and materials submitted before the market approval, but other post-approval information, including side-effect data since the launch, status in other countries and amendments to the approval made in relation to safety and efficacy.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Under the PAA and MDA, if a sponsor filed an application request in writing to protect information or data contained therein against disclosure, such information or data should not be disclosed unless otherwise required by the public interest. The PAA and MDA even impose criminal penalties for breaching the non-disclosure obligation above.

Further, the Korean Criminal Act (KCA) punishes a public official or former public official who divulges official secrets obtained in the course of performing their duties.

While the contents contained in the application is not disclosed, third parties may infer from the following circumstances that certain applications for market approval might be granted shortly:

- clinical trial approval status for drugs is published on the MFDS website; in particular, it can be inferred that generic drugs are scheduled to be released from the clinical trial approval status, since the submission of bioequivalence test results is required for approval of generic drugs; and
- the MFDS notices the DMF registration of APIs on its website.

3.8 Rules Against Illegal Medicines and/or Medical Devices

A person who sells pharmaceuticals or medical devices without market approval shall be punished by imprisonment for not more than five years or by a fine not exceeding KRW50 million. Also, the MFDS may suspend the manufacturing business for six months as an administrative sanction.

It should be noted that, unlike criminal punishment, an administrative sanction can be imposed regardless of a violator's intent.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The PAA and MDA have no regulation on the importation or exportation of counterfeit pharmaceuticals and medical devices.

However, the Korea Customs Service (KCS) should notify the owner of IP rights when discovering suspected counterfeits of the medical devices or pharmaceuticals which are protected by valid IP rights. Upon notification, the rightholder can request the KCS not to provide customs clearance to such counterfeits.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

A manufacturing plant of pharmaceutical products is subject to an authorisation for manufacturing pharmaceuticals under the PAA, and a manufacturing plant of medical devices needs an authorisation for manufacturing medical devices under the MDA. The MFDS grants such authorisation. When a person, who intends to manufacture pharmaceuticals or medical devices, prepares and files the application for manufacturing authorisation and necessary documents with the local district of MFDS to which the manufacturer belongs, such local district of MFDS reviews whether the applicant for manufacturing approval (in the case of a company, the representative) is qualified and whether all necessary documents are satisfied, and if appropriate, it grants authorisation. Once authorisation is granted, it will be valid without any other special renewal procedure unless grounds for revocation occur under the PAA or the MDA.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale of pharmaceuticals is subject to an authorisation from the head of Si/Gun/Gu (ie, the local government) in Korea. To obtain such authorisation, the applicant should meet qualifications and have a business place, warehouse and other facilities as prescribed by Presidential Decree of the PAA. The authorised wholesaler is in principle required to employ a pharmacist to manage the relevant tasks. Such authorised wholesaler can sell or acquire pharmaceuticals for sales purposes which comply with the standards for quality management of pharmaceuticals in distribution. There is no validity period for the authorisation of wholesale of pharmaceuticals.

For the wholesale of medical devices, the wholesaler should file a notification of distribution with the competent Special Self-Governing Mayor, Special Self-Governing Province Governor, or the head of a Si/Gun/Gu. Once such notifica-

tion of distribution is accepted, the person can distribute medical devices and there is no period of validity for wholesale notification.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified into OTC drugs and prescription drugs under the PAA.

OTC drugs refer to any of the following drugs, which meet the standards determined and publicly notified by the Minister of Food and Drug Safety, following consultations with the Minister of Health and Welfare:

- a drug, the misuse or abuse of which is of little concern, and whose safety and efficacy can be expected even when used without a prescription by a physician;
- a drug that may be used to treat a disease without a physician's or dentist's professional knowledge; and/or
- a drug which has a relatively small side effect on human bodies in light of their dosage form and pharmacological action.

Emergency drugs among the OTC drugs are used mainly for minor symptoms at the sole discretion of patients, and are publicly notified and prescribed by the Minister of Health and Welfare. Such emergency drugs can be purchased at places other than pharmacies. Conversely, prescription drugs mean drugs which are not OTC drugs and require a physician's prescription.

Meanwhile, orphan drugs mean either drugs used for the purposes of diagnosis or treatment of rare diseases under the Rare Disease Management Act or drugs with rare subject of application, whose alternative drug does not exist or whose safety or efficacy has been significantly improved compared to its alternative drug, which are designated by the Minister of Food and Drug Safety.

Other than the above, drugs essential for health and medical treatment, whose stable supply is difficult only as a result of the market function, are designated and managed as national essential drugs.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The PAA and MDA are the primary laws governing the import and export of pharmaceuticals and medical devices, while the Customs Act and Integrated Public Announcement promulgated by the Ministry of Trade, Industry and Energy (MOTIE) pursuant to the Foreign Trade Act, apply the requirements of the PAA and MDA to the actual customs procedure.

In principle, pharmaceuticals and medical devices manufactured abroad are subject to the same regulations as those manufactured domestically. The importers of such products are responsible for obtaining the necessary licences from the MFDS, such as import business licences and import authorisations for particular products, and complying with all obligations under the PAA or MDA, such as quality testing.

A manufacturing business licence and manufacturing authorisations for particular products are required for the manufacture of pharmaceuticals or medical devices, whether for domestic use or export. However, manufacturing authorisations

for pharmaceuticals or medical devices that are only exported, and not sold or distributed domestically, are exempted from certain requirements and do not require renewal.

The MFDS regulates licences and authorisations for both pharmaceuticals and medical devices, while the Korean Customs Service enforces the relevant regulations at the point of entry for imports.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Only those with an import business licence from the MFDS for pharmaceuticals or medical devices can act as their importer of record.

In order to receive an import business licence for either pharmaceuticals or medical devices, the entity applying for the licence must fulfil certain requirements, such as having the required storage facilities, quality testing facilities and equipment, and personnel such as import managers and safety managers. Additionally, local presence is required in order to hold an import business licence for pharmaceuticals and medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In principle, only entities with an import business licence and import authorisation for the particular imported product can import pharmaceuticals or medical devices into Korea.

Exceptions of varying degrees to this rule include imports for the treatment of rare diseases, emergency use, clinical trials, research and testing, and personal use.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The Customs Act requires those who import products required by law to have approval, licence, labelling or fulfil other requirements for their importation to show proof of the fulfilment of such conditions to the head of the competent customs office, which for pharmaceuticals and medical devices are the requirements imposed by either the PAA (for pharmaceuticals) or the MDA (for medical devices), see **6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies** to **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**.

Whether the imported product is subject to the regulations and requirements of either the PAA or MDA would be determined by whether the product satisfies the criteria for pharmaceuticals or medical devices as defined in the respective acts.

6.5 Trade Blocs and Free Trade Agreements

As of February 2023, Korea has entered into 21 economic partnership agreements and free trade agreements with other countries, all 21 of which (the RCEP and FTAs with Chile, Singapore, EFTA, ASEAN, India, the European Union, Peru, the United States, Türkiye, Australia, Canada, China, New Zealand, Vietnam, Colombia, MERCOSUR, the United Kingdom, Israel, Cambodia and Indonesia) are in force.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Korea, the price of pharmaceuticals and medical devices controlled by the government is consumer (ie, patient) prices (including 10% VAT), and the margin will be set according to each company's policies. The government's price control for pharmaceuticals is based on the relevant laws such as the National Health Insurance Act (NHIA), the Rules on the Standards of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Drugs. Also, the government's price control for medical devices is in accordance with NHIA, the Rules on the Standards of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Activity and Medical Materials for Treatment, etc. The MOHW, HIRA and national healthcare insurance system (NHIS) control the price of pharmaceuticals and medical devices.

Prices for the majority of medical services provided and pharmaceuticals sold in Korea are reimbursed by the Korean NHIS, and the substantial majority of legal residents of Korean are insured by NHIS. If a medical service or a pharmaceutical product is covered by NHIS, a patient cannot be charged more than the co-payment amount corresponding to the maximum reimbursement price published by the MOHW. If a medical service or pharmaceutical is not covered by NHIS, the healthcare provider is free to determine the price of such product or service.

In the context of medical device covered by NHIS, the medical device may be subject to its own maximum reimbursement price or the cost of the medical device may be included in the maximum reimbursement price for the relevant medical service utilising such device.

In order for pharmaceuticals and medical services to be reimbursed, a decision for reimbursement is required and the HIRA and MOHW decide whether to reimburse the cost for the medical services or pharmaceuticals and their costs, through the evaluation of clinical efficacy, cost effectiveness, etc.

7.2 Price Levels of Pharmaceutical or Medical Devices

For drugs, foreign prices may be referenced in the negotiation of drug price and upper limit of reimbursement. However, the economic evaluation for pharmaceuticals takes precedence over such external price referencing in determining the price of drugs. Foreign prices have direct effect only when deciding the price of drugs whose economic evaluation can be omitted.

Meanwhile, in the case of pricing of medical devices, foreign prices are not referenced but the import price or the price of listed products with similar function are considered.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical services (using medical devices) is covered by the health insurance scheme. However, even when covered by the health insurance scheme, the full amount is not paid by the health insurance, as the patient is responsible for the applicable co-pay amount.

There is a difference in the way pharmaceuticals and medical services are covered by health insurance. In the case of pharmaceuticals, products not listed on the reimbursement list are not

covered by health insurance (positive-list way), however, in the case of medical services, the MOHW stipulates medical services not covered by health insurance (negative-list way).

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

As for drugs, it is the principle of a positive list system to determine the eligibility for reimbursement and reimbursement amount on the basis of HTA (health technology assessment – ie, cost-utility analysis). In the case of pharmaceuticals for treatment of cancer or orphan diseases, however, economic evaluation may be omitted.

Meanwhile, for medical devices, the HTA would play a minor role only to a limited extent in determining the eligibility for reimbursement and reimbursement amount.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

After the separation of prescribing and dispensing in 2000, only physicians can prescribe drugs in hospitals, and only pharmacists can dispense drugs in pharmacies (this applies to the case of outpatient only, and dispensing drugs in pharmacies within the hospital is possible for inpatients). In order to prevent the over prescription of narcotic or psychotropic drugs such as propofol, monitoring of prescription details is performed through HIRA's big data management system.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no specific rules which regulate medical apps only. However, a medical app may be treated as a medical device if the medical app satisfies requirements for medical devices as prescribed by the MDA. That is, in case that a medical app is used for the purpose of diagnosing, curing, alleviating, treating or preventing a disease, it may be treated as a medical device under Article 2 of the MDA. If it is not used for the purpose above, however, it would not fall under the definition of a medical device.

8.2 Rules for Telemedicine

In principle, the MSA does not allow telemedicine between physician and patient. However, due to the COVID-19 pandemic, the Korean government is temporarily allowing limited telemedicine. According to the public notice of the MHW, doctors can consult with patients via phone and remote prescriptions for the time being when they believe safety is secured, but discussions on to what extent such cases should be allowed is ongoing.

8.3 Promoting and/or Advertising on an Online Platform

The Fair Labelling and Advertising Act (FLAA) applies to advertising of all products including pharmaceuticals and medical devices. Also, product advertising on an online portal, company webpage, social network, etc, will be subject to "Evaluation Protocols on Online Advertising", the regulation of the Korean Fair Trade Commission (KFTC).

The advertising and promotion of pharmaceuticals are also regulated by the PAA and supervised by the MFDS. Further, advertising and promotion of medical devices are regulated by the MDA, and online advertising of medical devices via online portal, company webpage, social network, etc, are required to receive an in-advance review of voluntary review institution under the MDA.

8.4 Electronic Prescriptions

Electronic prescriptions with digital signatures prescribed by physicians or dentists are regulated under Article 17-2 of the MSA. However, as there is no officially authorised system which transfers electronic prescription data from a medical institution to a pharmacy, filling prescriptions via electronic prescription is not currently implemented. At the moment, MOHW is reviewing the introduction of an official electronic prescription transfer system.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines are not permitted under the PAA. Conversely, medical devices can be sold by a person who notified such distribution to the mayor or governor of local government in the area where his or her business place is located. However, as for some products designated under Article 38 of Enforcement Rules of the MSA such as a thermometer, electronic automatic tonometer, etc, online sales are possible without notification of distribution of medical devices.

8.6 Electronic Health Records

Electronic health records contain extensive information on a patient's health. The PIPA considers such information sensitive data and therefore imposes strict regulation by preventing any use without consent from patients in principle. Having stated that, the PIPA stipulates that in the case of pseudonymisation of sensitive data, such data could be processed without the consent of data subjects for statistical, scientific research purposes, etc. However, discussions are ongoing on whether using pseudonymised electronic records without patients' consent would violate the MSA.

Meanwhile, if medical institutions satisfy the standards as set forth in "Guidelines for Facilities and Equipment Necessary for Managing and Keeping Electronic Medical Records" as published by MHW, they can store and keep such electronic medical records (EMR) in an outside system. Accordingly, in the event that medical institutions meet technical standards as prescribed by the above Guidelines (eg, network and system security equipment and back-up storage device), they can transmit EMR of patients to a cloud platform for storage.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The PAA and the Patent Act (PA) are the main laws governing patents on pharmaceuticals and medical devices in Korea. Every patent is subject to the PA. The main legal issues regarding patents on pharmaceuticals and medical devices are patent application and registration, patent validity and term as well as invalidation actions and lawsuits.

Meanwhile, Korea implements the Drug Approval-Patent Linkage programme, and the PAA regulates the programme.

There are no patentability requirements that are specific to pharmaceuticals or medical devices, and general patentability requirements still apply.

9.2 Second and Subsequent Medical Uses

It is possible to obtain an improvement patent in Korea for novel medical uses, dosage regimes and selected patient populations. For

this, the novel medical uses, dosage regimes or selected patient populations must be specifically described in the claim of the patent while satisfying the general requirements of novelty and inventiveness. In addition, experimental results supporting the effects of the drug, such as pharmacological data or some form of specific information that can substitute such experimental results, must be described in the patent specification.

The act of selling such patented pharmaceuticals labelled with the registered medical uses, dosage regimes or selected patient population without permission from the patent owner constitutes patent infringement.

9.3 Patent Term Extension for Pharmaceuticals

Korea implements a system where the patent term for pharmaceuticals may be extended by up to five years for periods that meet certain requirements in the drug approval process during which the patent inevitably could not be practiced. Specifically, in the case of a pharmaceutical manufactured with a novel active substance as its active ingredient which has received market approval for the first time in Korea, a term extension equal to the sum of the period elapsed for clinical trials and review by MFDS may be granted a single time.

An application for patent term extension must be filed with the Korean Intellectual Property Office (KIPO) within three months from the date of market approval, and the application must be made under the name of all co-owners when it is jointly owned. A third party may file a lawsuit seeking the revocation of the patent term extension.

9.4 Pharmaceutical or Medical Device Patent Infringement

Patent infringement on pharmaceuticals or medical devices occurs when a patent is practised without the consent of the patent owner. A patent is practised when a pharmaceutical or a medical device is manufactured, sold, used, leased, imported or offered for sale. In Korea, applying for market approval itself does not constitute patent infringement. It is possible to file a lawsuit based on the threat of infringement even if actual infringement has yet to materialise. The party claiming the threat of infringement should establish that there is a "likelihood of infringement" by a third party. A decision ordering product disposal and facility removal can be obtained.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Patent infringement is not found for:

- practising of the patent for research and experimental purposes;
- the existing pharmaceuticals or devices at the time of patent application;
- acts of combining more than two pharmaceuticals; and
- the resulting pharmaceuticals.

The Korean government can grant to itself or third parties compulsory licences on patents whose non-commercial practice is necessitated for public good during times of emergency or crises. Upon the decision by the chief of KIPO, compulsory licences can be granted to third parties in the following cases:

- if a patent is not sufficiently practised in Korea for three years without justifiable grounds;

- if there are findings of unfair trade practices by the executive or judicial authorities that call for remedial measures; or
- if the practice of the patent is necessary for exporting pharmaceuticals to the importing countries.

9.6 Proceedings for Patent Infringement

The patent owner or the exclusive licensee can seek a compensation of damages and an injunction by filing an infringement lawsuit. A preliminary injunction can be separately filed to expeditiously prevent the infringing product from entering the market by way of product disposal and facility removal. It is typical for the party accused of patent infringement to defend its action by filing a patent invalidation action or lawsuit. There are multiple cases in which the patent owner and the exclusive licensee file the patent infringement lawsuit and request a preliminary injunction at the same time.

9.7 Procedures Available to a Generic Entrant

The PAA provides that the generic entrant should declare its position on the patent of the original that is listed on the drug patent list on which the MFDS registers and maintains patents on drugs. In other words, the generic entrant should specify whether it plans to enter the market after the expiration of the patent term, obtain a grant of licence or challenge the validity of the patent. The generic entrant should establish that it has notified the patent owner of such declaration to obtain market approval.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The owner of valid intellectual property rights on pharmaceuticals or medical devices can make both civil (request for injunction and compensation of damages) and criminal claims against the manufacturer or seller of the counterfeits. Moreover, the Korea Customs Service should notify the owner of IP rights if its agents discover suspected counterfeits. Upon notification, the right-holder can request that such counterfeits do not receive customs clearance.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademark Act provides that a trade mark which indicates, in a common manner, the quality, efficacy or usage of the product, lacks distinctiveness and thus cannot be registered. The provision also applies to pharmaceuticals and medical devices. In addition, for pharmaceuticals and medical devices, it is not permitted to register as a trade mark a brand name that is widely known among consumers.

In the case of parallel importation of authentic goods, whether such importation is allowed varies among cases. If the owner of the Korean trade mark and the foreign trade mark is the same, products distributed overseas can also be sold locally. However, if such is not the case, the importation and local sale of the products that were distributed overseas is prohibited under the principle of territoriality.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Like other products, pharmaceuticals and medical devices can receive IP protection under trade

dress or design. The Unfair Competition Prevention and Trade Secret Protection Act (UCPA) provides for trade dress rights, whereas the Design Act provides for design rights.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

In Korea, data exclusivity is protected during the period for post-marketing surveillance (PMS). PMS periods vary depending on the types of pharmaceuticals:

- six years for a new drug, a new combination drug and a drug with a different route of administration;
- four years for a drug having a new indication; and
- ten years for orphan drugs (11 years for children's orphan drugs).

Korea does not make a distinction between chemical drugs and biologics when it comes to data exclusivity.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In order to effectively respond to pandemic issues such as COVID-19, the Special Act for the Promotion of Development and Emergency Supply of Medical Products to Respond to Public Health Crisis was both enacted and implemented on 9 March 2021. In the case of pharmaceuticals and medical devices designated as public health emergency response medical products:

- an expedited review procedure will apply; and
- the MFDS may take necessary measures to improve distribution with respect to the distributors, sales procedures, sales volumes and sales conditions of the relevant products.

11.2 Special Measures Relating to Clinical Trials

The MFDS had published its clinical trial follow-up policy for 2021. According to the policy, in consideration of the difficulties in visiting hospitals due to the spread of COVID-19, it was announced that phone counselling and prescriptions, proxy prescriptions and drug delivery to trial participants would be temporarily permitted during the clinical trials. In addition, the MFDS published guidelines titled "Considerations for Development of a COVID-19 Treatment" (14 April 2021) and "Considerations for Development of a COVID-19 Vaccine" (15 June 2021) detailing the pre-clinical and clinical trial requirements for market authorisation of COVID-19 treatments and vaccines.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Based on the Special Act for the Promotion of Development and Emergency Supply of Medical Products to Respond to Public Health Crisis, emergency approvals for the use of pharmaceuticals or medical devices can be granted if it is deemed necessary for appropriately responding to public health emergency or if there is a request from the chiefs of the relevant authorities in the central government. In the case of pharmaceuticals or medical devices that received emergency approval, it is possible to supply them either through importation or manufacture without obtaining market approval.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The MFDS officials have traditionally been required to conduct an on-site inspection on overseas manufacturing plants for pharma-

ceuticals and medical devices. As a result of COVID-19, since 2020, the MFDS implemented a policy of document reviews rather than on-site inspections. However, it announced the plan to resume the on-site inspection on overseas manufacturing plants in 2023 as Korea and most of the other countries are phasing out of COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

There are no restrictions or flexibilities concerning import/export procedures that have been introduced in relation to medicines or medical devices due to COVID-19, other than the special provision on authorisation for importation explained in **11.1 Special Regulation for Commercialisation and Distribution of Medicines and Medical Devices** and **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Under the PAA, telemedicine between the doctor and the patient is not allowed in principle. However, around March 2020, the MOHW made a public notice titled "Measures on Temporarily Allowing Phone Counselling, Prescription and Proxy Prescription". Pursuant to the public notice, telemedicine, drug prescription and courier delivery of drugs are temporarily allowed and continue to be implemented to this date.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Around December 2021, the National Assembly proposed an amendment to the Patent Act, which allows compulsory licences in cases of national emergency or extreme emergency if non-commercial practice of patents is necessary for public good. However, the amendment was not passed. There is no other announcement by the Korean government on compulsory licences.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

There are no liability exemptions introduced to existing or new provisions in connection with COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

There are no new provisions introduced, nor existing ones used, to allow the requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There are no notable changes to the system of public procurement of medicines and medical devices due to COVID-19.

SWITZERLAND

Law and Practice

Contributed by:
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Kellerhals Carrard

Contents

Kellerhals Carrard is a full-service law firm with more than 220 legal experts and offices in Basel, Berne, Geneva, Lausanne, Lugano, Sion and Zurich, as well as representative offices in Shanghai and Tokyo. The firm offers a full range of legal services for national and international clients in all areas of corporate and commercial law. The firm is known for its entrepreneurial spirit, understanding of business needs and pragmatic approach.

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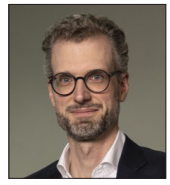

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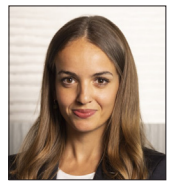

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Swiss healthcare regulation is spread over various statutes, ordinances and guidelines, including self-regulatory instruments such as best practice codes and references to international provisions. This makes navigating the life sciences landscape depend in large part on legal and regulatory expertise, as well as extensive practical industry experience.

The following key Acts provide the principles of the national regulation of pharmaceuticals and medical devices, whereby the legal terminology in Switzerland refers to "therapeutic products" as the generic term encompassing both "medicinal products" (pharmaceuticals) and "medical devices".

- Medicinal products – Therapeutic Products Act (TPA), Ordinance on Medicinal Products (OMP), Medicinal Products Licensing Ordinance (MPLO), Ordinance on the Requirements of Marketing Authorisation of Medicinal Products (OMAMP), Ordinance on Advertising of Medicinal Products (OMPA), and the Ordinance on Integrity and Transparency (OIT).
- Medical devices – TPA, Medical Devices Ordinance (MedDO) and Ordinance on In Vitro Diagnostic Medical Devices (IvDO). Switzerland recently revised its medical devices law to align it with Regulation (EU) 2017/745 on medical devices (EU-MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU-IVDR).

Duties and responsibilities for Swiss healthcare are divided among the federal, cantonal and municipal authorities, whereas this practice guide focuses on the federal level. As part of the Federal Department of Home Affairs (FDHA), the Federal Office of Public Health (FOPH) is responsible for public health in Switzerland. The Swiss Agency for Therapeutic Products (Swissmedic) is the Swiss authority responsible for the authorisation and supervision of therapeutic products. As a federal public law institution, Swissmedic is autonomous with respect to its organisation and management.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative decisions of regulatory bodies are usually issued in the form of a ruling and can be challenged in administrative procedures or administrative court proceedings. The appropriate legal action depends on whether a federal or a cantonal regulatory body has issued the decision. If issued by a federal authority, decisions can be appealed to the Federal Administrative Court. Decisions of the Federal Administrative Court are subject to further appeal to the Federal Supreme Court.

These challenge procedures in general also apply to other regulated products. In certain areas, such as public procurement or social security, special provisions may apply. Besides, criminal procedure rules may apply to administrative and criminal sanctions issued by regulatory bodies.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal products are divided into four dispensing categories:

- category A – medicinal products that may be dispensed on a one-time basis on a physician's prescription (Article 41 OMP);

- category B – medicinal products that require a prescription and can be obtained several times, whereby medicinal products on list B+ can also be dispensed without a prescription (Article 42 OMP);
- category D – medicinal products that may be dispensed without a prescription, but after specialist advice (Article 43 OMP); and
- category E – medicinal products that may be dispensed without a prescription and without specialist advice (Article 44 OMP).

The assignment to a particular category determines who is authorised to dispense, prescribe and use the medicinal product (Articles 24 et seq TPA). Non-prescription medicinal products, known as "over the counter" medicinal products, are intended for self-medication. The classification into the different categories is made by Swissmedic (Article 23a TPA).

The TPA further contains special provisions for blood and blood products (Articles 32 et seq TPA) as well as for veterinary medicinal products (Articles 42 et seq TPA).

Medical devices are divided into different categories (classes I, IIa, IIb, III) for which different conformity assessment procedures apply. The classification follows the respective regulation in the EU-MDR (Article 16 paragraph 1 MedDO) and is based on the intended purpose and the associated risk. Certain medical devices may be classified as intended for use by healthcare professionals (HCPs) only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are mainly governed by the TPA, the Human Research Act (HRA), the Human Research Ordinance (HRO), the Clinical Trials Ordinance (ClinO) and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). In principle, clinical trials with therapeutic products require prior authorisation from Swissmedic (Article 54 paragraph 1 TPA) and the competent ethics committee (Articles 24 et seq ClinO and Articles 9 et seq ClinO-MD). Regarding medicinal products, Swissmedic examines whether the Good Manufacturing Practice and safety requirements are met (Article 54 paragraph 4 lit a TPA); regarding medical devices, the assessment includes the conformity of the products with the safety requirements (Article 54 paragraph 4 lit b, Article 45 paragraphs 1 and 3 TPA).

Clinical trials must be conducted in line with the rules of good clinical practice as set out, with regard to medicinal products, in the ICH Guideline on Good Clinical Practice of 9 November 2016 and the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Article 5 paragraph 1 ClinO; Article 3 ClinO-MD). With regard to medical devices, the applicable rules on good clinical practice were incorporated into Swiss legislation by way of reference to Article 72 and Annex XV Chapters I and III of Regulation (EU) 2017/745 on medical devices (MDR) as well as in EN ISO 14155.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In order to secure authorisation for the conduct of a clinical trial, the investigator must submit an application to the ethics committee in the canton in whose territory the study is conducted (Articles 24 et seq ClinO; Articles 10 et seq ClinO-MD):

- acknowledgment of receipt/possible deficiencies' notification within seven (medici-

nal products) or ten (medical devices) days respectively; and
- decision within 30 (medicinal products) or 40 (medical devices) days respectively and information of Swissmedic in case an authorisation by Swissmedic is necessary; in case of multi-centre clinical trials with medicinal products, the deadline is extended to 45 days.

The submission of the application to Swissmedic is made by the sponsor:

- acknowledgment of receipt/possible deficiencies' notification within seven (medicinal products) or ten (medical devices) days respectively;
- as a general rule, decision within 30 (medicinal products) or 45 (medical devices) days respectively; and
- in certain circumstances, Swissmedic must obtain the opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) or the FOPH before granting the authorisation.

2.3 Public Availability of the Conduct of a Clinical Trial

Sponsors of authorised clinical trials with medicinal products are subject to registration obligations (Articles 64-67 ClinO). Before conducting a clinical trial with medicinal products, the sponsor must enter the clinical trial either in a primary register recognised by the World Health Organisation (WHO) or in the register of the National Library of Medicine of the United States of America as well as in the supplementary Swiss federal database using a Swiss national language. The publicly accessible portal SNCTP (Swiss National Clinical Trials Portal) displays studies that are being conducted in Switzerland as soon as they have been approved by the cantonal ethics committee and released for publication by the researchers. The data originates from (i) the cross-cantonal application submission platform BASEC and (ii) the international study database ICTRP (WHO database comprising 17 worldwide primary registers). The operation of the portal – as well as the supplementary federal database – is guaranteed by the co-ordination office Kofam (Article 67 paragraph 3 ClinO). The following data may be accessed publicly: a brief description of the clinical trial, the site(s) where the clinical trial is conducted, the criteria for the participation in the clinical trial, the disease category and the health condition investigated, as well as an indication of whether the clinical trial includes rare diseases.

Sponsors of clinical trials with medical devices are subject to analogous registration obligations (Article 41 ClinO-MD). Public access to the results of the clinical trials is ensured by publication in one of the above-mentioned registers (Article 42 ClinO-MD).

Generally, the results of clinical trials are not publicly available. However, physicians that are member of the Swiss Medical Association (FMH) are subject to a publication obligation contained in the ethical guidelines of the Declaration of Helsinki (2013) regarding the results of human research.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Personal data held for research purposes must be protected by appropriate operational and organisational measures (cf. Article 5 paragraph 1 HRO). The applicable ICH Guideline explicitly refers to the increasingly widespread use of electronic data handling and remote electronic trial data systems and outlines the additional requirements that must be met by the sponsor when using such tools (see Section 5.5.3 of the

Guideline for Good Clinical Practice EG(R2) of 9 November 2016). In addition, the use of online and electronic tools is subject to the limitations imposed by Swiss data protection law (in particular the Federal Act on Data Protection (FADP) and the respective Ordinance (DPO) both of which will be completely revised as of 1 September 2023).

2.5 Use of Data Resulting From the Clinical Trials

Health data is considered personal data requiring special protection. The HRA regulates in detail the further use and disclosure of health data that falls within its scope of application. In principle, the disclosure of health data is permissible both within an organisation and to third parties depending on the type of health data, the intended further use and the assignability to a specific person. The data protection provisions do not apply to anonymised and pseudonymised data, insofar as the data subjects are no longer identifiable.

2.6 Databases Containing Personal or Sensitive Data

According to the HRA and its implementing provisions (Article 43 HRA; Article 5 HRO), anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent the unauthorised use thereof, and must fulfil certain operational and professional requirements.

Since 2016, the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has complemented the Declaration of Helsinki.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The decisive criterion for the classification of a product as a therapeutic product – ie, as a medicinal product or as a medical device, is the intended purpose of the product, which – considering all objective (nature of a product) and subjective (designation and promotion of a product) circumstances of the individual case – must be the medical effect or application on the human organism.

As regards the distinction between medicinal products and medical devices, the decisive factor is not the material composition of the product, but whether its intended main effect in or on the human body is caused by pharmacological, immunological or metabolic means (medicinal products), or rather through mechanical, physical or physico-chemical effects (medical devices; Article 3 paragraph 1 lit a and b TPA; BVGE C-2093/2006, E. 3.5).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

No specific requirements need to be met for the authorisation of biological medicinal products (Article 2 paragraph 1 lit d Ordinance on the Simplified Marketing Authorisation Procedures (OSMA)). It is, however, necessary that an equilateral black triangle standing on its apex is included in the package leaflet and information, which is accompanied by the statement that this medicinal product is subject to additional monitoring (Article 14a lit b OMAMP).

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

The authorisation of medicinal products is initially valid for a period of five years and is subject to subsequent renewal upon application (Article 16 paragraph 2, Article 16b paragraph 1 TPA). If a medicinal product is not placed on the market within three years of the granting of the authorisation, or if it is no longer actually on the market during a period of three consecutive years after it has been placed on the market, Swissmedic may revoke the authorisation (Article 16a paragraph 1 lit a TPA). Medicinal products must fulfil their authorisation requirements for each production unit during the entire distribution period, whereby such requirements may only be modified, extended or restricted by a formal amendment procedure. Swissmedic may at any time review the authorisation, adapt it to changed circumstances or revoke it (Article 16c TPA).

Regarding medical devices, the necessary certificates of conformity (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical or Medical Devices**) are valid for a maximum of five years and are extended following a re-assessment (Article 26 MedDO). If a designated body finds that a manufacturer no longer fulfils the requirements of the MedDO, it must set a deadline for correction and otherwise suspend, revoke or restrict the certificate (Article 27 MedDO).

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

An authorisation to place medicinal products on the Swiss market is granted based on a respective application (Article 11 TPA) and after a detailed examination by Swissmedic. Applicants must hold a manufacturing, import or wholesale license issued by Swissmedic (see **4. Manufacturing of Pharmaceutical and Medical Devices**), have a registered address, office or branch office in Switzerland and must prove that the medicinal product is of high quality, safe and effective (Article 10 TPA).

Different authorisation procedures apply depending on the characteristics and the application of the medicinal product.

- Ordinary procedures for first authorisations of new active pharmaceutical ingredients (APIs) and major deviations (Article 9 paragraph 1, Articles 11 et seq TPA).
- Compassionate use authorisations (in a simplified procedure, Articles 14 et seq TPA) for a limited period – ie, for life-threating or debilitating diseases if they are compatible with the protection of health, their use is expected to have a major therapeutic benefit, and no authorised, alternative or equivalent medicinal product is available in Switzerland (Article 9a TPA; Articles 18 et seq OSMA).
- Fast-track procedures for first authorisations of new APIs and major deviations on request, available for promising therapies for the prevention or therapy of a severe, debilitating or life-threatening disease with a high therapeutic benefit and where the standard treatment is either unavailable or unsatisfactory (Article 7 OMP).
- Simplified procedures for certain categories of medicinal products where this is compatible with the quality, safety and efficacy requirements and where there is no conflict with Swiss interests or international agreements, in particular for generics (but not for biosimilars), orphan drugs and certain categories of medicinal products authorised and/or used in foreign countries (Articles 14 et seq TPA; Articles 12 et seq OSMA).

- The authorisation procedure on the basis of a notification, in particular for certain complementary medicines without indications and other medicinal products with a low-risk potential (Article 15 TPA).

Changes to an authorisation that have no or only minimal consequences for the quality, safety or efficacy of a medicinal product must be communicated to Swissmedic within 12 months of their implementation (Article 21 OMP). Substantial variations require an additional marketing authorisation procedure. Marketing authorisations are in principle transferable upon approval of a respective application by Swissmedic.

Medical devices do not require an authorisation by a public authority prior to being placed on the Swiss market. Instead, they must bear a respective conformity (MD or CE) marking testifying the conformity of the device with the general safety and performance requirements.

The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq MedDO; Articles 17 et seq IvDO). Depending on the risk qualification of the medical device (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**), the conformity is either to be declared by the manufacturer or by a private body certified to conduct conformity assessments.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

In principle, ready-to-use medicinal products may only be placed on the market after they have been authorised (Article 9 paragraph 1 TPA). However, there are a number of exceptions to this general rule.

- Medicinal products for which a review of the ordinary approval requirements (of high quality, safe and effective) is not necessary or useful – eg, formula magistralis, officinalis and hospitalis products or products intended for clinical trials (Article 9 paragraphs 2 et seq TPA).
- Orphan use – the use of medicinal products for the treatment of diseases that are so rare that there is hardly any incentive for a regular marketing authorisation to be approved in Switzerland for a limited period in a simplified approval procedure (Article 9a, Article 14 paragraph 1 lit f TPA).
- Temporary authorisation for use outside of clinical trials – Swissmedic may temporarily authorise the use of yet unauthorised medicinal products intended for clinical trials outside the scope of a clinical trial (Article 9b paragraph 1 TPA; Articles 52 et seq MPLO).
- Temporary authorisation to bridge temporary unavailability – medicinal products may be temporarily or quantitatively authorised by Swissmedic to bridge the unavailability of an identical medicinal product in Switzerland, provided that they are authorised in another country with an equivalent medicinal product control and no essentially identical medicinal product is authorised and available in Switzerland (Article 9b paragraph 2 TPA).
- Off-label use – off-label use – eg the use of a (properly) authorised medicinal product for other indications, is generally permissible within the scope of Articles 3 and 26 TPA.
- Unlicensed use – an unlicensed medicinal product may be imported under the restrictive requirements of Article 20 paragraph 2 TPA and Articles 48 et seq MPLO.

Manufacturers of medical devices must generally carry out a conformity assessment before placing the device on the market (see **3.4 Pro-**

cedure for Obtaining a Marketing Authorisation for Pharmaceutical or Medical Devices). However, in the interest of public health or patient safety or health, Swissmedic may, upon application, grant an authorisation even though the relevant conformity assessment procedure has not been carried out (Article 22 paragraph 1 MedDO; Article 18 paragraph 1 IvDO).

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Holders of marketing authorisations for medicinal products, as well as medical device manufacturers, must have a post-market surveillance system (ie, pharmacovigilance and materiovigilance plans) in place (Article 11 paragraph 2 lit a no 5 TPA; Article 56 MedDO; Article 49 IvDO).

Holders of marketing authorisations for medicinal products with a new API or a biosimilar must periodically and automatically file safety update reports (PSURs) with Swissmedic on the safety and risk-benefit ratio for four years after authorisation (Article 60 OMP). With its marketing authorisation, Swissmedic may impose additional conditions or obligations on the applicant, including further product evaluations (eg, in Phase IV clinical trials). Depending on the classification of a medical device, its manufacturer has similar trend report, periodic summary report and PSUR obligations to the designated body involved in the conformity assessment (Articles 59 et seq MedDO; Articles 52 et seq IvDO).

As for incident notification requirements, manufacturers of medicinal products, distributors of ready-to-use medicinal products and HCPs must notify Swissmedic of adverse events, adverse drug reactions and quality defects within 15 days in case of serious adverse reactions and within 60 days of non-serious reactions. Similarly, anyone placing medical devices on the Swiss market must report to Swissmedic all serious incidents as well as all field safety corrective actions that are undertaken in Switzerland (Article 66 MedDO; Article 59 IvDO).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Authorities must in principle treat all data collected within the framework of the TPA and its implementing regulations as confidential, including all data communicated to the authorities in the context of a marketing authorisation application (Article 62 TPA). Granted marketing authorisations for medicinal products are published in the monthly Swissmedic Journal, together with essential information about the medicinal product. Swissmedic publishes an assessment report (SwissPAR) for all medicinal products with a new API, as well as for transplant products, for which a decision to approve or reject authorisation has been issued. The SwissPAR includes the evaluation results of the application for new authorisation or additional indication of a medicinal product, but not the applicant's commercial or manufacturing secrets or personal data.

Regarding medical devices, the conformity assessment procedures by Swiss or European assessment bodies are not accessible to third parties. The successful completion of a conformity assessment is made public together with the issuance of the declaration of conformity for the respective product (Article 90 lit f MedDO).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Switzerland has signed and ratified the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime-Convention).

Accordingly, several provisions were introduced into the TPA, including mandatory licensing for persons trading medicinal products in foreign countries from Switzerland or acting from Switzerland as brokers or agents for medicinal products (Article 18 paragraphs 1 and 2 TPA), the designation of Swissmedic as the national contact point under the Medicrime Convention (Article 69 paragraph 4 TPA), and criminal provisions (Articles 90 et seq TPA).

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Customs authorities are involved in monitoring the importation, the transit and the exportation of therapeutic products. In particular, they monitor whether the medicinal products are authorised or compliant and whether the quantity lies within the maximum limit. In the case of suspicious shipments of goods, the customs office notifies Swissmedic and holds back the products in question. Decisions in application of healthcare regulations are, however, made exclusively by Swissmedic.

Following the ratification of the Medicrime-Convention (see **3.8 Rules Against Illegal Medicines and/or Medical Devices**), the Federal Office for Customs and Border Security (FOCBS) was granted the competence, alongside Swissmedic, to order secret surveillance measures (Article 90a TPA).

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacture of medicinal products in Switzerland is subject to a mandatory licence (Article 5 paragraph 1 lit a TPA). The same applies to anyone withdrawing blood from humans for the purpose of transfusion or the manufacture of therapeutic products or for supply to a third party (Article 34 TPA). The licence is issued if Swissmedic has successfully verified during an inspection that the necessary technical and operational conditions have been fulfilled and an appropriate system of quality assurance exists (Article 6 TPA; Articles 3 et seq MPLO). The licence is issued for an unlimited period of time, whereby Swissmedic performs periodic inspections and may revoke licences if the requirements are no longer fulfilled.

Manufacturers of medical devices are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and is registered with Swissmedic (Articles 51 and 55 MedDO; Articles 44 and 48 IvDO; Article 11 EU-MDR/ EU-IVDR).

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Any person engaged in the wholesale trade of medicinal products must possess a licence (Article 28 paragraph 1 TPA). The licence is issued following an inspection by Swissmedic (Article 28 paragraph 2 TPA; Articles 11 et seq MPLO).

No licences are required for the wholesale (Article 4 paragraph 1 lit i MedDO; Article 4 paragraph 1 lit h IvDO) of medical devices. Foreign manufacturers, however, need to appoint an authorised representative domiciled in Switzerland (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**).

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

Importation and exportation of medicinal products and medical devices are mainly governed by the TPA, MPLO, MedDO and the Swiss customs legislation. At the point of entry, the responsibility for the application and enforcement of the respective regulations lies with the FOCBS. The competent governmental authority for any subsequent market surveillance is Swissmedic. FOCBS and Swissmedic co-operate closely in their joint areas of competence (cf. Article 65 MPLO).

6.2 Importer of Record of Pharmaceutical and Medical Devices

Any person that professionally imports medicinal products intended for distribution or dispensing must possess a licence issued by Swissmedic (Article 18 paragraph 1 lit a TPA) following an inspection confirming that the necessary technical and operational conditions have been fulfilled and that an appropriate system of quality assurance exists (Article 19 paragraph 1 TPA; Articles 11 et seq MPLO).

Importers of medical devices (Article 4 paragraph 1 lit h MedDO; Article 4 paragraph 1 lit. g IvDO) are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and if the importer is registered with Swissmedic and is assigned a CHRN (Article 55 MedDO; Article 48 IvDO; see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In principle, only medicinal products that have been granted a marketing authorisation by Swissmedic can be imported into Switzerland (Article 9 TPA), and importation is subject to a specific licence (Article 18 paragraph 1 lit a TPA). Subject to certain exceptions, in particular in connection with an official batch release from a foreign control authority belonging to the

Official Control Authority Batch Release Network (OCABR), anyone wishing to import immunological medicinal products or blood and blood products generally requires a special licence for each individual shipment (Article 44 MPLO). Under certain circumstances, ready-to-use medicinal products without a marketing authorisation in Switzerland may be imported in small amounts by persons for private use or by HCPs (cf. Articles 48 and 49 MPLO).

While no licence for the import of medical devices is required (see **6.2 Importer of Record of Pharmaceutical and Medical Devices**), medical devices must, prior to their placing on the Swiss market, undergo a conformity assessment to ensure that general safety and performance requirements are met (Articles 6, 21 et seq MedDO; Articles 6, 21 et seq IvDO). Certifications of conformity (CE markings) issued by bodies from EU/EEA countries are unilaterally recognised in Switzerland (Article 25 paragraph 4 MedDO; Article 21 paragraph 4 IvDO).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant Harmonised Tariff Schedule (HTS) line will determine which market surveillance authority is competent to examine and approve import. The product-related laws and implementing ordinances set out the restrictions in detail.

6.5 Trade Blocs and Free Trade Agreements

Switzerland is a member of the European Free Trade Association (EFTA) and is, amongst others, signatory to the Free Trade Agreement with the EU of 1972 as well as to a network of currently 33 free trade agreements with 34 partners. The EU has unilaterally ceased the application of the Mutual Recognition Agreement as regards medical devices. As a result, exportation of medical devices from Switzerland into the EU has become more burdensome. Negotiations are currently taking place between the USA and Switzerland on a free trade agreement concerning the pharmaceutical sector, which is intended to facilitate market access for Swiss pharmaceutical companies.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Under Swiss law, prices of therapeutic products are controlled to the extent that they are reimbursed by the compulsory health insurance. With regard to therapeutic products not reimbursed by compulsory health insurance, manufacturers, wholesalers and retailers are, in principle, not restricted in their pricing.

Pharmaceuticals are reimbursed subject to a listing on the Specialties List (SL) where ready-to-use medicinal products are included. Medicinal products that are manufactured in a pharmacy are reimbursed if their APIs are included in the List of Medicines with Tariff (LMT). The requirements for the price fixing are mainly contained in the Health Insurance Act (HIA), the Health Insurance Ordinance (HIO) and the Ordinance on the Benefits under the Mandatory Health Insurance (OBHI). The SL determines the ex-factory price as well as the public price, which is the maximum amount (including VAT) that must be reimbursed by health insurers.

The FOPH decides on the inclusion of a medicinal product on the SL after consultation with the Federal Drugs Commission (EAK), except

in case of certain medicinal products, such as generics and new galenic forms or package sizes of already listed medicinal products (Article 31 paragraph 2 OBHI). An accelerated procedure applies in case of an accelerated market authorisation (Article 31a OBHI). The procedure is initiated by the market authorisation holder (Article 31 paragraph 1 OBHI). Medicinal products can only be included in the SL if the criteria of efficacy, appropriateness and cost-effectiveness are met (Article 32 paragraph 1 HIA). The prices are reviewed every three years (Article 65d HIO), and additional reviews take place upon patent expiry and in case of the authorisation of further indications.

The List of Items and Tools (LIT) determines which devices are covered by the compulsory health insurance. Unlike the SL, the LIT does not fix the ex-factory and public price, but only sets the maximum reimbursement amount. In principle, higher prices may be charged and the difference is borne by the patient. There are specific provisions governing the application for inclusion on the LIT. The FDHA decides upon consultation of the Federal Commission for Analyses, Instruments and Tools (FCAIT) on the addition, change, or delisting (cf. Articles 21 et seq OBHI). The criteria of efficacy, appropriateness and cost-effectiveness also apply to medical devices.

7.2 Price Levels of Pharmaceutical or Medical Devices

When setting and reviewing the prices of the medicinal products included in the SL, the FOPH relies on the following comparisons: (i) a therapeutic comparison in which the effectiveness of the medicinal products is assessed in relation to other medicinal products used for the same indication (Article 65b paragraph 4bis HIO); and (ii) a price comparison with the same medicinal product abroad (cf. Article 34a and 34b OBHI). The two comparisons are given the same weight. The latter comparison is carried out according to the guidance of the EAK taking into account foreign countries whose pharmaceutical sector is economically comparable with Switzerland.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Under the compulsory health insurance, insurers must reimburse costs for prescribed medicinal products listed in the SL and the LMT at the maximum amount set out therein. The reimbursement may be restricted to specific indications, quantities or durations. Reimbursement is, in general, only granted for listed medicinal products under the condition that they are used in connection with indications approved by Swissmedic and within approved quantities. Exceptions from this general rule apply on a case-by-case basis subject to the conditions set out in Article 71a HIO. In addition, there is also room for reimbursement in individual cases of medicinal products not yet authorised, not yet included in the SL or used outside their marketing authorisation (Articles 71b-d HIO).

Medical devices applied by the patient are reimbursed under the condition that they belong to a specific group of medical devices in the LIT, are prescribed by a physician or chiropractor and are dispensed by an authorised provider. The reimbursement of listed medical devices may be restricted to specific medical indications, quantities or durations. Case law has not yet addressed the question of whether the provisions of Article 71a-d HIO are also applicable to medical devices by analogy.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Among the conditions for the inclusion of medicinal products on the SL are their efficacy, appropriateness and cost-effectiveness, and the existence of these conditions must be periodically reviewed (Article 32 HIA). Medicinal products that no longer meet these criteria are removed from the SL by the FOPH. The same applies to medical devices (to be) included on the LIT.

It is usually undisputed that an authorised medicinal product is effective and appropriate. In practice, the main focus is therefore on the criterion of cost-effectiveness, including the respective comparisons with other medicinal products and markets (see **7.2 Price Levels of Pharmaceutical or Medical Devices**).

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

While the main purpose of the prescribing and dispensing regulations is to safeguard patient welfare and safety in the dispensing and use of medicinal products by requiring that only HCPs with sufficient education, training and continuing education are involved (Articles 24-26 TPA), HCPs are required by their professional duties and corresponding provisions in their self-regulations to also observe the aspect of economic efficiency. Furthermore, the legal provisions on the advertising of medicinal products explicitly provide for the inadmissibility of advertising, including to HCPs, which may encourage the excessive use of medicinal products (cf. Article 23 paragraph 1 lit b TPA). Lastly, the integrity provisions (cf. Article 55 TPA; OIT) prohibit the excessive prescribing of medicines.

In general, physicians may prescribe any authorised medicinal product for a given indication without regard to its price, and they are not obliged to propose a more affordable (generic) alternative. That said, if the SL contains different medicinal products containing the same API, the cost share that must be borne by the patient may vary. Physicians must inform their patients accordingly. Equally, for medicinal products that are not included in the SL or that are used off-label or off-limitation, HCPs must inform the patients that the costs might not be reimbursed under the compulsory health insurance. According to Article 52a HIA, pharmacists are allowed, but not obliged, to substitute a prescribed original medicinal product listed on the SL with a generic unless there is an explicit request by the prescribing physician or chiropractor to dispense the original.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps are not subject to specific regulation in Switzerland, but are considered medical devices provided that the app is intended to be used for a medical purpose as set out in the TPA (see **3.1 Product Classification: Pharmaceutical or Medical Devices**; Federal Administrative Court decision C-669/2016 of 17 September 2018). Therefore, such apps must comply with the legal requirements for medical devices, including regarding conformity assessments.

8.2 Rules for Telemedicine

While telemedicine is established in Switzerland, only few cantons have issued specific regulation (eg, § 8 Health Care Act of the Canton of Basel-Landschaft). Thus, telemedicine is governed by general healthcare law and the medical code of ethics. As soon as the treating physician can no longer assume that a patient can be treated carefully by means of telemedicine, the treatment must be adjusted and the patient must be

either physically examined or referred to another physician. The provisions of data protection and medical secrecy (Article 321 Swiss Criminal Code (SCC)) are also applicable to treatments using telemedicine methods.

8.3 Promoting and/or Advertising on an Online Platform

Electronic advertising of medicinal products, such as via online portals and social networks, without any access restriction, qualifies as advertising to the general public (Article 15(c) OMPA), which is prohibited for prescription medicines (Article 32 paragraph 2 lit a TPA). Access to professional advertising via electronic means must be restricted by appropriate technical and password protection to professionals authorised to dispense or apply medicinal products (Article 5a OMPA). The same applies to media releases and press kits which directly or indirectly reference the prescription of specific medicinal products (Swissmedic Guidance "Advertising of medicinal products on the internet").

There are no specific regulations governing online promotion and advertising of medical devices. The promotion to the general public of products intended solely for the use by HCPs is prohibited (Article 51 TPA; Article 69 paragraph 3 MedDO; Article 62 paragraph 3 IvDO).

8.4 Electronic Prescriptions

Rules on electronic prescription are part of the regulation on the electronic patient record. The FMH and the Pharmacists Association "Pharmasuisse" announced in a 2022 statement that they intend to create an electronic prescription, and initial pilot tests have already been launched.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicinal products is, in principle, prohibited (Article 27 TPA). By exception, a licence may be granted by the competent cantonal authorities to persons already in possession of a cantonal retail authorisation to run a public pharmacy if (Article 27 paragraphs 2 and 4 TPA; Article 55 paragraph 2 OMP):

- there is a physician's prescription for the medicinal product (irrespective of whether it qualifies as a prescription-only product);
- no safety requirements oppose it; and
- appropriate consultation and sufficient medical supervision of the effect of the medicinal product are guaranteed.

The online sale of medical devices is, in principle, permitted (Article 7 MedDO; Article 7 IvDO).

8.6 Electronic Health Records

In 2017, the Federal Act on the Electronic Patient Record (EPR) and the related ordinances came into force and regulate the conditions for the introduction and implementation of the electronic patient dossier (EPD). The EPD is a filing system for treatment, with relevant information containing copies of medical records, whereby the decision whether to open an EDP is left to the patients (opt-in). The data is stored in encrypted form and can only be viewed by the patients and authorised HCPs. The EPR is currently being revised.

Health-related data is regarded as sensitive data pursuant to the FADP and the DPO, provided that the data directly or indirectly references an identified or identifiable person's physical or mental health. This means that, in principle, anonymised data is not regarded as sensitive data.

More stringent requirements apply to sensitive data, including requiring data controllers to:

- inform the person concerned about the collection of their data;
- ensure that the disclosure of sensitive data to third parties is based on a legal justification; and
- comply with specific registration and notification obligations with the Federal Data Protection and Information Commissioner (FDPIC).

Moreover, the general provisions of the FADP must be complied with. The transfer and storage of health data on a cloud platform is, in principle, permitted under the FADP. However, this is only possible if, among others, no legal or contractual confidentiality obligation prohibits such transfer. Physicians are bound by professional secrecy regarding the medical history or the contents of the patient file (Article 321 SCC). They remain responsible for keeping confidentiality even when transferring the data and therefore must ensure that the patient data is protected against unauthorised processing. The FMH recommends that physicians do not store health data of their patients in clouds located abroad.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Federal Act on Patents and Inventions (PatA) and the Ordinance on Patents and Inventions (PatO) apply to patents in Switzerland. Further, Switzerland is a member of the major international patent treaties, such as the European Patent Convention (EPC) and the Patent Co-operation Treaty (PCT).

Generally, patents are granted for new inventions applicable in the industry (Article 1 paragraph 1 PatA). This applies equally to medicinal products and medical devices. Certain inventions, such as gene sequences, are excluded from patent protection. Accordingly, the patentability of medicinal products developed from human gene sequences must be subject to a particularly critical examination. Methods for medical treatment are also excluded from patent protection. While it is in essence undisputed that the exclusion from patentability only refers to the methods, and not to products, used in such methods, it can be difficult to draw a clear distinction between device-related methods and functional device features.

9.2 Second and Subsequent Medical Uses

Pharmaceutical substances or compositions that – even though they are part of the state of the art as such – do not yet form the state of the art in relation to a specific use in a surgical, therapeutic or diagnostic method that is distinct from the first medical use, are deemed to be new and, hence, patentable, provided they are intended for use in the manufacture of a means to a surgical, therapeutic or diagnostic end (Article7d PatA). Consequently, the use of a substance or composition for the manufacturing of a means for a medical procedure is patentable. Such claims are referred to as Swiss-type claims.

New dosage regimes and the indication for a new or selected patient population as such cannot be patented. However, if a dosage regime or indication is new and based on an inventive step, such new dosage regime or new indication can be patented. In most cases, however, a new dosage regime will be considered obvious and, hence, not patentable.

To date, it is unclear what activities constitute infringement of second and subsequent patents of medicinal products. More specifically, it has yet to be decided whether and to what extent the exclusive rights conferred by a traditional substance claim, by a claim for second and subsequent medical use under Article7d PatA and by a purpose-oriented substance claim under Article 54(5) of the EPC differ from each other.

9.3 Patent Term Extension for Pharmaceuticals

In principle, patent protection is granted for a term of 20 years from the filing date of the application and cannot be extended. For medicinal products, the Swiss Intellectual Property Institute (IPI), upon application, grants a supplementary protection certificate (Certificate) for the APIs or a combination of APIs upon application. Such Certificate takes effect on expiry of the maximum patent term for a period equal to the period which elapses between the date of filing and the date of the first authorisation of the medicinal product in Switzerland minus five years, but for a maximum term of five years. Subject to statutory conditions, the Certificate's term of protection may be extended once for a period of six months. Anyone may file a request with the IPI to revoke such extension.

9.4 Pharmaceutical or Medical Device Patent Infringement

Medicinal products and medical device patents confer the exclusive right to commercially use the invention in Switzerland. This exclusive right can be infringed through direct or indirect misconduct. A direct infringement occurs when an unauthorised party uses a patent commercially by, inter alia, manufacturing, storing, offering, advertising to Swiss customers, placing on the market, importing, exporting and carrying in transit a patent-protected product, or by possessing the patent-protected product for any of these purposes. An indirect infringement occurs if a party contributes to a direct patent infringement – ie, if a party instigates, participates in, favours, facilitates or contributes in other ways to a direct patent infringement. Such contribution must have an adequate causal link to the direct patent infringement.

Apart from actual patent infringements, the mere threat of infringement is actionable as well. In such cases, the claimant must deliver proof of a sufficient interest in legal protection. Such an interest exists if the unlawful act is imminent – ie, if the alleged infringement of rights is to be seriously expected.

Acts that are necessary for obtaining a marketing authorisation and an SL listing in Switzerland are not covered by the effects of the patent and are, hence, not actionable (Article 9 paragraph 1 lit c PatA).

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

In Swiss patent litigation proceedings, both the validity of a patent as well as the question of infringement are examined in detail. Consequently, the key defences relate to the invalidity of a patent as well as the lack of an infringement.

Further, as the effect of a patent does not extend to acts undertaken for research or experimental purposes under Swiss law (Article 9 paragraph 1 lit b PatA), the defence of experimental use may be raised. Additionally, acts undertaken as part of a medical activity by legally authorised persons concerning an individual person and involving a medicinal product (Article 9 paragraph 1 lit g PatA) and the direct individual preparation of medicinal products in pharmacies

in accordance with a physician's prescription (Article 9 paragraph 1 lit h PatA) are excluded from patent protection.

9.6 Proceedings for Patent Infringement

Patent infringement proceedings may be initiated by the patent owner and by a patent licensee who holds an exclusive licence and whose right to initiate an infringement action is not explicitly excluded in the licence agreement. Exclusive and non-exclusive licensees are eligible to join a pending infringement proceeding in order to claim their own loss or damages.

Through a patent infringement proceeding, a claimant may seek a variety of remedies, such as injunctive relief, the remedying of an unlawful situation, damages or a declaratory judgment. Further statutory remedies are the provision of information, the destruction of infringing goods, the recall of patent infringing goods or the publication of the decision.

Typical patent infringement actions are carried out in the form of inter partes preliminary injunction proceedings for interim relief, followed by ordinary proceedings on the merits.

A defendant may raise the defence of invalidity in preliminary injunction proceedings. If such a defence is raised, the Federal Patent Court examines both the question of validity and the question of infringement in almost as much detail as in ordinary proceedings on the merits. In ordinary proceedings on the merits, the invalidity may be invoked either as a defence or through a counterclaim.

9.7 Procedures Available to a Generic Entrant

There is no requirement of a declaratory action for a generic product to enter the Swiss market. While a prior marketing authorisation is required for a medicinal product to enter the market, such authorisation procedure is not considered to result in a patent infringement.

At the same time, the simplified authorisation procedure used for generic entry in Switzerland (Articles 14 et seq TPA; Articles 12 et seq OSMA) references the marketing authorisation documents of the medicinal product with the known APIs that are protected for a period of ten years from the marketing authorisation of such product. Accordingly, the marketing authorisation for generic entrants can, in principle, only be granted upon expiry of the document protection.

For medical devices, Swiss law does not foresee a marketing authorisation procedure. It is for the competitor to decide on its market entry, and for the holder of a patent in the original medical device to take legal action.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

In Switzerland, various intellectual property laws and procedures exist against the counterfeiting of medicinal products and medical devices, including the following:

- the PatA, the Trade Mark Protection Act (TmPA), the Federal Design Act and the Federal Act on Copyright and Related Rights, are the main laws that protect intellectual property rights in Switzerland. In case of infringements, these statutes grant remedies such as injunctions, damages and account of profits;
- under criminal law, counterfeiting medicinal products and medical devices constitutes a criminal offence. The Swiss intellectual

property laws provide for criminal penalties against counterfeiters, including custodial sentences of up to five years and monetary penalties; and
- under customs law, the FOCBS is responsible for enforcing intellectual property rights at the Swiss border – eg, by withholding goods and notifying the proprietor of the intellectual property right if there is a suspicion that the import, export or transit of such goods infringes rights in Switzerland.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Medicinal products and medical devices are generally eligible for trade mark registration. The examination of trade marks may take place at different stages.

- The IPI refuses trade mark protection if the registered sign (i) is in the public domain, (ii) is misleading, (iii) is contrary to public policy, morality or applicable law, or (iv) if the registered shape constitutes the nature of the goods themselves or is technically necessary (Article 2 TmPA).
- Swissmedic takes appropriate measures within the marketing authorisation proceedings if there is a risk of confusion between medicinal products with a similar name or similar design and if the confusion could have serious consequences. Such measures include the use of capital letters in parts of the name (so-called Tall Man Letters) or a change of the name or of the graphic design.
- If there is any suspicion of the imminent import of medicinal products and medical devices into Switzerland that unlawfully bear a trade mark, the FOCBS is authorised to notify the proprietor of the trade mark and to withhold such goods at the border (Article 70 to 72 TmPA).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

In principle, the design of medicinal products and medical devices, as well as their packaging, are eligible for trade mark, design and copyright protection. The scope of protection will depend on the (intellectual property) right that is being sought and on the level of distinctiveness of the specific design or trade dress.

- Upon registration, trade mark protection is granted in Switzerland to protect the distinctive appearance of a product and/or its packaging. In order to be protected, such trade mark must be distinctive.
- Upon registration, design protection is granted in Switzerland to protect the appearance of a product and/or its packaging. A design is protected to the extent that it is new and has individual character.
- Copyright protection is granted as of the moment of the creation of a design. No registration is required. The design must, however, qualify as an original work of authorship to be protected.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

The documents that are submitted to obtain marketing authorisation for medicinal products are generally protected for a period of ten years from the granting of the marketing authorisation in Switzerland (Articles 11a et seq TPA). In the case of an important orphan medicinal product, document protection is granted, upon request, for a period of 15 years. This applies both to drugs of chemical or biological origin. Accordingly, subsequent marketing authorisation submissions cannot rely on the protected documents.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Numerous (temporary) regulations were issued in connection with the COVID-19 pandemic, also affecting the marketing and distribution of therapeutic products. As of today, the key regulation in this respect is the Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3), which is intended to ensure that Switzerland can maintain adequate medical care for the population and sufficient essential medical supplies. To this end, the COVID-19 Ordinance 3 establishes notification requirements for stocks of essential medical supplies, procurement and distribution requirements and simplifying exemptions for the placing on the market and importation of medicinal products and medical devices for the prevention and control of COVID-19.

11.2 Special Measures Relating to Clinical Trials

Swissmedic and Swissethics issued joint recommendations for the handling of clinical trials with medicinal products during the COVID-19 pandemic ("Joint Guidance"). The Joint Guidance provided, among other things, that applications for clinical trials related to COVID-19 were prioritised and that applications for clinical trials could be submitted electronically and in bundles of multiple applications. Furthermore, for the period of the pandemic, specific amendments regarding the distribution of investigational medicinal drug products and the monitoring of clinical trials were provided.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

During the pandemic, different exemptions from the general authorisation requirement for medicinal products were issued.

- Certain medicinal products used for the treatment of COVID-19 patients, can already be placed on the market during the approval process (Article 21 paragraph 1 of the COVID-19 Ordinance 3).
- The same applies to medicinal products that prevent the COVID-19 infection of immunosuppressed persons under certain conditions (Article 21 paragraph 1bis COVID-19 Ordinance 3).
- Variations to the authorisation for certain authorised medicinal products can be implemented immediately upon application (Article 21 paragraph 2 COVID-19 Ordinance 3).
- Swissmedic was enabled to approve the import of essentially identical medicinal products as a short-term solution for any temporary non-availability of medicinal products (Article 22 paragraph 3 COVID-19 Ordinance 3).

Likewise, certain exemptions were introduced for medical devices.

- Subject to approval by Swissmedic, medical devices that have not (yet) undergone the required conformity assessment procedure in Switzerland or in a recognised third country (eg, the EU) may nevertheless be placed on the Swiss market under certain requirements (Article 23 paragraph 1 COVID-19 Ordinance 3).
- Face masks that have not undergone a conformity assessment procedure can be placed on the market, provided that they are not used in the medical field and are labelled

accordingly (Article 23 paragraph 4 COVID-19 Ordinance 3).

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No simplifications regarding manufacturing licences were introduced in connection with the pandemic. However, for a short period of time, Swissmedic inspections were suspended or modified, and Swissmedic confirmed that all GMP certificates issued in 2017/2018 would remain fully valid until the end of 2021 or the next routine inspection. In January 2023, Swissmedic provided an update according to which all planned routine inspections in Switzerland were carried out and that it was no longer necessary to generally extend GMP certificates. Extended EU GMP certificates are, however, accepted by Swissmedic.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Different regulations were introduced during the pandemic to facilitate the import of medicinal products.

- Following the submission of an authorisation application according to Article 21bis COVID-19 Ordinance 3, the applicant can import the medicinal product before the decision on the authorisation or entrust a company carrying a wholesale or import licence with the import (Article 22 paragraphs 1 and 2bis COVID-19 Ordinance 3).
- Pharmacists who have pharmaceutical responsibility in a hospital pharmacy are authorised to import certain medicinal products (Article 22 paragraph 1bis COVID-19 Ordinance 3).
- For the temporary non-availability of a medicinal product, Swissmedic may allow the temporary import of an identical medicinal product, provided no other essentially identical medicinal product is authorised and available in Switzerland (Article 22 paragraph 3 COVID-19 Ordinance 3).
- Article 22 paragraph 4 Covid-19 Ordinance 3 permits the import and storage of COVID-19 vaccines before their authorisation, under certain conditions.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Under the pandemic, a wider range of remote services delivered by HCPs was reimbursed by the compulsory health insurance in order to comply with the requirements of social distancing.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Applicants may bring action before Swiss courts for a compulsory non-exclusive licence for the manufacture of patent-protected medicinal products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to epidemics (Article 40d paragraph 1 PatA). However, no such licence has been granted to date in the medicinal products area, including for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were introduced for COVID-19 treatments and vaccines in Switzerland, and the general product liability rules continue to apply.

In addition to these general rules, the Epidemics Act (EpA) provides a special ground for liability claims for vaccines. Accordingly, anyone who is

harmed by an officially ordered or officially recommended vaccination is entitled to damages, and also to moral compensation of maximum CHF70,000, if the severity of the impairment justifies it (Articles 64 et seq EpA). However, the Swiss State only grants compensation if the damage cannot be covered otherwise with reasonable efforts – eg, by the vaccine manufacturer. While this compensation scheme existed already prior to the COVID-19 pandemic, it has attracted greater attention since.

11.9 Requisition or Conversion of Manufacturing Sites

There was no requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The Swiss Armed Forces Pharmacy has been granted extended rights in connection with the procurement of essential medical goods if requirements cannot be covered through the normal procurement channels (Article 14 COVID-19 Ordinance 3).

THAILAND

Law and Practice

Contributed by:
Radeemada Mungkarndee, Tanakrit Tangburanakij, Praewpan Hinchiranan and Tienkul Kangwanwong
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Contents

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LEXEL IP CO, LTD is a new specialist intellectual property (IP) law firm which provides exceptional legal services. Founded in October 2022 by highly ranked senior members of the legal profession, the LEXEL team has many years of exclusive IP experience and has been recognised for its expertise in patents, trade marks, copyright and design protection, providing advice to prestigious Thai and international clients. The firm advises a cross-section of industries, including life sciences, healthcare, healthtech, pharmaceuticals, biotech, chemicals, petrochemicals, biochemicals, software, consumer goods, mechanical engineering, packaging and materials, process engineering, automobiles and film production. The life sciences and healthcare team has broad knowledge and expertise, consisting of lawyers and practitioners with extensive experience across various practice areas. Key areas of the firm's practice relating to the life sciences sector include IP protection, IP enforcement and dispute resolution, regulations on innovation development, regulatory compliance, data protection and privacy.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Legislation and Regulations

The primary legislation governing pharmaceuticals in Thailand is the Drug Act, B.E. 2510 (1967), along with its amendments and ministerial regulations and notifications, which encompass specific regulations and requirements (collectively referred to as the "Drug Law"). Similarly, the primary legislation governing medical devices in Thailand is the Medical Devices Act, B.E. 2551 (2008), along with its amendments and ministerial regulations and notifications, which encompass specific regulations and requirements (collectively referred to as the "Medical Devices Law"). These acts provide regulatory frameworks for pre-market and post-market controls for pharmaceuticals and medical devices in Thailand, respectively.

Regulatory Bodies

The Thai Food and Drug Administration (the "Thai FDA"), which falls under the Ministry of Public Health (MOPH), serves as the primary government administrative and regulatory body overseeing pharmaceuticals and medical devices in Thailand. The Drug Control Division of the Thai FDA is the primary regulatory body responsible for drug regulation, including pre-market control, post-market control, and development of standards and regulations. Similarly, the Medical Device Control Division of the Thai FDA is the main regulatory body for medical device control in Thailand.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Under the Drug Law, if the licensing authority refuses to grant or renew a licence, the applicant has the right to appeal against that decision to the MOPH within 30 days of receiving notice of the decision. Failure to appeal within the designated timeframe will result in licence revocation. While the Drug Law does not specify a timeframe for appeal consideration, the period for appeal consideration will follow the Administrative Procedure Act, B.E. 2539 (1996), which is 30 days from the date of receiving the appeal.

Regarding medical devices, if the authority fails to issue an establishment licence, licence, or specifications declaration receipt, or does not renew an establishment licence, the applicant has the right to appeal that decision to the MOPH within 30 days of receiving notice of the non-issuance. According to the Medical Devices Law, the MOPH must complete the appeal process within 120 days of receiving the appeal. If, due to extenuating circumstances, the consideration cannot be completed within the specified period, a written notice must be sent to the appellant before the expiration of the period. The appeal consideration period may be extended for up to 120 days beyond the initial 120-day consideration period.

Under the Drug Law and the Medical Devices Law, the decision of the Minister of Public Health shall be final. However, if the appellant is dissatisfied with the MOPH's decision, they have the right to file a case before the Administrative Court.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

Under the Drug Law, pharmaceuticals are categorised into the following categories:

- modern drugs: drugs intended for use in the practice of modern medicine, or the cure of an animal disease;
- traditional drugs: drugs intended for use in the practice of the traditional medicine or the cure of animal diseases which appear in a pharmacopoeia of traditional drugs notified by the Minister, or drugs notified by the Minister as a traditional drug, or drugs of which the formula has been registered as that of a traditional drug;
- dangerous drugs: modern or traditional drugs notified by the Minister as a dangerous drug;
- specially controlled drugs: modern or traditional drugs notified by the Minister as a specially controlled drug;
- external drugs: modern or traditional drugs intended for external use;
- specific place drugs: modern or traditional drugs intended for use in specific places for ears, eyes, nose, mouth, anus, vagina or urinal tract;
- household medicine (equivalent to over-the-counter (OTC) drugs): modern or traditional drugs notified by the Minister as a household medicine;
- pre-packed drugs: modern drugs manufactured in a pharmaceutical from, which are packed in a closed or sealed container or packed and are labelled in accordance with the Drug Law; and
- herbal drugs: drugs derived from plants, animals or minerals which have not yet been compounded, dispensed or denatured.

Medical Devices

Under the Medical Devices Law, medical devices are categorised into three main categories as follows:

- medical devices that require manufacturers or importers to obtain a licence from the Thai FDA before manufacturing or importing;
- medical devices that require manufacturers or importers to notify the Thai FDA of the device details before manufacturing or importing; and
- medical devices that require manufacturers or importers to register with the Thai FDA before manufacturing or importing.

In addition, the Notification of the MOPH Regarding Medical Device Classification According to Risk Level B.E. 2562 (2019) (the "MOPH Notification 2019") further classifies medical devices based on the degree of risk as listed below in order to align with the Association of Southeast Asian Nations Medical Device Directives (AMDD):

- Class 1 – low risk, requiring registration with the Thai FDA;
- Class 2 – low to moderate risk, requiring declaration to the Thai FDA;
- Class 3 – moderate to high risk, requiring declaration to the Thai FDA; and
- Class 4 – high risk, requiring a license from the Thai FDA.

Therefore, according to the Medical Devices Law and the MOPH Notification 2019, medical devices are classified as follows:

- Licensed Medical Devices (equivalent to Class 4 Medical Devices);
- Detailed Notification Medical Devices (equivalent to Class 2 and Class 3 Medical Devices); and

- Listed Medical Devices (equivalent to Class 1 Medical Devices).

2. Clinical Trials

2.1 Regulation of Clinical Trials

There is no specific law governing clinical trials in Thailand. Furthermore, there is no requirement that clinical trials must be conducted locally in order to obtain marketing authorisation in Thailand. However, the informed consent process is indirectly governed by the following:

- the Civil and Commercial Code;
- the Personal Data Protection Act B.E. 2562 (2019) (PDPA);
- the National Health Act, B.E. 2550 (2007);
- the Mental Health Act, B.E. 2551 (2008); and
- the Declaration on the Rights and Responsibilities of the Patients B.E 2558 (2015).

In addition, there are many regulations that govern health professionals conducting clinical trials including:

- the Medical Profession Act B.E. 2525 (1982);
- the Regulations of the Medical Council of Thailand on maintaining the ethics of the medical profession about research studies and human trials B.E. 2565 (2022);
- the Regulations of the Medical Council of Thailand on maintaining the ethics of the medical profession regarding stem cell transplantation for treatment B.E. 2552 (2009);
- the National Policy and Guidelines for Human Research 2015 issued by the National Research Council of Thailand (NRCT); and
- the Ethical Guidelines for Research on Human Subjects in Thailand 2007 issued by the Forum for Ethical Review Committee in Thailand.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Any research institute that wishes to undertake a clinical trial must establish a research ethics committee to review and approve research projects involving clinical trials. The committee must be certified by either the NRCT (under the National Ethics Committee Accreditation System of Thailand (NECAST)) or The Strategic Initiative for Developing Capacity of Ethical Review/Forum for Ethical Review Committee in Asia-Pacific (SIDCER/FERCAP).

If a clinical trial is conducted for a pharmaceutical, the above committee must be approved by the Thai FDA. In addition, the pharmaceutical must be used only in research projects approved by the Thai FDA.

2.3 Public Availability of the Conduct of a Clinical Trial

In general, the research institute undertaking clinical trials usually publishes annual reports of the clinical trial on its website. These reports contain only an overview and progress of the clinical trials undertaken in such research institutes without disclosing results of the trials. While these reports must be submitted to the Thai FDA, the authority does not currently provide a publicly accessible database of the reports.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no laws or regulations that restrict the use of online tools to support clinical trials, provided that such tools comply with the PDPA.

2.5 Use of Data Resulting From the Clinical Trials

There is no specific law or regulation that categorises data obtained from clinical trials as personal or sensitive data. However, resulting data

from the clinical trials may be deemed personal or sensitive data under the PDPA, depending on the information in such data.

Under the PDPA, personal data is defined as any information relating to a natural person, which enables the identification of such person, whether directly or indirectly, but not including information of deceased persons. Although, the PDPA does not provide an explicit definition of sensitive data, the PDPA does list several categories of personal data that are subject to greater protection, including health data. The PDPA requires that the processing of sensitive personal data must meet a higher standard of consent and security measures than non-sensitive data.

Under the PDPA, such resulting data from the clinical trials may be transferred to a third party or an affiliate after receiving explicit consent from persons involved in the clinical trials. Additionally, all data management activities, including the transfer of such resulting data, must comply with provisions stipulated in the PDPA.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data obtained from clinical trials would not be subject to any requirements beyond those proscribed in the PDPA.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The term “pharmaceutical” under the Drug Law refers to substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness. It also includes substances which are pharmaceutical chemicals or semi-processed pharmaceutical chemicals, as well as substances intended to affect the health, structure or function of the human or animal body. However, this term does not include substances intended for use as food for humans, sport devices, medical apparatus, cosmetics or devices for use in the practice of healing arts or practice of medicine or components thereof, or those intended for use in a science laboratory for research, analysis or verification of diseases that are not directly related to the human body.

The term “medical device” under the Medical Devices Law refers to an instrument, tool, mechanical device or object that is used for insertion into a human or animal body, fluid for laboratory examination, product, software or any other object specifically intended by the manufacturer for specific uses (such as therapy, medical practice, dental practice, diagnosis, prevention, monitoring, treatment, relief or cure of human or animal disease or injury) either solely or as a constituent or accessory of any other object. It also includes equipment or a constituent of an instrument, tool, mechanical device product or object thereof. However, the accomplishment of the above purposes, which occurs within a human or animal body, must not be the result of a pharmacological, immunological or metabolic process.

For a combination product that includes both a drug and a device, its classification as either a drug or medical device will be based on its intended use. The Thai FDA will make a final decision to classify such a combination product at its discretion, where it cannot be clearly distinguished. However, the Division of Innovative Health Products and Services under the Thai

FDA provides an online consultation service regarding this.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

There are no specific requirements for biologic medicinal products, including biosimilars, to receive a marketing authorisation. Importantly, the marketing authorisation procedures for new, generic, biologic, and biosimilar drugs do not differ.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

For marketing authorisations, pharmaceuticals are classified into three categories as follows:

- New Drugs: a drug formula that has not previously been registered in Thailand which include products of a new chemical entity (NCE), a new combination, a new dosage form, a new drug delivery system, a new indication, a new strength or a new route of administration;
- New Generic Drugs: a drug formula containing the same active pharmaceutical ingredient(s), dosage form, indication(s), route of administration and strength as a reference drug that had previously been approved by the Thai FDA after B.E. 2534 (1991); and
- Generic Drugs: a drug formula containing the same active pharmaceutical ingredient(s), dosage form, indication(s), route of administration and strength as a reference drug that had previously been approved by the Thai FDA before B.E. 2534 (1991).

Under the Drug Law, the marketing authorisation of a drug formula must be renewed every seven years. An application for renewal must be submitted before the expiration date.

Under certain conditions, the marketing authorisations of a drug formula can be revoked in cases where:

- the drug formula does not have the properties as registered;
- the drug formula may be unsafe for use;
- the drug formula is counterfeit; and/or
- the drug formula has been altered to become a substance intended for use as food or cosmetics, and has been granted permission to produce and sell as a specially controlled food or cosmetic in accordance with relevant laws and regulations.

As mentioned in **1.3 Different Categories of Pharmaceuticals and Medical Devices**, medical devices are classified as follows:

- Licensed Medical Devices (Class 4 Medical Device);
- Detailed Notification Medical Devices (Class 2 and Class 3 Medical Device); and
- Listed Medical Device (Class 1 Medical Device).

All classifications of medical devices are valid for a period of five calendar years and renewable.

Marketing authorisations of medical devices may be revoked in certain conditions including:

- information on the medical devices does not correspond to the true facts or benefits thereof;
- the medical devices are counterfeit;
- the medical devices are unsafe for use;
- the intended purpose of the medical devices has changed to be used as drugs, psychotropic substances, narcotics, hazardous substances or cosmetics without permission; and/or

- the medical devices do not possess benefits as claimed, as evidenced by reliable scientific sources.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Pharmaceutical Products

Individuals or juristic persons must obtain a licence from the Thai FDA to manufacture, sell or import drugs.

The manufacturer or importer must file an application for manufacturing or importing drug samples as appropriate, to request a marketing authorisation. For imported drugs, a certificate of Good Manufacturing Practice (GMP) of the overseas manufacturer must also be provided. The amount of the drug to be manufactured or imported for the marketing authorisation are subjected to the Notification of Drug Control Division.

The manufacturer or importer must file a marketing approval application, along with drug samples, certificate of such drugs including product characteristics, technical and safety information and data concerning the results of clinical trials, and other pertinent data to the Thai FDA in order to obtain marketing authorisation.

Medical Devices

Individuals or juristic persons must obtain an establishment licence from the Thai FDA to manufacture or import medical devices.

The manufacturer or importer must file a marketing approval application to the Thai FDA in order to obtain marketing authorisation. The Note for Licence and Detailed Notification Medical Devices, Common Submission Dossier Template (CSDT) according to the AMDD must be applied.

To amend a marketing authorisation for pharmaceuticals and medical devices, such as therapeutic indication, formulation, packaging or labelling, the marketing authorisation holder must submit a request for the amendment, along with supporting documents, to the Thai FDA.

Transfer of Marketing Authorisation

According to the Drug Law, it is possible for a marketing authorisation holder to transfer its licence to another holder under certain conditions. A marketing authorisation holder can transfer its licence to another holder with the approval of the Thai FDA. The transfer must be made in writing and must include the reasons for the transfer, as well as the details of the transferee. Both the transferor and the transferee must be licensed by the Thai FDA to manufacture or import drugs. The transferee must also have the technical capability to manufacture or import the drug covered by the licence.

The Thai FDA will evaluate the application for the transfer of the licence based on the information provided by the transferor and the transferee. If the transfer is approved, the transferee will become the new marketing authorisation holder and will be responsible for complying with all applicable regulations and guidelines.

However, the Medical Device Law in Thailand does not provide regulations for the transfer of licences from marketing authorisation holders to another holder.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The Drug Law and Medical Device Law do not explicitly outline compassionate-use programmes.

However, pharmaceuticals manufactured and imported for the following purposes will not be subject to a marketing authorisation, if they comply with the requirements outlined in the Notification of the MOPH:

- for the purpose of research or analysis;
- for exhibition; or
- for charitable purposes.

In addition, only the following entities are authorised to produce and import pharmaceuticals without possessing a licence:

- ministries, public bodies and departments that have a duty to prevent or treat disease;
- the Thai Red Cross Society; and
- the Government Pharmaceutical Organisation.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The Medical Device Law requires licence holders to prepare and maintain a record of the manufacturing, importation and sale of their medical devices for a specific period of time. Moreover, there are notifications issued by MOPH and the Thai FDA that regulate licence holders to report the device malfunction and/or adverse event.

For pharmaceuticals, the Safety Monitoring Programme (SMP) of new drugs has been in place in Thailand since 1991 and has been updated periodically. In 2017, the Thai FDA issued a notification on the risk-based approach of the SMP. The Health Product Safety Surveillance Centre (HPVC), an organisation under the Strategy and Planning Division of the Thai FDA, has also made a publicly available adverse event reporting website. The HPVC is responsible for collecting reports and managing the adverse event database of health products, including drugs, food, cosmetics, medical devices, herbs and more.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

In general, third parties are not allowed to access pending applications for marketing authorisations for pharmaceuticals and medical devices in Thailand as the Thai FDA considers these applications as confidential information. However, there may be some circumstances under which third parties could access information in pending applications, such as in cases where the information is required for legal proceedings or public health and safety reasons. In these circumstances, the third party would need to obtain special permission from the Thai FDA or other relevant authorities to access the information.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Both the Drug Law and the Medical Devices Law prescribe criminal penalties for any illegal acts regarding the production, import, marketing and/or distribution of pharmaceutical products and medical devices, including but not limited to:

- manufacturing a counterfeit drug is liable to imprisonment for a term of from three years to life and to a fine from THB10,000 to THB50,000;
- importing or selling a counterfeit drug is liable to imprisonment for a term of 1-20 years and to a fine from THB2,000 to THB10,000;
- manufacturing or importing a counterfeit medical device is liable to imprisonment for a term not exceeding ten years or to a fine not exceeding THB1 million or both; and
- selling a counterfeit medical device shall be liable to imprisonment for a term not exceed-

ing five years or to a fine not exceeding THB500,000, or both.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

In Thailand, there is a customs recordal system to tackle counterfeit products at the borders. Trade mark or copyright owners (or their representatives) may file an application specifying any preliminary information that customs officers may use to verify the authenticity of goods being exported, imported or transited through Thailand on the spot. The application must be filed with the Customs Department, not the Department of Intellectual Property (DIP) as previously done. The customs recordal will be valid for three years and is renewable. Rights holders who have previously filed a customs recordal with the DIP need to re-file the customs recordal with Customs Department.

If the rights holders proceed with customs recordal, the Customs Department may look out for suspected counterfeit products, including but not limited to, pharmaceuticals and medical devices and proceed with their ex-officio action against suspected counterfeit products.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Generally, manufacturers of pharmaceuticals and medical devices are subject to an authorisation for manufacturing from the Thai FDA.

Pharmaceuticals

To obtain a licence for pharmaceutical manufacturing, a manufacturer must apply for the licence along with necessary documents to the Thai FDA. A licence will be granted if the applicant's facility is qualified under the Pharmaceutical Inspection Co-operation Scheme (PIC/S), Good Manufacturing Practices (GMP), and all necessary documents are satisfactory. Once a licence is granted, it will be valid up until 31 December of the year in which the licence is issued. An application for renewal must be submitted before expiration of the current licence.

Medical Devices

To obtain a licence for medical device manufacturing, a manufacturer must apply for the licence along with necessary documents to the Medical Device Control Division of the Thai FDA. The Thai FDA will grant a licence if the applicant's facility is qualified with the GMP and all necessary documents are satisfactory. Once a licence is granted, it will be valid up until 31 December of the fifth year from the year in which the licence was issued. An application for renewal must be submitted before expiration of the current licence.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale of Pharmaceuticals

The wholesale of pharmaceuticals is subject to the authorisation of the Thai FDA. To obtain a wholesale licence, an application must be submitted to the Thai FDA, and the applicant must meet qualifications outlined in the ministerial regulations. The wholesale licence is valid until 31 December of the year in which it is issued,

after which an application for renewal must be submitted before the current licence expires.

In addition, under the Drug Law, a person who obtains a manufacturing licence or import licence is also licensed to engage in the wholesale of pharmaceuticals.

Wholesale of Medical Devices
The wholesale of medical devices also requires authorisation of the Thai FDA. An application for a sale licence must be submitted to the Thai FDA, and the applicant must meet the qualifications outlined in the ministerial regulations. The wholesale licence is valid until 31 December of the year in which it is issued.

5.2 Different Classifications Applicable to Pharmaceuticals
See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies
The importation and exportation of pharmaceutical and medical devices are mainly governed by the following laws and government authorities:

- the Medical Devices Law governed by the Thai FDA;
- the Drug Law governed by the Thai FDA;
- the Customs Act governed by the Customs Department; and
- the Export and Import of Goods Act governed by the Ministry of Commerce (MOC) and the Ministry of Finance.

The importation of pharmaceuticals requires a licence from the Thai FDA prior to importation into Thailand. The manufacturer or importer must obtain a local drug registration for that drug prior to the importing, manufacturing, marketing or selling of the said drug. It should be noted that registration requirements of the drugs differ for each type of drug.

To import medical devices, importers must first obtain an importing establishment licence and subsequently an import licence. Depending on the type of medical device, importers of medical devices could either be subject to a licensing, notification or listing requirements according to the Thai FDA's classification of medical devices. Please note that requirements for the importer to comply with the Thai FDA differ for each type of medical device.

The exportation of pharmaceuticals and medical devices are not subject to additional licences. Manufacturers of pharmaceutical and medical devices, as holders of a manufacturing licence, must report regarding its exportation activities as well as submit the required information to the Thai FDA to obtain certificates required for the customs clearance process.

6.2 Importer of Record of Pharmaceutical and Medical Devices
Only the entity that has been granted licences by the Thai FDA for the importation of pharmaceuticals and medical devices in Thailand can act as the importer of record for such products.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices into Thailand requires prior licensing and local product registration (market authorisation), notification or listing as regulated by the Thai FDA.

The importation of pharmaceuticals into Thailand is subject to a licence from the Thai FDA prior to importation. Moreover, the manufacturer or importer must obtain a local drug registration for that drug before importing, manufacturing, marketing or selling it. Please note that the registration requirements of drugs vary for each type of drug.

Importing medical devices into Thailand requires importers to first acquire an importing establishment licence, followed by an import licence. Depending on the type of medical device, the importer may be required to comply with licensing, notification or listing requirement based on the Thai FDA's classification of medical devices. Please note that requirements for importers vary for each type of medical device.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Importation of pharmaceuticals and medical devices into Thailand is governed by a licensing and market authorisation system as stipulated by the Thai FDA.

In general, the Thai FDA and other relevant agencies in Thailand have the authority to restrict importation and exportation of certain products that may harm consumers or be contrary to public order or good morals. For example, under the Export and Import of Goods Act, the Minister of Commerce has the authority to stipulate goods that are subject to importation and exportation restrictions.

6.5 Trade Blocs and Free Trade Agreements

Thailand has been a member of WTO since 1995, and ASEAN since 1967. Additionally, Thailand has signed 14 free trade agreements with 18 countries, including but not limited to, China, Japan and USA.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Thailand, there are no specific laws and regulations that govern pricing of pharmaceuticals and medical devices. The pricing of medicinal products is subject to control only if they are listed in the National List of Essential Medicines (NLEM), which is announced by the NLEM's Drug System Development Committee. Medicinal products listed on the NLEM are usually prescribed and dispensed in public hospitals and public health services. Public hospitals purchase medicinal products at a price not exceeding the median price indicated on the NLEM. However, private hospitals and drug stores can set their own prices for the medicinal products they sell at their establishments.

7.2 Price Levels of Pharmaceutical or Medical Devices

Generally, price levels of pharmaceuticals or medical device do not depend on or are not influenced by the prices of the same products in other countries. However, the prices of pharmaceuticals for the same products in other countries may be a factor for the determination of pricing decisions for drugs listed in the NLEM.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In Thailand, the costs of pharmaceuticals and medical devices are reimbursed from public funds to varying extents, depending on the type of product, the patient's health insurance coverage and the healthcare setting. There are three main schemes for public health coverage as set out below.

- The Civil Service Welfare Scheme for civil officers and their family, which is funded and administered by the Comptroller General's Department of the Ministry of Finance.
- The Social Security Scheme for eligible employees in the private sector, which is funded and administered by the Social Security Office.
- The Universal Coverage Scheme (UCS) for all other Thai nationals, funded and administered by the National Health Security Office under the National Health Security Act, BE 2545 (2002). The UCS provides coverage to a limited extent for a range of medical services, including inpatient and outpatient care, emergency services and maternity care.

It is worth noting that all three schemes use the NLEM as a basis for reimbursable medicinal products. The medicinal products outside of the NLEM can also be reimbursed, only with a prescription by medical professionals in charge stating it is necessary to cure the patient of a sickness. Reimbursement is subject to the conditions set by the Thai National Health Security Office (NHSO) or other relevant authorities.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In Thailand, health technology assessments (HTAs) are used in determining what price should be paid and reimbursed for pharmaceuticals and medical devices.

The NHSO is responsible for the HTA healthcare interventions. The NHSO' HTA process involves a comprehensive analysis of the clinical effectiveness, safety and economic value of a product.

The results of the HTA are used to inform pricing negotiations with pharmaceutical companies and to determine the reimbursement status of a product. Products that are deemed to be cost effective and have a favourable budget impact may be listed in the NLEM, which is used as a basis for reimbursement decisions by government healthcare insurance schemes.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Generally, there are no specific regulations for pharmaceutical prescriptions and dispensing by pharmacies in Thailand.

Specially controlled drugs (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**) can be dispensed to patients by a licensed pharmacist with a prescription from a licensed medical practitioner.

Pre-packed drugs and dangerous drugs can be dispensed to patients by a licensed pharmacist, without a prescription.

Household medicines (OTC drugs) are not required to be prescribed by medical practitioners or to be dispensed by a pharmacist. Common household drugs can be sold to consumers by anyone, for example, supermarkets or convenience stores.

8. Digital Healthcare

8.1 Rules for Medical Apps

Software is included under the definition of a "medical device" under the Medical Devices Law. Depending on the function of the software, the app could be subject to regulation as a medical device.

The Thai FDA has issued example guidelines of its assessment of software subject to regulation as a medical device, as set out below.

Software which is not considered a medical device:

- telemedicine software; and
- medical apps used in hospitals or healthcare facilities to facilitate the workflow of physicians and nursing facilities, eg, queue management, appointment management, cashier management.

Software which is considered a medical device:

- software used to detect a diabetic retinopathy; and
- Automated External Defibrillator (AED) tracking software.

It is worth noting that this is not an exhaustive list and the Thai FDA may classify software differently based on its function and intended use.

8.2 Rules for Telemedicine

Telemedicine services are regulated under the MOPH Notification Regarding Standards of Service of Medical Facility via the Telemedicine System B.E. 2564 (2021) (the "MOPH Telemedicine Notification") and the Medical Council of Thailand Notification No 54/2563 (2020) Regarding Guideline for Telemedicine (the "Medical Council Telemedicine Guideline").

According to the MOPH Telemedicine Notification, medical facilities that wish to provide telemedicine service must apply for an additional service from the MOPH. In addition, medical facilities providing telemedicine services are subject to additional criteria under the MOPH Telemedicine Notification, namely ensuring there is no effect to the main service provided on-site at the medical facility, ensuring a secure telemedicine system, and being liable for any consequence arising from the provision of its telemedicine service. Physicians are also required to only provide a telemedicine service through a medical facility, according to the Medical Council Telemedicine Guideline. In this case, a medical facility refers to a medical facility which is licensed to operate a medical facility under the Medical Facilities Act B.E. 2541(1998).

The Medical Council Telemedicine Guideline also prescribes additional rules for physicians to follow professional codes of conduct, understand the limitations of technology in telemedicine, assess whether a condition or disease is suitable for treatment via the telemedicine system, and more.

8.3 Promoting and/or Advertising on an Online Platform

Advertising medicines and medical devices require prior approval from the Thai FDA, regardless of whether the dissemination will be through online or offline media channels. The entity wishing to advertise a drug or medical device must submit the image, text and sound that makes up the advertisement to the Thai FDA for review and approval. The criteria for approval are prescribed under the Drug Law and the Medical Device Law. The criteria differ depending on the type of drug

or medical device and whether the advertising is targeted at the general public or healthcare professionals. For example, drugs categorised as "dangerous drugs" and "specially controlled drugs" are only allowed to be advertised directly to healthcare professionals and not to the general public.

For medical devices, the entity wishing to advertise a medical device is required to obtain an advertising licence for medical devices and approval prior to dissemination. However, if the advertising will be targeted directly at healthcare professionals meeting criteria prescribed by the Thai FDA, an advertising licence would not be required.

8.4 Electronic Prescriptions

Online prescriptions of medicine by pharmacists are permitted under the Pharmacy Council of Thailand Notification No 56/2563 (2020) Regarding Prescription of Standards and Procedures for Providing Telepharmacy (the "Telepharmacy Regulation"). However, any prescriptions that do not comply with the Telepharmacy Regulation would be considered prohibited as per the Drug Law, which prohibits the sale of drugs outside of the specified location mentioned in the seller's drug sale licence.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicine are permitted under the Telepharmacy Regulation. However, any sales of medicine that do not comply with the requirements stated in the Telepharmacy Regulation are currently prohibited as the Drug Law, which restricts the sale of drugs outside of the location specified in the seller's drug sale license.

8.6 Electronic Health Records

Electronic health records are not specifically regulated in Thailand, but they must comply with the PDPA (please refer to **2.5 Use of Resulting Data From the Clinical Trials**).

There is no specific prohibition for processing data on cloud platforms. However, if personal data is processed via cloud platforms, it must comply with the PDPA requirements regarding security standards and the transfer of data to locations outside of Thailand.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Thailand, the primary legislation governing patents is the Patent Act B.E. 2522 (1979) along with its amendments and relevant regulations (collectively referred to as the "Patent Law"). Pharmaceutical and medical device products may encounter several issues under the Patent Law, (including meeting standard criteria including novelty, inventive step and industrial applicability) as well as complying with disclosure requirements. Additionally, determining the patentability of subject matter can also be an issue.

Regarding the inventive step, subsequent pharmaceutical patents that modify existing active pharmaceutical ingredients (also known as "evergreening patents") can be controversial, as the changes made to the original invention may not constitute a substantial improvement to justify the grant of a new patent.

In terms of patentability of subject matter, the Patent Law imposes certain restrictions on patent-eligible subject matter, which includes:

- naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants;
- scientific or mathematical rules or theories;
- computer programmes;
- methods of diagnosis, treatment or cure of human and animal diseases; and
- inventions contrary to public order, morality, health or welfare.

Furthermore, it is important to note that the Thai Patent Examination Guideline provides extensive guidance and instructions to patent examiners on how to assess patent applications. The guideline includes examples of inventions that would not qualify as patent-eligible subject matter, such as a genetically-edited microorganism that mimics naturally occurring variants and a subsequent medical use that involves a method of administration or dosage regime (please refer to **9.2 Second and Subsequent Medical Uses**).

9.2 Second and Subsequent Medical Uses

In general, second and subsequent medical uses of a known product (such as a known chemical substance) in the form of a "Swiss-type claim" (eg, use of substance X in the preparation of a medication for the treatment of disease Y) can be patented in Thailand. However, if a Swiss-type claim involves a method of administration or dosage regime, which is considered a method of treatment claim, it will not be patentable. Additionally, the Swiss-type claim must be sufficiently supported by the patent specification.

9.3 Patent Term Extension for Pharmaceuticals

There are currently no mechanisms for patent term extension in Thailand under the Thai Patent Law.

9.4 Pharmaceutical or Medical Device Patent Infringement

According to the Patent Law, the patent holder has the following exclusive rights:

- for a product patent, the patent holder has the right to produce, use, sell, have in the possession for sale, offer for sale or import the patented product; and
- for a process patent, the patent holder has the right to use the patented process, to produce, use, sell, have in the possession for sale, offer for sale or import the product produced by the patented process.

Any person who violates the exclusive rights of the patent holder without the consent or permission of the patent holder will be in infringement of the patent unless an exemption applies.

It is worth noting that the mere act of applying for marketing authorisation for pharmaceuticals is not considered patent infringement in Thailand. There is a patent infringement exemption allowing a person to seek regulatory approval for a product even when there is a valid patent for the product.

However, it is important to note that only actual infringement is actionable under the Thai Patent Law. The threat of infringement, without actual infringement, is not actionable. Additionally, there is no requirement of "imminent" infringement. The patent holder must show its ownership of the infringed patent as well as prima facie

evidence of infringement when filing a complaint against an infringer.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Specific defences to patent infringement in relation to pharmaceuticals and medical devices include:

- any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder;
- the production of the patented product or use of the patented process, provided that the producer or user, acting in good faith and without knowing or having no reasonable cause to know of the patent application, has engaged in the production or has acquired the equipment prior to the date of filing of the patent application in Thailand;
- the compounding of a drug specifically to fill a doctor's prescription by a professional pharmacist or medical practitioner, including any act done to such pharmaceutical product;
- any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term; and
- the use, sale, having in possession for sale, offering for sale or importation of a patented product when it has been produced or sold with the authorisation or consent of the patent holder.

In addition, any ground such as lack of novelty and/or inventive step, or non-patentable subject matter which may invalidate or revoke the patent, can be considered as a ground of defence to patent infringement.

Compulsory Licensing

According to the Patent Law, any person can submit a request for a compulsory licence of a patent at any time after three years from the grant of a patent or four years from the filing date of an application, whichever is later, subject to the following conditions:

- the patented product has not been produced or the patented process has not been applied for manufacture in Thailand; or
- the patent holder does not sell the products protected by the patent in the Thai market in sufficient quantity, or such products are sold at an excessive price.

Moreover, a person who submits a request for a compulsory licence must demonstrate that they have made efforts to obtain a licence from the patent holder by proposing reasonable conditions and remuneration but failed to reach an agreement within a reasonable time period.

9.6 Proceedings for Patent Infringement

A patent holder including its authorised attorneys can bring proceedings for patent infringement before the court and claim for remedies or damages. However, only actual provable damages will be awarded. There are no punitive or statutory damages for patent infringement. A patent holder may calculate requested damages based on reasonable royalties or loss of profits and any other provable monetary damages and would have to prove that such damages were incurred directly from the infringing actions. If the judgment is ultimately in favour of the plaintiff, the court will consider the evidence from both the plaintiff and the defendant to determine appropriate damages.

In Thailand, both criminal and civil actions are available for patent infringement. Brief general procedures of each action are as follows.

Civil Action
A patent holder may initiate a civil case by filing a written complaint directly with Central Intellectual Property and International Trade Court (the "IP Court"). The complaint must describe which patent and which of the claims are being infringed. After the complaint has been filed, the IP Court will serve the complaint on the defendant, providing the defendant an opportunity to file a defence to the complaint. A settlement of issues hearing will be held following the filing of the defence. At that hearing, the IP Court will schedule the trial dates. A full trial will follow, and a decision will then be rendered by the IP Court. Any party that is dissatisfied with the IP Court's decision may file an appeal directly to the Specialised Court of Appeal and then to the Supreme Court.

Criminal Action
There are two types of criminal action, state criminal action and private criminal action.

For a state criminal action, a patent holder can lodge a complaint directly with the police officer so that the officer may request a search warrant from the Court and conduct a search of the alleged infringer's premises. If infringing products including materials relevant to the case are found, they will be seized as evidence and the alleged infringer will be arrested.

Once the officer finds there is sufficient grounds to prosecute the case, and if the public prosecutor agrees with the officer's conclusion, the public prosecutor will prosecute the case before the IP Court. The Court will schedule the trial and a decision will be rendered by the Court. At any time before the Court issues its decision on the case, a patent holder may file an application requesting permission from the Court to join as a co-plaintiff, to assist the public prosecutor and preserve its right to appeal. Any party dissatisfied with the Court's decision may file an appeal directly to the Specialised Court of Appeal and then to the Supreme Court.

For a private criminal action, a patent holder may initiate a criminal case by filing a criminal complaint directly with the Court. However, for this case, the Court will set a Preliminary Examination Hearing to examine the merits of the case before it is accepted for trial. If the Court rules that it will accept the case, a trial will follow, and a decision will be rendered by the Court. As mentioned, the Court's decision may be appealed directly to the Specialised Court of Appeal and then to the Supreme Court.

In addition, patent invalidity is available as a defence patent infringement and can be invoked at pleadings stage of proceeding. Also, a counterclaim for patent invalidity can also be filed by the defence.

9.7 Procedures Available to a Generic Entrant

Under the Drug Law, a new drug applicant in Thailand is required to submit documents showing patent/petty patent rights or rights related to traditional Thai medicinal wisdom for regulatory approval of a drug.

However, there is currently no patent linkage system or mechanisms in place for a potential generic entrant during the process of marketing approval. Currently, submitted documents relating to patent/petty patent rights are not considered by the Thai FDA in the marketing approval process.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The main legislation related to counterfeiting of pharmaceuticals and medical devices can be summarised as follows:

- the Medical Devices Law: counterfeiting medical devices is subject to criminal penalties;
- the Drug Law: counterfeiting pharmaceuticals is subject to criminal penalties;
- the Patent Law: infringement of a patent may occur where any person uses, produces, sells, possesses for sale, offers for sale or otherwise imports into Thailand the patented product or process without authorisation or consent from the patent holder;
- the Trademark Act: infringement of a trade mark may occur where any person, with bad faith, (I) counterfeits another person's trade mark registered in Thailand (ie, identical mark); or (II) imitates another person's trade mark registered in Thailand in order to deceive the public (ie, confusingly similar mark);
- the Copyright Act: infringement of a copyright may occur when there is an act of reproduction, adaptation, communication to the public of a copyright work, carried out without licence, authorisation or consent of the copyright owner;
- the Penal Code: unauthorised use of a name or logo may be subject to criminal penalties;
- the Civil and Commercial Code: in addition to the above criminal offences, the right holder may rely on tort/bad faith provisions to seek damages and/or a permanent injunction restraining the infringer from further acts of infringement; and
- the Customs Act: the import or export of counterfeit products is subject to criminal penalties.

The available procedures/actions against counterfeiting of pharmaceuticals and medical devices include, among others:

- warning letters: sending a cease-and-desist letter/warning letter to the infringer;
- police raids (state criminal action): filing a criminal complaint to the police to proceed with a police raid against the infringer;
- private criminal action: filing a criminal complaint directly to the IP Court to prosecute the infringer before the IP Court; and
- civil action: file a civil complaint directly to the IP Court to prosecute the infringer before the court to seek damages and/or a permanent injunction restraining the infringer from further acts of infringement.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There is no specific restriction on trade marks used for pharmaceuticals and medical devices.

Although parallel import is not deemed trade mark infringement under the Trademark Act, parallel import may be subject to certain other offences (ie, tax) in Thailand.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Thailand does not have specific provisions on trade dress. As such, trade dress may be subject to relevant laws (ie, Trademark Act, Copyright Act, Penal Code, Civil and Commercial Code) depending on the facts and surrounding circumstances of each case.

The design of pharmaceuticals and medical devices can be protected as a design patent under the Patent Law and may receive a protection term of ten years from the application filing date.

A design patent must be novel and capable of industrial application. A novel design means:

- it must not have existed nor has been widely used in Thailand before the application filing date;
- a substantial part must not have been disclosed or published, whether in Thailand or abroad;
- it must not be a design which has been published under the Thai design patent application system; and
- it must not be a design nearly resembling to any of the designs mentioned above as to be an imitation.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Thailand currently does not have specific provisions on data exclusivity for pharmaceuticals and medical devices.

However, the Trade Secrets Act B.E. 2545 (2002), along with its amendments and relevant regulations, (the "Trade Secret Law") provides protection of trade secrets and other confidential information against unauthorised use and/or disclosure of such information to be an actionable offence, subjected to both civil and criminal penalties.

Since data submitted to the Thai FDA to obtain marketing authorisation may contain trade secrets in the form of clinical trials data, testing results and/or preparation methods, the Trade Secrets Act and the MOPH's Ministerial Regulation Regarding Trade Secrets allow the information holder, such as drug originator seeking marketing authorisation, the right to request the Thai FDA to keep such submitted data confidential. Upon approval of the request, the Thai FDA must maintain the confidentiality of such data for five years.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, various regulations provided different levels of exemption depending on the specific categories were issued. For instance, the Thai FDA allowed importers, without an establishment licence, to distribute listed medical devices such as surgical face masks, personal protective equipment (PPE), and products relevant to COVID-19 antigen testing. However, there was no exemption on imports for pharmaceuticals for commercialisation. Instead, with the collaboration between the MOPH and the MOC, import tariffs were temporarily waived.

It is worth noting that as of October 2022, the Thai government declared COVID-19 as endemic, and the above-mentioned exemptions were revoked.

11.2 Special Measures Relating to Clinical Trials

No special regulations were issued in relation to ongoing clinical trials for COVID-19 treatments or vaccines. However, in May 2020, the Thai FDA issued the guideline for conducting clinical trials during the periods of widespread COVID-19 in accordance with Good Clinical Practice. The guideline provided recommendations for alter-

native methods of obtaining informed consent, such as by telephone or video conference, and for remote monitoring of trial participants. They also allowed for the use of home delivery of medication and for telemedicine visits, where appropriate. It should be noted that the guideline has been applied to clinical trials for any treatments or vaccines, not only for COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

According to the Thai FDA's Notification Regarding Conditional Approval for Emergency Use of Medicinal Products B.E. 2563 (2020), which mainly focuses on new efficient drugs and vaccines, modern drugs as defined by the Drug Law can be processed under the conditional registration scheme for the purpose of diagnosing, treating, relieving, curing or preventing COVID-19. This scheme permits licensed pharmaceutical producers or importers to apply for emergency use of pharmaceuticals in accordance with guidelines and ASEAN Common Technical Dossier (ACTD) or Common Technical Document by the International Council on Harmonisation (ICH-CTD) by providing details of the product, research, status of overseas approval and other relevant information.

However, in October 2022, the Thai government declared the COVID-19 pandemic had become endemic and cancelled many relevant regulations. As of March 2023, the FDA has approved six COVID-19 vaccines, and any regulation related to emergency approval or import has been revoked.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Pharmaceutical manufacturers must meet the standard of PIC/S and obtain a GMP licence, which is renewed annually. As of August 2022, due to the difficulty of on-site inspections and loosened documentary requirements, the Notification of the Thai FDA extended the validity of GMP certificates for domestic and overseas pharmaceutical manufacturers which expired before 31 December 2023 until 31 December 2023.

The authorised importer may submit the GMP certificate without notarisation/legalisation to the Thai FDA if they have not received the notarised/legalised overseas manufacturer GMP certificate. Nevertheless, the fully notarised or legalised GMP certificate must be submitted to the Thai FDA within 180 days from the issue date of the GMP certificate.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Since 2020, the Thai FDA has introduced several import flexibilities in its procedures to increase the supply of COVID-19-related vaccines, drugs and medical equipment in Thailand. These measures include reducing the period of obtaining import licences for devices that the Thai FDA considers to be immediately necessary, such as surgical masks and PPE. Additionally, the Thai FDA has issued the conditional approval procedure for manufacturing or importation of certain drugs for emergency use. Furthermore, the Thai FDA has issued a notification to temporarily allowing alcohol sanitiser gels to follow the approval process as a "cosmetic" product instead of as a "medical device". This change in classification reduces the approval process and restrictions.

11.6 Drivers for Digital Health Innovation Due to COVID-19

In Thailand, the telemedicine regulations as prescribed by the MOPH and various professional councils, such as the Medical Council of Thai-

land, Thailand Nursing and Midwifery Council, and Thai Traditional Medical Council, are among the most significant measures implemented to promote digital healthcare and digital transformation in response to COVID-19.

To promote the digital transformation of Thailand's national healthcare system, several long-term initiatives following the e-health strategy and digital health strategy of the MOPH are currently underway. These include the development of health information standards, data interoperability, and the national health information platform, which enables health information to be exchanged among related parties in the healthcare service chain. In implementing these strategic goals, the MOPH collaborates with other governmental agencies, including the Ministry of Digital Economy and Society, the Electronic Transactions Development Agency under the MDES, and the National Broadcasting and Telecommunications Commission.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

As of March 2023, there has been no announcement from the Thai government regarding the issuance of compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

There has been debate regarding a proposed royal decree to exempt medical personnel from liabilities resulting from COVID-19 treatment, including the use of vaccines and their effects. However, the draft decree did not pass the parliamentary process.

As of March 2023, the only relevant law that exempts medical personnel from being sued by an injured person is the Act on Tortious Liability of Officials B.E. 2539 (1996), which applies to medical personnel who act in good faith while performing their duties.

11.9 Requisition or Conversion of Manufacturing Sites

As of March 2023, there are no existing or new provisions allowing the use of or requisition or conversion of manufacturing sites due to COVID-19 or any intention to issue any such provisions.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

At the outset of the pandemic, the Public Procurement and Supplies Administration Ruling Committee issued guidelines for public procurement of supplies relating to prevention, control or treatment of COVID-19. The guidelines waived several regulations related to procurement costs and imposed procedures. The guidelines provided temporary permission for responsible authorities to proceed with the procurement of supplies related to the prevention, control or treatment of COVID-19 before reporting to the chief of each administration. Such report would be considered as proof of acceptance, mutatis mutandis.

Trends and Developments

Contributed by:
Radeemada Mungkarndee, Tanakrit Tangburanakij, Praewpan Hinchiranan and Tienkul Kangwanwong
LEXEL IP CO, LTD

LEXEL IP CO, LTD is a new specialist intellectual property (IP) law firm which provides exceptional legal services. Founded in October 2022 by highly ranked senior members of the legal profession, the LEXEL team has many years of exclusive IP experience and has been recognised for its expertise in patents, trade marks, copyright and design protection, providing advice to prestigious Thai and international clients. The firm advises a cross-section of industries, including life sciences, healthcare, healthtech, pharmaceuticals, biotech, chemicals, petrochemicals, biochemicals, software, consumer goods, mechanical engineering, packaging and materials, process engineering, automobiles and film production. The life sciences and healthcare team has broad knowledge and expertise, consisting of lawyers and practitioners with extensive experience across various practice areas. Key areas of the firm's practice relating to the life sciences sector include IP protection, IP enforcement and dispute resolution, regulations on innovation development, regulatory compliance, data protection and privacy.

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Cannabis Legislation in Thailand

In 2018, Thailand began the process of legalising cannabis by amending the Narcotics Act B.E. 2522 (1979) and issuing several ministry regulations and notifications that allowed for the medical use of cannabis. In November 2021, the Thai government enacted the Use of the Narcotics Code B.E. 2564 (2021) (the "Narcotics Code"), which came into force on 9 December 2021. This Narcotics Code revoked previous legislation, including the Narcotics Act and its amendments, as well as related ministry regulations and notifications. The Narcotics Code categorises narcotics into five categories (Category 1 to Category 5), with cannabis being classified as Category 5.

On 8 February 2022, the Ministry of Public Health (MOPH) issued the Notification Regarding Prescribing the List of Narcotics Under Category 5 (the "MOPH Notification"). The MOPH Notification came into effect on 9 June 2022 and delisted cannabis and hemp from Category 5. According to the MOPH Notification, only extracts obtained from any parts of cannabis or hemp plants that belong to the cannabis genus are considered narcotics with the exception of:

- extracts containing tetrahydrocannabinol (THC) not exceeding 0.2% by weight, which are only permitted for licensed extraction from cannabis or hemp cultivated in Thailand; and
- extracts obtained from cannabis or hemp seeds cultivated in Thailand.

Following the legalisation of cannabis and hemp on 9 June 2022, possessing, cultivating, distributing, consuming, and selling any part of cannabis and/or hemp (excluding the extracts mentioned above) is legal without the need for a licence. Moreover, recreational use of cannabis or hemp products is also legal. Despite the fact that the usage of cannabis products is still governed by the Narcotics Code, the absence of comprehensive and secure regulations for controlling such products after legalisation has sparked numerous concerns. Numerous notifications have been released by various government authorities to address these concerns, including the following.

- In March 2022, the Department of Health under MOPH issued the Notification Regarding the Use of Cannabis Leaves in the Preparation or Cooking of Food in Food Establishments, under the Public Health Act B.E. 2535 (1992). The Notification restricts the use of cannabis leaves in food or drink to a certain extent. Additionally, restaurants are required to disclose information about the presence of cannabis in their dishes to customers.
- In June 2022, the MOPH released the Notification Regarding the Prescription of Creations of Odour, or the Smoke from Cannabis, Hemp or Other Plants that Cause Nuisance under the Public Health Act B.E. 2535 (1992). This Notification aims to prevent the misuse of cannabis or hemp, such as recreational smoking of cannabis, that could affect others' quality of life or be harmful to health.
- In July 2022, the Ministry of Education also issued the Notification to Restrict the Use of Cannabis in Educational Institutions. This Notification also encourages educational institutions to offer education and training about cannabis to students and staff members so that they can be educated about using cannabis appropriately.
- Additionally, in July 2022, the Health Product Vigilance Centre (HPVC) under MOPH, issued the Guideline For Recording Adverse Event Reports From The Use Of Cannabis Product to monitor the safety and efficacy of medical cannabis used in Thailand by providing a sys-

tematic approach to identifying and addressing any adverse events that may occur. Any persons including healthcare professionals, cannabis product owners and/or consumers/patients can report adverse events to the HPVC. Adverse events include undesirable experience while using cannabis products, such as side effects, or other unexpected events. Detailed information regarding the patient, the cannabis product used, and the adverse event itself must be provided to the HPVC when reporting such events.

- In November 2022, the MOPH issued the Notification Regarding Controlled Herbs (Cannabis) under the Protection and Promotion of Traditional Thai Medicine Wisdom Act, B.E. 2542 (1999). This Notification states that only the inflorescence (complete flower head) of cannabis is considered a controlled herb, while other parts are not. If an individual or entity wishes to conduct activities such as studying, researching, exporting, distributing or transforming controlled herbs for commercial purposes, they must obtain a licence from the licensing authority. Additionally, the Notification stipulates specific restrictions on selling cannabis, for example, selling it to individuals who are under 20 years of age and/or students is prohibited.

Despite the existence of regulations, restrictions and licensing requirements, there are still legal loopholes that, for example, allow young people to use cannabis in private areas. Furthermore, there have been occasional reports of patients being hospitalised due to cannabis use since legalisation. To address these issues, a draft cannabis and hemp act has been proposed, but it is currently suspended due to an upcoming election in Thailand.

Digital Healthcare

Software as Medical Devices

In November 2022, the Thai Food and Drug Administration (the "Thai FDA") issued guidelines outlining its determination criteria for software as medical devices. The guidelines issued by the Thai FDA outline criteria for determining whether 11 types of software qualify as medical devices, which include both embedded and standalone software that are subject to risk classification for medical devices. These software types include those related to vital signs monitoring, sleep monitoring, fall detection and risk assessment. For each type of software, the guidelines provide examples of both software that is not considered a medical device as well as software that is considered a medical device. Additionally, the guidelines offer examples of risk-based medical device categories for the latter case.

The Thai FDA guidelines also provide examples of software that do not qualify as a medical device under the Medical Devices Act. These include the following:

- telemedicine software: and
- medical apps that facilitate workflows of healthcare professionals in hospitals or healthcare facilities, such as health records, queue management, appointment management and cashier management.

On the other hand, examples of software that are considered a medical device under the Medical Devices Act include:

- software used for detecting a diabetic retinopathy; and
- automated External Defibrillator (AED) tracking software.

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Telemedicine

Since 2020, telemedicine services have been permitted in Thailand and their growth has been accelerated by the COVID-19 pandemic. In October 2022, the National Health Security Office (NHSO) launched a telemedicine pilot programme starting initially in Bangkok, which began providing remote care services in December 2022.

To provide remote care services to patients for this pilot programme, the NHSO partnered with four private digital health service platforms, namely Good Doctor Technology, Clicknic, Mordee and Saluber MD, to offer remote care to patients. Currently, the telemedicine pilot programme covers 42 general diseases and/or symptoms, including red eyes, conjunctivitis, osteoarthritis, food poisoning, sinusitis, headache, stomach ache, sore throat, back pain and the flu. To use the telemedicine programme, patients are required to verify their identities and consult with healthcare consultants, which typically takes between 10 and 15 minutes. Medicines are delivered to patients within 24 hours following the consultation.

Target Patent Fast-Track Programme For Medical Inventions

Efficient treatments, such as pharmaceuticals, vaccines and medical devices, play a crucial role in enhancing people's health, particularly during the COVID-19 pandemic. In May 2022, the Department of Intellectual Property (DIP) released a notification announcing the Target Patent Fast-Track programme (referred to as "Patent Fast-Track"), which is aimed at expediting the grant of invention and petty patents that could aid in the development of medical treatments including those for COVID-19.

To participate in the Patent Fast-Track, applicants must meet certain requirements and file a request with the DIP, as set out below.

- The application must be filed in Thailand as a priority country or as a receiving office under the Patent Cooperation Treaty (PCT).
- For invention patents, the application must already be in the process of substantive examination for invention patent, which means that the applicant must have already submitted a request for substantive examination. For petty patents, the application must have already been filed with the DIP for at least three months.
- The invention must be related to products, processes, materials, compositions and/or devices in the medical technology field, with the potential to contribute to public health benefits.
- The application must not exceed ten claims.

Moreover, applicants must submit an explanation of (i) the invention's potential contribution to public health benefits, and (ii) its commercialisation potential, including production, commercialisation and/or licensing plans.

If an application is selected for the Patent Fast-Track, the DIP will expedite the examination process thereof. For invention patents, a final office action will be issued within 12 months from the selected date, and for petty patents, within 6 months.

As of February 2023, seven invention patent applications and eight petty patent applications have been selected to participate in the Patent Fast-Track.

Contributed by: Radeemada Mungkarndee, Tanakrit Tangburanakij, Praewpan Hinchiranan and Tienkul Kangwanwong, **LEXEL IP CO, LTD**

Personal Data Protection Act B.E. 2562 (2019)
Prior to the enactment of Thailand's Personal Data Protection Act B.E. 2562 (2019) (PDPA), several legal protections existed for health data. Specifically, the National Health Act B.E. 2550 (2007) protected health information from unauthorised disclosure, and the unauthorised disclosure of health information by health professionals was expressly prohibited as a criminal offense under the Thai Penal Code. Such an act would also constitute a violation of the ethical code for certain healthcare professionals, such as the Medical Council of Thailand's Regulation on Medical Ethics.

The PDPA was enacted in response to the increasing number of privacy violations in Thailand. It was enacted on 27 May 2019, and was initially scheduled to take full effect on 27 May 2020. However, due to the COVID-19 pandemic, the full implementation of the PDPA was postponed twice, and it finally came into effect on 1 June 2022.

The PDPA imposes additional requirements and prohibitions on the collection, use and disclosure of personal data, and recognises the rights of data subjects, which entities subject to the PDPA must comply with. The PDPA applies to entities located in Thailand and may extraterritorially apply to entities processing personal data of data subjects located in Thailand, as per the prescribed criteria. Both private and public entities may be subject to the PDPA, unless they fall within the exemptions provided in the PDPA. For example, foundations, associations, religious organisations which are non-profit organisations are exempt from certain data processing requirements under the PDPA.

The obligations under the PDPA would differ between personal data categorised as "general personal data" and "sensitive personal data". Health data is classified as "sensitive personal data" under the PDPA, and any processing of it would be subject to stricter requirements regarding its collection and disclosure. For instance, the legal basis for processing sensitive data is more limited than general personal data. If no other legal basis is available, explicit consent would be required to process health data.

The PDPA establishes a complaint filing mechanism and grants certain authority to the Expert Committee (also established by the PDPA) and competent officials to issue orders and exercise authority for the protection of personal data and the rights of data subjects.

The PDPA provisions are intended to serve as a general data protection law for Thailand. Consequently, where there is a sector-specific law or regulation regarding personal data protection applicable to an entity, the provisions of the PDPA and penalties will apply in addition to those sector-specific laws or regulations. Where the sector-specific law does not provide a complaint filing process and officials' authority with respect to personal data protection, or where such mechanism and authority exist but the protection is not equal to that of the PDPA, the provisions of the PDPA would be applicable.

The Thailand Research and Innovation Utilisation Promotion Act B.E. 2564 (2021)
According to Thailand 4.0, an economic model and national strategy developed by the Thai government to transform Thailand into a high-income country driven by innovation, technology and creativity, the government has identified medical tourism as one of the "S-Curve" industries, with the aim of positioning Thailand as a leading medical hub in Asia. As part of this initiative, the Thai government is promoting the

development of new technologies and industries, improving the country's competitiveness, and enhancing the quality of life for Thai citizens through research and innovation activities. To support this goal, the Thailand Research and Innovation Utilisation Promotion Act B.E. 2564 (2021) was enacted and came into effect on 7 May 2022 in order to establish a comprehensive system that encourages and supports research and innovation activities in both the public and private sectors in Thailand. The Act, along with relevant regulations subsequently released (collectively referred to as the "TRIUP Law"), plays a critical role in driving the development of the medical hub under Thailand 4.0. It creates a supportive environment for the development of new medical technologies and treatments by providing incentives for researchers and private sector organisations to invest in research and development.

Under the TRIUP Law, inventors and researchers at universities, research institutes and business entities ("Scholarship Recipient") that receive government funding for their research projects will be entitled to own and manage innovations or research results ("Work") including intellectual property pertaining thereto. It is worth noting that Work includes any discoveries or results arising from innovation creations, research, experiments, investigations or studies, as well as any knowledge and know-how, regardless of whether it is protectable under intellectual property laws.

The conditions under which a Scholarship Recipient will gain ownership of their Work are that they will have to disclose the Work, along with its utilisation plan to the Scholarship Provider, which is usually a government agency, within a specified timeframe. If the Scholarship Recipient does not wish to obtain ownership or fails to disclose their Work within the designated time period, the researchers involved in the Work will subsequently be entitled to request ownership using the same process.

After receiving the disclosure and utilisation plan, the Scholarship Provider will have to promptly issue a confirmatory statement of ownership to the Scholarship Recipients. Then, the Scholarship Recipient or researchers will have to utilise the Work according to the disclosed utilisation plan within two years, otherwise all rights over the Work will revert to the Scholarship Provider. Nevertheless, the two-year period may be extended upon request including submission of evidence showing the Scholarship Recipient and/or researcher's efforts to utilise the Work.

The TRIUP Law also prescribes a profit-sharing principle to oblige funding recipients to provide incentives to researchers involved in their research and innovation work, if there are revenues earned from the commercialisation or utilisation of the research and innovation work.

Similar to the Thai Patent Law, the TRIUP Law outlines a principle regarding compulsory licenses, which enables the Science, Research, and Innovation Promotion Committee (the "Committee") to grant a licence to any person who wishes to license the Work but fails to reach an agreement with the holder of the intellectual property rights, while proposing reasonable remuneration to the holder. Any licence granted by the Committee is considered a licence under the relevant intellectual property law.

Furthermore, the Prime Minister, with approval from the cabinet, has the authority to issue compulsory licenses for public interest in situations of national emergency to utilise and exploit the Work.

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COVID-19

After three years of the COVID-19 pandemic, the Thai government declared the COVID-19 pandemic to be endemic. The MOPH issued a notification on 1 October 2022, reclassifying COVID-19 from a "dangerous communicable disease" to a "communicable disease under surveillance".

The mandatory face mask policy has been relaxed, meaning that wearing a face mask outdoors is now voluntary. However, the government highly recommends wearing a face mask in crowded areas, such as public transport, exhibitions or concert venues. Furthermore, many exemptions and regulations related to the COVID-19 pandemic have been revoked, including regulations on the commercialisation or distribution of medicines and medical devices, as well as regulations on the conditional approval for the emergency use of medicinal products.

In addition, in response to the declaration of COVID-19 as an endemic, MOPH issued two notifications in March and October 2022 to update the criteria, methods and conditions for determining expenses related to operations for critically ill emergency patients. In brief, these notifications outline the reimbursement scheme for medical facilities that provide treatment to COVID-19 patients in a critically ill state, whereas the previous reimbursement scheme during the pandemic had applied to medical facilities treating COVID-19 patients in an emergency state. These notifications were issued under Universal Coverage for Emergency Patients (UCEP) programme, which provides free-of-charge emergency medical services to all patients, regardless of their ability to pay or insurance coverage. The UCEP programme was launched in 2002 as part of Thailand's Universal Coverage Scheme (UCS).

Furthermore, in November 2022, the NHSO has partnered with the National Drug System Development Committee to expand the National List of Essential Medicines (NLEM) to include COVID-19 treatment medications including nirmatrelvir and ritonavir, remdesivir, favipiravir and molnupiravir. Their inclusion in the NLEM enables COVID-19 patients with varying degrees of severity of the disease to access these medications under Thailand's National Health Security System, reducing the financial burden associated with acquiring COVID-19 treatments.

HIV/AIDS

The marginalisation of HIV-positive individuals has been an ongoing issue for several decades. For instance, requiring a blood test as a prerequisite for employment or education has been common practice. Testing positive for HIV is often cited as grounds for rejection, despite violating fundamental human rights. In an effort to combat stigmatisation and discrimination against individuals living with HIV, MOPH and its affiliated networks have been actively supporting the development and passage of the draft Act on the Elimination of Discrimination Against Individuals. The draft Act was open for public hearing on the parliament website from 31 January to 19 August 2022, and aims to reduce social exclusion not only for HIV-positive individuals, but for all marginalised groups.

UK

Law and Practice

Contributed by:
Jackie Mulryne, Beatriz San Martin, Ewan Townsend, Adela Williams and Libby Amos-Stone
Arnold & Porter

Contents

Contributed by: Jackie Mulryne, Beatriz San Martin, Ewan Townsend, Adela Williams and Libby Amos-Stone, **Arnold & Porter**

Arnold & Porter is an international law firm at the intersection of business, law and regulatory policy, serving clients whose business needs require expert US and/or European cross-border regulatory, litigation and transactional services. The firm has a particularly high reputation for advising on UK and EU law relating to pharmaceuticals, biotechnology and healthcare products and medical devices, and for assisting clients in interpreting and complying with the regulatory framework that surrounds these products. The authors would like to acknowledge the contributions of Shishu Chen, Katya Farkas, Eleri Williams and Sofia Wilson.

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Beatriz San Martin focuses her practice on the life sciences sector and innovative technologies. She has significant experience in handling cases before the UK courts and the Court of Justice of the European Union, including high-profile European litigation. In addition to her patent and SPC experience, she also counsels on and litigates other IP rights, including copyright, trade mark, passing off, design rights, database rights and confidential information. Her cases have involved a wide range of technologies, including pharmaceuticals, medical devices, agrochemicals, insulation products, software, medical imaging and disease control textiles.

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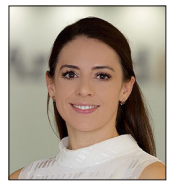
Ewan Townsend is a partner at Arnold & Porter who specialises in transactional and regulatory work in the life sciences sector. He has experience in drafting and negotiating a wide range of complex, high-value agreements, such as licences and collaboration agreements, manufacture and supply agreements, technology transfers and clinical trial agreements. He is uniquely placed in his ability to advise on the regulatory issues that arise in the context of those transactions, particularly in relation to marketing authorisations, manufacturing and distribution, pricing, advertising and promotion, freedom of information and data protection.

Adela Williams is a partner at Arnold & Porter, specialising in regulatory advice and litigation on behalf of life sciences clients. She provides a broad range of regulatory and compliance advice in relation to medicines, medical devices, cosmetics and foods, including borderline issues and the implication of data privacy requirements (including GDPR). She has extensive experience in pricing and reimbursement matters, assisting clients to navigate the Voluntary and Statutory Schemes on the pricing of branded medicines and providing support and representation in the context of health technology appraisals by NICE and similar bodies. Adela also acts for clients in litigation arising from regulatory decisions in UK and European courts, and represents pharmaceutical and medical device clients in product liability litigation.



Libby Amos-Stone acts for life sciences companies in product liability and public law litigation before the UK and EU courts. She also advises clients on the pharmaceutical, medical device, food, cosmetic and cannabis regulatory framework in the UK and EU, and assists companies on strategic issues arising during the life cycle of pharmaceutical products. Libby also advises companies on the boundaries of the ABPI and EFPIA codes of practice, and on UK and EU legislation regarding the promotion of medicinal products, including the use of social media.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

On account of Brexit, the UK is no longer subject to EU single market rules or the EU legislative framework. However, under the EU–UK Withdrawal Agreement's Protocol on Ireland and Northern Ireland, Northern Ireland continues to follow EU rules. In addition, pre-existing domestic legislation that implemented EU law continues to have effect in the UK.

UK regulation of medicinal products derives from EU legislation, principally Directive 2001/83/EC (EU Directive 2001/83) and Regulation (EC) 726/2004 (EU Regulation). The key UK legislation is the Human Medicines Regulations 2012 (SI 2012/1916), as amended (HMRs).

Similarly, UK regulation of medical devices derives from three EU Directives (the Medical Device Directives):

- Council Directive 93/42/EEC on Medical Devices;
- Council Directive 90/385/EEC on Active Implantable Medical Devices; and
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD).

These directives are implemented in UK domestic law through the Medical Devices Regulations 2002/618, as amended (UK Medical Devices Regulations).

The more recent EU Regulations on medical devices – Regulation (EU) 2017/745 on medical devices (EU MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR) – do not apply to Great Britain, but do to Northern Ireland.

In addition, the General Product Safety Regulations 2005/1803 and the Consumer Protection Act 1987 apply in the UK to medical devices that are also consumer products.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency sponsored by the Department of Health and Social Care (DHSC). The MHRA acts on behalf of the UK Licensing Authority, comprising the Secretary of State and the Ministers for Health,

Social Care and Public Health or Safety, with the statutory responsibility to apply and enforce laws governing pharmaceuticals and medical devices in the UK.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of the MHRA can be challenged by way of judicial review in the Administrative Court, King's Bench Division.

To this end, an application must be made promptly, and in any event within three months of the decision to be challenged, and the applicants must be able to show a sufficient interest in the matter to which the application relates. This will be shown where a decision of the MHRA directly affects the legal rights of enterprises to market or deal in their products – eg, refusal to grant a marketing authorisation (MA).

The court's permission is required to proceed with a claim for judicial review.

The grounds for judicial review are evolving, but can be summarised as:

- illegality;
- irrationality;
- procedural unfairness; and
- legitimate expectation.

In addition, MHRA decisions to issue certain notices and notifications to medical device manufacturers can be appealed through the Chartered Institute of Arbitrators.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are three categories, or legal classifications, of medicinal products, which determine the level of control over supply. In part, classification rests on how much healthcare professional (HCP) input is needed to diagnose and treat the conditions for which the medicine might be used. The three legal classifications are:

- prescription-only medicines (POMs) – these have to be prescribed by a doctor or other authorised HCP and have to be dispensed from a pharmacy or from another specifically licensed place;
- pharmacy (also known as P, over the counter or OTC) – these have an intermediate level of control and can be bought only from pharmacies and under a pharmacist's supervision; and
- general sales list (GSL) – these may be bought from general retail stores or vending machines.

Medical devices are given a classification depending on the level of risk associated with their use. How a medical device is classified will depend on factors such as:

- the intended purpose of the device;
- how long it is intended to be in use; and
- if the device is invasive/surgically invasive, is implantable or active, or contains a substance which in its own right is considered to be a medicinal substance.

General medical devices and active implantable devices fall within the following categories:

- Class I – low risk;
- Class IIa – medium risk;
- Class IIb – medium risk; and
- Class III – high risk.

All active implantable medical devices and their accessories fall under the highest risk category (Class III).

In vitro diagnostic (IVD) medical devices are currently categorised differently into four main groups – namely, those which are:

- considered as general IVD medical devices;
- within the classifications stated in Annex II List A of the IVDMD (which is referred to in UK legislation);
- within the classifications stated in Annex II List B of the IVDMD; and
- for "self-test" intended to be used by a person at home.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The current UK law governing clinical trials of medicinal products is the Medicines for Human Use (Clinical Trials) Regulations 2004/1031, which transposed the EU Clinical Trials Directive 2001/20/EC into UK law, and has been amended to reflect the UK's departure from the EU. Clinical trials must be conducted in accordance with good clinical practice (GCP), the terms of the approved protocol, clinical trial authorisation and research ethics committee (REC) approval. The EU Clinical Trials Regulation 536/2014, which came into full effect on 31 January 2022, does not apply in Great Britain but, as a result of the Northern Ireland Protocol, does apply in Northern Ireland.

The MHRA undertook a public consultation in early 2022, outlining proposals to reform UK law and guidance on clinical trials for medicinal products. The aim is to streamline clinical trial approvals, enable innovation, enhance clinical trial transparency, enable greater risk proportionality, and promote patient and public involvement.

Clinical investigations for medical devices are regulated by the UK Medical Devices Regulations. Requirements relating to clinical investigation under the EU MDR and the EU IVDR apply in Northern Ireland.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Before a clinical trial can commence, an REC must give a favourable opinion, and authorisation must be obtained from the MHRA. A sponsor of a clinical trial must be established in the UK or in a country on an approved country list, which includes EU/EEA countries. Otherwise, the sponsor must have a legal representative.

As of 1 January 2022, applications for all new clinical trials for investigational medicinal products must be prepared, submitted and reviewed via the combined review service – a single application route with co-ordinated review by the MHRA and the REC, leading to a single UK decision on the application. Applications must be submitted via a new part of the Integrated Research Application System (IRAS).

Additional detail is required in applications for trials with complex innovative designs, characterised by the presence of prospective major adaptations. Such information includes justification for choice of design.

After receipt of a valid application, a combined review assessment will be conducted within 30 days. Following assessment, and ordinarily within 60 days of the submission, the MHRA and the REC will either:

- accept the request;
- accept the request subject to conditions; or
- not accept the request.

The MHRA will focus on the safety and scientific value of the trial, while the REC will focus on the research proposals and review certain documents relating to the trial, including the trial protocol, the informed consent form, the suitability of the personnel, investigator and facilities, and the investigator's brochure.

The MHRA must be notified by the sponsor at least 60 days in advance of the commencement of a clinical investigation involving medical devices. Applications should be submitted via the IRAS. The MHRA will consider the documentation and assess the safety and performance of the device, as well as the design of the investigation. A letter will be sent to the sponsor within 60 days with a decision (providing either an "objection" or "no objection"). In addition, an opinion of the REC is required.

2.3 Public Availability of the Conduct of a Clinical Trial

Any favourable opinion by an REC is conditional upon the clinical trial being registered on a publicly accessible database.

For any submissions made up to 31 December 2021, clinical trials were required to be registered using an established international register such as the International Standard Randomised Controlled Trial Number (ISRCTN) registry or ClinicalTrials.gov. Since 1 January 2022, the Health Research Authority (HRA) automatically registers clinical trials submitted through IRAS with the ISRCTN registry.

Information about trials being conducted in the UK is made publicly available on the HRA research summaries website and on the UK "Be Part of Research" website.

In addition, the advertising code for the pharmaceutical industry published by the Association of the British Pharmaceutical Industry (ABPI) requires companies to disclose details of clinical trials in accordance with international pharmaceutical association requirements.

There are no obligations relating to the publication of information on clinical investigations relating to devices.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials or clinical investigations. However, all advertising and all materials provided or directed to subjects will be reviewed by the REC.

2.5 Use of Data Resulting From the Clinical Trials

Data resulting from clinical trials is likely to be considered as special category (sensitive) personal health data for the purposes of the data protection legislation, even if it is in coded/pseudonymised form, and will be afforded greater protection than non-special category personal data. The Data Protection Act 2018 and the UK GDPR provide that pseudonymisation is a security measure that can be used to protect personal data, but it does not address data beyond the scope of the UK GDPR.

The resulting data can be transferred to a third party or affiliate, provided that any UK GDPR provisions governing such a transfer are complied with.

2.6 Databases Containing Personal or Sensitive Data

If a database contains personal or special category (sensitive) personal health data, the UK GDPR would need to be complied with. The key requirements are as follows:

- the data is processed lawfully;
- the data stored is relevant, up to date and limited to what is required;
- sufficient security measures are put in place;
- the data is not stored for longer than is necessary; and
- the relevant individuals have been informed of the use and storage of their data.

The party managing the database would also need to comply with the UK GDPR more widely.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The HMRs define a medicinal product as:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
- any substance or combination of substances that may be used by or administered to human beings with a view to:
  - (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action; or
  - (b) making a medical diagnosis.

The UK Medical Devices Regulations define a medical device as any instrument, apparatus, appliance, software, material or other article, used alone or combined, for humans to:

- diagnose, prevent, monitor, treat or alleviate disease;
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap;
- investigate, replace or modify the anatomy or a physiological process; or
- control conception.

To distinguish between medical devices and medicinal products, it is important to consider:

- the intended purpose of the product, taking into account the way the product is presented; and
- the method by which the principal intended action is achieved.

Where the assessment is not straightforward, or where disagreement arises, the MHRA's Medicines Borderline Section is able to issue determinations. Where there is doubt, a product will be classified as a medicinal product.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The general rule is that a medicinal product may only be placed on the UK market if it has been granted an MA. Applications must be made to the MHRA.

Biological medicinal products must meet the same quality, safety and efficacy criteria to obtain an MA as those for non-biological medicinal products. However, since biological medicinal products are especially sensitive to change in starting materials or manufacturing conditions, they are subject to specific requirements, as set out in Annex I to EU Directive 2001/83, as amended by Schedule 8B of the HMRs.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

MAs for medicinal products in the UK are valid for an initial period of five years. However, an MA ceases to be valid if the product is not placed on the market within three years of the date of authorisation (known as the "sunset" clause).

The renewal application should be submitted to the MHRA six months before expiry. The authorisation may be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the MA will be valid for an unlimited period, unless there are justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal.

The MHRA may revoke, vary or suspend a UK MA in certain situations, including if the MHRA believes that the product is harmful or that the positive therapeutic effects of the product do not outweigh its risks to the health of patients or the public, or that the product's composition is not as described in the application for the MA or the material supplied with it.

With regard to medical devices, a UK Conformity Assessed (UKCA) mark is valid indefinitely, and the underlying conformity assessment does not require renewal unless the specifications of the device change.

The MHRA has the power to issue various notices to manufacturers (eg, prohibition notices) to ban the supply of any goods that are considered unsafe or that do not comply with the UK Medical Devices Regulations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Medicinal Products

An application for a UK national MA must be made to the MHRA and must include the particulars and research data or justifications for exceptions that are described in the HMRs. Following Brexit, UK MAs are split into various types, depending on the parts of the UK to which they apply.

A number of new routes have been introduced post-Brexit to allow for the quick recognition of products that are approved in the EU, and to allow greater flexibility in UK procedures (such as a "rolling review" that permits the submission of an application in modules).

Applications intended to cover the marketing of a product in Northern Ireland must continue to comply with the requirements of EU Directive 2001/83 and EU Regulation 726/2004.

Medical Devices

As of 1 January 2021, there is a new route to place a device on the Great Britain market, with an accompanying mark based on the requirements derived from current EU legislation: the UKCA. EU CE marking (the acronym for the French "*Conformité Européenne*" or "European conformity") will continue to be recognised in Great Britain, and certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market, until 31 December 2024.

EU rules will continue to apply in Northern Ireland, and EU CE marking is required. In addition, if the manufacturer chooses to use a UK Notified Body for mandatory third-party conformity assessment for purposes of the Northern Ireland

market, the UKNI mark must be applied in addition to the CE mark.

As previously noted, medical devices are given a classification depending on the level of risk associated with their use. Each risk classification also has a separate conformity assessment procedure. If the relevant requirements are met, the Approved Body will issue a UKCA certificate. Only UK-Approved Bodies may conduct conformity assessments in relation to a UKCA mark. They are not able to issue CE certificates other than for the purposes of the "CE UKNI" marking, which is valid in Northern Ireland.

Low-risk Class I medical devices do not need to go through a conformity assessment procedure. For all devices, once the relevant assessment has been completed successfully, the manufacturer may place a UKCA mark on their medical device and put it on the market in Great Britain.

To be placed on the Great Britain or Northern Ireland market, all devices must now be registered with the MHRA, which will only accept the registration of devices from manufacturers where the manufacturer is based in the UK. Therefore, manufacturers based outside the UK are required to appoint a UK Responsible Person that is established in the UK.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The HMRs state that a person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product, or a medicinal product other than in accordance with the terms of an MA. However, the UK allows exceptions whereby a product can be placed on the market without an MA. The main exception is often called "named-patient supply" and applies if the medicinal product is:

- supplied in response to an unsolicited order;
- manufactured and assembled in accordance with the specification of a person who is authorised to prescribe; and
- for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient.

Certain conditions set out in the HMRs must also be met.

When named-patient supply of medicinal products is offered to a co-ordinated patient group, this is referred to as a "compassionate-use scheme". However, the legislative provisions of named-patient supply continue to apply.

The Early Access to Medicines Scheme is a voluntary, non-statutory scheme that allows patients to access innovative unlicensed medicines earlier than the current MA procedures permit, but applies only to medicines that target life-threatening or seriously debilitating conditions for which there are no existing satisfactory treatments.

Devices that are custom-made for individual patients or intended for clinical investigation do not need a UKCA mark. Custom-made medical devices are defined as devices manufactured specifically in accordance with a duly qualified medical practitioner's written prescription that gives specific design characteristics, under their responsibility, and is intended for the sole use of a particular patient. The manufacturer of a custom-made medical device must meet the requirements of the UK Medical Devices Regulations that relate to custom-made devices.

The MHRA may also approve exceptional use of a non-compliant device on humanitarian grounds. These devices do not need a UKCA mark. A manufacturer can apply to the MHRA to supply a medical device that does not comply with the law to protect a patient's health if there is no legitimate alternative available. The same provision may be made for custom-made devices that have not complied with the standard conformity assessment procedure.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

MA holders must operate a pharmacovigilance system to monitor the safety of their product's life cycle, and to detect any change to their risk-benefit balance. They must:

- have an appropriately qualified person (QP) responsible for pharmacovigilance located in the EEA (however, where this person does not reside and operate in the UK, there will be a need for a national contact person for pharmacovigilance who resides and operates in the UK);
- maintain a pharmacovigilance master file;
- operate, monitor and update a risk management system for the product;
- record and report all suspected adverse reactions occurring in relation to their products; and
- submit periodic risk-benefit evaluation reports for their products.

The MHRA may grant an MA subject to one or more conditions, including post-marketing obligations such as the requirement to conduct post-authorisation safety and efficacy studies. The MA holder must incorporate any such condition into the risk management system for the product.

Once a medical device has been placed on the UK market, the MHRA requires the manufacturer to monitor and report to it any serious adverse incidents associated with the product. The manufacturer must also take appropriate safety action when required.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Requests for information about MAs and pending MAs for medicinal products may be submitted to the MHRA under the Freedom of Information Act 2000 (FOIA).

The MHRA releases very little information in relation to pending applications.

Following the grant or refusal of an MA, the MHRA generally releases detailed information about the application and authorisation, both proactively via disclosures on its website and also in response to third-party information requests. The FOIA provides mechanisms whereby personal data, confidential information and commercially sensitive information may be withheld or redacted from documents requested by third parties, and the MHRA typically allows MA holders to comment on any proposed redactions prior to their release.

For medical devices, Approved Bodies are private entities. Therefore, access to information provisions that apply to public bodies do not apply. As such, both before and after UKCA marking, the information pertaining to the device remains the property of the manufacturer. Once registered with the MHRA, a manufacturer's details will be added to the Public Access Database for Medical Device Registration. Other information held by the MHRA could be requested under the

FOIA, but will only be provided where no exceptions under the FOIA apply.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The EU Falsified Medicines Directive (FMD) ceased to apply in Great Britain at the end of the transition period. As such, pharmacies in Great Britain are no longer using the UK Medicines Verification System and medicines with an MA valid only in Great Britain are not required to have a Unique Identifier. However, the MHRA encourages companies to retain the tamper-evident device.

Under the Northern Ireland Protocol, Northern Ireland will continue to comply with the FMD, for at least four years from the end of the transition period.

The Medicines and Medical Devices Act 2021 includes a power to put in place a bespoke falsified medicines system, and a public consultation on the system is expected.

Falsified medicines should be reported to the MHRA via the Yellow Card reporting site.

The Medicines and Medical Devices Act 2021 consolidated and streamlined the MHRA's enforcement powers regarding medical devices, which cover the falsification and illegal distribution of medical devices. The MHRA may issue compliance, suspension, safety and requests for information notices, as well as civil sanctions. It is a criminal offence for a manufacturer to breach a notice.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

See **10. IP Other Than Patents**.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

A manufacturer licence issued by the MHRA is required in order to manufacture, assemble or import licensed, unlicensed or investigational medicinal products. The process involves the submission of an application and the inspection of the designated manufacturing site by the MHRA to verify compliance with good manufacturing practice (GMP). A manufacturer licence remains in force until it is revoked or surrendered.

Manufacturers of medical devices are not required to obtain a specific authorisation for the manufacture of their products, but are required to register with the MHRA in order to place the medical devices on the market in the UK. A statutory fee of GBP100 applies to registration and updating information. As previously noted, the MHRA will only register devices where the manufacturer or their UK Responsible Person has a registered place of business in the UK.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

A wholesale distribution authorisation (WDA) issued by the MHRA is required in order to:

- sell, supply, offer for sale, procure, hold or export POM, P/OTC, traditional herbal and GSL medicines on a wholesale basis in the UK;

- import QP-certified medicinal products into Great Britain from EEA countries; and
- export medicinal products to EEA countries.

WDA holders located in Northern Ireland can still bring medicinal products into Northern Ireland from Great Britain, provided certain additional conditions are met.

The facility involved in wholesale distribution is subject to inspection by the MHRA before a licence is granted. A WDA remains in force until it is revoked or surrendered.

Distributors of medical devices are not required to obtain an authorisation to engage in wholesale trade.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The importing and exporting of medicinal products are governed by the HMRs (or EU Directive 2001/83 in relation to Northern Ireland). The importing of medical devices is governed by the UK Medical Devices Regulations (or the relevant EU Directive in relation to Northern Ireland). There are no specific rules regarding the exporting of medical devices.

HM Revenue and Customs is responsible for border control. The MHRA Enforcement Group is responsible for applying and enforcing the HMRs and the UK Medical Devices Regulations.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Importers of pharmaceuticals and medical devices require an Economic Operator Registration Identification number, which is entered onto all UK customs declarations. Importers must be a UK-resident business for certain UK customs issues, including the declarations.

The designation of a particular entity as the importer of record for customs purposes will not be conclusive in determining who should hold any required import authorisations from a regulatory perspective.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importing medicinal products into Great Britain from outside the EEA requires a manufacturer's import authorisation granted by the MHRA. Importing QP-certified medicines into Great Britain from the EEA may be performed under a WDA that authorises import. Importing medicinal products into Northern Ireland from Great Britain may be conducted under a WDA, provided certain additional conditions are met.

Import for personal use by the importer or a member of their immediate family (up to a three-month supply) does not require an authorisation.

No authorisation is required to import medical devices, but importers should notify the UK Responsible Person or the Northern Ireland-based Authorised Representative (as described in **3.4 Procedure for Obtaining a Marketing**

Authorisation for Pharmaceutical and Medical Devices), as they are required to provide the MHRA with a list of device importers.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Details of specific tariff duties and measures that apply to particular goods in the UK are contained in the Integrated Tariff of the UK. An importer or exporter is responsible for the correct tariff classification of goods. His Majesty's Revenue and Customs (HMRC) has developed an online trade tariff tool to assist in product classification.

6.5 Trade Blocs and Free Trade Agreements

Under the EU–UK Trade and Co-operation Agreement, there are no tariffs or quotas on trade in medicinal products and medical devices between the EU and the UK, and mutual recognition of GMP inspections and certificates. The UK has also entered into a free trade agreement with Japan, which provides for mutual recognition of drug-safety testing and inspections before export. The UK has also signed a free trade deal with Norway, Iceland and Liechtenstein, and remains a member of the World Trade Organization.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Statutory controls on pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation.

The 2019 voluntary scheme for branded medicines pricing and access (VPAS) is a voluntary agreement negotiated between the DHSC and the ABPI, which controls the prices of branded medicinal products by:

- controlling profits made by scheme members from their National Health Service (NHS) business; and
- establishing a budget cap on the total expenditure by the NHS on branded health service medicines, with member companies making scheme payments to the DHSC as quarterly rebates (calculated as a percentage of eligible net sales) to cover excess expenditure.

The VPAS is an agreement which is not binding under the law of contract; however, the Secretary of State may enforce sums payable under the Scheme.

New branded health services medicines that contain a new active substance and are supplied by VPAS member companies are subject to free pricing at launch, as are line extensions of such medicines launched within 36 months of licensing of the initial indication in the UK. The prices of such products must be notified to the DHSC prior to launch. The price for all other branded health service medicines supplied by VPAS member companies must be agreed with the DHSC.

If a company is not a member of the VPAS, it is regulated by the parallel Statutory Scheme, currently set out in the Branded Health Service Medicines (Costs) Regulations 2018 (as amended). The Statutory Scheme is applicable only to branded health service POMs. Since 1 April 2018, it has involved a payment scheme, calculated as a percentage of net sales, similar to the VPAS. The maximum price that may be charged for a branded health service medicine within the Statutory Scheme is that directed by the Sec-

retary of State. The DHSC has indicated that it will maintain broad commercial parity between the schemes; it is therefore likely that payment percentages under the Statutory Scheme will remain similar to those under the VPAS.

Prices may also be limited as a result of competition, including through tenders. In primary care, the price of some medicinal products may be indirectly controlled by the reimbursement price, as set out in the Drug Tariff (a monthly publication specifying the amounts to be paid to contractors for providing relevant goods and services). These prices are calculated based on sales information provided by pharmacies, manufacturers and wholesalers. Where the Drug Tariff does not list a reimbursement price for a medicine, or where a product is prescribed by brand name, it will be reimbursed at the manufacturer's NHS list price.

Medical devices will only be routinely dispensed in primary care through the NHS if they are included in the Drug Tariff. The DHSC/NHS Business Services Authority (NHSBSA) agrees the reimbursement price of the medical device with the manufacturer at launch, and this is principally determined by comparing the device with similar products on the market and their respective prices. If there are no comparable devices or if the applicant submits evidence to support a different price, the reimbursement price is determined by negotiation between the parties. The sale of any device not listed within the Drug Tariff is a matter for negotiation between the seller and the local NHS.

7.2 Price Levels of Pharmaceutical or Medical Devices

There is no formal system of international reference pricing, although the cost of the presentation in other markets is specifically listed as a relevant criterion to which the DHSC should have regard when agreeing or directing a price under the VPAS or the Statutory Scheme.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

All authorised medicines validly prescribed on an NHS prescription may in principle be reimbursed from public funds, unless expressly excluded under the National Health Service (General Medical Services Contracts) (Prescription of Drugs, etc) Regulations 2004.

In primary care, patients receive medicines prescribed by their GPs from community pharmacies. Patients in England must pay a fixed price for NHS prescriptions, unless exempt. Prescription charges have been abolished in Northern Ireland, Scotland and Wales.

Medicinal products used in NHS hospitals are funded by commissioners in accordance with the "national tariff", a set of prices for defined procedures and items of care (currencies) established under the Health and Social Care Act 2012. Hospitals are paid for procedures performed or care provided (including the costs of associated medicines and devices), based on amounts fixed in the national tariff. Certain new and high-cost medicines and medical devices are reimbursed outside the tariff system, and enhanced payments may be made for some patients.

In England, most new medicines (and new indications for existing products) undergo health technology appraisal by the National Institute for Health and Care Excellence (NICE), which issues recommendations on NHS use based on its assessment of clinical effectiveness and cost effectiveness. NHS bodies in England are required by regulations to make funding avail-

able so that patients can access treatments recommended by NICE. NICE assesses some medical devices and diagnostic tests through parallel procedures.

The All Wales Medicines Strategy Group (AWMSG) issues guidance in Wales on new technologies immediately following launch. In Scotland, the Scottish Medicines Consortium (SMC) assesses all new medicines and new indications for existing medicines and issues guidance close to the product launch. In Northern Ireland, the Department of Health, Social Services and Public Safety (DHSSPS) considers NICE guidance and reviews it for legal, policy and financial consequences only, before deciding on implementation.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In theory, NHS prescribers may prescribe any product considered clinically appropriate for their patients but, in practice, NHS commissioners control which medicines may be prescribed through local or national formularies, largely determined by the cost-effectiveness of individual products. Treatments recommended by NICE should be included automatically in NHS formularies in England; products not recommended by NICE are generally not funded on a routine basis. An equivalent approach is taken to products recommended by the AWMSG, the SMC and the DHSSPS.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Community pharmacists purchase products from manufacturers or wholesalers and are reimbursed by the NHSBSA at the rate specified in the Drug Tariff, or, where no reimbursement price is set in the Drug Tariff, at the manufacturer's list price. When the price paid by the pharmacist is less than that reimbursed by the NHSBSA, the pharmacist makes a margin of profit. The extent of this margin is monitored by the NHSBSA, and claw-backs are imposed to ensure that pharmacy profits do not exceed defined limits.

There is no generic substitution by community pharmacists in the UK, and the Medicines Act 1968 requires the particular product prescribed to be dispensed. However, in general, doctors are encouraged to prescribe products using their international non-proprietary name (INN). Where a product is prescribed by its INN, the pharmacist may dispense any product that meets the specifications/INN described, and is likely to select the lowest-cost product. Generic substitution is standard practice in the hospital context.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no specific rules governing medical apps in UK. Standalone software and medical apps that meet the definition of a medical device will be regulated as medical devices, and are required to be UKCA-marked.

8.2 Rules for Telemedicine

Physicians can, and do, provide medical attention remotely in the UK, including through mobile devices. However, there are currently no specific or separate rules for telemedicine. Under English law, the provision of telemedicine services constitutes the provision of healthcare, which is a regulated activity under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, subject to the supervision of the Care Quality Commission, which is the independent regulator of health and social care services in England.

The practice of medicine is regulated by the General Medical Council. The same standards apply to doctors regardless of whether they practise in physical or virtual clinics.

8.3 Promoting and/or Advertising on an Online Platform

There are no special legal provisions applicable to the online advertising and promotion of medicines and medical devices. Pharmaceutical and medical technology companies may use online portals, web pages and social networking sites to promote or provide information about their products, provided they follow the applicable UK medicines advertising legislation and the medical devices legislation (which implement the existing EU rules), guidance and codes of practice. Breaches of these requirements through online activities are enforced in the same way as activities involving traditional methods of communication.

In practice, pharmaceutical companies rely on the guidance provided by the MHRA and, under the self-regulatory system, the Prescription Medicines Code of Practice Authority (PMCPA) and the Proprietary Association of Great Britain (PAGB).

The MHRA Blue Guide confirms that material posted on UK websites (including social networking sites, blogs and discussion forums) and/or aimed at a UK audience is subject to UK medicines advertising legislation.

The ABPI Code, which is administered by the PMCPA, covers the online advertising and promotion of POMs, and states that promotional material directed to a UK audience provided digitally must comply with all relevant requirements of the Code. In addition, specific guidance was published in 2023 on the use of social media.

Digital promotional materials relating to OTC medicines, over which companies have full editorial control, must comply with the PAGB Consumer Code and, like other forms of advertising of OTC medicines to members of the public, must be submitted to the PAGB for approval (in an offline format).

The Association of British Healthcare Industries (ABHI) provides a self-regulatory regime for the medical technology or devices sector, as set out in its Code of Business Practice. The ABHI Code confirms that online advertising of medical devices is subject to the same requirements as other forms of advertising. The web-based promotion of self-care medical devices is subject to the PAGB Medical Devices Consumer Code.

The advertising of OTC medicines and medical devices is also subject to supervision by the Advertising Standards Agency.

8.4 Electronic Prescriptions

Electronic prescriptions are used commonly within the NHS in the UK, and may also be used for private prescriptions. They must comply with data protection laws and confidentiality requirements.

8.5 Online Sales of Medicines and Medical Devices

Online sales are regulated in the same way as traditional sales channels. Therefore, POMs may only be supplied online after being dispensed from a registered pharmacy by a pharmacist in accordance with a prescription from an appropriately qualified HCP.

Distance-selling pharmacies may remain on the NHS pharmaceutical list, entitling them to dispense medicines from an NHS prescription if they comply with the requirements of the Nation-

al Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

8.6 Electronic Health Records

Electronic health records are not subject to specific regulation in UK, but they must comply with data protection laws and confidentiality requirements.

Where special category (or other) personal data is transferred to a cloud platform, both the transferring entity and the cloud platform must comply with the UK data protection legislation, including the associated requirements for transferring personal data out of the UK.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

UK patent law is governed by the Patents Act 1977.

On 1 January 2021, the Patents (Amendment) (EU Exit) Regulations 2019 (the Patents Regulations 2019), the Intellectual Property (Amendment, etc) (EU Exit) Regulations 2020 (the IP (Amendment) Regulation 2020) and the Supplementary Protection Certificates (Amendment) (EU Exit) Regulation 2020 (the SPC Regulation 2020) came into effect, to bring EU legislation into UK law as far as possible to maintain the systems and processes that were in place before Brexit. UK patent law remains substantively unchanged, including the patent enforcement system in the UK.

Patent infringement and validity claims form the bulk of cases issued before UK courts. The increasing amount of data required to be disclosed in patent specifications is a challenge for the grant of pharmaceutical and biotech patent inventions, particularly in relation to second or further medical uses.

A number of exclusions to patentability relate exclusively to pharmaceutical or biotech inventions (eg, methods of treatment by surgery or therapy, methods of diagnosis, and uses of human embryos for industrial or commercial purposes).

9.2 Second and Subsequent Medical Uses

Claims to second and subsequent medical uses (and, indeed, first medical uses), including in relation to dosage regimes and new or selected patient populations, are patentable as long as:

- they fulfil the usual requirements of patentability, with the claimed therapeutic effect needing to be plausible; and
- the claims are drafted in a particular approved form, which, since 2010, is in the form "substance X for use in the treatment of indication Y".

Such claims can include, in certain circumstances, second or further medical uses to medical devices (eg, a dye used for surgery where the dye is a medical device).

9.3 Patent Term Extension for Pharmaceuticals

Patent term extensions in the UK are in the form of supplementary protection certificates (SPCs). The Patents Regulation 2019, the IP (Amendment) Regulation 2020 and the SPC Regulation 2020 have largely retained the pre-Brexit processes and systems under EU Regulation 469/2009 (the SPC Regulation, as amended) and

Regulation 1901/2006 (the Paediatric Regulation, as amended).

An SPC provides for a period of extended exclusivity for a patented medicinal product for a maximum of five years. New applications for a six-month paediatric extension to SPCs are considered based on provisions in the HMRs. Since 1 January 2021, the process of applying for a UK SPC has remained largely the same, although greater care is needed, including monitoring the MAs granted in the UK and the EEA, as the SPC filing deadlines and SPC expiry dates may differ between the UK and the EEA. In addition, the territorial scope of SPCs granted in the UK only extends to the part of the UK for which a valid MA has been granted on filing the SPC application, unless the applicant subsequently applies for the UK SPC to be extended to cover the whole of the UK. Moreover, holders of SPCs granted prior to 1 January 2021, which were based on authorisations from the EMA, may need to provide information on the converted UK authorisation for recordal purposes.

9.4 Pharmaceutical or Medical Device Patent Infringement

Where a patent covers a pharmaceutical product or medical device, it is an infringing act to make, sell, offer to sell, use, import or keep the product or device in the UK. It is not an infringing act to make an offer to sell a product before patent expiry if the offer is to sell the product after patent expiry. It is also not an infringing act merely to apply for, or obtain, authorisation to sell a pharmaceutical product or medical device before patent expiry.

Where a patent covers a method for making a pharmaceutical product or medical device, it is an infringing act to use the patented method in the UK. It is also an infringing act to sell, offer to sell, use, import or keep a product "obtained directly" by means of the patented process.

It is also an (indirect) infringement to supply, or offer to supply, in the UK the means relating to an essential element of the invention, for putting the invention into effect, knowing (or it being obvious to a reasonable person in the circumstances) that those means are suitable for putting, and are intended to put, the invention into effect in the UK.

It is possible to apply for an injunction restraining a party from infringing a patent on the basis of a threat of infringement, even if no actual infringement has occurred. There is no requirement for the infringement to be "imminent" in order for an injunction to be granted; the patent holder only needs to prove that there is a sufficiently strong probability that, in the absence of an injunction, the other party will infringe the patent.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

A number of general exemptions from patent infringement might apply to pharmaceutical products and medical devices, including:

- acts carried out privately and for purposes that are not commercial;
- acts carried out for experimental purposes relating to the subject matter of the invention, including anything done in or for the purposes of a medicinal product assessment, which in turn includes work done in the UK for the purposes of obtaining an MA for a medicinal product anywhere in the world and health technology assessments (there is no equivalent express provision relating to medical devices); and

- the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner, or dealing with a medicine so prepared.

A compulsory licence of a UK patent is available if, where the patented invention is a product, demand for that product is not being met on reasonable terms. A compulsory licence is also available if the patent holder's behaviour is causing the establishment or development of commercial or industrial activities in the UK to be unfairly prejudiced, or if the exploitation of an important technical advance of considerable economic significance is being hindered. These compulsory licence provisions are rarely asserted and are therefore of limited relevance in practice.

9.6 Proceedings for Patent Infringement

An action for infringement may be brought by the patent holder or by an exclusive licensee.

The remedies available for infringement are:

- an injunction to prevent future infringement;
- damages; or
- an account of the infringer's profits.

The patent holder may also seek delivery or destruction of all infringing articles in the possession or power of the infringer.

In recent years, there have been an increasing number of cases where the patentee does not seek an injunction, provided an appropriate royalty is agreed or awarded by the court for future infringement.

An action for infringement can be brought in the Patents Court or in the IP Enterprise Court (IPEC), both of which are part of the English High Court. The IPEC is designed to deal with lower value, less complex cases with a more streamlined procedure.

Higher value claims must be brought in the Patents Court.

An infringement action is commenced with the issue of a claim form and particulars of claim, outlining the patent holder's claim for infringement. The alleged infringer then submits its defence and any counterclaim, which may include a counterclaim for invalidity. If the alleged infringer raises a counterclaim, the patent holder will serve its own defence. Parties may then reply to any defences. Following the exchange of formal pleadings, the court will schedule a case-management conference to set the timetable for the action and the estimated trial date.

A two-year mandatory disclosure pilot scheme was introduced after 1 January 2019 and became permanent as of 1 October 2022; it is now incorporated within the Civil Procedure Rules as Practice Direction 57AD. The alleged infringer may still submit a product or process description to avoid giving disclosure in relation to infringement.

Expert evidence is typically exchanged before trial in written witness statements, and the experts are cross-examined on the content of these statements during the trial. If necessary, the parties mayalso provide evidence of experiments relating to infringement or validity, subject to a tightly controlled procedure.

Disclosure, as well as witness and expert evidence, is significantly more limited in IPEC cases.

Invalidity is available as an effective defence to an infringement claim on the basis that there cannot be infringement of an invalid patent. If validity is challenged, the alleged infringer is required to serve "grounds of invalidity".

9.7 Procedures Available to a Generic Entrant

There is no requirement for pre-launch declaratory actions by a generic entrant. There is no patent linkage between the authorisation for a pharmaceutical product and the patent position. However, a generic entrant who does not clear the way risks facing infringement claims or injunction applications by patent holders, and this may prevent the launch of the product.

A generic entrant that wishes to clear the way may start an action to revoke a patent or SPC. Alternatively, or in addition, the generic entrant may seek declaratory relief from UK courts that:

- its proposed product does not infringe an issued patent or SPC;
- in the case of a pending patent or SPC application, its product was known or obvious at the priority date of the relevant patent application; and/or
- any application for an SPC would be invalid because it would not comply with the conditions in the SPC Regulation.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

A rights holder has a number of options to tackle counterfeit pharmaceuticals and medical devices, such as trade mark infringement, patent infringement, copyright infringement or passing off.

A trade mark infringement action is typically more straightforward than a patent infringement action, and is generally the action of choice. Trade mark infringement carries both civil and criminal liabilities under the UK Trade Marks Act 1994. It is possible to bring a private criminal prosecution against an infringer, although criminal proceedings are more usually brought by the UK's Trading Standards Authorities or the MHRA. In addition, the MHRA has the power to bring criminal proceedings against counterfeiters under the HMRs. Civil proceedings may be appropriate when dealing with counterfeiting on a large scale, or where the rights holder wishes to take advantage of the procedural tools and remedies offered in civil proceedings (eg, search orders or injunctions).

Counterfeit goods may be subject to border seizure actions. HMRC, together with the Border Force, is responsible for preventing counterfeit goods from entering the UK.

The following has applied since 1 January 2021:

- existing EU applications for actions (AFAs) filed via an EU Customs office remain valid and enforceable in the EU, but have ceased to have effect in the UK;
- existing EU AFAs filed via HMRC remain valid and enforceable in the UK but have ceased to have effect in the EU;
- any new EU AFA filed via an EU Customs office will apply across the EU only and will not be enforceable in the UK; and
- new UK AFAs must be filed online via the HMRC portal. Applicants must specify whether the AFA is to cover Great Britain and Northern Ireland, Great Britain only, or Northern Ireland only. Only UK IP rights can be relied upon in the new UK AFAs.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The MHRA assesses the invented name of medicinal products individually and in conjunction with a specific medicinal product. Where the proposed invented name has been registered as a trade mark in the UK for use with a medicinal product, an assessment by the MHRA – including safety considerations – determines whether the proposed invented name is suitable for use for the medicinal product. When reviewing proposed invented names, the MHRA applies criteria based on public health concerns, such as the potential for confusion with other products.

The UK Medical Devices Regulations provide that trade marks used in connection with the labelling, instructions for use, making available, putting into service or advertising of a medical device are prohibited if they may mislead the user or the patient with regard to the device's intended purpose, safety and performance.

Trade mark owners can, in principle, prevent imports of genuine medicines and medical devices into the UK if they were not first placed on the UK market by the owner or with its consent. The doctrine of exhaustion of IP rights also applies to genuine medicines and medical devices that have first been placed on the market in the EEA by the trade mark owner or with its consent.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for the trade dress and design of pharmaceuticals, medical devices and their packaging. The packaging of a product, the precise design of a tablet or the design of a medical device may potentially be protected by copyright, registered or unregistered design rights, and sometimes by trade marks. The applicability and extent of such protection will depend on whether the trade dress or design in question meets the criteria for such protection. In addition, medicinal products or medical devices may be protected by a right in the tort of passing off, which protects the goodwill associated with those products.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Innovator pharmaceutical companies developing a chemical or biological medicinal product may benefit from a period of regulatory data protection and marketing protection to protect the investment made. The regulatory data protection period is eight years, during which a generic applicant cannot cross-refer to the innovator's pre-clinical and clinical data to obtain an MA for a copy product. The marketing protection period is a further two years (making a total of ten years), during which a copy product that is lawfully authorised based on the innovator's pre-clinical and clinical data cannot be placed on the market. This combined period of eight-plus-two years is often referred to as the data/marketing exclusivity period.

The marketing protection period can be extended by an additional year on the approval, within eight years of the first grant of the medicinal product, of a new indication bringing significant clinical benefit when compared with existing therapies. Non-cumulative periods of one year of regulatory data protection can be awarded in respect of research data to support new indications added to established products or that were required to accomplish a switch from POM to pharmacy supply. Orphan medicinal products may benefit from an exclusivity period of ten years, or 12 years with an extension for conducting paediatric studies, during which no applica-

tion for a similar medicinal product in the same indication can be accepted by the regulatory authorities.

There are no exclusivities for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The MHRA and the DHSC have implemented temporary flexibilities in the regulation of medicines and medical devices to support the supply chain and wider response to COVID-19. These flexibilities typically do not displace or diminish the applicable regulatory obligations, but provide flexibilities from certain requirements, such as deferral of periodic supplier and customer requalification and the ability for responsible persons to act for another company within the same group of companies without variation, and other related initiatives.

11.2 Special Measures Relating to Clinical Trials

The MHRA has put measures in place to prioritise and provide assistance for clinical trial applications submitted for COVID-19, such as dedicated contact points and procedures for rapid scientific advice, reviews and approvals.

The National Institute for Health Research set out a framework in May 2020 for restarting research activities paused as a result of COVID-19, providing a flexible structure for local decision-making.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The HMRs permit temporary authorisation of a medicinal product in response to the confirmed or suspected spread of pathogenic agents, etc. The HMRs were amended on 16 October 2020 in response to the COVID-19 pandemic. Among other things, the amendment strengthened existing provisions that allow for the temporary licensing of medicines and vaccines, following which several COVID-19 vaccines were granted temporary authorisations.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The MHRA introduced exceptional GMP flexibilities for medicine manufacturers during the COVID-19 outbreak, enabling manufacturers to release additional quality system capacity to focus on ensuring the continuity of supply using quality risk management principles, and to address specific challenges created by international travel restrictions.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The MHRA adopted a flexible approach for medicines imported from third countries, and has published guidance allowing, for example, certain unexpected minor deviations in the finished product specifications where, in the QP's professional judgement, safety and efficacy are not compromised.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The government and regulators have supported the use of existing regulatory flexibilities in a number of areas, such as the switch to remote consultation in primary care delivery and the use of digital data collection tools.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The government has not announced any intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The HMRs protect MA holders or the person responsible for placing the product on the market, manufacturers (and their respective employees) and HCPs from civil liability for loss and damage resulting from the use of an unauthorised or off-label medicinal product, if that use was required or recommended by the UK licensing authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that may cause harm to human beings – including COVID-19. The HMRs were amended on 16 October 2020 in response to the COVID-19 pandemic, to expand the immunity from civil liability afforded to healthcare workers and manufacturers to also include companies producing the vaccine, among other things.

11.9 Requisition or Conversion of Manufacturing Sites

No existing provisions were used, nor were any new ones introduced, to allow the requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

In March 2020, the Cabinet Office issued a Procurement Policy Note (PPN 01/20) on options available to public bodies (including NHS bodies and local authorities) in relation to procurements under the Public Contract Regulations 2015 in the context of COVID-19. The PPN focused on procurements conducted in situations of extreme urgency, including the use of accelerated timelines, extending or modifying a contract during its term and contracts awarded without competition or advertisement.

In February 2021, the Cabinet Office issued Information Note PPN 01/21, which reminded contracting authorities of the above options and built on the guidance in the former PPN. In particular, PPN 01/21 provided advice on the commercial risks inherent in direct awards without competition, such as higher prices and limited due diligence. To combat these risks, the PPN encouraged contracting authorities to seek contractual mechanisms that would allow them to secure price reductions through the life of the contract and publish some form of advertisement, run an informal competition or hold discussions with multiple suppliers. PPN 01/20 was withdrawn on 31 January 2023 and is now out of date, but PPN 01/21 remains in place.

USA

Law and Practice

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Contents

Arnold & Porter is a 1,000-lawyer firm with a global reach and extensive experience in virtually every area of life sciences law. Arnold & Porter offers renowned regulatory, white-collar defence, product liability and commercial litigation, antitrust, IP and transactional capabilities to clients that include a wide variety of pharmaceutical, biotech, medical device and diagnostic companies and trade associations, as well as non-profits and universities. The firm has nearly 200 attorneys who provide integrated counselling to life sciences companies and represent 80% of the top 50 leading life sciences companies. The lawyers at Arnold & Porter help clients navigate their day-to-day legal problems as well as their most complex and high-stakes matters.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing the authorisation, marketing, sale and supply of pharmaceutical products by the US Food and Drug Administration (FDA) is the Federal Food, Drug and Cosmetic Act (the "FD&C Act"), which has been amended many times throughout the years to reflect increasing FDA mandates for the regulation of pharmaceutical products. The Public Health Service Act (the "PHS Act") is the specific authority used to approve or license biologic (including biosimilar) products. The primary FDA regulations governing drugs and biologics are found in Chapter 21 of the Code of Federal Regulations. Controlled substances, such as opioids, are also scheduled and subject to quotas and distribution controls under the Controlled Substances Act administered by the Drug Enforcement Administration (DEA).

A drug is defined as:

- an article recognised in the US Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, or the National Formulary;
- an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease;
- an article (other than food) intended to affect the structure or any function of the body; and
- an article intended for use as a component of a drug but not as a device (or a component, part or accessory of a device).

A biologic is defined under the PHS Act as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component (or derivative), allergenic product, protein (or analogous product), or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment or cure of a disease or condition of human beings". Notably, a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. Biological products are included within the drug definition and are generally covered by most of the same laws and regulations; however, differences exist in the regulatory approach.

Medical devices are also regulated by the FDA under the FD&C Act and – although subject to similar intent standards – such products are primarily intended to act via mechanical rather than chemical or biological modes of action. Medical devices are classified by risk and may be:

- exempt from FDA review;
- subject to a "510(k)" pre-market notification process if they show substantial equivalence to a "predicate" device;
- subject to down-classification via the de novo submission process; or
- eligible for full approval via a pre-market approval application (PMA).

Although the FDA has traditionally been given significant independence as an agency, and the Commissioner is confirmed by the Senate, the FDA is part of the Department of Health and Human Services (HHS).

The government agencies touching on pricing and reimbursement vary, depending upon the payer programme, and include the Centers for Medicare & Medicaid Services (CMS) (also part of the HHS), the Veterans Health Administration, and state Medicaid agencies. In addition, the HHS Office of Inspector General oversees laws governing fraud and abuse in the sale of bio-

medical products and healthcare services. The Federal Trade Commission (FTC), an independent agency, regulates the advertising of non-prescription drugs and non-restricted medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Agency decisions may be challenged either informally (via guidance-driven processes governing dispute resolution) or via more formal regulatory processes specified under FDA regulations. In addition, a general-purpose vehicle for bringing issues before the agency is the Citizen Petition, which allows the petitioner to bring a request before the agency and initiate a public docket in which comments can be lodged. The FDA also maintains ombudsmen in the various centres where products are reviewed, whose role is intended to facilitate the resolution of disputes. Although procedures for dispute resolution vary, depending on the specific statutory provisions at issue and the FDA Center responsible for the category of products, such processes generally follow Administrative Procedure Act (APA) standards for permitting due process and creating an administrative record.

Once administrative processes are exhausted, parties with appropriate standing may challenge FDA agency decisions in court under the APA. Although administrative processes vary by category, APA requirements are largely the same across products and typically involve a demonstration that an agency action was arbitrary or capricious or otherwise not in accordance with governing law.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Although the default status for drug approvals is technically OTC (ie, non-prescription), most initial drug approvals specify that new drug products are subject to prescription drug controls. Prescription drugs must be labelled as such and are subject to physician prescribing, pharmacy dispensing, and substitution controls under state law.

However, it is possible to seek an initial FDA approval for the sale of a drug product OTC or to seek to "switch" a prescription product to OTC status by demonstrating that the condition can be self-diagnosed and treated in accordance with labelling. Moreover, throughout the decades, the FDA has also developed OTC monographs that permit the marketing – without approval – of certain OTC drugs that meet the specific terms (eg, ingredients, dosing, and directions for use) for that class of drug under the relevant monograph. Such drugs remain subject to establishment registration, listing, labelling and current Good Manufacturing Practice (cGMP) requirements. Recent legislation liberalised the processes for amending OTC monographs, which could help reinvigorate OTC product development in the US.

Additionally, the FDA has issued a proposed rule that – if finalised – would permit OTC drugs with an "additional condition for non-prescription use" (ACNU). The purpose of this is to increase options for the development and marketing of safe and effective non-prescription drug products via use of tools (such as digital apps) that support patient self-diagnosis and treatment.

Medical devices may also be assigned to non-restricted (including OTC) or restricted status, depending on their classification and the FDA's

determination as to appropriate status under clearance and approval processes.

2. Clinical Trials

2.1 Regulation of Clinical Trials

For drugs and biologics, unless subject to specific exemptions, an investigational new drug application (IND) must be submitted to obtain FDA clearance prior to engaging in clinical research. Such submissions typically include extensive pre-clinical data, information on chemistry, manufacturing and controls, prior human data and the proposed protocol(s). The FDA has 30 days either to allow the clinical study to proceed or to impose a clinical hold until outstanding issues are resolved.

Similar rules apply to medical device research and, depending upon the risk posed by the device, a device study may require the submission of an investigational device exemption (IDE) prior to initiating clinical research. Non-significant risk device studies may be conducted with just Institutional Review Board (IRB)/Ethics Committee approval. The FDA maintains an array of good clinical practice regulations governing clinical research, including study sponsor, IRB, and investigator responsibilities.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

As noted, in addition to obtaining clearance to proceed with clinical research by filing an IND or IDE (as appropriate), virtually all studies must be reviewed by one or more IRBs prior to initiation. FDA regulations specify the requirements applicable to the composition and activities of IRBs.

2.3 Public Availability of the Conduct of a Clinical Trial

The US National Institutes of Health maintains a database at clinicaltrials.gov, where most controlled, interventional clinical investigations – other than Phase I clinical investigations – of drugs or biologic products subject to FDA regulation must be registered and study results must be posted. Although there is no general requirement to publish clinical trial data in journals, the industry has pledged to seek such publications wherever possible, as matter of practicality.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Online tools may be used as long as they comply with applicable requirements – for example, privacy, data security, informed consent and other good clinical practice requirements, as well as establishing lawful status if such tools incorporate certain regulated medical device functionalities. Particular requirements apply to recruiting subjects for clinical studies, whether online or otherwise.

2.5 Use of Data Resulting From the Clinical Trials

The personal data resulting from clinical trials is considered protected. However, in certain scenarios the sponsor and the FDA will have access to such information (including patient-identifiable information) in order to conduct and analyse the data from the study properly. As long as any transfer of resulting data to a third party or an affiliate is consistent with contractual obligations, informed consent, and privacy protections, such transfers are permitted.

2.6 Databases Containing Personal or Sensitive Data

A database containing personal or sensitive data may be subject to both contractual and statutory

protections obliging maintenance of data security and privacy.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Such determinations are typically made by assessing the primary mode of action of the product and whether it works by chemical, biological, mechanical or other means. If the product incorporates combined chemical, biological and/or mechanical modalities, a Request for Designation may be submitted. Notably, Congress recently addressed the decision in the Genus v FDA case, which required compliance with device requirements in certain cases where the FDA has previously treated certain products solely as drugs. The revision to the law now defines contrast agents, radioactive drugs and OTC monograph drugs as drugs and not devices.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Drug products are approved via New Drug Applications (NDAs). Additional indications, dosage forms, etc, may be added via NDA supplements. Biologic products are approved in a virtually identical process via Biologics License Applications (BLAs). The standard for approval is "substantial evidence" of safety and effectiveness (technically "safety, purity and potency" for biologics), resulting from at least one – and typically several – adequate and well-controlled clinical studies. The typical drug or biologic review process takes ten months after initial acceptance for filing (a 60-day period); however, a priority review of six months is given to certain drugs and biologics intended to treat serious or life-threatening conditions.

Substantial user fees – currently as high as approximately USD3.1 million for an NDA or BLA containing clinical data – are required to facilitate a review of applications.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

There is no mandatory re-authorisation process for approved products. However, the FD&C Act and FDA regulations include processes for the withdrawal or revocation of an approval based upon a significant safety or effectiveness issue or non-compliance with approval requirements. These processes can be expedited in the event of an imminent hazard; however, processes for challenging a revocation may be invoked in most cases. Such actions are rare and, in most cases, a manufacturer will withdraw a product voluntarily rather than pursue a formal hearing. In general, a marketing authorisation may not be revoked merely because the product has not been placed on the market – although a failure to market an orphan drug could result in a loss of orphan exclusivity.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

As noted, the pathways for approval of drugs consist of:

- the submission of an NDA (including a 505(b)(2) NDA relying on data for which the applicant does not have a right of reference); and
- the Abbreviated New Drug Application (ANDA) for generic products, which demonstrates equivalence to a reference listed drug.

A biologic is licensed via the submission of a BLA; however, that process is largely the equivalent of an NDA submission. A biosimilar application demonstrates that, based on the totality of the evidence, the biosimilar is either "highly similar" to – or interchangeable with – a reference biologic.

The FDA is authorised to require paediatric studies of drugs or biologics when other approaches are insufficient to ensure that the products are safe and effective for use in children. The agency may also issue a written request for paediatric research and, if the sponsor fulfils the data request, it may obtain six months of paediatric exclusivity.

As noted, changes to an existing marketing authorisation may be obtained through supplements or amendments to existing applications. With regard to medical devices, the submission of additional 510(k) submissions can result in the clearance of significant changes to previously cleared device products. A PMA may also be supplemented or amended. In many cases, the transfer of a clearance or approval without manufacturing site or significant product changes requires only fairly simple notifications to the FDA.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The FDA maintains regulations permitting expanded access to investigational products. Such expanded access to INDs and IDEs may relate to an individual patient (often called a "compassionate use") or may allow broad use by patients not eligible for controlled clinical trials, depending upon the seriousness of the disease and the availability of alternative treatments. Sponsors of such INDs may not charge patients for the investigational drug without specific authorisation from the FDA permitting cost recovery only.

In addition, the 2018 "Right to Try" Act permits certain eligible terminally ill patients to have broad access to eligible investigational drugs in certain circumstances. To date, most companies have shown a reluctance to permit their products to be used via this pathway in lieu of the more traditional IND pathway.

There is also a very limited Humanitarian Device Exemption (HDE) pathway for approval of a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects – or is manifested in – not more than 8,000 individuals in the USA per year.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Every drug, biologic or device product is subject to ongoing requirements relating to establishment registration, product listing, compliance with cGMPs/quality systems, track-and-trace requirements, and safety/adverse event reporting regulations. In certain cases, the FDA may require closer, ongoing oversight of a drug or biologic under a Risk Evaluation and Mitigation Strategy (REMS) or may mandate post-market studies or trials.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

While the FDA does release approval letters and – after review for redaction of confidential and trade-secret information – summary review and approval documents, it does not currently publish "complete response letters" that reject

an application under review. Available information on approved products may be obtained via the FDA's Drugs@FDA website. Often, extensive information about pending applications is released in the form of briefing papers and presentations used at FDA Advisory Committee meetings. The FDA does not reveal the existence of pending INDs or IDEs unless the sponsor has publicly acknowledged the filings.

Third parties may submit requests for information under the Freedom of Information Act (FOIA); however, there are a variety of exceptions from disclosure, as well as a major FDA backlog of requests. Most importantly, the FDA has an obligation under the FOIA to refrain from publication of trade secrets or confidential commercial or financial information. Sponsors/applicants are afforded an opportunity to review potential releases of information and request confidential treatment under those FOIA exceptions.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Drug Supply Chain Security Act (DSCSA) mandated a system to identify and trace certain prescription drugs as they are distributed in the USA. The aim is to enhance the FDA's ability to:

- help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful; and
- improve detection and removal of potentially dangerous drugs from the drug supply chain.

Although a Unique Device Identification System is being implemented for medical devices, that identification system serves various purposes, including:

- providing a standardised identifier that will allow manufacturers, distributors and healthcare facilities to manage medical device recalls more effectively; and
- providing a foundation for a global, secure distribution chain to help address counterfeiting and diversion.

The FDA's Office of Criminal Investigation (OCI) has primary responsibility for policing drug and medical device counterfeiting and diversion. At times, companies will approach the OCI and other law enforcement bodies to seek an investigation and enforcement action.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The FDA and Customs and Border Protection work together to identify and detain counterfeit medical products. It is possible to work with those agencies to seek enhanced surveillance with regard to potential importation of such products. The FDA has extensive powers to stop products at the border if they are suspected of being adulterated or misbranded.

In addition, companies may file actions seeking an investigation under Section 337 of the Tariff Act with regard to unfair acts in the importation of articles. However, such actions may fail if positioned as an attempt to enforce the FD&C Act privately.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

In general, manufacturing plants are not subject to a separate authorisation from the related

product approvals – although they must be registered with the FDA (and the products produced at the facility must be listed as associated with the establishment). Moreover, in most cases, the FDA will conduct a pre-approval inspection of the facility before approving a drug or device. Such establishments are also subject to both routine (typically every two years) and for-cause (eg, in response to a product defect and recall) inspections.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

In general, wholesale activities are subject to licensure requirements at the state level and registration as distributors at the federal level. The requirements and length of such licences vary by state.

The FDA may inspect any facility holding drugs for shipments – although state inspection activities and fees vary greatly. Significant additional requirements administered by the DEA and states apply to wholesale trade in controlled substances.

The authorisation to trade in pharmaceuticals varies greatly by state; however, most pharmaceutical distributors must hold a state licence. Such requirements often do not apply to entities that are not physically handling drug products.

5.2 Different Classifications Applicable to Pharmaceuticals

Drugs may be either prescription – ie, as defined under state law, generally subject to prescription by a designated healthcare practitioner and dispensing by a licensed pharmacist – or OTC (permitting sale without intervention by a healthcare practitioner or pharmacist). Certain products (eg, pseudoephedrine) must be kept behind the pharmacy counter due to specific statutory requirements. The FDA has issued a proposal that could expand direct availability of drug products via, for example, use of mobile apps and kiosks in pharmacies that permit education and diagnostic screening.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The FD&C Act and general import and export administration laws govern the import/export of pharmaceuticals and medical devices. Typically, imported medicines and medical devices must be subject to an approval or clearance (if applicable) in the USA. Only the original manufacturer of a drug may reimport a drug product back into the USA, subject to limited programmes – aimed at demonstrating how the importation of certain drugs can be accomplished in an attempt to reduce prices – that may nor may not proceed in the coming years. The importation of even an identical drug produced at a facility that is not inspected in the course of the US approval would be considered unlawful. Limited exceptions are permitted for individuals to engage in personal, physical importation of foreign products for their own use, if based upon a prescription from a healthcare professional and a lack of alternatives in the USA.

At the border, the primary regulators are the FDA, administering the FD&C Act for potential

violations, and US Customers and Border Protection, administering the broad array of US laws governing customs matters. Other agencies – for example, the Department of Commerce and the Department of Agriculture – may have responsibilities as well, depending on the nature of the imported article.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Importers of record may be designated by the manufacturer or distributor and they have specific responsibilities. A US importer of record (ie, the owner, purchaser, or licensed customs broker designated by the owner, purchaser, or consignee) files entry documents for the goods with the port director at the goods' port of entry. It is the importer of record's responsibility to arrange for the examination and release of the goods. Initial importers may also be responsible for registration and listing requirements. Customs requires the importer of record to file an importation bond that is, typically, equal to at least three times the invoice value of the goods.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In order to be lawfully imported, a drug or medical device must be either:

- cleared or approved (and the product properly listed in association with a registered establishment); or
- the subject of an active IND or IDE.

Exceptions are made for importation of a very limited amount of a product for personal use. The FDA will also work with potential importers in certain situations (eg, compassionate use or short supply) to expedite satisfaction of regulatory requirements.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Upon entry into the USA, declarations and information must utilise the Customs Harmonised Tariff Schedule codes according to the Harmonized Tariff Schedule of the US (HTSUS) and FDA product codes. Such declarations are subject to specific regulations issued by Customs and the FDA. A failure to classify a product properly may result in an improper payment of Customs duties and, consequently, associated penalties.

6.5 Trade Blocs and Free Trade Agreements

The USA is a member of the WTO and has free trade agreements in effect with 20 countries. Some are bilateral agreements, but others are multilateral in nature. The USA is also a party to Trade and Investment Framework Agreements that provide frameworks for governments to discuss and resolve trade and investment issues at an early stage, as well as bilateral investment treaties that help protect private investment, develop market-oriented policies in partner countries, and promote US exports. The FDA is also a party to various memoranda of understanding and mutual recognition agreements aimed at facilitating global discussions and risk assessments with regard to, for example, inspections.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Until recently, the USA had little in the way of pricing limitations on pharmaceutical products and medical devices. Therefore, in most cases, the manufacturer of a product sets the initial price and adjusts prices (including rebates and

other price concessions) over time in response to market conditions. However, in a major shift, the Inflation Reduction Act 2022 (IRA) incorporated provisions to lower prescription drug costs for those covered by Medicare and reduce drug spending by the federal government. Among others, the IRA requires the following provisions.

- From 2026, the federal government will be required to negotiate prices – and establish a "maximum fair price" – for certain drugs covered under Medicare Part B and Part D with the highest total spending (excluding specific categories of drug). Under this Drug Price Negotiation Programme, the number of drugs subject to price negotiation will be ten Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. The drugs will be chosen from the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. A prohibitive excise tax will be levied on drug companies that do not comply with the negotiation process.
- From 2023, drug companies will be required to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries.
- Out-of-pocket spending will be capped for Medicare Part D enrollees and other Part D benefit design changes will be made as of 2024.
- Monthly cost sharing for insulin will be limited to USD35 for people with Medicare as of 2023.

There are also other federal laws that cap pharmaceutical prices for certain purchasers or require minimum rebate levels in the following ways.

- Subject to ongoing litigation over the scope and terms of the programme, manufacturers sell their outpatient drugs to "covered entities" (typically, certain clinics and hospitals believed to serve safety-net functions) at or below a statutorily set ceiling price under the 340B Drug Pricing Programme.
- Manufacturers must sell brand name drugs to four federal agencies (the Department of Veterans' Affairs, the Department of Defence, the Public Health Service and the Coast Guard) at or below a "federal ceiling price" determined by a statutory formula.
- Manufacturers must pay a rebate set by a statutory formula on each unit of their outpatient drugs paid for by the Medicaid programme. This is not literally a "price-control" programme because it only controls the rebate paid to Medicaid after the drug has been dispensed or administered. As such, the price that Medicaid pays up front to the dispensing pharmacy or to a physician's office or clinic that administers a drug is not affected by the Medicaid rebate programme.

7.2 Price Levels of Pharmaceutical or Medical Devices

The price level of a pharmaceutical or medical device does not depend on the prices for the same product in other countries. Programmes developed under the Trump Administration that would incorporate international reference pricing have now been abandoned in favour of other approaches, such as that taken under the IRA.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The largest healthcare programme in the USA today is the Medicare programme, which provides healthcare coverage for people who are 65 and older, are disabled (for two years or more),

or have end-stage renal disease. Medicare accounts for roughly 20% of US health spending. Most pharmaceutical products are eligible for some form of Medicare coverage, either through:

- Part B (Medicare's traditional outpatient benefit, which covers a small but important set of drugs, including physician-administered drugs);
- Part D (the Medicare drug benefit, which has provided broad coverage for pharmacy-dispensed oral drugs since 2006); or
- Part A (Medicare's inpatient benefit, which covers drugs provided as part of covered inpatient hospital stays and in certain other inpatient settings).

The second-largest healthcare programme today – accounting for roughly 17% of US health spending – is the Medicaid programme, which is a joint federal–state programme providing coverage for certain low-income individuals (with the specific eligibility criteria varying by state). Medicaid is run chiefly by states, with federal government oversight, and state Medicaid programmes generally provide broad coverage for prescription drugs. Medicaid programmes have sometimes imposed coverage restrictions on high-cost drugs that arguably conflict with their statutory obligations.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The process and evidence that US payors use to make decisions about pharmaceutical and medical device coverage varies widely by payor (and is not always entirely transparent). These variations can include:

- the criteria considered appropriate for evaluation (eg, whether a product's cost or cost-effectiveness is taken into account in coverage decisions);
- the scientific rigour of the evidence considered and the weight placed on the types of evidence considered;
- the decision-making body and the processes for making coverage decisions; and
- the legal standards that apply to the coverage decision-making process and the resulting package of covered products and services.

Many organisations are engaged in developing value-assessment tools of various sorts. Essentially, these tools are designed to help payors, healthcare providers and patients compare certain demonstrated outcomes of competing pharmaceuticals on a systematic basis and thereby reach conclusions about their value in a more systematic and rigorous way than is currently usual.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Pharmacists are paid for dispensing prescriptions by the patient's insurer (assuming the patient is insured and the product is covered) and the patient. The circumstances in which pharmacists may dispense a substitute for the prescribed product without obtaining the prescriber's authorisation are governed by state law. State laws on this issue can vary but, in general, they permit pharmacists to substitute a product approved by the FDA as a generic equivalent for the prescribed product (unless the prescription specifically states "dispense as written" or a similar phrase indicating no substitution).

During the past several years, the standards for permitting pharmacists to substitute a "biosimilar" product for a prescribed biological product have been a topic of considerable debate. The

provisions of these laws vary but often only permit biosimilar pharmacy-level substitution if:

- the substituted product has been designated as "interchangeable" with the prescribed biological product by the FDA;
- the prescriber and the patient are both notified of the substitution; and
- the pharmacist maintains records of the substitution.

8. Digital Healthcare

8.1 Rules for Medical Apps

The FDA has been very active in providing guidance in this area and has carved out defined categories of apps and platforms from regulation. The FDA has issued several guidance documents designed to "encourage innovation" and "bring efficiency and modernisation" to the agency's regulation of digital health products. The guidance documents address, in part, the important changes made by Section 3060 of the 21st Century Cures Act (the "Cures Act") to the medical device provisions of the FD&C Act – whereby five distinct categories of software or health products were espressly excluded from the definition of medical device. The FDA's extensive guidance documents in this area include guidance on Clinical and Patient Decision Support software, regulation of software as a medical device (SaMD), and general wellness products, which establishes common principles for regulators to use in evaluating the safety, effectiveness and performance of SaMD. The FDA has also issued a discussion paper on the regulation of SaMD incorporating AI.

8.2 Rules for Telemedicine

The FDA does not regulate the practice of medicine and generally defers to the states in order to determine what is a valid physician–patient relationship and prescription. Although telemedicine has expanded enormously in the US owing to the pandemic, and more and more physician consultations are being provided online via chat-based or video examinations, the regulation of such activities varies by state. Various laws govern issues such as the corporate practice of medicine, minimum rules for a genuine patient relationship, cross-border prescribing and lab orders, privacy, and payments and referrals to telemedicine physicians. The availability of electronic prescribing also varies by state; nonetheless, states generally permit online dispensing of approved drug and medical device products pursuant to valid prescriptions.

8.3 Promoting and/or Advertising on an Online Platform

Medicinal and medical device products may usually be promoted online, on company websites, and via social media. However, such media present special challenges when ensuring that the promotion is fairly balanced, truthful and non-misleading, as well as transparent with regard to the company's involvement, and adequately provides safety information.

The FDA has developed several guidance documents in this area for the purpose of informing companies about when the agency considers user-generated information on a company's web page or social media to be promotional (largely based on the level of control over the site and placement of information) and how to convey information properly in a character-limited social media environment. Additional rules apply to online marketing practices – for example, the FDA and FTC requirements pertaining to endorsements and testimonials by paid "influencers" in online promotion.

8.4 Electronic Prescriptions

Electronic prescribing of drug products is governed by state laws and Board of Pharmacy rules. Most states do permit some form of electronic prescribing, even though the specific rules (such as those for specifying use of the brand-name drug) vary by state. Special rules may apply to interstate prescribing, particularly with regard to controlled substances, and licensure in multiple states may be required where reciprocity in licensure recognition is not provided.

8.5 Online Sales of Medicines and Medical Devices

Online sales of prescription drug and device products are permitted if there is otherwise a valid prescription for the product and the pharmacy is duly licensed in the states to which the products are shipped. Special rules apply to certain controlled substances. To the extent that prescribing of the drug or device also occurs online, the prescriber must satisfy state requirements pertaining to valid physician–patient relationships and telemedicine-based prescribing. Special rules apply to controlled substances sales. Online sales of drugs into the USA from ex-US pharmacies, whether or not pursuant to a valid prescription, are generally prohibited.

8.6 Electronic Health Records

In addition to the previously mentioned FDA rules regarding digital tools that convey health records and images, there are many other aspects to the regulation of electronic health records in the USA. Specifically, the HHS Office of the Co-ordinator for Health Information Technology (ONC) is responsible for implementing statutory provisions related to advancing inter-operability, clarifying the Health Insurance Portability and Accountability Act (HIPAA) privacy rules, prohibiting information-blocking, and enhancing the usability, accessibility, privacy and security of health IT.

The Health Information Technology for Economic and Clinical Health (HITECH) Act 2009 provided the HHS with the authority to establish programmes in order to improve healthcare quality, safety and efficiency through the promotion of health IT, including electronic health records and private and secure electronic health information exchange.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The statutory framework for US patent law is mainly set out in United States Code (USC) Title 35. The Leahy-Smith America Invents Act (AIA) effected sweeping changes to US patent law. One of the most significant of these changes was to bring the USA largely into compliance with the rest of the world with regard to prior art determinations. Prior to the AIA, the USA was considered a "first inventor" jurisdiction (ie, the first person to invent the invention was entitled to the patent). Following the AIA, the USA is a "first-inventor-to-file" jurisdiction that uses the "first-to-file" methodology employed virtually everywhere else in the world.

As explained in further detail later, in the USA, patent protection and certain regulatory exclusivities may share certain traits but they are distinct. The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, amended the FD&C Act and affected the government's regulation of generic drugs. Hatch-Waxman provides for brand prod-

uct exclusivities, as well as 180-day exclusivity to companies that are the "first-to-file" an ANDA against branded drug patent-holders. This regulatory exclusivity is in addition to the patent term of patents claiming the branded drug and a statutory 30-month stay of approval permitted in the event of patient litigation.

Similarly, the Biologics Price Competition and Innovation Act 2009 (BPCIA) amended the PHS Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product.

To be patentable under US law, an invention must be:

- patentable subject matter;
- novel; and
- not obvious.

Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter" (35 USC Section 101). Novelty requires that the invention has not previously been "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" (35 USC Section 102). Finally, an invention must not be obvious – ie, it cannot be the case that "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains" (35 USC Section 103).

In addition to these requirements, a patent must "contain a written description of the invention – and of the manner and process of making and using it – in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains (or with which it is most nearly connected) to make and use the same" and "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention" (35 USC Section 112).

There are no requirements specific to pharmaceutical products or medical devices. Nevertheless, various claim-drafting structures and statutory requirements are commonly at issue in cases involving pharmaceuticals or medical devices.

In the wake of two 2012 Supreme Court decisions regarding what constitutes patentable subject matter, companies have sought to distinguish their inventions from laws of nature and unpatentable phenomena through narrower claim drafting. The case law in this area is evolving. As of the beginning of 2023, method-of-treatment claims involving treatment steps are patent-eligible even if they also recite diagnostic steps. Nonetheless, method-of-diagnostic claims remain patent-ineligible, while certain method-of-preparation claims have been held patent-eligible.

9.2 Second and Subsequent Medical Uses

Patent protection is available for new uses of known compounds, processes, manufactures, etc, that satisfy the general requirements for patentability (including novelty and non-obviousness). As noted in **9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices**, claims may be directed to "methods of treatment".

A new dosage regime may be patentable if it satisfies the requirements for patentability; however, such claims are often subject to obviousness challenges. A claim could be directed to a method of treating a patient suffering from new disease X by administering an effective amount of known compound Y to the patient. A claim could also be directed to a method of treating a selected patient with disease X by administering compound Y at dose Z to the patient, wherein the selected patient has tested positive for a biomarker.

Direct or indirect infringers (as well as inducers of infringement) may be sued – although induced infringement can be found only when one "party" performs every step of a patent. In Limelight Networks Inc v Akamai Technologies Inc et al, the Supreme Court held that induced infringement can be found only when one party performs every step of a patent.

9.3 Patent Term Extension for Pharmaceuticals

35 UC Sections 154 and 156 address certain adjustments and extensions of patent term, with Section 156 being particularly applicable to drugs and biologics. Certain medical devices may also be eligible for patent-term extension; however, such devices must be reviewed and approved via PMA. The FDA assists the United States Patent and Trademark Office (USPTO) in determining a product's eligibility for patent-term restoration and provides information to the USPTO regarding a product's regulatory review period. The USPTO is responsible for determining the period of extension, subject to statutory requirements.

A third party may file a due diligence petition challenging the FDA's regulatory review period determination by alleging that an applicant for patent-term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement may occur if the defendant has made, used, sold, offered to sell, or imported an infringing invention or its equivalent. A generic applicant may file an ANDA, which allows that applicant to rely on the safety and efficacy studies supplied by the brand name manufacturer if the generic manufacturer shows that its generic product contains the same active ingredient as – and is bio-equivalent to – the brand-name drug listed in the Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the "Orange Book".

In doing so, the generic applicant must make one of four certifications with regard to any patents associated with the drug. The fourth is that the "patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted" (21 USC Section 355(j)(2)(A)(vii)). Such a "Paragraph IV" certification is deemed a constructive act of infringement, and the patent-holder then has 45 days to file an infringement lawsuit against the ANDA applicant. If such a lawsuit is filed, the FDA generally may not grant final approval of the ANDA for 30 months after the filing date or until the ANDA filer prevails in litigation. If patent validity and infringement remain unresolved after the 30-month stay, the FDA may approve the ANDA.

The BPCIA provides a conceptually similar (albeit procedurally very different) framework, according to which the filing of a biosimilar application by an applicant is an artificial act of infringement giving rise to a statutorily prescribed process

that governs subsequent patent-infringement litigation and biosimilar regulatory approval. A BLA sponsor is required to provide certain patent information regarding the reference product to the FDA within 30 days of such information being provided to the biosimilar applicant as a part of the "patent dance". The FDA must then include this patent information when it updates the Purple Book every 30 days. There is no equivalent statute and regime for medical devices.

As regards patent infringement, the threat of infringement can form the basis of a declaratory judgment action, which can examine the validity of patents and whether the action constitutes infringement. As this action is brought by the alleged infringer, the alleged infringer is able to select the venue for the case, which can have great strategic value in US patent litigation. However, given that many patent-owners desire to avoid a declaratory judgment action, notice letters and cease-and-desist letters are not as commonly used as in the past, and patent-litigation suits are often filed before the alleged infringer has the chance to claim that the threat of infringement exists.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Under 35 USC Section 271(e)(1), it is not an act of infringement to make, use, sell, or offer to sell within the USA or import into the USA a patented invention "solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use or sale of drugs or veterinary biological products". In Merck KGaA v Integra Lifesciences I, Ltd, the Supreme Court held that the statute exempts from infringement all uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use or distribution of drugs.

This safe harbour continues to be narrowed in recent district court decisions. In an early 2022 decision, the District Court of Delaware excluded the use of patented host cells to produce gene therapy product from safe-harbour protection, after it reasoned that the patented host cells are merely tools used in the preparation of the product to be approved.

Compulsory licences are available only in very specific situations and generally not under patent law. By way of an example, the US National Institutes of Health may, under certain circumstances, threaten to issue a compulsory licence if a licensee has failed to take effective steps to pursue the government-licensed invention or in certain scenarios involving public health need. It has never done so, however.

9.6 Proceedings for Patent Infringement

Typically, the patent-owner brings the suit alleging patent infringement. Depending on the wording of the licence agreement, an exclusive licensee may also have standing to enforce the licensed patent. Remedies may include a temporary or permanent injunction, destruction of infringing articles, the award of damages (including the infringer's profits) and, in certain limited circumstances, attorneys' fees.

Patent litigation is much like other civil litigation in the federal district courts in the USA (including a very high settlement rate). First, the plaintiff files a complaint alleging infringement of one or more US patents. Then, the plaintiff serves the complaint on the defendant, who typically answers by alleging non-infringement and asserting defences such as patent invalidity

and other equitable defences. Common invalidity defences include invalidity based on ineligible patentable subject matter, combination of prior art references, and double patenting. The defendant may also assert a counterclaim, such as a declaratory judgment of non-infringement. The defendant may also file a motion to dismiss for improper venue in view of TC Heartland LLC v Kraft Food Group Brands LLC and Valeant Pharmaceuticals North America LLC v Mylan Pharmaceuticals Inc. A case-management conference regarding scheduling, among other matters, is required. Certain district courts may have local patent rules that set forth additional requirements. Next, fact and expert discovery are conducted, which typically includes depositions, document requests, interrogatories, expert reports and the like. Often, a claim construction hearing (also known as a Markman hearing) occurs, in which the parties ask the court to interpret certain terms of claims in the patent(s) at issue. The parties also typically file various motions, such as a summary judgment motion of patent invalidity.

If the case proceeds, pre-trial briefing and then trial (by judge or jury) and post-trial practice occur. A jury may render an opinion as to whether the patent is invalid. An appeal may be taken to the Federal Circuit and then to the Supreme Court if the Supreme Court grants a petition for certiorari.

In addition to raising invalidity as a defence in court, a potential infringer (or any third party) can challenge the validity of a patent in proceedings before the Patent Trial and Appeal Board (PTAB). A "post-grant review" permits a person who is not the owner of a patent to challenge a patent's validity on any ground that could be raised under Section 282(b)(2) or (3) no later than nine months after the date of the grant of the patent (35 USC Section 321). An "inter partes review" (IPR) may be requested by a person who is not the owner of a patent nine months after the grant of the patent or the termination of a post-grant review (whichever is later), if one has been instituted (35 USC Section 311(a), (c)). However, an IPR may not be filed more than one year after the complainant has been served with a complaint alleging infringement. The validity of a patent subject to an IPR can only be challenged on a ground that could be raised under Sections 102 or 103 – and only on the basis of prior art consisting of patents or printed publications (35 USC Section 311(b)).

In SAS Institute Inc v Iancu (SAS), the Supreme Court did away with the PTAB's prior practice of "partial institutions" of IPR challenges. Going forward, the PTAB must decide the validity of all challenged claims when it institutes review of a patent. In light of SAS, the Federal Circuit held in California Institute of Technology v Broadcom Ltd that an infringer is barred under Section 315(e) from challenging the invalidity of a patent in a civil action on all grounds that reasonably could have been asserted against the claims in its previously filed IPR petition. A petition for certiorari was filed to challenge the Federal Circuit's holding and remains pending as of February 2023.

9.7 Procedures Available to a Generic Entrant

As previously described in **9.4 Pharmaceutical or Medical Device Patent Infringement**, an ANDA filer must make one of four certifications with regard to any patents associated with the drug. It is possible that, after making a Paragraph IV certification, the patent-holder may elect not to file an infringement lawsuit. If the patent-holder does not bring suit, the FDA may approve the ANDA.

An ANDA filer may not file a declaratory judgment suit during the 45-day period in which the patent-holder may elect to bring a suit. If the patent-holder files suit against the generic applicant within the 45-day period, the generic may file a declaratory judgment counterclaim, as long as an actual case or controversy continues to exist. A generic drug-maker may be able to request correction or delisting of a patent claim from the Orange Book as part of a counterclaim or non-infringement declaratory judgment action. An ANDA filer and the patent-holder may also reach a licensing or other agreement – although such "reverse payment" settlements can be subject to antitrust scrutiny.

The phrase "clearing the way" is not a term of art in US patent law; however, a generic drug manufacturer may launch "at risk" if patent validity and infringement remain unresolved after the 30-month stay and the FDA approves its ANDA. In such cases, the generic may be liable for damages if the patent(s)-in-suit are ultimately held to be valid and infringed.

An NDA includes patent information for listing in the FDA Orange Book and the FDA considers patent listing part of the approval process for brand drug applications. If a patent that covers the drug exists and is listed, marketing approval will not be granted to a generic until the patent has expired or is found to be invalid or not infringed.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Trade mark and trade dress owners can sue manufacturers and sellers of counterfeit pharmaceuticals and medical devices for infringement. Additionally, a general exclusion order can be sought in the International Trade Commission (ITC), which can help to combat counterfeits that are being imported into the USA. Under the general exclusion order, any such infringing articles would be seized at the border by customs.

The possession, trafficking and purchasing of counterfeit pharmaceuticals and medical devices can also be criminally actionable at the federal or state level.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Other than general trade mark requirements, the controls on trade marks are usually regulatory in nature. By way of an example, trade marks that could be deemed claims must not be false or misleading (ie, may not misbrand the product). In the case of prescription drugs, the trade-marked brand name – known as the "proprietary name" – is subject to approval by the FDA as part of the drug and biologic approval process. This is done to ensure that it does not misbrand or create a risk of medical errors.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Trade dress protection is available for colour and shape (including pill shape). A "US adopted name" (USAN), which is a non-proprietary name reviewed by the World Health Organization, is necessary in order to market a pharmaceutical in the USA. The USPTO reviews and registers federal trade marks (pursuant to the Lanham Act). In doing so, the USPTO considers the likelihood of confusion with other marks and whether the mark is:

- distinctive;
- a surname;

- a likeness;
- geographically descriptive of the origin of the goods;
- disparaging or offensive;
- a foreign term that translates to a descriptive or generic term; or
- purely ornamental.

The US Trademark Trial and Appeal Board (TTAB) hears petitions related to the status of trade marks (including their cancellation). The TTAB may cancel a mark if it finds that:

- a registrant was using the mark to misrepresent the source of the corresponding goods; or
- differences with prior marks do not offset the likelihood of confusion.

The FDA has authority under the FD&C Act to determine whether a pharmaceutical is "misbranded" – ie, "its labelling is false or misleading" (21 USC Section 352(a)). This can be due to the proprietary name of the product, which the FDA must approve as part of the drug application.

The Lanham Act and the Tariff Act may provide a basis to bring claims in a federal district court against parallel importers for damages and injunctive relief. Any resulting injunction would be enforced through the federal courts rather than through the Customs and Border Patrol. Sometimes, the district court action is stayed pending the outcome of an ITC proceeding.

Parallel importation may violate Section 337 of the Tariff Act, which grants the ITC jurisdiction to investigate claims of trade mark infringement. The ITC cannot award damages but can issue exclusion orders that are enforced by the Customs and Border Patrol. The ITC can bar the importation of items that infringe US trade marks, copyrights or patents.

Customs and Border Patrol works with the FDA to prevent parallel import. Trade mark owners typically contact the FDA and then the FDA contacts the Customs and Border Patrol.

Trade dress protection is available for colour, shape (including pill shape) and packaging that identifies the source of the product and otherwise distinguishes the product but is not purely functional or likely to be confused with the trade dress of another product.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

For drugs, under the previously described Hatch-Waxman Act, there is a period of data exclusivity of five years from the date of approval for new chemical entities. There is also a period of data exclusivity of three years from the date of approval for supplemental applications incorporating clinical studies sponsored by the applicant that are essential to the approval. The first approved biologic may be subject to 12 years of exclusivity; however, subsequent supplemental applications for the product will not accrue additional exclusivity without clinically meaningful changes to the product. Such periods can run irrespective of – but concurrent with – any patent term associated with the drug or treatment using the drug.

Other exclusivities are available for:

- designated orphan drugs for rare diseases (seven years of market exclusivity);
- designated Qualified Infectious Disease Products (five years of additive exclusivity);
- first generic applicants filing a patent certification (180 days); and

- satisfying paediatric study requests (six months of additive exclusivity).

There is no exclusivity framework for medical devices, and 510(k)-cleared devices may be designated as predicate devices immediately upon clearance. However, subsequent applicants for a Class III device generally may not rely on data in PMA-approved medical device products.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The FDA relaxed various regulatory requirements relating to COVID-19 countermeasures, as well as FDA-regulated products generally. Many of these policies were intended to provide some flexibility, given the limitations of virtual interactions and similar constraints. A complete directory of the various FDA policies in this area can be found on the FDA website. The US government is now winding down COVID-19 emergency measures and has issued guidance on the disposition of products authorised for emergency use during the pandemic. In addition, the HHS has issued a fact sheet providing a "roadmap" for transitioning from the COVID-19 public health emergency. Notably, despite the ending of the COVID-19 public health emergency, the FDA will for the time being retain separate authority to continue the authorisation of products for emergency use – and new Emergency Use Authorisations (EUAs) can be issued (see **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices** for further detail). However, flexibilities and waivers provided in other areas will be curtailed.

11.2 Special Measures Relating to Clinical Trials

The FDA issued and has periodically updated an extensive guidance entitled Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency. Under the HHS roadmap for transitioning from COVID-19, certain FDA pandemic-related guidance documents for industry will end or be temporarily extended. The FDA is in the process of addressing which policies are no longer needed and which should be continued (with any appropriate changes). As such, the agency will announce plans for each guidance prior to the end of the public health emergency.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The FDA has utilised existing powers to permit unapproved medical products or approved medical products for unapproved uses to be manufactured and distributed under specific conditions and labelling during the period of a declared pandemic or other health emergency. The FDA has issued hundreds of such EUAs for pandemic-related therapeutics, devices, diagnostics and vaccines (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**). Ultimately, the agency will permit an additional time-period for ensuring proper disposition of the product when the EUA is revoked. An EUA is neither a substitute for – nor intended to delay – applications for actual clearance or approval, and the FDA can revoke or terminate an EUA at any time.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The FDA does not provide separate certifications for manufacturing, but rather inspects facilities both prior to product approval/licensure and then on a periodic or for-cause basis (see **4.1**

Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices). Although now actively inspecting, the FDA has faced considerable difficulties in accomplishing inspections during the COVID-19 emergency and had been relying largely on record reviews and other measures where inspections were deemed too risky in light of the pandemic. This has resulted in delays in approval of products and supplements in certain cases, along with a large backlog.

In order to continue to provide oversight during the pandemic, the FDA introduced alternatives to in-person inspections in the form of remote regulatory assessments (RRAs). RRAs are remotely conducted examinations of regulated establishments to evaluate compliance with FDA requirements where traditional inspections are deemed impracticable. Based on the FDA's experience with RRAs during the pandemic, the agency has concluded that RRAs should continue to be used after the pandemic, as a supplement to FDA's inspection programme, and recently issued a draft guidance on this practice.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The Trump Administration had imposed restrictions on the export of masks and other protective equipment, which was modified over time owing to a significant backlash, and also prioritised US citizens in the distribution of US-made vaccines. The Biden Administration modified those policies to focus on ensuring an adequate US supply of vaccines and diagnostics, with a selective use of the Defence Production Act (DPA), which put the US government at the "front of the line" as a customer. The use of such powers will likely be significantly moderated or abandoned as the pandemic emergency comes to an end. More generally, there is an ongoing policy debate – subject to continued legislative and regulatory activity – about ensuring a more secure and domestic supply chain for products needed during an emergency.

11.6 Drivers for Digital Health Innovation Due to COVID-19

There has been an extensive relaxation of limitations on virtual and telemedicine interactions during the pandemic, as well as policies fostering the use of digital devices to address public health needs during the pandemic. As noted, this has had a significant impact on innovation in clinical trial conduct, use of digital health tools, and telemedicine (among other areas). See the FDA website for further details.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Under the Bayh-Dole Act, the US government has very limited "march-in" rights with regard to IP licensed from the government. To date, despite some controversies over the use of government IP and pressures due to COVID-19 product pricing, this authority has not been utilised. Unrelated to COVID-19, the National Institutes of Health recently denied another petition for such a "march-in" on government-licensed patents for a drug product.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The 2005 Public Readiness and Emergency Preparedness (PREP) Act, which has been invoked in a declaration in the case of COVID-19, provides immunity for the manufacture, testing, development, distribution, administration and use of specific covered countermeasures against threats such as COVID-19. Individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions may seek redress from the Counter-

measures Injury Compensation Program (CICP), which is administered by the Health Resources and Services Administration.

Immunity protections are broad and contrary state and local laws and rulings are widely pre-empted. In practice, the only time a manufacturer of a COVID-19 countermeasure would not benefit from PREP Act immunity would be if a suit were brought in the US District Court for the District of Columbia by a plaintiff who has:

- suffered a serious injury or death;
- rejected a payment from the fund; and
- demonstrated by clear and convincing evidence that the manufacturer engaged in "wilful misconduct" (as defined in the statute).

With the end of the public health emergency, the HHS has indicated that, although PREP Act liability protections will not be affected, "PREP Act liability protections for countermeasure activities that are not related to any US government agreement (eg, products entirely in the commercial sector or solely a state or local activity) will end unless another federal, state or local emergency declaration is in place for area where countermeasures are administered". The HHS is currently reviewing whether to continue to provide this coverage going forward.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions have been used and new ones introduced to allow the requisition or conversion of manufacturing resources owing to COVID-19. The DPA is the primary source of Presidential powers to expedite and expand the supply of materials and services from the US industrial base, including for certain emergency preparedness activities and the protection or restoration of critical infrastructure.

Under the DPA, the government can impose "rated" or "priority orders", pursuant to which the President may compel companies to accept and prioritise contracts for supplies critical to national defence. These orders also flow down the recipient's supply chain, such that subcontractors or suppliers must also prioritise the rated order over competing obligations. The government can also impose "allocation orders" to compel industry, on a proportional basis, to allocate resources – for example, by reserving manufacturing capability or supplies in anticipation of a rated order or allocating manufacturing capability to a particular purpose. Failure to comply with a DPA order carries a criminal penalty. These authorities have been invoked with regard to certain diagnostic devices, personal protection equipment, and vaccine production capacity in the US. In other cases, the US government has funded the development of additional production capacity, such as for vaccine vials.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

As noted throughout **11. COVID-19 and Life Sciences**, the US government has used a wide variety of public procurement and funding strategies for needed medical countermeasures during the pandemic. Some of these have been unprecedented and based upon emergency authorities.

Trends and Developments

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Ropes & Gray LLP is a pre-eminent global law firm with approximately 1,400 lawyers and legal professionals serving clients in major centres of business, finance, technology and government. The firm has offices in New York, Boston, Washington, DC, Chicago, Los Angeles, San Francisco, Silicon Valley, London, Dublin, Hong Kong, Shanghai, Tokyo and Seoul, and has consistently been recognised for its leading practices in many areas, including private equity, M&A, finance, asset management, real estate, tax, antitrust, life sciences, healthcare, IP, litigation and enforcement, privacy and cybersecurity, and business restructuring.

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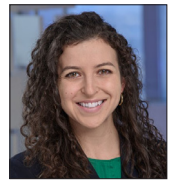

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Introduction

The life sciences industry in the USA continues to be significantly impacted by the COVID-19 pandemic. Companies experienced a record number of deals and high valuations during the biotech boom in 2020 and 2021. This past year marked the turning point – with economic instability, rising inflation, and ongoing supply chain disruptions cooling the rapid expansion and bringing uncertainty within the industry. Such market unpredictability will likely persist throughout 2023. This article will examine emerging trends and regulatory updates in the biotechnology, pharmaceutical, medical device, and digital health sectors.

Biotechnology and Pharmaceuticals

After a record-setting pace of biotech investment activity in 2021, 2022 was a relatively sobering year for the industry – particularly in comparison with the pre-pandemic economic boom. During 2022, 22 biotech companies debuted on public markets, which is less than half of the number in each of the previous four years (including 104 IPOs in 2021).

Pharma companies also faced difficulties in the bear market. Rising inflation cut into profitability and this appeared to contribute to lower deal volume. The volume of higher-value M&A deals in 2022 was lower than previous years as well, with only 17 deals topping USD1 billion in value. Concerns over a prolonged recession in 2022 were a factor in turning venture capital financing options colder, making pharma deal activity less aggressive, and significantly reducing valuations for public market biotech financing. Moreover, uncertainty around the longer-term effects of the Biden Administration's implementation of the Inflation Reduction Act (IRA) and increased enforcement of regulatory requirements have had an impact on the industry.

The wide-ranging IRA has become a point of strong interest to the biopharma industry – at least in part owing to the potential for lower profits and uncertain sales projections resulting from the IRA's enactment. The new legislation, signed into law in March 2022, gives Medicare the ability to negotiate pricing for the 50 highest-selling medications that lack competition. Under the IRA, Medicare can target "small molecule" drugs just nine years after market approval and can target "large molecule" drugs after 13 years. Some in the biopharma industry have raised concerns that, as a result, the IRA will disincentivise small molecule development. While the actual effects of the IRA on the biopharma industry will likely not be fully understood for years (or, potentially, decades), the uncertainty around pricing may depress sales projections and therefore further limit financing options for biotech companies. Also, biotech companies are increasingly expected to share in the impact of any pricing reduction related to the IRA under pharma partnerships.

Additionally, the headwinds in the regulatory space point towards the Food and Drug Administration (FDA) more strictly enforcing the requirements around the accelerated approval programme, including as reflected in the Food and Drug Omnibus Reform Act (FDORA) enacted on 29 December 2022. At a high level, the accelerated approval programme allows for expedited approvals for drugs serving unmet needs. After accelerated approval, confirmatory trials are often required. However, there has been increasing concern over the enforcement of this requirement, transparency of the conditions related to accelerated approval, and the perceived reluctance by the FDA to require a market withdrawal of a drug if such conditions are not met.

The FDORA provides the FDA with more tools to require the conduct of confirmatory trials – for example, by requiring that such trials are initiated prior to accelerated approval being granted. It also requires more public-facing information to be disclosed regarding both the conditions of accelerated approvals and the satisfaction of such conditions, as well as creating a pathway for the FDA to require more expedited mandatory market withdrawals if such conditions are not met. In 2023 and beyond, there is growing belief in the pharma industry that the FDA will move to enforce these requirements more closely for accelerated approval. This could result in increased research and development costs being baked into product budgets and lead to the negotiation of downstream economics between biotech and pharma companies.

Despite depressed biotech valuations that would seem to be attractive targets for larger pharma companies, pharma was not as active in the deal space in 2022 as might have been expected. Pharma continued to cautiously deploy cash in an uncertain market and sometimes instead relied on stock buybacks and investment in homegrown pipelines to buoy themselves through the market instability, resulting in biotech companies needing to make difficult decisions in the face of fewer funding options. For biotech companies, redirecting funds into research and development may require a temporary or permanent reduction in resources, including personnel. In 2022 alone, more than 100 biotech companies made the decision to conduct lay-offs.

Overall, there are reasons to believe that deal volume in 2023 will increase from that of 2022. By way of an example, more than 50 drugs are set to face patent expiration in 2023, including some drugs that historically have been very profitable. This may result in pharma companies evaluating the available assets of biotech companies with more intention to partially compensate for lost profits from their recently or soon-to-be off-patent drugs.

In addition, biotech valuations are already showing signs of starting to tick up – as evidenced by the benchmark biotech exchange-traded fund, XBI, experiencing a steady rise towards the end of 2022 after it hit rock bottom in June. As such, participants in the biotech industry may be ready to partner with larger pharma companies that are looking to bolster their research and development pipelines.

As described earlier, large biopharma M&A may increase. However, for any number of reasons, this will not be a viable solution for the majority of biotech companies who may be looking for financing and/or partnerships. Biotech companies looked to more unique and creative financing and partnership options in 2022, and this trend appears to be continuing in 2023.

With valuations stubbornly remaining low, royalty financings have grown in popularity. Royalty financings come in two varieties: traditional and synthetic. In a traditional royalty financing, a biotech company sells off a portion or the entirety of a royalty stream created by an existing licence. (Generally these existing licenses are with larger pharmaceutical partners to whom the biotech company licensed technology, and which are now utilising – or about to utilise – licensed technology to achieve commercial sales). In synthetic royalty deals, a biotech company with an emerging or already commercially viable drug will sell a portion of the sales of such drug for a large upfront payment. In synthetic financings, because the biotech company is still responsible for the development and commercialisation of the drug, the deals can be more complex so as

to provide more comfort to the financing partner. These transactions are attractive to cash-hungry biotech companies because they provide large, non-dilutive payments that may help keep companies afloat through the uncertain market. Continue to look for royalty financings and similar debt-style deals as biotech companies work to avoid committing equity at deeply discounted rates.

Medical Devices

Medical device M&A slowed down in 2022, with Johnson & Johnson closing out the year by completing the acquisition of Abiomed for USD16.6 billion in December. According to data from consulting and accounting firm Ernst & Young, there were only 11 mega-deals valued at more than USD1 billion in 2022 – compared with nearly double that number in 2021. Many of the deals that happened in 2022 were for assets that used the 510(k) programme created by the FDA, which lets manufacturers obtain approval by showing that the new devices are "substantially equivalent" to products already on the market. For acquiring companies, this greatly lowers the risk associated with regulatory clearance in the USA and could be a persisting trend in deal-making in 2023.

Strategic M&A buyers will continue to hunt for innovations in technology and digital health in order to strengthen their rosters, along with implementing trimming and divestment strategies. In January 2023, General Electric Company completed their spin-off of GE HealthCare, which manufactures medical diagnostics equipment and agents. Medtronic has also announced plans to spin out their patient monitoring and respiratory divisions now that the demand for ventilators has dropped below pre-pandemic levels.

On the private and venture-backed side, deal activity for medical device companies may be on the rise, despite the continued lukewarm IPO market. One effect of the pandemic, unfortunately, is a growing ageing population that faces lasting medical needs likely to benefit from long-term device monitoring. Compared with the volatility in other economic sectors, many view healthcare and medical devices as a safer investment alternative. M&A demand and deal-making for medical device manufacturers may increase alongside the growing number of elective procedures that have been steadily on the rise since the height of the pandemic. Small and mid-size companies with new technological advances could have many interested potential acquirers, with perhaps overall less market interest for larger mega-deals as potential acquirers assess their asset portfolios with greater care owing to economic instability.

Certain innovations and growing demand for hospital-to-home care may also greatly impact deal-making in the medical device space. New breakthrough technology – from AI-guided surgery to wearable devices for remote monitoring – are attractive targets for acquisitions. With hospitals overwhelmed during the height of the COVID-19 pandemic, demand for remote monitoring of vitals and other personal health information has increased rapidly during the past few years and is expected to continue in 2023. Growth in implantable medical devices, such as cardiovascular implants and intraocular lenses, is also expected to increase with the post-pandemic steady resumption of elective surgery and procedures across multiple medical specialties. The heightened global demand for COVID-19 testing is on the decline, but new variants and regional outbreaks could continue to provide steady demand for medical device and diagnostics companies in the near future.

On the regulatory side, the FDA User Fee Reauthorisation Act of 2022 was signed into law, thereby authorising the Medical Device User Fee Amendments (MDUFA V) for the next five years. MDUFA V funding will provide resources to the FDA's medical device review programmes, including the recent launch of the Center for Devices and Radiological Health's Total Product Life Cycle Advisory Programme (TAP) Pilot. TAP aims to increase predictability and reduce time from concept to commercialisation, in part by encouraging robust engagement early on with the FDA, industry and key stakeholders. The first phase of the programme launched on 1 January 2023. TAP is expected to give certain medical device manufacturers access to an advisory programme that could help identify the right level of evidence to support FDA submissions and help developers better address patient needs and anticipate reimbursement and market adoption considerations. This pilot programme, along with the Breakthrough Devices Programme and the Early Feasibility Study Programmes, will provide greater opportunities for new innovative medical devices to hit the market.

In the EU, the Medical Devices Regulation (MDR), which came into effect in May 2021, has been deemed by some as complicated to implement. The current transitional periods provided in the MDR require an estimated 23,000 devices certified under the previous directives to be re-certified by May 2024 and May 2025 under the much stricter safety criteria of the MDR. Devices that are not re-certified by this date may not lawfully be placed on the market of the European Economic Area. This has caused consternation for device manufacturers that are unable to meet certification requirements on time or bear the increased costs associated with the re-certification, which in some cases include the cost of performing one or more new clinical trials.

The European Parliament voted on 16 February 2023 to adopt a legislative proposal to extend the transition period for certain legacy devices to 2027 and 2028 in order to prevent widespread shortages of life-saving medical devices. The amendment will include staggered deadlines for re-certification, depending on the risk profile of a device if such device continues to meet certain conditions – one such condition being that there are no significant changes in the design and intended purpose. This deadline extension could provide valuable time for SMEs to keep their devices on the market while pursuing re-certification. However, certain questions – such as how these legacy devices are to be monitored for compliance during this extension – have yet to be answered.

The outlook for medical devices and technology companies is generally optimistic. Industry insiders and analysts expect to see more deal activity for small to mid-size companies, given that some economic pressures are predicted to stabilise in 2023. Technological trends and growing demands for remote monitoring and AI will be important factors driving deal-making, and the effects brought on by major regulatory changes in the USA and the EU could provide both opportunities and challenges for medical device companies to navigate.

Digital Health

Digital health innovation in 2022 was bolstered in part by the still-present COVID-19 pandemic, ongoing staff shortages of skilled healthcare workers, employee turnover in the medical field, and increasing comfort with – and awareness of – digital healthcare options for patients. Challenges in the digital health space in 2022 included economic concerns, such as inflation and less access to funding, and anticipated and enacted regulatory and legislative initiatives

that, in the aggregate, created a less predictable environment for digital health transactions and advancement. Looking ahead, the overall economic picture in early 2023 is a departure from the same period in 2022. Interest rates are up, inflation is higher, supply chain issues persist, and investors remain cautious about funding.

With regard to digital healthcare options such as telehealth, availability of these options expanded in 2022 as concern over COVID-19 variants and the perceived ease of access factored into patients' decisions to continue to seek virtual medical care and increased the likelihood that certain digital healthcare options will become a permanent feature of medical treatment in the USA and worldwide. Indeed, rates of telehealth utilisation have maintained a steady pace since the drop of usage from the height of the pandemic.

Notably, in 2022, Congress paved the way for additional digital health expansion with passage of the IRA, which was signed into law in August of 2022. The IRA extends certain pandemic-related telehealth permissions until the end of 2024 for Medicare patients, thereby enabling more patients to receive care virtually. Relatedly, the Interstate Medical Licensure Compact, which allows medical providers to become licensed in multiple states to provide interstate virtual care, continues to expand – growing from 33 states to 37 in 2022. With the reversal of Roe v Wade, virtual health is also gaining attention as a proposed avenue for patients seeking reproductive care across state lines.

One example, however, of a complicating factor in the growth of telehealth is the decision by the Biden administration to end – as of 11 May 2023 – the federal public health emergency (PHE) waiver that had previously been renewed by the US Department of Health and Human Services every 90 days during the COVID-19 pandemic. This waiver, among other things, afforded flexibilities related to telehealth, such as permitting audio-only telehealth for certain medical services and allowing more healthcare professionals to provide and bill for Medicare telehealth services. Certain exempted activities will remain permitted for a period of time – for example, audiologist and speech-language pathologists will be able to provide telehealth services until the end of 2024. However, many other telehealth waivers that have remained in place since January 2020 will end.

When the federal PHE ends, telehealth providers (including those that cover patients on Medicare) will be required to comply with the latest in regulations. As a result, anticipation of the federal PHE expiration has created hesitation for current telehealth providers who entered the market during the pandemic and barriers to entry for certain would-be telehealth providers. With almost half of all physicians in the USA currently providing some version of telehealth services, the impact of the end of the PHE waiver may be significant.

Unlike the 2021 record-setting venture funding and M&A transactions for digital health companies, economic concerns and inflation created a less predictable environment for digital health transactions in 2022. Digital health start-ups received unprecedented financing in 2021 but hit only 48% of that success in 2022. Slower and unstable market conditions have, in some instances, required venture-stage digital health companies (including in the direct-to-consumer digital healthcare sector) to seek financing through smaller M&A deals or collaboration and licensing arrangements. Larger industry players are also pivoting within their own digital health

initiatives under renewed government scrutiny in areas such as antitrust and FDA regulation.

Increasing integration between mobile apps and wearables/medical devices also continues as a popular initiative in the digital health field. With this integration comes a growing wealth of health and consumer data that digital health providers and tech players are responsible for managing in compliance with international, federal and state data privacy laws, which continue to evolve. As of 1 January 2023, California, Virginia, Colorado, Connecticut, and Utah all have new or revised comprehensive data privacy laws that digital health companies are mandated to comply with when processing patient data.

Companies producing medical devices and wearables, which are a cornerstone of the digital health industry, must also follow the FDA's Clinical Decision Support Software (CDSS) Guidance that was released in September 2022. This new guidance outlines a determination of whether technologies used in the medical care space are considered CDSS and therefore whether they are considered medical devices subject to FDA oversight. The September 2022 guidance revises existing 2019 draft guidance and, in part, these revisions result in certain software functionalities – which, previously, were exempt from FDA oversight – now being subject to such oversight. And beyond the USA, digital health players wanting to operate globally are required to comply with the ever-growing and often varied data privacy laws in various countries, including in more than 70% of all UN countries.

Conclusion

Despite continuing uncertainty and high inflation in the market, there is hope for a return to normalcy in 2023. Deal activity may remain slow for the first half of the year, but many biotech and pharma companies have adequate cash reserves to weather the storm and push potential drug candidates through clinical trials with innovative financing and partnership options. Medical device companies are looking at a slow but likely recovery, as consumer demand by an ageing population remains strong. Digital health companies will continue to innovate alongside increased emphasis on remote patient care and other wellness-monitoring trends. On the regulatory side, it is still too soon to tell how new frameworks like the IRA will impact the life sciences and healthcare industries. However, companies are updating their long-term strategies to account for repercussions on existing and future product pipelines.

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