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Pharmaceutical Advertising 2023

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Contributing Editor
Bart Van Vooren
Covington & Burling LLP

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Pharmaceutical Advertising

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Chambers Global Practice Guides

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Chambers and Partners
165 Fleet Street
London
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Tel +44 20 7606 8844
Fax +44 20 7831 5662
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Contributed by: Bart Van Vooren and Raj Gathani, **Covington & Burling LLP**

Introduction

Welcome to the 2023 edition of the Chambers Global Practice Guide on pharmaceutical advertising.

Consistent with global trends in recent years, this sixth edition covers more than "advertising" in the strict sense. A once narrow set of rules regulating how to promote medicines to healthcare professionals (HCPs) now extends to cover a range of related areas, such as:

- relationships with HCPs, patient organisations and sometimes patients themselves;
- sponsorship and contractual engagements;
- transparency and disclosure;
- the borderline between advertising and general corporate communications; and
- the internal/external review of those communications.

As the world emerges from the global pandemic, the landscape for pharmaceutical advertising and HCP interactions has fundamentally altered, in many ways permanently. Virtual or hybrid models of engagement are now the norm. This brings additional compliance challenges and regulatory scrutiny, particularly for virtual meetings and social media activities. These also carry additional uncertainty and risk, especially when online activity is accessible globally and by various stakeholders.

With the industry's ongoing focus on rare disease and specialty medicines, interactions with HCPs, patient organisations and the wider clinical community come more sharply into focus. The opportunity to be informative and engaging comes with some complexity.

An often-made complaint from the industry over recent years is that regulators and regulations have been slow to respond to new and dynamic models of promoting and communicating about medicines. Internationally, the rules are disjointed and can be difficult to navigate in a coherent way. While many of these issues remain apparent, 2022 has seen some early signs of co-ordination, with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) collaborating on some joint guidelines.

Much of this goes to show that the regulation of pharmaceutical advertising, communications and stakeholder interactions is in a state of evolution. This underlines the importance of taking and giving clear advice; and it is hoped this edition is both timely and helpful.

Digitised Models and Challenges

Accelerated by the pandemic, virtual and hybrid interactions now pervade through almost all types of pharmaceutical companies' engagements. This stretches from promotional activity, such as e-detailing, organising virtual meetings, attending virtual congresses and symposia, to delivering public-facing and patient-facing communications digitally.

Virtual and hybrid meetings and conferences

A recurrent question concerns the jurisdiction under which virtual meetings and congresses fall and which compliance rules apply. What is the governance framework for international online meetings? Are these events innately "supranational"? Is there a way to make content available in compliance with international (rather than national) norms and rules? Can pharmaceutical

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companies provide hospitality for virtual/hybrid events? What about the publication of recordings and "live" events?

In 2022, EFPIA, IFPMA and the Pharmaceutical Research and Manufacturers of America (PhRMA) issued the *Joint Guidance on Virtual and Hybrid International Medical Congresses*. This represented the first meaningful attempt to find an international consensus on the regulation of international virtual meetings and has gone far in clarifying an otherwise murky area.

Thorny issues in social media

Social media is the default mode of communication for many people in the modern world. It is fast paced and highly penetrative, and the standard for many for consuming news and information. It is also a very public communication medium, where content can reach far and wide. Understandably, the pharmaceutical industry has sought to embrace social media, but in doing so it has been stung by regulatory uncertainty and a volume of enforcement activity.

In Europe, this has largely concerned breaching the prohibition against direct-to-consumer (DTC) advertising of prescription-only medicines, or pre-licence promotion. In the USA, where DTC is in principle lawful, issues have concerned interactions with influencers, and whether a social media post is accurate, balanced, truthful and non-misleading, and consistent with the approved labelling. Further complications arise when company posts are liked, shared or engaged with internationally, introducing the possibility of engaging and breaching local-market laws which may be unexpectedly restrictive.

In September 2022, EFPIA and IFPMA issued *Joint Guidelines Concerning the Use of Social Media and Digital Media Channels by Pharmaceutical Companies*. Although this is a helpful first step to carving out an established international framework, current approaches outside the USA remain fragmented and potentially contradictory. There is some progress, but likely more evolution to come.

Multi-channel and omni-channel HCP marketing

With increased HCP interactions, pharmaceutical companies have the benefit of increasingly sophisticated data and feedback from clinicians. This has shed light on a once homogenous audience, revealing contours and nuances. This leads to ever-more personalised content and modes of interaction, suited to what an HCP feels might help the most.

The intersection with data protection laws and regulation at an international level is fascinating, and will be an area the industry watches closely. There are also practical compliance considerations. How do you generate and review personalised content? Is it possible to maintain the traditional distinction between promotional and non-promotional communications, when all communications are "joined up"?

Multi-channel and omni-channel marketing are buzz words in the industry. The development of these concepts, in the face of a relatively old-world regulation, will be a point of focus in the coming months.

Growing Sophistication of Advertising and Communication Approaches

As the industry increasingly focuses on personalised medicine and rare diseases, advertising and communication norms are also challenged. Patients and caregiver communities are often smaller, very well-informed and calling out for

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engagement, updates and advocacy. Similarly, the clinical community may be more tight-knit, and well-informed.

In this environment, traditional boundaries between "patients", "the public" and expert audiences begin to blur. Grey areas also emerge when advertising activity is focused on a small group of active, expert clinicians. This niche group may be well known to, and have already engaged with, the company – and this can often blur lines.

Many regulatory schemes in various jurisdictions have failed to keep pace with this environment; the changes being seen are often in attitudes to enforcement rather than with the rules themselves.

Advertising or information

The thin line between "advertising" and "information" is key to the communication strategy of any pharmaceutical company. Where regulators or courts draw the line often depends on subtle nuances in the content, form and context of the advertising. Depending on where the cut-off lies, online information on prescription drugs, for instance, could qualify as DTC advertising, which is prohibited in most countries (with a few notable exceptions, such as the USA and New Zealand).

Transparency

As public opinion and regulators are increasingly focusing on the interactions between the pharmaceutical industry and healthcare sector stakeholders, transparency is clearly gaining importance. Nonetheless, the sophistication of transparency rules varies dramatically depending on the jurisdiction. While some countries only impose disclosure obligations on the industry, others put the burden on HCPs instead of on companies.

Furthermore, transparency rules are often not legally binding. While the US Sunshine Act has been around for several years, for instance, only a handful of EU member states have sunshine laws. Instead, in most EU member states, transparency is driven by and enforced through the industry's self-regulatory codes.

Enforcement

While enforcement continues in an upward trend, the enforcement environment remains diverse and multifaceted. The USA continues to be a crucible, where the impact of committing advertising and ethical breaches can be very significant for pharmaceutical companies. Elsewhere, the environment is often less onerous, but the picture is mixed. In Germany, for example, pharmaceutical advertising controversies are settled largely through fast-paced litigation in the courts between competitors or other activist organisations. These are often the most active guardians of German advertising rules. In other countries, a system of industry self-regulation supplements (and often goes further than) the law. This system is usually the primary way of resolving advertising complaints. Although the sanctions can be relatively low-impact, the risk of reputational damage is an important driver for compliance.

As the number of complaints and enforcement cases steadily increases (significantly so in some countries), how to manage and respond to investigations and complaints has become a key consideration for legal and compliance teams. This has gone hand-in-hand with potentially vexatious complaints, or complaints brought anonymously.

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Conclusion

An advanced and workable regulatory regime for pharmaceutical advertising plays a crucial role in building the much-needed trust of the public in the pharmaceutical sector. It can be a driver of effective and transparent collaboration between the industry and the healthcare community, and goes to the core of the industry's reputation and continuous development. For all these reasons, it is more important than ever that practitioners are aware of the boundaries that authorities and peers expect them to live by.

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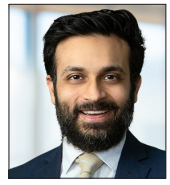
Covington & Burling LLP offers one of the largest and most comprehensive life sciences practices in the world. Covington's clients in the pharmaceutical industry range from start-up ventures to multinational corporations and trade associations, who for decades have trusted the firm with their most challenging business problems. Clients know that they can rely on Covington for practical, efficient solutions, rooted in a sophisticated knowledge of their business, the law and science, which only comes from deep immersion in the industry and decades of dedicated service. From the firm's offices in Brussels, Frankfurt and London, the tight-knit life sciences team offers advice on EU and national laws across the European continent.

Contributing Editor

Bart Van Vooren is a partner in Covington & Burling LLP's Brussels office. He has a broad regulatory practice under EU and national laws, advising pharmaceutical, food, biotech and device companies. His significant experience includes orphan medicines, advanced therapy medicinal products (ATMPs), advertising, regulatory exclusivities and transparency issues. He has handled more than three dozen cases before the EU Court of Justice, and is a leading global expert on life sciences companies' compliance with the Biodiversity Convention and the Nagoya Protocol. Bart regularly writes and speaks on life sciences issues, and has written several handbooks on EU law.

Co-author



Raj Gathani is a senior associate at Covington & Burling LLP, based in London and Dublin. Raj specialises in pharmaceutical advertising matters both in Europe and the UK, and regularly publishes on this topic, both online and in print. He has advised and represented numerous clients both on compliance and in internal and external investigations regarding alleged breaches of advertising rules. He also advises pharmaceutical, medical device and healthcare clients in adversarial/complaint proceedings before regulatory and self-regulatory advertising bodies.

Covington & Burling LLP

Manhattan Bolwerklaan 21
Avenue du Boulevard
B-1210 Brussels
Belgium

Tel: +32 2 549 52 50
Email: bvanvooren@cov.com
rgathani@cov.com
Web: www.cov.com

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ARGENTINA

Law and Practice

Contributed by:
Maria Morena del Rio, Fernando Martinez Zuviria, Lucrecia Re and Luciana Gonzalez
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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Advertising of medicines in Argentina is regulated by a combination of laws and regulations issued by the National Ministry of Health and the National Administration of Medicines, Food and Medical Technology (ANMAT), jointly with a code of conduct adopted by the pharmaceutical industry. The ANMAT is the national enforcement authority in charge of regulating and controlling medicines and medicinal products, including advertising of medicines.

General Rules

Law No 16,463 (the "Medicines Act") and its Regulatory Decree No 9763/1964 regulate the most relevant activities in the pharmaceutical industry, including advertising of medicines.

ANMAT Disposition No 4980/2005 regulates the advertising of over-the-counter medicines, as does the National Ministry of Health's Resolution No 20/2005 which states that any advertising regarding over-the-counter medicines must observe the ANMAT's criteria.

The National Ministry of Health's Resolution No 627/2007 regulates the promotion of prescription-only medicines. Additionally, the National Ministry of Health's Resolution No 6516/2015 regulates the obligation of pharmaceutical companies to notify the ANMAT of the advertising they intend to introduce to HCPs, as discussed further in **6.1 Requirements for Prior Notification/Authorisation**.

Also, the ANMAT's Disposition No 2845/2011 introduces the "Programme for Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance", whose objectives are described in **11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements**.

In addition, Law No 24,240 (the "Consumer Protection Act") as well as National Decree 274/2019 (the "Fair Trading Decree") and the National Civil and Commercial Code provide general mandatory guidelines for advertising any types of products and services, including medicines.

Finally, Argentine provinces and the Autonomous City of Buenos Aires are competent for the issuance of rules on advertising of medicines. In this respect, some of the most relevant local regulations are:

- Autonomous City of Buenos Aires – Health Law No 153;
- Buenos Aires – Medicines Law No 11,405;
- Cordoba – Pharmaceuticals Law No 8,302 and Disposition No 4/2008; and
- Mendoza – Medicines Law No 5,897.

In general, the provincial laws are aligned with national laws and regulations.

Code of Ethics

The Argentine Chamber of Medicinal Specialties (CAEMe), which represents most foreign pharmaceutical and biotechnology companies that develop and commercialise medicines in Argentina, has adopted a code of ethics which sets forth certain standards for the promotion of pharmaceutical products and interactions with healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs).

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

In Argentina, CAEMe's self-regulated code of ethics is applicable to all pharmaceutical companies that are members of CAEMe. The code of ethics sets forth standards for:

- ethical promotion of medicines; and
- interactions between CAEMe's members (or their agents) and HCPs, HCOs, public officials, POs and other stakeholders, to ensure that these interactions are appropriate, ethical and transparent.

CAEMe's members must comply with the ethical standards set forth in this code, and are therefore responsible for both their non-compliance and for third parties' non-compliance (ie, those who enter into contracts or any type of agreement with CAEMe's members).

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The Medicines Act and its related regulations consider advertising as any form of announcement to the general public, including through all forms of media, whether traditional media such as television, radio and ads in public roads, or others such as the internet and so-called non-traditional advertising (NTA).

The ANMAT defines pharmaceutical advertising or propaganda as a technique applied in an organised manner through the media to inform or promote features, benefits or qualities of medicines to encourage their sale.

CAEMe's self-regulating code of ethics understands pharmaceutical advertising as being any action carried out, organised or sponsored by a member company, directly or indirectly through a third party, aimed exclusively at HCPs for the purpose of promoting the prescription, recommendation, acquisition, distribution, dispensing, administration or consumption of its medicines through any means of communication.

Therefore, advertising is considered as any:

- advertising directed to the general public;
- advertising directed to HCPs capable of prescribing or dispensing medicines;
- visits by medical sales representatives or informative agents of companies to HCPs capable of prescribing or dispensing medicines;
- supply of medicinal samples;
- sponsorship of promotional meetings which HCPs capable of prescribing or dispensing medicines attend;
- sponsorship of scientific, academic or update meetings attended by HCPs capable of prescribing or dispensing medicines; and
- promotional items provided in the course of medical visits and offered at events attended by HCPs.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Information refers to a product's technical characteristics which the regulations require to be included explicitly in all medicines' labels, prospectuses and advertisements. Thus, in contrast to advertising, information refers specifically to medicines' particularities that the patients must be aware of in order to be fully informed before purchasing and consuming the medicines (eg, technical information, dosage, adverse effects),

which excludes any other type of promotion of the medicines' features, benefits or qualities to encourage their sale.

It should also be noted that, according to CAEMe's code of ethics, the following activities will not be considered advertising of medicines:

- a response by the medical department of a member company to spontaneous requests by an interested HCP related to non-authorised medicines or off-label indications, where the response expressly states that the medicine or therapeutic indication subject matter of the request has not been licensed in Argentina;
- adequate disclosure of scientific data regarding non-authorised drug substances or off-label indications in Argentina, at scientific events organised by third parties, such as national and international conferences and symposiums, provided they have no promotional purpose;
- public disclosure of information related to non-authorised medicines or off-label indications, to shareholders and other interested parties as required by current rules and regulations; and
- information or documents that member companies deliver to HCPs to be given to patients, with respect to certain medicines, which due to the complexity of dosage, route of administration, etc, require the supply of additional information, and provided such information is intended to improve treatment compliance.

Disease awareness campaigns are allowed in Argentina, but they are considered advertising if they mention the pharmaceutical company's name, or any other information related to it, including websites, address or any contact information. However, it should be noted that if the campaign is made by a pharmaceutical company that markets or manufactures over-the-counter medicines, it will be considered as advertising permitted by the legal framework.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases on prescription-only medicines are prohibited when they are accessible to the general public. However, publications in magazines, newsletters, books, or audio-visual media directed exclusively towards HCPs authorised to prescribe or dispense medicines are allowed.

The Argentine Supreme Court of Justice has considered irregular the publication of an article in a newspaper of massive diffusion that promoted a prescription medicine. It was considered that, notwithstanding the fact the advertisement was addressed to the HCPs, the general public had access to it and, therefore, it breached the rules on advertising of medicines.

According to CAEMe's code of ethics, the following shall not be considered promotional activity, provided there is no relationship between the member company or brand/medicine owner and the company responsible for the edition or the author of the information: texts written and prepared by journalists in the course of their professional work in regular editions, supplements, special issues or editions, or others, of newspapers, magazines, television or radio programmes, etc, in which information about drug therapies, specific treatments, medicines submitted as novelties, scientific studies, papers, references to a medicine, lines of research, product launches, press conferences, publications, etc is presented as a news item, an interview, a debate, an editorial or another similar format.

2.4 Comparative Advertising for Medicines

In Argentina, comparative advertising is a commercial announcement that explicitly or implicitly alludes to a competitor, its brand or the products offered by it. The comparison will be acceptable as long as it follows the guidelines set forth by the Fair Trading Decree – ie, as follows:

- it must be objective and truthful;
- it must not contain statements that affect the good name of third parties;
- it must be applied to similar or comparable products; and
- it must be scientifically supported in a publication.

In particular, based on the Fair Trading Decree, the comparative advertisement for the medicine should not:

- create confusion with the comparison;
- ridicule or denigrate the other product;
- distort the image of the other product;
- infringe upon the good name or prestige of third parties;
- attempt to create a situation of rejection towards the competitor's products or its users;
- mention active ingredients not contained in the advertised product; and
- mention possible adverse or collateral side effects of active ingredients not contained in the advertised product.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Under Argentine regulations, advertising of unauthorised medicines or indications is not allowed.

In this respect, CAEMe's self-regulating code of ethics provides that medicines should not be promoted in the country until the relevant authority grants the medicine a marketing authorisation.

However, CAEMe's code of ethics sets forth that the activities listed in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** shall not be considered prohibited promotion of unauthorised medicines or indications.

3.2 Provision of Information During a Scientific Conference

In accordance with CAEMe's code of ethics, information distributed to HCPs participating at national or international scientific conferences may refer to unauthorised medicines or indications, as long as it is not promotional in nature.

In the case of international conferences in particular, CAEMe's code of ethics sets forth that the following rules must be met:

- the meeting must be a truly international scientific event with a significant proportion of speakers and attendees from countries other than the host country;
- promotional material (excluding promotional aids) for a pharmaceutical product that is

not registered in the host country must be accompanied by a statement indicating the countries in which the product is registered and that the product is not registered in the host country;
- promotional materials concerning prescribing information (indications, warnings, etc) authorised in one or more countries other than that in which the event is held should be accompanied by an explanation indicating that the conditions of registration vary from one country to another; and
- the countries in which the product is registered must be identified and it must be made clear that it is not available locally.

3.3 Provision of Information to Healthcare Professionals

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, CAEMe's code of ethics:

- stipulates that no pharmaceutical product should be promoted with a commercial intention until a marketing authorisation has been granted by the enforcement authority; and
- describes certain delivery of information to HCPs that shall not be considered prohibited promotion of unauthorised medicines or indications.

In this respect, the code of ethics expressly states that the prohibition described in the first item above does not intend to impede the right of the scientific community and the public to be fully informed about scientific and medical progress. Also, it does not intend to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination in the scientific or general media and at scientific conferences of research findings.

The code of ethics provides that it is proper and permissible to debate on and expose the scientific sphere regarding the breakthrough of new medicines, even where they are not yet approved by the health authorities.

3.4 Provision of Information to Healthcare Institutions

In Argentina, the CAEMe's code of ethics stipulates that sending information on unauthorised medicines or indications to HCOs so that they can prepare budgets is allowed, as long as the pharmaceutical companies do not induce or provide promotional statements. Therefore, they must expressly demonstrate that their intention is not to promote or advertise the product, but to provide information in order to help prepare budgets.

3.5 Information About Early Access or Compassionate Use Programmes

The ANMAT has in place an exceptional regime for patients to obtain medicines that have not been yet authorised in Argentina. Hence, it is permitted to publish the availability of such programmes as long as all the provisions set forth by the ANMAT's Disposition No 4616/2019 are complied with.

In summary, the Disposition provides for specific situations where the early access exception may be requested, and for all the documents that the applicant must present. For advertising of medicines, the Disposition expressly prohibits the commercialisation or promotion of medicines brought into the country under the exceptional regime, on penalty of initiating the corresponding administrative and/or penal actions.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

The Medicines Act stipulates that the only medicines that can be advertised to the general public are over-the-counter medicines, whose requirements are further described in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

The Medicines Act expressly forbids the promotion or advertising of prescription-only medicines to the general public, in any form. Promotion of prescription-only medicines is only allowed when directed exclusively to HCPs.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Only advertising for over-the-counter medicines can be directed to the general public. ANMAT Disposition 4980/2005 provides that the following information must be included:

- the trade product's name, as authorised in the registration certificate;
- the product's active ingredient(s), which shall be expressed by its generic name(s) in compliance with Decree No 150/92; and
- the legend "read the prospectus carefully and at the least doubt consult your physician and/or pharmacist", which must be presented in a way that it is clearly perceptible to the addressee and always horizontally, must be in accordance with the size used in the graphics, and must be easy to read.

Conversely, the following information is prohibited:

- encouraging indiscriminate use of the product, and providing exaggerations or responses not scientifically demonstrated;
- suggesting that the use of the product should be permanent and/or that the product has curative properties for chronic or incurable diseases, unless contemplated and/or authorised in its prospectus;
- suggesting that the product prevents disease and, therefore, proposing its use in healthy people to improve their condition, unless scientifically proven and specified in the indications;
- suggesting that the advertised product is the only alternative by terms such as "the product", "the one of choice", "the only one", "the most frequently recommended", "the best", etc;
- using phrases that provoke fear or distress, and suggesting that the subject's health will be affected if they do not consume the promoted product;
- including phrases such as "proven in clinical trials" which have not been recognised by the ANMAT, and "approved, endorsed or recommended by experts and/or institutions" when they do not have the documentation to accredit this;
- including messages such as "advertising authorised by the Health Authority" or "product endorsed by the Health Authority", whether such authority is national or international;
- using messages that try to measure the degree of reduction of disease risk by taking the product, unless contemplated and/or authorised in its prospectus;
- including messages tending to mask the real essence of the medicine or indirect benefits by presenting it as a food, candy, cosmetic or other product that is not a medicine;

- being exclusively or mainly directed to minors, pregnant and/or breastfeeding women, unless the products have been approved for that purpose;
- having children refer to the product, who may not directly or indirectly promote it;
- claiming that a product is "safe" and/or "uniformly well tolerated", or assuring that it is not toxic, that it has no side effects or risks of addiction, or including equivalent phrases which, due to their broadness or vagueness, lead to interpreting that the product has a non-existent and/or false attribute;
- suggesting that a medical act or surgical intervention is unnecessary, postponable or substitutable;
- suggesting that the safety or efficacy of the product is due to the fact that it is natural – for products obtained from substances of natural origin, the advertisement may only state "made (obtained) from substances of natural origin" or "with ingredients obtained from substances of natural origin";
- claiming that the action or mode of action of the product is "natural", or that it "naturally restores the functional state" or "naturally causes an effect" such as those that occur without the use of the product, thus assigning it a natural property;
- using false, alarming or misleading terms about changes in the human body caused by illness or injury;
- advertising a product or a modification of one already existing in the market as "new", after two years have elapsed from the date of the beginning of its commercialisation to the public;
- encouraging the purchase of the product with the exclusive motivation of donation or humanitarian destination, in order to avoid unnecessary consumption of the product; and
- modifying the indications and uses contained in the labels and/or prospectus of the product.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

CAEMe's code of ethics allows member companies to interact with patients, patient experts, patient advocates and caregivers, observing the following guidelines:

- having a legitimate interest for the interaction;
- complying with current laws and regulations on personal data protection;
- no promotion of prescription-only medicines; and
- if a fee is paid for the provision of the service, such fee should be fair market value, and a written agreement should be entered into.

Conversely, CAEMe's member companies may interact with POs in the following cases:

- providing collaboration in cash or in kind for educational, scientific or professional purposes – however, collaboration in kind through the delivery of samples or medicines is not allowed;
- development of joint activities or sponsorship of educational, awareness, early detection and disease prevention activities, and development of capabilities enabling POs to represent patient's voices in the various spheres in which health-related issues are discussed;
- hiring of advisory and/or consultancy services; and/or
- sponsorship for PO representatives to attend events related to their condition, provided the primary goal of the event is professional, educational and scientific in nature or that it

supports, in some other way, the mission of the PO.

CAEMe's code of ethics also presents a "Patient Support Programme" which refers to any programme organised by a member company aimed at assisting patients who have already been prescribed medication by an HCP and/or caregivers in the management of their disease with the appropriate use of medication, among other topics of interest related to the patient's health.

The code of ethics also presents a "Diagnostic Support Programme" which refers to the support that member companies can provide for necessary diagnostic tests for patients, prior to a medicine prescription.

However, companies cannot use these programmes in order to promote their medicines (including prescription-only medicines) or unauthorised products.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The National Ministry of Health's Resolution No 627/2007 dictates that advertisements directed at HCPs must provide the technical-scientific information necessary to make them aware of the medicine's therapeutic properties, and in order to do so, must at least include the following.

- The product's essential information according to the approved characteristics identification data, including at least the medicine's:
  - (a) generic and trade name;
  - (b) quantitative and qualitative composition;
  - (c) pharmaceutical form;
  - (d) indications and contraindications;
  - (e) adverse effects;
  - (f) warnings and precautions;
  - (g) dosage; and
  - (h) holder's name and address.
- The product's prescription regime and dispensing conditions.

The fact that the regulation foresees what minimum information advertisements must include implies that any other information (which must be certain, objective and verifiable) concerning the product may be submitted to HCPs.

In respect of prohibitions, the aforementioned Resolution sets forth that advertisements directed towards HCPs are forbidden for medicines that have not been authorised by the enforcement authority with the corresponding marketing authorisation.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The National Ministry of Health's Resolution No 627/2007 expressly states that any promotional literature related to a medicine that is disseminated to HCPs should include at least the information referred to in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, so any reference to data not included in the summary of product characteristics may be delivered to HCPs as long as it is certain, objective and verifiable.

In this respect, CAEMe's code of ethics dictates that the advertising may refer to data or other clinical studies that are not included in the summary of product characteristics, as long as

it respects the meaning and objectives of the original file, and cites its sources.

Additionally, when the promotional material refers to published studies, these must be faithfully reproduced or provide a clear reference to them, to be able to know how to find them. Faithful reproduction should be understood as an accurate reflection of the meaning and content of the original source, without adding or excluding any information that could mislead or confuse the recipient.

5.3 Advertising of Combination Products

Advertising the use of a medicine in combination with a medical device is permitted as long as the advertising materials are consistent with the summary of product characteristics of both products. In this respect, ANMAT Disposition No 7446/2019 stipulates that a combined product means any product consisting of two or more components, which when combined constitute a single entity. In this Disposition, the ANMAT provides a guideline for the procedure for obtaining the combination product's approval and authorisation.

As regards advertisements, the rules described in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals** are applicable.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies may provide reprints of journal articles to HCPs, since they are considered an advertisement media; however, the reprints must observe the directions described in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, which should be made exclusively in publications or events for scientific dissemination only for professionals authorised to prescribe or dispense medicines; see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

The National Ministry of Health's Resolution 627/2007 stipulates that quotes, tables and other illustrations taken from medical journals or scientific works that may be used in promotional literature should respect the meaning and objectives of these, and cite their sources.

Likewise, CAMe's code of ethics provides that quotations taken from medical and scientific literature or personal communications should accurately reflect the author's opinion and, where appropriate, should mention the product on which the author based their opinion.

5.5 Medical Science Liaisons

To date, there are no relevant regulations in Argentina regarding medical science liaisons.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising for medicines is not subject to prior authorisation from the regulator.

For over-the-counter medicines directed to the general public, ANMAT Disposition No 9660/2016 sets forth that it is not necessary to submit the advertising materials for the ANMAT's control. The requirements for promoting over-the-counter medicines are described in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

Regarding prescription-only medicines, ANMAT Disposition No 6516/2015 provides that companies who intend to promote prescription-only medicines to HCPs must notify the ANMAT of such advertising, together with the corresponding promotional piece. The advertising requirements are described in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**. This notification to the ANMAT must be made within 48 hours from the beginning of the materials' dissemination, in the form of a sworn statement.

6.2 Compliance With Rules on Medicinal Advertising

The Ministry of Health's Resolution No 267/2007 on "Good Advertising Practices of Prescription-only Medicines" stipulates that pharmaceutical companies are responsible for establishing appropriate procedures for the training of medical advertising agents and/or medical visitors with sufficient scientific knowledge to present the information of the company, in order to provide the HCPs with all the information regarding the therapeutic benefits, adverse effects, contraindications, interactions, other therapeutic benefits and risks derived from the use of prescription-only medicines.

Likewise, CAEMe's code of ethics dictates that member companies must ensure internal structures and procedures (including appropriate employee training) in order to ensure that promotional activities are conducted in a responsible and ethical manner.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising medicinal products on the internet is subject to the same requirements imposed on traditional channels.

In this sense, when prescription-only medicines are advertised on the internet, companies must do so through a specific website, to which the general public has no access, since, as previously mentioned, their promotion must be exclusively directed towards HCPs.

In this respect, the ANMAT, through Disposition 4980/2005, clarifies that the internet may not be used as a mechanism for the direct sale of any types of medicines. All medicines (over-the-counter or prescription-only) may only be dispensed through pharmacies. It also suggests that the population refrain from acquiring and consuming any type of drug of unknown origin and that is not sold through legitimate channels of commercialisation (ie, pharmacies). This includes those offered through web pages and email messages as well as those promoted through classified advertisements.

Additionally, CAEMe's code of ethics states that companies should have internal structures and procedures (including adequate training of employees) and ensure these activities are performed in a responsible and ethical manner, and in strict compliance with the regulations.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

See **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

7.3 Provision of Disease Awareness Information to Patients Online

Companies are allowed to provide disease awareness information to patients online, as long as they observe the provisions described in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry** and **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

7.4 Online Scientific Meetings

Even though Argentina has no special regulation on online scientific meetings, CAEMe's code of ethics stipulates that any type of similar scientific, promotional and/or educational activity should be understood as a scientific meeting.

Therefore, member companies may organise, sponsor or support scientific, educational or professional training events for the different actors of the healthcare system, in order to improve their level of knowledge in matters related to healthcare, the improvement of the healthcare system, and the quality of life of patients.

The objective and focus of the congresses or scientific events should be to provide scientific, educational and/or professional information, and to update; but under no circumstances should social and/or recreational activities be sponsored.

In order for a congress to be understood as "international", most of the participants must be foreigners, and the relevant resource or expertise should be located abroad, being the main object of the event. In the case of organising or sponsoring of international events, member companies must also comply with the specific provisions of the relevant country, and the codes of good practice of the country where the event takes place in addition to CAEMe's code of ethics.

When member companies organise or participate in events, this fact should be stated in all documents relating to the invitation, as well as in any paper or document to be published.

At these types of events, promotional items may be handed out; however, they should be related to the scientific and/or educational activities attended by HCPs – eg, articles that serve as containers of scientific information and/or that can be used by HCPs. However, under no circumstances may money be offered to compensate for the time spent by HCPs to attend the event (loss of profit). Additionally, the sponsorship of HCPs or any other actor of the health system may not be conditional on the obligation of their prescription, recommendation, purchase or promotion of a medicinal product, or to obtain an undue advantage in favour of the member company.

7.5 Use of Social Media

In Argentina, there are no legal rules specifically concerning the advertising of medicinal products on social media. Hence, advertising medicinal products on social media is subject to the same requirements imposed on traditional channels, as described in **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

National Law No 17,132 on the Practice of Medicine (which applies to the Autonomous City of

Buenos Aires) and similar provincial anti-benefits regulations (following the national standard guidelines) set forth general principles, but do not regulate in detail restrictions on economic benefits, value of the content or agreements with content-generating vendors. Therefore, the pharmaceutical industry – including local and foreign laboratories – in Argentina has issued industry self-regulations with specific and modern standards to be followed.

The Practice of Medicine Act sets forth a general prohibition on HCPs obtaining any profit from pharmaceutical companies that would imply inappropriate influence on the prescription practices of an HCP.

The National Ministry of Health's Resolution No 627/2007 on "Good Advertising Practices of Prescription-only Medicines" provides anti-bribery rules applicable to interactions between pharmaceutical companies and HCPs, prohibiting pharmaceutical companies from delivering any types of benefits, such as bonuses, pecuniary advantages or in kind, to HCPs. Their liability will extend to any person acting on their behalf and/or representation.

Also, the Argentine Criminal Code includes part of the Argentine anti-corruption legislation (Sections 256 to 259), which prohibits active and passive bribery of public officials as well as active bribery of foreign public officials. These regulations also apply to benefits provided to public HCOs. In this respect, CAEMe's code of ethics sets forth that medical and scientific personnel working at a public or partially public hospital, clinic or university, or other similar public or partially public entity, will be considered "public officials".

Additionally, CAEMe's code of ethics provides that all relations with public officials must comply with applicable rules and regulations – ie, any rule or provision applicable to Argentine public officials or imposed by their employer. Member companies should adopt policies and procedures so that all relations with public officials occur in a justified and transparent way, and are duly documented and recorded. Therefore, companies may incur criminal liabilities for bribes offered or given to public officials by the companies' employees, directors or other persons under their control, who may act in their name and/or representation.

8.2 Legislative or Self-Regulatory Provisions

The National Ministry of Health's Resolution No 627/2007 on "Good Advertising Practices of Prescription-only Medicines" establishes the prohibition on pharmaceutical companies from granting, offering or promising to HCPs and/or to persons related or close to them any types of benefits of any nature, such as bonuses, pecuniary advantages or in kind, or of any other type.

CAEMe's code of ethics stipulates that donations, grants or contributions in cash or in kind to HCOs are only permitted if:

- they are legally constituted and fiscally registered entities;
- they are carried out with the purpose of collaborating with healthcare, research, teaching/training, social or humanitarian assistance;
- they are made on the basis of written requests or acceptances by the entity, clearly describing the programme or project and its objective, including how patients will benefit and/or how the quality of patient care will be

improved by their request, and indicating how the funds will be used;
- they are formalised in documents, and copies of these documents are kept by the member company;
- they do not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of medicinal specialties; and
- the evaluation process and the approval of donations or grants will be outside the commercial, marketing or sales areas.

Along the same line, the code of ethics provides that it is not permitted to give donations and/or grants to HCPs.

Conversely, the code of ethics allows the granting to HCPs of promotional items (also called merchandise or gimmicks) that are intended to serve as a reminder of the product brand and/or company logo only for over-the-counter products, as well as items of medical utility if they are of modest value, and informative or educational articles for the professionals' and/or their patients' education about diseases and their treatments, provided that the articles are primarily for educational purposes.

As mentioned in **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals**, companies may incur criminal liabilities for bribes offered or given to public officials by the companies' employees, directors or other persons under their control, who may act in their name and/or representation. CAEMe's code of ethics identifies a "public official" as any person holding an official position, including medical and scientific personnel when working in a public or partially public hospital, clinic or university, or other similar public or publicly owned entity.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

As stated previously, the National Ministry of Health's Resolution No 627/2007 on "Good Advertising Practices of Prescription-only Medicines" establishes the prohibition on pharmaceutical companies from granting, offering or promising to HCPs and/or to persons related or close to them any types of benefits of any nature, such as bonuses, pecuniary advantages or in kind, or of any other type.

Nonetheless, educational support may be granted to HCPs on an individual basis, such as rotations in reference health institutions, professional updating scholarships, and research support in reference health institutions, as long as they meet the requirements described in **9.3 Sponsorship of Scientific Meetings** and payment is made directly to the educational provider involved.

9.2 Limitations on Providing Samples to Healthcare Professionals

Pharmaceutical companies may provide HCPs with free samples of medicines for the purpose of improving patient care. These samples may not be sold or used inappropriately.

Companies must have adequate control, tracking and follow-up systems for samples given to HCPs.

The samples provided to HCPs should be identifiable by the generic and commercial name, with the same size and prominence for both. In the case of medicines consisting of two or more generic names, the size of the typography for each of them may be reduced proportionally. They should also contain abbreviated infor-

mation in approved labels and package inserts referring to indications, posology, adverse effects and contraindications, and should not add promotional expressions. Pharmaceutical companies should maintain an adequate control system verifiable through the production books.

Pharmaceutical companies are not allowed to provide samples of medicines containing psychotropic or narcotic substances or that may create dependence or generate public health problems due to their inadequate use.

9.3 Sponsorship of Scientific Meetings

The National Ministry of Health sets forth that pharmaceutical companies may grant scholarships to HCPs through training courses, participation in congresses, symposiums and strictly scientific meetings. Requirements include:

- informing HCPs, in advance and publicly, of the conditions of access to the scholarships and the selection procedure, respecting equality and transparency; and
- that the selection must be made by academic or teaching committees, or department or service heads, if applicable.

Also, CAEMe's code of ethics provides that pharmaceutical companies are allowed to sponsor the attendance of HCPs at scientific meetings or congresses, provided that such sponsorship meets the following conditions:

- the event complies with the accommodation and subsistence requirements;
- the sponsorship of HCPs is limited to the payment of travel expenses, accommodation, lodging and registration fees;
- no payment is made to HCPs for time spent attending the event;
- sponsorship of an HCP is not conditional on the HCP's obligation to prescribe, recommend or promote a medicinal product; and
- all these values must be reasonable.

Pharmaceutical companies must not pay for any costs related to persons accompanying the HCPs as guests.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to organise or sponsor cultural, sports or other non-scientific events in relation to scientific conferences. Hospitality cannot include the sponsorship or organisation of entertainment or leisure activities.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

As indicated in **9.1 Gifts to Healthcare Professionals**, pharmaceutical companies are not allowed to grant, offer or promise, in their name and/or representation, to HCPs and/or persons related or close to them any types of benefits of any nature, such as bonuses, pecuniary advantages or in kind.

See **8.2 Legislative or Self-Regulatory Provisions** as regards CAEMe's code of ethics concerning permitted donations, grants or contributions to HCOs.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

In Argentina, the grant of rebates or discounts to HCPs is expressly forbidden by Resolution No 627/2007 with respect to prescription-only medicines. This prohibits pharmaceutical companies from granting, offering or promising to HCPs and/or to persons related or close to them

any types of incentives or benefits of any nature, such as bonuses, pecuniary advantages or in kind.

Also, see **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals** and **8.2 Legislative or Self-Regulatory Provisions** for the restrictions applicable to rebates or discounts directed towards HCOs.

9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies are allowed to pay for services provided by HCPs provided certain conditions are met.

In this respect, CAEMe's code of ethics establishes the permission to hire HCPs individually or in groups for the provision of advisory or consulting services (ie, lecturers or moderators at meetings, training activities, expert meetings, etc). Fees paid to the HCPs should be based on market criteria and related to the time devoted, the work performed and the responsibilities assumed. It is mandatory to conclude a written agreement covering the lawful provision of this kind of service, which needs to include a provision pursuant to which the HCPs commit to state that they provide services to the company whenever they make a public statement about an issue that is the subject matter of their agreement with the company.

Hence, the payment of reasonable fees and reimbursement of expenses related to the provision of the service, including travel, to moderators and speakers at these meetings, congresses, symposiums and events of a professional or scientific nature is acceptable.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The National Ministry of Health sets forth that pharmaceutical companies may grant scholarships to HCPs through training courses, participation in congresses, symposiums and strictly scientific meetings, provided:

- the companies inform the HCPs, in advance and publicly, of the conditions of access to the scholarships and the selection procedure, respecting equality and transparency; and
- the selection is made by academic or teaching committees, or department or service heads, if applicable.

Besides this, no other prior authorisation is required from a regulatory authority for these activities.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The Autonomous City of Buenos Aires is the only jurisdiction that has issued a regulation on transparency obligations applicable to pharmaceutical companies. Act No 5,709 of the Autonomous City of Buenos Aires, issued in 2017, sets forth that manufacturers, importers and distributors of medicines have the obligation to inform the Ministry of Health of the City of Buenos Aires when they provide benefits or goods of pecuniary value to HCPs with offices or that undertake their activities in the Autonomous City of Buenos Aires.

Benefits or goods that fall within the scope of this obligation are:

- payments in cash;
- payments of professional fees;
- payments to cover any professional training activity;
- payments to cover travel expenses; and
- issuance of securities, tickets, gifts, lodgings, entertainment, expenses, meals or any other property of economic value.

The submitted information must contain at least the following data:

- identification of the contributing company with indication of the products manufactured, imported or distributed;
- full name of the receiving HCP;
- the HCP's specialty;
- nature of the incentive, and if applicable, the amount or payments made and/or the quantification of the transfers, contributions or gifts made; and
- the dates on which the payments, transfers, contributions or gifts were made.

CAEMe's code of ethics establishes that member companies should duly document, in accordance with their internal procedures, any transfer of value that they directly or indirectly make to health system actors. This includes, but is not limited to:

- fees paid for services rendered;
- collaboration provided for scientific and professional events; and
- hospitality expenses incurred in connection with an event, including the costs of transport, registration, accommodation and meals, and the provision of medical and scientific publications.

Likewise, the duty of documentation covers all donations or contributions that member companies make, directly or indirectly, to actors of the healthcare system.

There are no exceptions regarding the disclosure obligation due to COVID-19 incidences.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Foreign companies and companies that do not yet have products on the market are not subject to transparency regulations.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The responsibility for enforcing advertising and incentive rules lies with the national health authorities, in particular the ANMAT, the National Ministry of Health, the provincial health authorities and that of the Autonomous City of Buenos Aires. The ANMAT is the enforcement authority in charge of monitoring compliance with the Medicines Act and of receiving complaints for the respective infringements, under the terms of Decree 1490/92 and Decree 341/92.

CAEMe's code of ethics is applied by its control committee and board of directors, with the power to control and sanction members in the case of infringements of the provisions of the code.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The ANMAT has a specific programme established by Disposition No 2845/2011 for the

"Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance", which allows any interested party to file complaints online about medicinal advertisements. Complaints can also be made via email or telephone.

In the case of complaints to the ANMAT by a third party, or when the ANMAT detects non-compliance, the offender shall be notified by means of an injunction to cease the dissemination of the advertising and/or promotion involved. The ANMAT will also include such injunctions on the institutional website with public access, without prejudice to any other actions that may be applicable.

It should also be noted that any advertising that violates the Fair Trade Decree can be denounced by any individual or legal person, public or private, before the Secretariat of Commerce.

The company affected by an infringing advertisement made by a competitor may also take legal action before the courts, for non-compliance with the Fair Trade Decree. The following actions may be initiated:

- action to cease the advertising act, or to prohibit it;
- action for compensation for damages caused by the prohibited advertising – compensation may include the publication of the judgment; and
- injunctive relief.

The referred actions may be brought by any individual or company participating in the market, whose economic interests are directly harmed or threatened by the prohibited advertisement. They may also be brought by the following entities:

- associations, or professional or representative corporations, of economic interests, where the interests of their members are affected in accordance with the provisions of Article 10ter of the Paris Convention for the Protection of Industrial Property, approved by Law No 17,011; and
- associations whose purpose, according to their statutes, is consumer protection – in this case, standing shall be subject to the condition that the advertising directly affects the interests of consumers.

In the case of a complaint by an affected party, the latter may initiate the above-mentioned procedure before the Secretariat of Commerce, or choose to initiate legal action directly before the courts. However, if the affected party chooses to initiate the administrative procedure, once this has been initiated, the legal action will lapse, except for the action for damages.

CAEMe's code of ethics stipulates that member companies – without prejudice to the direct request for the allegedly infringing member company to cease the dissemination of the advertising and/or promotion involved – undertake to raise before the compliance committee any complaints they may have against the promotional or health professional practices of other member companies in the first instance and prior to recourse to the courts or the health authorities, as well as to abide by and comply with the mediation agreements reached and the content of the resolutions of the committee.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The Medicines Act provides for the following penalties:

- warnings;
- fines;
- total or partial, temporary or permanent closure, depending on the seriousness of the the offence;
- suspension or disqualification from the exercise of the activity or profession for up to three years (in the case of extreme seriousness or multiple reiteration of the offence or offences, the disqualification may be permanent);
- confiscation of the effects or products of the infringement, or of the compounds involving the elements or substances in question; and/or
- cancellation of the authorisation to sell and manufacture the products.

In practice, the sanctions generally imposed are warnings and fines.

The ANMAT will evaluate the sanction to be applied according to the seriousness of the offence and the particular background of the case and the offender. For this reason, if the rules on medicinal advertising or prescription inducement are not complied with, the ANMAT could, ex officio or in the framework of a complaint, initiate an administrative procedure and eventually impose a penalty.

Decisions taken by regulatory bodies may be challenged through an administrative appeal and through judicial review. Where the ANMAT initiates an administrative procedure for the application of the fine, it is mandatory to exhaust the administrative procedure prior to appealing the application of the fine before the courts.

CAEMe's code of ethics regulates offences and sanctions according to the seriousness and background of the offender. It is thus established that sanctions will be suggested by the compliance committee to the board of directors, depending on the seriousness of the offence, and these sanctions may include:

- a warning;
- suspension of membership rights for a period of one month to one year, with maintenance of the obligations corresponding to the member's obligations of their class of membership; and
- expulsion.

11.4 Relationship Between Regulatory Authorities and Courts

CAEMe's code of ethics states that, prior to raising the issue before the regulatory authorities or the courts, companies approaching CAEMe must first file their claims against the promotional practices of other companies before the bodies in charge of enforcing the code.

Notwithstanding the foregoing, the regulatory authorities mentioned in **11.1 Pharmaceutical Advertising: Enforcement Bodies** may investigate matters on their own initiative, even if the issue is already being considered or measures have been taken by CAEMe.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

During the last few years, there have been no significant (publicly known) cases regarding advertising of medicinal products.

However, in a notable publicy known case from 2013, the ANMAT decided to fine a pharmaceutical company for violating Section 19 (c) of the Medicines Act, which prohibits any form of advertisement of prescription-only medicines to the general public. The pharmaceutical company made an advertisement using a gigantogra-

phy in which no brand of prescription medicines was incorporated, but the phrase "changing the future of diabetes", among others, was included and signed by a famous polo player, as well as the company's isologotype, telephone number and website address.

The ANMAT understood that, although the advertisement did not mention a particular pharmaceutical company, the mentioning of the pathology, and the company's corporate name, telephone number and website induced the promotion of prescription-only medicines. Therefore, the enforcement authority fined the pharmaceutical company and its technical director for indirect advertising of prescription-only medicines.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

In Argentina, there is a separate legal regime for advertising veterinary medicines.

The enforcement authority is the National Service of Agri-Food Health and Quality (SENASA), which is responsible for regulating and controlling veterinary medicines.

Consequently, the regulation on veterinary medicines differs somewhat from the regulation on human medicines. SENASA Resolution 1642/2019 is the main regulation on veterinary medicines, which expressly allows for advertising veterinary medicines, as long as such medicines and their indications are duly registered with SENASA, subject to the following restrictions. Veterinary products must not be described or presented with labels or advertisements which:

- use words, denominations, symbols, emblems, illustrations or other graphic representations that could make the information false, incorrect, insufficient, or that may mislead, confuse or deceive the consumer as to the true nature, composition, origin, type, quantity, quality, duration, performance or manner of use of the product;
- attribute effects or properties to the product that it does not possess or that cannot be demonstrated; and
- use superlative terms or terms that induce comparison with other similar products registered by other registered individuals or entities – including words of other languages that are commonly used in Argentina.

In general, the advertising of veterinary medicines is subject to the same requirements and principles as human medicines, since the information provided to the general public must be certain, objective, real, and must not mislead or confuse the consumers.

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Allende & Brea

Allende & Brea is one of the leading law firms in Argentina. It was founded in 1957, and enjoys a long-established reputation for superior legal work. It is a full-service law firm mainly oriented towards sophisticated transactional international and local practice, advising large, medium-sized and small companies on a permanent basis, or acting as special counsel in a variety of commercial transactions carried out in Argentina or abroad. The firm is organised into dedicated and specialised groups in all areas of business law and industry sectors, including life sciences. The life sciences team is focused on matters of the pharmaceutical, medical devices, biotechnology, food, beverages and cosmetics industries. The team of two partners and five associates assists clients in their daily operations and in local and cross-border M&A transactions, collaboration, manufacturing, licence and distribution agreements, intellectual property, data privacy, regulatory matters, litigation and anti-competitive practices.

Authors

Maria Morena del Rio joined Allende & Brea in 2003. She was named a partner of the firm in 2006 and heads the department of administrative and environmental law, and co-heads the ESG and life sciences departments. Her practice covers regulatory, infrastructure and environmental matters. Her regulatory and administrative law practice includes bids and public contracts, administrative procedures, administrative processes, claims against the administration, defence in punitive proceedings, regulatory advice and consumer defence. She is a member of the Bar Association of the City of Buenos Aires.

Fernando Martinez Zuviria joined Allende & Brea after graduating magna cum laude from Universidad Austral in 2005. He attended the Academy of American and International Law (Texas, 2007) and obtained a master's degree (LLM) at the University of Illinois in 2012. He worked as a foreign associate at Holland & Knight LLP law firm in Miami. He has been a partner of the firm since 2019 and co-heads the life sciences department. His practice focuses on assisting pharmaceutical companies with their daily operations in corporate, contractual and regulatory matters. Fernando is a member of the Bar Association of the City of Buenos Aires.

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Allende & Brea

Lucrecia Re joined Allende & Brea in 2021. She is an associate of the administrative law and life sciences departments, and graduated from Universidad Torcuato Di Tella in 2014. She has practised in the field of administrative law since 2014, and in 2019 completed her master's degree studies in Administrative Law at Universidad Austral. She represents pharmaceutical and medical device companies in a wide range of matters, including legal advice and comprehensive management of cases in administrative proceedings and life sciences regulatory matters.

Luciana Gonzalez joined Allende & Brea in 2021. She is an associate of the administrative law and life sciences departments. Luciana received her law degree from the Universidad de Buenos Aires in 2022, before working as a paralegal. She assists pharmaceutical and medical device companies in regulatory matters.

Allende & Brea

Maipu 1300
Floor 11
C1006ACT
City of Buenos Aires
Argentina

Tel: +54 11 43189933
Fax: +54 11 43189999
Email: fmartinez@allende.com
Web: www.Allende.com

Trends and Developments

Contributed by:
Maria Morena del Rio, Fernando Martinez Zuviria, Lucrecia Re and Luciana Gonzalez
Allende & Brea see p.37

Introduction

The regulations on advertising of medicines provide that only over-the-counter medicines can be advertised to the general public and prescription medicines can only be advertised to healthcare professionals (HCPs).

The advertising of these products must comply with a series of general and specific guidelines. For instance, they must include the phrase "Read the prospectus carefully, and in case of any doubt, consult your physician and/or pharmacist" in a way that is visible and maintained for a period of time allowing consumers to read the full legend. The pharmaceutical company will be responsible for ensuring that the use of the name, attributes or messages related to the promoted products are appropriate, taking into consideration the particular characteristics of each advertisement.

The latest trends and developments in connection with pharmaceutical advertising in Argentina include the following matters:

- advertising and sale of medicines through the internet and social media;
- visits by medical sales representatives of pharmaceutical companies to HCPs;
- conflicts of competence; and
- latest regulatory changes.

This article analyses each of these matters, providing background information and relevant context when needed.

Advertising and Sale of Medicines Through the Internet and Social Media

E-commerce

The internet has had a major impact on the world of computing, communications, business, and naturally the advertising and commercialisation of goods and services (e-commerce). Through the internet, companies have found a tool to reduce purchasing costs and to speed up procurement, logistics and inventory, and production planning.

This new form of commerce has given rise to the phenomenon of the "virtual company", which, through computer networks, advertises its goods and services, carries out transactions and also links up with other companies. For instance, in Argentina, "Mercado Libre" is a local platform through which people may offer and buy any kind of products, like with Amazon in the USA.

The increasing supply of medicines through websites, social networks and emails is a major concern of the health authorities. Under current circumstances, laws and regulations forbid the sale, purchase and dispensing of any type of over-the-counter medicines or prescription-only medicines through the internet. In this respect, the National Administration of Medicines, Food and Medical Technology (ANMAT) expressly requested that the general public not acquire medicines from unknown websites, since the quality of these medicines cannot be guaranteed.

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The liability of internet intermediaries for advertisements included on their websites is a matter of debate, since Argentina does not have an applicable specific legal framework. However, there are judicial precedents that provide some certainty: the courts have ruled that internet intermediaries are liable in the case of omission or inadequate or unjustifiable late removal of an illegal advertisment, or the failure to adopt preventative measures to block them. This means that courts analyse the intermediary's conduct to determine whether they have taken all the necessary precautions to remove advertisements that are deemed illegal from the moment they became aware of such ads, or to determine whether they have been negligent. Therefore, in Argentina there are no relevant precedents ruling that no intermediary should be liable for illegal content posted or shared by individuals on their platforms, or where an intermediary was found liable for content generated by third parties and published on its media regardless of whether or not such intermediary had knowledge of that content.

In this respect, in 2011 the ANMAT created the "Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance Programme" (the "Programme"), which aims to monitor and evaluate advertisements in the mass media and specialised media with respect to products subject to sanitary surveillance, such as medicines. The Programme seeks to foster integration and interaction with other governmental agencies (both provincial and national), regulated sectors, NGOs and educational institutions, for the collaboration of advertising monitoring activities. Also, the Programme strengthens the link with consumers, who will be able to easily access all regulatory information.

Since 2012, due to the substantial increase of digital commerce, the Programme surveys advertisements and publications disseminated through the internet, with a particular focus on the most widely used marketing platform in the country, Mercado Libre. In 2020, the Programme surveyed around 68,000 advertisements promoting pharmaceutical products referring to COVID-19; and during 2021, thanks to more strict controls, the number of monthly surveys doubled in four months, causing the removal of lots of advertisements that were promoting unregistered medicines, or that included sales bans and misleading advertising.

For this purpose, the ANMAT has a collaboration agreement in place with Mercado Libre, to control the sale of medicines and other relevant health products through that virtual platform. The purpose of the agreement is to exchange information on the products regulated by the ANMAT (medicines, medical devices, dietary supplements and cosmetics, among others) that are offered for sale in Mercado Libre's platform. In addition, the agreement also includes the provision of certain technical and legal advice by the ANMAT to Mercado Libre and mutual collaboration for the detection of advertisments that may infringe the regulations. There is an email address in place that is available for the delivery and processing of notifications and removal of notices posted on Mercado Libre's website that infringe the legal framework, as per the ANMAT's criteria.

Mercado Libre's website expressly provides the following notice:

"If you have doubts about any product, first of all find out if it is legal to sell it. Basically, if the law does not allow it, neither do we. For example:

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pharmaceutical products, prescription medicines, endangered animals and many others."

As a result of this collaboration agreement, the ANMAT and Mercado Libre cancelled appoprximately 1,600 advertisements corresponding to illegitimate pharmaceutical products or that were considered misleading advertising.

Social media

Under Argentine regulations, any form of promotion of medicines to the public, including through traditional or non-traditional media, would be considered advertising.

Even though there is currently no legal framework applicable to influencers or social media with respect to advertising of medicines, there is an advertising self-regulatory board (CONARP), which has issued general guidelines directed to those people promoting any types of goods and/or services on social media, including medicines. These guidelines are not compulsory but constitute good practices on advertising that should be followed.

In general, these guidelines provide the following:

- the message must include the phrase "Content in collaboration with… (brand)" or "#SponsoredContent";
- the message must be truthful and avoid any deception or exaggeration that violates the good faith of the public, abuses their trust or exploits their lack of culture, knowledge or experience;
- no message, directly or indirectly, may contain descriptions, images or text that contribute to confusing the consumer (follower) or making them believe that the promoted good or service does something that is not within its capabilities, unless obvious exaggerations are used to amuse or attract attention;
- the message must not mislead as to the characteristics of the product or service, as well as to its nature, origin, manufacture, composition, quantity, usefulness, quality or property, value or mode of use, as well as the conditions of purchase, discounts, delivery and warranty conditions, among others;
- the message may only include authentic testimonials or recommendations, related to the experiences of those who provide their statement, either the influencers themselves or third parties; and
- the message must not indicate that the product or service has professional and/or institutional endorsement or recommendation without having previously obtained the corresponding authorisation.

It is worth mentioning that a legislative bill providing a legal regime for influencers in digital advertising services and electronic telecommunications networks was introduced in the Senate.

Visits by Medical Sales Representatives of Pharmaceutical Companies to HCPs

In Argentina, the visits carried out by medical sales representatives of pharmaceutical companies are deemed as promotion activities, since they supply to HCPs samples of the medicines offered at the market, in order for them to evaluate their characteristics, effects, and eventually, if they consider appropriate, to prescribe them. Promotion of any non-authorised medicinal product or off-label indication is forbidden. Sales representatives should not use any incentive or make any payment to obtain an interview with an HCP.

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The regulations set forth that visits to HCPs carried out by pharmaceutical companies' representatives should have the main purpose of informing about technical and scientific knowledge, adequate for the objective assessment of a therapeutic application. Pharmaceutical companies are responsible for establishing appropriate procedures for the training of medical advertising agents and/or medical propaganda in order to transmit and facilitate to HCPs all the information regarding the relevant therapeutic benefits, adverse effects, contraindications, interactions and others.

Since Argentina is a federal country with 24 jurisdictions, each of them has their own competence to rule on this subject, as follows:

- Autonomous City of Buenos Aires– Law No 1,713;
- Buenos Aires – Law No 10,851;
- Tucuman – Law No 5,926; and
- Misiones – Law No 2,290.

Conflicts of Competence

In recent years, there have been a number of judicial cases in which the courts ruled on competence issues between the ANMAT and the enforcement authorities of Law No 24,240 (the "Consumer Protection Act") and of National Decree 274/2019 (the "Fair Trading Decree") in connection with medicinal advertising complaints.

In this regard, it is important to highlight that the ANMAT is the enforcement authority specially empowered by law to verify compliance with the provisions on medicinal advertisements. However, the Consumer Protection Act and the Fair Trading Decree provide general guidelines to be complied with for the advertising of any types of products and services, including medicines.

In particular, the Consumer Protection Act sets forth that suppliers are obliged to provide to consumers certain clear and detailed information on the essential characteristics of the goods and services, and the conditions of their commercialisation. Section 5 establishes that goods and services must be supplied or rendered in such a way that, when used under foreseeable or normal conditions of use, they do not present any danger to the health or physical integrity of consumers or users. Additionally, Section 8 establishes that the clarifications made in advertising or in announcements, leaflets, circulars or other means of dissemination are deemed to be included in the contract with the consumer and are binding on the offeror. In Argentina, patients are deemed consumers.

The Fair Trading Decree prohibits any kind of presentation, advertising or publicity that, through inaccuracies or concealment, may lead to error, deception or confusion concerning the characteristics or properties, nature, origin, quality, purity, mixture, quantity, use, price, marketing conditions or production techniques of goods, real estate or services. In turn, Section 15 sets forth the guidelines that determine when comparative advertising is allowed (these guidelines are similar to those established by ANMAT Disposition 4980/2005, which regulates the advertising of over-the-counter medicines).

Therefore, although these general rules do not refer specifically to medicines, they are mandatory for pharmaceutical companies. As a result, in recent years there have been some competence conflicts between the ANMAT and the enforcement authorities of the Consumer Protection Act and the Fair Trading Decree, on issues related to advertising of medicines.

In particular, it is worth mentioning a recent ruling of June 2022 in which the City of Buenos Aires Federal Court of Appeals confirmed that the authority in charge of controlling and supervising medicines advertisements is the ANMAT. The case started with an ex officio investigation of the enforcement authority of the Consumer Protection Act based on the analysis of an advertisement of a medicine, disseminated both in social networks and traditional mass media, since the information of the campaign infringed consumer protection regulations as the advertisement granted the medicinal product properties tending to modify physical appearance when, according to the prospectus, it was intended to counteract occasional constipation.

The Court ruled that the ANMAT was the agency empowered to determine whether the use of certain phrases included in the advertisement violated the specific regime and, in such case, to apply sanctions provided for in the regulations, since it is the authority in charge of controlling the advertising of over-the-counter medicines.

Similarly, in a previous case of December 2018, in which the regulatory agency of the former Law of Fair Trade intervened in a complaint for misleading advertising of a medicine, the Federal Contentious Administrative Chamber confirmed that the ANMAT is the competent agency for supervising medicinal advertising.

Latest Regulatory Changes

The most relevant regulatory change in relation to medicinal advertising occurred in 2016, when the ANMAT, through Disposition 9660/2016, established that, with respect to over-the-counter medicines, pharmaceutical companies are no longer required to submit to the ANMAT the advertising materials in advance. Some bills have been submitted to the Congress regarding the advertising of over-the-counter medicines, but they have not been further developed thus far.

It is also worth mentioning that there has been great expansion on the use of cannabis for medicinal purposes in Argentina. The Congress has passed Law No 27,350, which provides the legal framework for medical and scientific research on the medicinal, therapeutic and/or pain-palliative use of the cannabis plant and its derivatives. In this context, the ANMAT has authorised new medicines containing cannabis derivatives, specifically for the treatment of epilepsy. Also, the Congress passed Law No 27,669, which expands the use of cannabis for medicinal and industrial purposes. Cannabis medicines are prescription-only medicines, so as such they cannot be advertised to the general public, only to HCPs.

In addition, in 2022, the Ministry of Health created a new category of medicines called “cannabis-based plant products and their derivatives intended for use and application in human medicine”. Only pharmacies are allowed to dispense these medicines, and their condition of sale is “under prescription”, considering the nature and consequences of their misuse. The regulations prohibit the advertising and/or production, delivery and circulation of free samples, samples for professionals, samples without commercial value, or any other denomination of similar scope of these products.

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Allende & Brea is one of the leading law firms in Argentina. It was founded in 1957, and enjoys a long-established reputation for superior legal work. It is a full-service law firm mainly oriented towards sophisticated transactional international and local practice, advising large, medium-sized and small companies on a permanent basis, or acting as special counsel in a variety of commercial transactions carried out in Argentina or abroad. The firm is organised into dedicated and specialised groups in all areas of business law and industry sectors, including life sciences. The life sciences team is focused on matters of the pharmaceutical, medical devices, biotechnology, food, beverages and cosmetics industries. The team of two partners and five associates assists clients in their daily operations and in local and cross-border M&A transactions, collaboration, manufacturing, licence and distribution agreements, intellectual property, data privacy, regulatory matters, litigation and anti-competitive practices.

Authors

Maria Morena del Rio joined Allende & Brea in 2003. She was named a partner of the firm in 2006 and heads the department of administrative and environmental law, and co-heads the ESG and life sciences departments. Her practice covers regulatory, infrastructure and environmental matters. Her regulatory and administrative law practice includes bids and public contracts, administrative procedures, administrative processes, claims against the administration, defence in punitive proceedings, regulatory advice and consumer defence. She is a member of the Bar Association of the City of Buenos Aires.

Fernando Martinez Zuviria joined Allende & Brea after graduating magna cum laude from Universidad Austral in 2005. He attended the Academy of American and International Law (Texas, 2007) and obtained a master's degree (LLM) at the University of Illinois in 2012. He worked as a foreign associate at Holland & Knight LLP law firm in Miami. He has been a partner of the firm since 2019 and co-heads the life sciences department. His practice focuses on assisting pharmaceutical companies with their daily operations in corporate, contractual and regulatory matters. Fernando is a member of the Bar Association of the City of Buenos Aires.

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Allende & Brea

Lucrecia Re joined Allende & Brea in 2021. She is an associate of the administrative law and life sciences departments, and graduated from Universidad Torcuato Di Tella in 2014. She has practised in the field of administrative law since 2014, and in 2019 completed her master's degree studies in Administrative Law at Universidad Austral. She represents pharmaceutical and medical device companies in a wide range of matters, including legal advice and comprehensive management of cases in administrative proceedings and life sciences regulatory matters.

Luciana Gonzalez joined Allende & Brea in 2021. She is an associate of the administrative law and life sciences departments. Luciana received her law degree from the Universidad de Buenos Aires in 2022, before working as a paralegal. She assists pharmaceutical and medical device companies in regulatory matters.

Allende & Brea

Maipu 1300
Floor 11
C1006ACT
City of Buenos Aires
Argentina

Tel: +54 11 43189933
Fax: +54 11 43189999
Email: fmartinez@allende.com
Web: www.Allende.com

BELGIUM

Law and Practice

Contributed by:
Olivier Van Obberghen, Pieter Wyckmans and Michiel D'herde
QUINZ see p.60

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BELGIUM

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The general legal rules on the advertising of medicines for human use are provided by the Law on Medicinal Products of 25 March 1964 (LMP) (particularly Articles 9 and 10) and the Royal Decree on information and advertising of medicinal products for human use of 7 April 1995 (RDAMP).

Furthermore, the Law of 18 December 2016 on "various provisions on health", which entered into force on 23 June 2017 (the "Sunshine Act") is also of high relevance in the context of pharmaceutical advertising in Belgium. The Sunshine Act imposes an obligation of legal transparency on pharmaceutical companies to document and to (annually) disclose premiums and benefits that were granted to healthcare professionals, healthcare organisations or patient organisations. The Sunshine Act is further executed by the Royal Decree of 14 June 2017 on the execution of the Sunshine Act (the "RD Sunshine Act").

Self-Regulatory Deontological Codes

Four self-regulatory deontological codes provide specific provisions on pharmaceutical advertising in Belgium. They were issued by the following professional associations:

- pharma.be, a professional association of innovative pharma companies based in Belgium;
- the Belgian Association for the Consumer Healthcare Industry (BACHI), which focuses on over-the-counter medicines and healthcare products sold in pharmacies;
- Mdeon, a common platform between different professional associations and healthcare professionals/organisations; and
- Medaxes, a professional association of Belgium-based generic/biosimilar medicine companies.

Additionally, the general principles laid down in the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (the "EFPIA Code of Practice") provide important guidelines for pharmaceutical advertising in Belgium.

Legal Framework

The focus of this chapter is on the general legal framework for the advertising of medicinal products (including the Sunshine Act) applicable to all pharmaceutical companies in Belgium. The self-regulatory deontological codes referred to above (notably the pharma.be Code of Deontology, which applies to 90% of Belgian innovative pharmaceutical companies) will be addressed if they add information or insights to further interpret or better understand the general legal framework, and contain further material obligations for their members or install relevant a priori or a posteriori approval or control procedures regarding pharmaceutical advertising.

Advertising to the General Public and Healthcare Professionals

Lastly, the LMP and the RDAMP make a clear distinction between advertising medicinal products for human use towards the "general public" on the one hand, and towards "healthcare professionals" on the other hand. Within the scope of the LMP and the RDAMP, only medical doctors, dentists and pharmacists are considered "healthcare professionals". Nursing personnel are regarded as part of the general public. However, under the Sunshine Act, nurses, paramed-

ics and hospital directors also fall under the definition of "healthcare professionals".

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Each of the four self-regulatory deontological codes discussed in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines** is binding (only) to the members of the relevant professional associations (provided that Mdeon has been entrusted with formal regulatory authority in relation to the granting of visas for sponsoring scientific manifestations under Article 10 LMP; see **9.3 Sponsorship of Scientific Meetings**).

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Article 9 of the LMP provides the following definition of advertising: "any form of door-to-door information, canvassing activity or stimulation which is designed to promote the prescription, release, supply, sale or consumption of medicinal products". Patient information leaflets, product labels and general information regarding health and disease areas with no direct or indirect reference to a medicinal product are however excluded from the definition of "advertising". Information and documentation provided in the context of package changes, compliance with pharmacovigilance requirements, and sales catalogues and pricing lists also fall outside the definition of advertising, to the extent such information and documentation does not include product-specific information.

Also not regarded as advertising is the provision of so-called "unsolicited" medical information about a particular drug product, given by a pharmaceutical company following a patient's or healthcare professional's specific request, as long as such information is strictly necessary to answer such particular request, and does not contain unsolicited promotional content (for the distinction between information and advertising, see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

The definition and exclusions provided under Article 9 of the LMP are identical to those of Article 86 of Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use.

Article 2, Section 2 of the RDAMP further supplements the definition of advertising by naming specific examples, such as:

- providing samples;
- visiting healthcare professionals;
- sponsoring scientific conferences; and
- inciting to deliver or prescribe medicines by providing financial or in-kind benefits.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The difference between information and advertising is extremely relevant for the pharmaceutical sector, since the provision of mere medical information is subject to fewer restrictions and regulations than the advertising of pharmaceutical products. However, in practice, said distinction is often difficult to draw. The test generally used to differentiate both types of communication is the question of whether the communication promotes or enhances, or intends to promote or enhance, the sale of a particular pharmaceutical product.

The definition of advertising is commonly interpreted broadly by the supervising authorities, who will often be inclined to assume that any type of medical communication is promotional, unless clearly proven otherwise.

General Information

Article 9 of the LMP explicitly provides that general information regarding health and disease areas, with no reference (directly or indirectly) to a medicinal product, is not regarded as advertising. Therefore, disease awareness campaigns would typically not qualify as advertising, provided that such campaigns cannot be considered as soliciting requests for information from the addressee. A Patient Information Leaflet (PIL) will reasonably not be qualified as a form of advertising, since it is intended to inform the patient about the characteristics of a certain medicinal product after it has been purchased by the patient. Information about patient support programmes, which usually pertain to a specific medicinal product, should only be provided upon the specific request of the patient. Otherwise, such information will likely be considered to have a promotional purpose.

Borderline Cases

For borderline cases, pharmaceutical companies often apply the following rules-of-thumb to mitigate the risk of a re-qualification of "scientific information" into "advertising" by the supervising authorities:

- ensuring that the communication emanates from the medical affairs department (and not from the sales team); and
- keeping a written file able to demonstrate (if need be) the clear non-promotional intent of said communication (and the assessment made by the company prior to sending it).

The implementation of such rules-of-thumb can, of course, never entirely eliminate the re-qualification risk.

2.3 Restrictions on Press Releases Regarding Medicines

Given the broad interpretation applied by the supervising authorities, press releases are very often to be considered as advertising medicinal products and must, in such cases, comply with the general rules and requirements concerning advertising towards the general public or healthcare professionals, as the case may be. Since it is prohibited to promote prescription-only medicines to the general public (see 4**.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**), no such press releases may be issued in the general media, unless it can be established that they are purely informative (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

Conversely, it is permitted to publish articles concerning prescription-only medicines in specialised trade magazines that are only consulted by healthcare professionals, as long as the general rules provided in Articles 9 and 10 of the RDAMP are complied with (see **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**).

Finally, the advertising of unauthorised products or off-label indications is prohibited under Article 9 LMP (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**). Therefore, a press release concerning such unauthorised products or off-label indications is only allowed if such press release is purely informative and is not considered promotional (see **2.2 Information or Advertising:**

Disease Awareness Campaigns and Other Patient-Facing Information).

It is generally accepted that companies may provide the specialised media with updates on their pipeline pharmaceutical products during the development or marketing authorisation phases. Such press releases must, however, be drafted in such a way that they cannot be considered as an advertising tool, inter alia, by only providing objective and scientifically verifiable information and by mentioning the non-proprietary name of the active pharmaceutical ingredient rather than the anticipated trade name of the product.

It is interesting to note that the Belgian Financial Services Market Authority (FSMA) has issued specific guidance for (listed) biotech companies regarding the provision of information on their pipeline, following the increasing focus on the pharmaceutical and biotech sector in COVID-19 times. Pursuant to such guidance, listed biotech and pharmaceutical companies have a regulatory obligation to proactively communicate on their pipeline when concrete development milestones have been reached, which is generally done via press releases. This is based on the more general Belgian Market Abuse Regulation principle, which stipulates that inside information needs to be shared with the public as soon as possible and false or misleading signals must be avoided.

Notwithstanding this obligation to proactively communicate, companies should be careful and ensure that the communication remains factual, balanced, does not contain any promotional content and is not aimed at encouraging the sale or prescription of the relevant product (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

2.4 Comparative Advertising for Medicines

The requirements for legitimate comparative advertising are laid down in Article VI.17 of the Code of Economic Law. Comparative advertisements:

- must compare similar products;
- must compare one or more essential, relevant, verifiable and representative elements of the product (such as the price);
- must not be misleading;
- must not create confusion between the advertiser and the competitor or between their brands, trade names or other distinguishing marks;
- must not discredit or disparage the competitor and its products/activities; and
- must not represent products as being a counterfeit or imitation of products whose brand or trade name is protected.

Moreover, pursuant to the pharma.be Code of Deontology, comparative advertisements must present the compared product in a way that is fair, complete, scientifically accurate and based on the most recently available data.

Given the general prohibition of advertising non-approved medicines or indications (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), making comparative advertisements concerning a medicinal product that has not (yet) been authorised would be deemed illegal (ie, even if such comparison is in line with the above requirements). Comparative scientific statements concerning a medicinal product that has not (yet) been authorised may be permitted if it is purely informative, is scientifically validated (eg, on the basis of objective head-to-head clinical data) and is not considered promotional (see **2.2**

Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Article 9 LMP explicitly forbids all advertising of medicines that are not yet authorised, including the advertising of a medicine for indications for which it has not (yet) been granted marketing authorisation (off-label indications). However, this prohibition applies only to advertisements and not to medical information. Note also that the provision of unsolicited medical information does not constitute an advertisement of a pharmaceutical product, regardless of who requests such information (see **2.1 Definition of Advertising**). Therefore, a pharmaceutical company can provide a patient/healthcare professional with specific information on unauthorised medicines or off-label indications if:

- such information is provided at the specific, unsolicited request of a patient/healthcare professional;
- such information does not contain any promotional content and is not aimed at encouraging the sale or prescription of the relevant product; and
- to the extent the information is necessary to answer the patient's or the healthcare professional's request.

Besides this, information on non-authorised medicines or off-label indications can be published in independent scientific (preferably peer-reviewed and, in any case, non-commercial) magazines or journals. These publications may not be used as promotional material by a pharmaceutical company (eg, by extending copies of the journal to healthcare professionals).

All other publications of non-authorised medicines or off-label indications will, in principle, be deemed promotional and therefore illegal.

3.2 Provision of Information During a Scientific Conference

It is generally accepted that scientific information on non-authorised medicines or off-label indications (eg, results of clinical studies) can be presented to healthcare professionals during scientific meetings, in so far as the presentation remains strictly scientific and is not (blatantly) intended to promote the relevant medicine. Such intention can be harder to refute when the meeting is (materially) sponsored by the product owner. In addition, it is always preferable to have such presentations brought by an independent expert faculty.

With respect to the provision of information during international scientific congresses, in accordance with Article 8 of the EFPIA Code of Practice, it is also permitted to provide promotional information in relation to medicines or indications which are not authorised in the country where the congress takes place, or which are registered under different conditions, as long as:

- any such promotional material is accompanied by a suitable statement indicating the countries in which the medicine is registered and makes clear that the medicine or indication is not registered locally; and
- any such promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries

where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

3.3 Provision of Information to Healthcare Professionals

In principle, the circulation of information on unauthorised medicines or unauthorised indications, even to healthcare professionals, would qualify as advertising (which in accordance with Article 9 of the LMP is not allowed), unless the information was shared reactively, upon the unsolicited request of a relevant third party.

3.4 Provision of Information to Healthcare Institutions

The provision of information on unauthorised medicines or indications to healthcare institutions is likely to be considered advertising and in breach of Article 9 of the LMP, unless the healthcare institutions expressly requested this information.

3.5 Information About Early Access or Compassionate Use Programmes

The publication of the availability of compassionate use programmes or other forms of early access falls under the general prohibition of advertising of unauthorised medicines (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**) and is therefore, in principle, illegal.

A pharmaceutical company can however provide information on such early access programmes if:

- such information occurs at the specific, unsolicited request of a patient or a healthcare professional;
- such information does not contain any promotional content and is not aimed at encouraging the sale or prescription of a medicinal product; and
- such information is necessary to answer the patient's or healthcare professional's request.

Furthermore, it is acceptable for information on early access programmes to be published in independent scientific (preferably peer-reviewed and, in any case, non-commercial) magazines or journals (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Belgian law (Article 9 of the LMP) expressly prohibits the advertising of prescription-only medicines to the general public.

Advertising over-the-counter medicines is permitted, except when such advertising:

- gives the impression that a medical consultation or surgical operation is redundant;
- suggests that the effects of taking the medicinal product are guaranteed or that no side effects exist;
- suggests that the patient's health can be enhanced by taking the medicinal product or can be affected by not taking it;
- is directed exclusively or primarily at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who could encourage the medicinal products' consumption due to their status;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

- suggests that the efficacy or safety of the product stems from the fact that it is natural;
- could lead to an incorrect self-diagnosis; or
- uses improper, alarming or misleading terms or pictorial representations (see Article 7 of the RDAMP).

Pursuant to Article 5 of the RDAMP, certain means for advertising medicinal products are prohibited (irrespective of the public to whom the advertising is directed) – eg, advertising by means of aeroplanes, billboards, telephone, text messages, fax, email, mailing, children's magazines, leaflets, contests and software programs. It is equally prohibited to promote medicinal products by promising, offering or granting any direct or indirect compensation where the patient is unsatisfied with the product.

For the sake of completeness, it should be mentioned that the advertising of pharmaceutical products is also governed by the general rules on advertising, included in the Belgian Code of Economic Law; see **2.4 Comparative Advertising for Medicines**.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Generally, all advertisements (both to the general public and to healthcare professionals) must present the characteristics of the medicinal product in such a manner that it is compatible with the Summary of Product Characteristics (SmPC) and ensures a rational use of the medicinal product (Article 9 of the LMP). Moreover, the applicable legal framework and deontological codes provide that the presentation of a medicinal product in advertisements must be accurate, up to date, objective, sufficiently complete, truthful, verifiable and compatible with the most recent content of its marketing authorisation file, reflect generally accepted scientific knowledge and be backed by bibliographical data.

Specifically, in terms of advertising of over-the-counter medicines directed at the general public, Article 8 of the RDAMP requires that it should be designed in such a way that it is clear that the message is an advertisement, and include the following minimum information:

- the name of the product (as well as the generic name if the medicinal product contains only one active substance);
- the information required for correct use;
- the statement "this is a medicinal product, no long-term use without medical advice";
- an explicit, legible invitation to carefully read the instructions on the package leaflet or on the outer packaging, as the case may be – in the case of radio advertisements, such an invitation must be explicit and clearly audible; and
- the (trade) name of the product's marketing authorisation holder.

There is no legal or deontological rule that requires that the price of the pharmaceutical product be mentioned in the advertisement.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Neither the LMP nor the RDAMP contains provisions on relations with patient organisations. A patient organisation having a healthcare professional among its members should, in any event, be treated as a healthcare organisation to which Article 10 of the LMP applies (see **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals** and **8.2 Legislative or Self-Regulatory Provisions**). Pharmaceuti-

cal companies should ensure that their public interaction with patient organisations within a certain therapeutic area does not qualify as an advertisement to the general public regarding their related drug products.

Chapter 3 of pharma.be's Code of Deontology does contain rules on relations with patient organisations. Pharmaceutical companies may:

- provide financial support to a patient organisation;
- call on patient organisations for the performance of certain services for the support of healthcare or research; or
- sponsor events organised by patient organisations if such support is covered by a written agreement.

In addition, pharma.be requires its members to make the support it has attributed to patient organisations available to the public on a yearly basis. This transparency obligation in respect of transfers of value to patient organisations is also included in the Sunshine Act, which applies to all companies, not only to the members of pharma.be.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

As mentioned in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**, all advertising must present the characteristics of the medicinal product in such a manner that it is compatible with the SmPC and ensures a rational use of the medicinal product (Article 9 of the LMP). Moreover, the presentation of a medicinal product in advertisements must be accurate, up to date, objective, sufficiently complete, truthful, verifiable and compatible with the most recent content of its marketing authorisation file, reflect generally accepted scientific knowledge and be backed by bibliographical data.

Mandatory Data to Be Contained in Advertising to Healthcare Professionals

Specifically, for advertisements towards healthcare professionals, Article 9 of the RDAMP specifies that advertisements in the press directed towards healthcare professionals must contain the following essential data, which must cover at least 50% of the total advertisement space:

- the product's name, its qualitative and quantitative composition in terms of active substances and its pharmaceutical form;
- all information regarding indications, posology, contraindications and side effects contained in the SmPC;
- the package leaflet or the labelling in the case of a homeopathic medicinal product; and
- the (trade) name of the marketing authorisation holder and the number of the marketing authorisation or product registration.

The FAHMP has issued very specific guidance regarding the layout and readability requirements for advertising of pharmaceutical products (Circulars 407 and 441).

As opposed to advertisements of over-the-counter medicines, advertisements towards healthcare professionals should also contain the applicable retail price per approved formulation/pack size. Such prices must appear in bold, on a contrasting background in the advertisement's upper right-hand corner and should cover at least 0.5% of the print advertisement.

Lastly, advertisements towards healthcare professionals must explicitly mention the date of the product's creation or the date of its last revision.

For the sake of completeness, it must be mentioned that the restrictions on the means of advertising provided under Article 5 of the RDAMP (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**) also apply to the advertising towards healthcare professionals.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

In accordance with the LMP, all information in an advertisement for medicinal products must comply with the information as set out in the SmPC. Further to the European Court of Justice decision held in Novo Nordisk AS v Ravimiamet (C-249/09; 5 May 2011), it is generally accepted that the inclusion in advertisements directed to healthcare professionals of information, which is not part of the SmPC, is allowed as long as such information confirms, clarifies or supplements (ie, does not directly or indirectly contradict) the specifications made in the SmPC and is not misleading.

5.3 Advertising of Combination Products

Reference to combined use of products is acceptable if such combined use is authorised for the particular indication for which it is being promoted (otherwise it would constitute an illegal promotion for an unauthorised indication; see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), this reference does not directly or indirectly contradict the specifications made in the SmPC (see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**) and the promotional claim is presented in an accurate, up to date, objective, sufficiently complete, truthful, verifiable and faithful manner.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

The distribution by a pharmaceutical company to healthcare professionals of scientific papers (or proceedings of congresses) that refer directly or indirectly to a drug product of said company will, in principle, be considered an advert and therefore subject to those rules (including the prohibition of advertising on unauthorised products/off-label indications). Distribution by pharmaceutical companies will also be subject to the rules related to gifts to healthcare professionals.

5.5 Medical Science Liaisons

Medical Science Liaisons (MSLs) are regarded as therapeutic-area scientific experts within the pharmaceutical company, who act as a liaison between the company and healthcare professionals and other external stakeholders. MSLs are responsible for discussing the company's pipeline, products, patient treatment trends and studies in the therapeutic areas in which the company is involved, on a peer-to-peer basis with an audience of external clinical and non-clinical stakeholders.

The MSL's communications with healthcare professionals must always comply with applicable legislation. Therefore, the MSL may only respond to unsolicited questions raised by healthcare professionals about unapproved products or off-label uses of approved products, and not proactively provide such information. The MSL is, however, allowed to proactively exchange information on ongoing trials and communicate scientific information on the company's products within label.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

For advertisements towards the general public, the applicable approval and notification procedure depends on the medium used for such an advertisement.

If an advertisement is made on the radio and/or television, the company must obtain prior approval from the Ministry of Health (Article 16, Section 1 of the RDAMP), which will base its decision on the advice from the Commission on the Supervision on Advertising of Medicinal Products. This commission operates as an independent commission within the Federal Agency for Medicines and Health Products (FAMHP). The Ministry of Health must make a decision within 45 days of the receipt of a complete request for approval (Article 17, Section 5 of the RDAMP).

All other forms of advertising (of medicinal products) to the general public (eg, in a newspaper or online) should merely be notified to the Ministry of Health 30 days prior to their publication (Article 16, Section 2 of the RDAMP). The Ministry of Health may require the company to provide additional documents in the context of this notification, which could potentially lead to a postponement of the relevant advertisement. The Ministry of Health may also prevent any (intended) advertising, if it does not comply with applicable legal requirements. Both the visa and notification require the payment of a retribution by the company (EUR995.20 and EUR592.33, respectively) and are valid for a period of two years.

For advertising towards healthcare professionals, prior notification to or approval by the Ministry of Health is not required.

6.2 Compliance With Rules on Medicinal Advertising

Pursuant to Article 13 of the RDAMP, every marketing authorisation-holding company must designate a qualified person (responsible for the information) who will be accountable for the advertising and for providing scientific information on medicinal products for that company. The qualified person must be a pharmacist or physician and registered with the Ministry of Health. Information as well as advertisements to healthcare professionals and the general public should always be ratified in advance by that qualified person.

There are no relevant legal or code requirements to have specific standard operating procedures in place to cover advertising activities.

Also note that pharmaceutical companies must adequately train sales representatives visiting healthcare professionals (including on the scientific aspects of the medicinal products).

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The general rules for pharmaceutical advertising as already set out, and in particular Article 9 of the LMP and the principles of the RDAMP, also apply to internet advertising.

Book XII of the Code of Economic Law, setting forth the rules on the digital economy, contains more specific rules on electronic advertising (on

websites, by email or through other electronic means). Pharma.be has also issued guidelines on mandatory information to be included in internet advertising.

In a nutshell, an advertisement on a website by a pharmaceutical company must comply with the following rules:

- it must contain a clearly visible, legible and unambiguous statement that it is an advertisement;
- the pharmaceutical company must be identifiable;
- the relevant general requirements for pharmaceutical advertisements must be complied with; and
- the advertisement must have been notified to the Ministry of Health in advance.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

No specific rules exist on the required website security for advertisements directed at healthcare professionals. Nevertheless, a company should take all security means to prevent access by the general public to a website that contains information regarding prescription-only medicinal products, as a lack of adequate measures will constitute a violation of Article 9 of the LMP.

The same applies to websites which contain scientific information regarding non-authorised medicines or off-label indications. A company should take all security means to prevent unrestricted access by the general public to such a website, as any provision of scientific information should generally occur based on a specific unsolicited request (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**).

It is a common practice that pharmaceutical companies make certain parts of their website only accessible to healthcare professionals if they log in with their RIZIV/INAMI-number (RIZIV/INAMI is the Belgian National Institute for Health and Disability Insurance).

7.3 Provision of Disease Awareness Information to Patients Online

As mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, the provision of disease awareness information generally does not qualify as advertising, as long as no direct or indirect reference is made to a specific medicinal product. Hence, companies are allowed to provide such disease awareness information to patients online. The online provision of information is not subject to any stricter rules than the offline provision of information; however, the potentially broader reach of online information affects the risk associated therewith.

7.4 Online Scientific Meetings

MDeon has issued specific rules governing the sponsorship of online scientific meetings or virtual attendance by healthcare professionals. A pharmaceutical company's contribution to online scientific meetings shall logically be limited to the organisational cost (eg, the cost of the meeting host, compensation for the speakers, etc) or the registration fees for the healthcare professional's attendance at the event. It will not be permissible to sponsor or provide any travel, accommodation or meals in the context of an online scientific meeting, since there is no required travel that would justify the provision of such hospitality. Further, it is clarified that the sponsoring of virtual meetings is subject to the visa requirement if they take place over several consecutive calendar days of which the regis-

tration fee is offered (see **9.3 Sponsorship of Scientific Meetings**).

As set forth in **9.3 Sponsorship of Scientific Meetings**, any offered hospitality must in any case be subordinate to the scientific purpose of an event.

In addition, the pharmaceutical industry federations EFPIA, PhRMA and IFPMA have issued specific joint guidance to clarify the rules and principles in relation to virtual events. For information that is shared during such a virtual event, the guidance requires that the pharmaceutical company incorporates adequate safeguards in the virtual booth to be able to identify those wishing to view its booth (HCP or Non-HCP) and therefore determine what information is appropriate for such audience.

7.5 Use of Social Media

There are no specific rules for the advertising of medicinal products on social media in Belgium. Such communications are subject to the general rules on advertising and communication on the internet. For the advertising of medicinal products on social media, see **7.1 Regulation of Advertising of Medicinal Products on the Internet**. EFPIA has also included guidelines on the use of digital channels in Annex G of the EFPIA Code of practice.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Articles 504 bis and 504ter of the Belgian Criminal Code provide the Belgian anti-bribery rules concerning the bribery of private legal entities and private individuals (ie, private bribery). These are the anti-bribery rules applicable to pharmaceutical companies.

Furthermore, Articles 246 to 252 of the Belgian Criminal Code provide the rules concerning the bribery of public legal entities and individuals holding a public function (ie, public bribery). The rules on public bribery will apply to state-owned (university) hospitals, as well as healthcare professionals employed by such hospitals, since they are then considered to hold a public office.

8.2 Legislative or Self-Regulatory Provisions

Pursuant to Article 10 of the LMP, it is forbidden, within the framework of the supply, prescription or administration of medicines, to offer, supply or promise (in)direct benefits to healthcare professionals and the healthcare organisations where they work. There are, however, certain exceptions to this prohibition; see **9.1 Gifts to Healthcare Professionals**.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Article 10 of the LMP contains a broad prohibition on providing premiums or benefits in cash or in kind to "wholesalers, intermediaries, persons who are entitled to prescribe, dispense or administer medicinal products or to institutions where such prescription, dispersion or administration takes place".

Article 10 of the LMP does, however, contain a limited number of exceptions to this prohibition. As such, it is permitted to provide gifts to healthcare professionals to the extent such gift has a very low value and directly relates to the medical

profession of the healthcare professional concerned. Other exceptions are the invitation to and the funding of participation in a scientific event, including hospitality (see **9.3 Sponsorship of Scientific Meetings**) and the reimbursement of legitimate services of a scientific nature, in so far as this reimbursement remains within reasonable limits (see **9.7 Payment for Services Provided by Healthcare Professionals**).

During the parliamentary discussions on the LMP it was acknowledged that EUR50 (VAT included) per gift per healthcare professional or organisation, with an absolute maximum of EUR125 (VAT included) per healthcare professional or organisation per year, could be considered sufficiently limited. Even though these thresholds were not explicitly withheld in the LMP, these amounts are considered as the standard within the entire sector (also, pharma.be uses these amounts as the maximum amounts for all its members).

It is not possible to give cash to healthcare professionals, as this cannot be considered "directly related to the medical profession". The Mdeon Code of Ethics further provides for concrete examples of other types of gifts which are generally not deemed appropriate, such as:

- decorative objects;
- digital photo frames;
- iPods;
- champagne coolers;
- coffee machines;
- mp4 players;
- gift vouchers;
- discount vouchers;
- cameras;
- bottles of wine;
- tickets for the theatre or other cultural, sporting or recreational events;
- mobile phones;
- photo scanners;
- radios;
- suitcases;
- sport/travel bags;
- alarm clocks;
- cups; and
- watches.

Gifts that may be appropriate include medical/pharmaceutical scientific reference works, writing instruments, clinical material and professional-use IT accessories.

9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of free samples is possible, as long as the rules and obligations of Article 12 LMP and the Royal Decree of 11 January 1993 on medical samples are respected.

As a general principle, samples may only be provided to a healthcare professional authorised to prescribe such a product at their specific request – on the condition that a marketing authorisation has been obtained in Belgium for such medicinal products. The provision of samples is limited to eight samples per product (in its smallest available pack size), per year, per treating physician. Additionally, each healthcare professional may receive no more than 600 samples, in total, per year.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies may, in principle, both sponsor the attendance of healthcare professionals to continuing medical education (including hospitality) and sponsor the associations that organise such continuing medical education (see **9.1 Gifts to Healthcare Professionals**). Article 10 of the LMP, however, determines that this is only allowed if:

- the event is by its nature exclusively scientific;
- the hospitality is strictly limited to the scientific objective of the event;
- the location, date and duration of the event do not create confusion about the scientific nature of the event;
- the financial contribution to the participation (including the offered hospitality) is strictly limited to the official duration of the event; and
- the coverage of the costs is strictly limited to the healthcare professionals concerned by the event.

For events with an overnight stay or for online events that take place over several consecutive calendar days of which the registration fee is offered, a prior visa must be obtained from Mdeon (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**). Mdeon has provided additional guidelines regarding the hospitality that can be offered to healthcare professionals in the framework of a scientific event. For example, the cost of an overnight stay (breakfast and taxes included) is in principle limited to EUR250. An exception applies to destinations where a higher limit is set according to the Ministerial Decree of 2 July 2018, in which case this higher limit applies. Further, the cost of lunch is limited to EUR45; the cost of a dinner is limited to EUR90; the cost of refreshments is limited to EUR23; and the maximum hospitality for meals and drinks is limited to EUR23 per hour per person, with a maximum of EUR135. This maximum amount implies that there are at least six hours of scientific programme that day and is all-inclusive (drinks, coffee breaks, VAT, hall rental). Further, travel within Europe should always be in economy class.

These rules are applicable to hospitality offered to Belgian healthcare professionals or healthcare professionals exercising their profession in Belgium, for scientific events in Belgium as well as abroad.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The hospitality offered within the framework of a scientific congress must be limited to the organisation, payment or reimbursement of the healthcare professional's travel, meals, overnight stay and registration for the congress. The hospitality may in no case comprise the organisation or funding of any cultural, sports or other leisure activities or any other form of entertainment.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Grants and donations to healthcare professionals, healthcare organisations/charitable organisations are not expressly exempt from the prohibition under Article 10 of the LMP.

In practice, however, the industry can provide grants or donations (eg, money to organise an activity, research equipment) for educational, humanitarian or philanthropic purposes to healthcare organisations and charitable organisations. Grants or donations directly to healthcare professionals are not allowed.

The pharma.be Code of Deontology specifies further that these donations are allowed only if they are made available for supporting healthcare or research and if they do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products. A grant or donation can be provided in cash or in kind.

A typical example of a permitted grant would be the financial support of a scientific research project organised by a healthcare organisation.

A permitted donation could consist of making company expertise available for free to an NGO for a humanitarian purpose. However, as the scope of the exception to Article 10 of the LMP in relation to grants and donations is not expressly codified in the legal texts, such events should always be evaluated on a case-by-case basis. Donations relating to the day-to-day operations of the healthcare organisation (payment of the salary of the nursing personnel, renovation works in the hospital, etc) should always be considered as borderline at best and treated with appropriate restraint.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts/rebates (including volume-related discounts) are permitted if they are in line with the (general) principles of economic law (in particular those included in the Code of Economic Law) and applicable competition principles (including on abuse of dominance). The rules on advertisement and inducement may, however, still have an impact on the validity of certain discounts. It is, for instance, almost impossible to offer free authorised medicinal products (except in the case of samples as discussed in **9.2 Limitations on Providing Samples to Healthcare Professionals**, or other very specific circumstances that would require expert regulatory assistance).

9.7 Payment for Services Provided by Healthcare Professionals

Paying healthcare professionals for the provision of services is possible if it concerns services of a scientific nature having a legitimate character. Such services could be, for example, speaker engagements, participation in advisory boards, consultancy and clinical trial services.

Specific Mdeon guidelines prescribe that the healthcare professional's compensation should be reasonable, proportionate, consistent, a reflection of the "fair market value of the services and be in line with the scope and duration of the services" (in function of the complexity, level of experience of the healthcare professional, degree of urgency, etc). It is allowable to reimburse reasonable costs incurred by such healthcare professional in the performance of these services, such as travel, meal and accommodation costs. The prescription behaviour of the healthcare professional must not be a factor for determining the applicable compensation. The provision of services by a healthcare professional may not be used as a loophole to provide (prohibited) advantages to healthcare professionals.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

As mentioned in **9.3 Sponsorship of Scientific Meetings**, a prior visa must be obtained from Mdeon in the case of hospitality for HCPs for scientific events with an overnight stay, or for online events that take place over several consecutive calendar days of which the registration fee is offered.

The provision of expert services by a healthcare professional may be subject to explicit prior approval from such healthcare professional's employer. In such cases, it is recommended to request proof of such approval from the healthcare professional.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

This requirement is set out in Chapter 1 of Title 3 of the Sunshine Act. This Act imposes on pharmaceutical (and medical devices) companies, whether Belgian or foreign, the legal obligation to document and annually disclose on the platform betransparent.be (the Belgian Transparency Register co-created by multiple deontological organisations) the premiums and benefits that they granted (in)directly to healthcare professionals, healthcare organisations or patient associations.

The transparency obligation is applicable to contributions to the costs of a scientific manifestation, fees for services and consultancy, and donations or grants provided to – as applicable – healthcare professionals having a practice in Belgium, healthcare organisations established in Belgium or patient organisations established in Belgium. Gifts, meals and drinks offered during a scientific manifestation, samples, and arms'-length market discounts offered for the sale of medicinal products do not fall within the transparency obligation under the Sunshine Act.

The provision of premiums and benefits must be made public on an individual basis (on behalf of the recipient who received them directly or indirectly). Each company subject to the notification obligation must make public, for each individual beneficiary, the amounts of the premiums and benefits granted during a calendar year.

The Belgian Transparency Register (betransparent.be) is used for all disclosures under the Sunshine Act. As a general principle, companies must disclose the relevant transfers as described above on a yearly basis, and ultimately on May 31st of the year following the calendar year in which the transfer of value has been made. When a premium or benefit was granted to a healthcare professional indirectly, such as through a healthcare organisation or corporation, the disclosure should still be made in the name of the healthcare professional.

Disclosure and Transparency

The disclosure must include the name and company number of the company subject to notification, the name and company number/RIZIV-INAMI number of the beneficiary or any other number that allows the FAHMP to identify the beneficiary and the total amount of the attributed premiums and benefits in respect of the relevant calendar year.

Data published on betransparent.be remains public for three years and will be removed afterwards.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The transparency obligations are binding upon all companies within the pharmaceutical (and medical devices) sector (including pharmaceutical companies, importers, manufacturers and distributors), irrespective of whether they are based in Belgium or abroad.

Companies that consist of different legal entities (in different countries) may combine their disclosures in a single publication. In this case, the company that makes the disclosure must provide an explanatory note explaining which legal entities (both Belgian and foreign) were grouped in the single publication.

According to Article 1.3 of the RD Sunshine Act, companies subject to notification which are established outside the European Union must make the notification by and in the name of an affiliated company established in the European Union or by a legal representative established in the European Union.

The companies subject to the notification obligation are:

- the holders of an authorisation for placing the medicinal products on the market;
- importers, manufacturers and distributors of medicinal products;
- persons engaged in the brokering of medicinal products; and
- distributors, retailers and manufacturers (Article 41, Section 1.1 of the Sunshine Act).

Companies that do not yet have a marketing authorisation are hence not subject to the notification obligation.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Since breaches of the rules on the advertising of pharmaceutical products are penalised with criminal sanctions under the LMP and the Belgian Criminal Code, the Public Prosecutor and the criminal courts are primarily responsible for the enforcement of the pharmaceutical advertising rules.

The public prosecutor will typically only open a file upon the request of the FAMHP, which may also propose a settlement with the company instead of requesting prosecution with the prosecutor.

The pharmaceutical professional associations also have a separate set of penalties susceptible to being imposed on their members following a breach of the applicable deontological code. The Committee for Deontology and Ethics in the Pharmaceutical Industry (DEP Committee) of pharma.be, for example, may impose various corrective, supervisory and financial sanctions on its members. It is also possible for individuals (eg, patients) and competitors to submit a complaint against a pharma.be member at the secretariat of pharma.be (for the attention of the Committee for Deontology and Ethics in the Pharmaceutical Industry). The DEP Committee shall then rule on such complaints. An appeal can be brought before pharma.be's Chamber of Appeal.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Although direct actions by competitors before the court are not expressly organised under the rules governing the advertising of medicines, competitors can initiate proceedings under general torts law or for breaches of the Code of Economic Law that includes general market practice principles – eg, if they believe that a company's advertising is misleading or creates unfair competition. The Code of Economic Law provides remedies such as cease and desist procedures and the request for compensation for damages on the grounds of unfair competition.

In addition, as breaches of the advertising rules are criminally sanctioned, a competitor can also file a complaint with a view to the initiation of criminal proceedings by the public prosecutor (see **11.3 Penalties for Violating Pharmaceu-**

tical Advertising Rules and Rules on Inducements to Prescribe).

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Infringements of the rules governing the advertising of pharmaceutical products are sanctioned with fines ranging from EUR1,600 to EUR120,000 and imprisonment from one month to one year for individuals, and with fines ranging from EUR4,000 to EUR240,000 for legal entities. Both the beneficiary of an inducement to prescribe (generally a healthcare professional) and the pharmaceutical company providing such inducement can be sanctioned.

11.4 Relationship Between Regulatory Authorities and Courts

The self-regulatory deontological codes must be considered as independent rules and means of enforcement. Nevertheless, the pharma.be Code of Deontology explicitly determines that no procedures can be started before the pharma.be deontological bodies if another procedure (on similar grounds) was already conducted in front of another competent authority. If a procedure is initiated before the deontological bodies of pharma.be and a separate procedure is initiated before another competent authority during such procedure, the decision by the pharma.be deontological body will be deferred until the other competent authority has taken a decision (Article 78 pharma.be Code of Deontology).

It is also possible that a deontological organisation notifies a breach by one of its members to the regulatory authorities or the public prosecution (this is, for instance, explicitly provided for in the pharma.be Code of Deontology). Of course, regulatory authorities, courts or the public prosecution will only be competent to decide on a breach of a deontological code if it also constitutes a breach of the applicable legal framework (notably the LMP and the RDAMP).

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

There are no noteworthy developments in relation to the enforcement of the rules on pharmaceutical advertising.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

With the entry into force of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (VMR), and the subsequent new and revisited national legislation (such as the Act of 5 May 2022 regarding veterinary medicinal products and the Act of 28 August 1991 regarding the exercising of the veterinary profession), the main legal framework applicable to veterinary medicinal products and medicinal products for human use, which previously were both largely governed by the same legal instruments such as the LMP, has now been split. Consequently, veterinary medicinal products are now subject to a separate, dedicated legal framework, and the LMP has been expressly dedicated to medicinal products for human use.

However, currently the legal framework specifically applicable to advertising of veterinary medicinal products is not entirely clear. The debate is ongoing in Belgium as to the extent the Belgian legislature may implement national rules on the advertising of veterinary medicinal products, going beyond strictly procedural measures implementing the main substantive

rules embedded in Articles 119 to 121 of the VMR.

Furthermore, Article 10 of the LMP still regulates the provision of premiums and benefits to veterinarians, despite the above-mentioned split between legal frameworks.

Article 119 and following of the VMR contain the following requirements for advertising veterinary medicinal products:

- advertising is only permitted for veterinary medicinal products which are authorised in the relevant member state;
- it must be clear that the communication constitutes an advertisement and that it aims at promoting the supply, sale, prescription, distribution or use of the veterinary medicinal product;
- the advertising must be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide;
- the advertising must be in compliance with the summary of product characteristics of the advertised veterinary medicinal product;
- the advertising cannot include information in any form which could be misleading or lead to incorrect use of the veterinary medicinal product;
- the advertising must encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties;
- advertising during suspension of the marketing authorisation of the veterinary medicinal product is prohibited in the member state in which it is suspended;
- only small quantities of promotional samples can be distributed, and are not allowed for antimicrobial veterinary medicinal products or for products that contain psychotropic or narcotic substances;
- such samples must be appropriately labelled indicating that they are samples and shall be given directly to veterinarians or pharmacists during sponsored events or by sales representatives during their visits; and
- specifically for prescription-only veterinary medicinal products, advertising is only allowable towards veterinarians and pharmacists.

Finally, pharma.be has issued a separate Code of Deontology for veterinary medicinal product manufacturers.

QUINZ is a Brussels-based law firm, founded in 2011, with a strong focus on life sciences. The firm's life sciences team consists of 12 lawyers. Quinz assists the global, regional (EMEA, LATAM, APAC) and local (Belgian, Luxembourg and the Netherlands) legal departments of pharmaceutical companies in a broad array of transactions (strategic, operational, licensing and M&A) throughout the life cycle of a life sciences product. Quinz has also developed a sound expertise in regional and local regulatory work, including pricing and reimbursement, clinical trials, data transparency, marketing authorisation procedures, cGMP and compliance matters, including transfers of value, promotion of drug products, antitrust compliance questions and patient-directed programmes.

Authors

Olivier Van Obberghen works exclusively for clients in the life sciences and innovative technologies sectors and co-heads the life sciences department at Quinz. Olivier's initial expertise in the life sciences sector was mainly transactional, covering the entire life cycle of a drug product, including M&A, product divestments and licensing deals. Since 2013, Olivier's practice has focused on healthcare compliance, tackling questions on the promotion of drug products and medical devices, interactions with HCPs/HCOs, patient support programmes, and the use of healthcare data. Olivier has worked in-house for the legal department of UCB.

Pieter Wyckmans provides expert advice to companies and organisations active in the (bio) pharmaceutical, biotech and smart devices sectors and co-heads the life sciences department at Quinz. Pieter's transactional expertise covers the entire life cycle of a drug product, including M&A, product divestments and licensing deals. Over the last few years, Pieter has developed regulatory expertise under EU and national laws. He provides his clients with advice on a broad array of legal and strategic issues regarding clinical trials and market access, including early access programmes, marketing authorisation procedures and pricing and reimbursement. Pieter worked in-house for the legal department of UCB.

Michiel D'herde is a member of Quinz's expert panel on healthcare compliance. Michiel has broad experience in assisting pharmaceutical companies and biotech companies with the set-up and implementation of their compliance programmes (including the establishment of internal policies, procedures and SOPs), reviewing product-related communications, and providing expert advice on questions in relation to the promotion of drug products and medical devices and interactions with HCPs/HCOs. Additionally, Michiel has developed particular expertise in international R&D agreements and consortium agreements in the life sciences sector (including Horizon 2020, Horizon Europe).

QUINZ

Business & Mediapark
Medialaan 28B
1800 Vilvoorde
Belgium

Tel: +32 02 255 73 80
Fax: +32 02 253 42 19
Email: info@quinz.be
Web: www.quinz.be

BRAZIL

Law and Practice

Contributed by:
Marcos Lobo de Freitas Levy, Mariana Carneiro Lopes Muniz and Julio Garcia Morais
Lopes Muniz Advogados see p.77

Contents

Contributed by: Marcos Lobo de Freitas Levy, Mariana Carneiro Lopes Muniz and Julio Garcia Morais,
Lopes Muniz Advogados

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The manufacturing, distribution, marketing, import and export of medicinal products in Brazil are mainly regulated by the National Sanitary Surveillance Agency ("ANVISA" or the "Regulatory Agency").

The advertising of pharmaceuticals, as well as of other products that may affect human health, as provided for in paragraphs 3 and 4 of Article 220 of the Federal Constitution, are subject to legal and regulatory restrictions. The limits that the Regulatory Agency has in the imposition of restrictions on the advertising of non-prescription drugs are the subject of heated debate between the regulated sector and the government, including a few judicial discussions.

The main legal instruments that essentially regulate advertising and the promotion of medicinal products in Brazil are as follows.

Laws and Decrees

- 6.360/76 regulates the sanitary surveillance to which medicinal products and their ingredients, medical products, cosmetics and cleaning products are subject – the implementation of this law is regulated by Decree 8.077/2013;
- 6.437/77 defines violations of the federal sanitary legislation and establishes the corresponding penalties;
- 8.078/90 the Consumer Protection Code;
- 9.294/96 imposes restrictions on the advertising of medicinal products, products for smoking, alcoholic beverages, therapies, and crop-protection products – the implementation of this law is regulated by Decree 2.018/96; and
- 9.782/99 sets forth the statutory competence of the Regulatory Agency, ANVISA – the implementation of this law is regulated by Attachment I of Decree 3.029/99.

Resolutions and Other Ancillary Regulations Issued by ANVISA

- RDC 096/2008 (as amended by RDC 023/2009) regulates advertising and promotional actions in all their forms and media (some concepts are defined in Normative Instruction ANVISA 05/2009);
- RDC 060/2009 regulates the production, distribution and control of free samples; and
- Ordinance 344/98, issued by the Ministry of Health before ANVISA was created, remains in force and regulates medicinal products containing substances under special control (narcoleptics, anorexigenic drugs, antiretroviral drugs, immunosuppressants, and others), including their advertising and promotion.

Resolutions of the Federal Council of Medicine – "CFM"

- 2.217/2018 – Medical Profession Code of Ethics.
- 1.939/2010 – prohibits medical doctors from participating in the supply, to patients, of coupons or cards that give discounts on medicines.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes in Brazil, in general, apply only to members of class associations that have enacted these codes. Pharmaceutical Class Associations that have enacted self-regulatory codes to date are:

- INTERFARMA (Brazilian Association of Research-Based Pharmaceutical Industries);

- ABIMIP (Brazilian Association of Manufacturers of Non-prescription Drugs); and
- SINDUSFARMA (Pharmaceutical Employers Union of the State of São Paulo).

Brazil also has a National Council of Self-Regulation in Advertising ("CONAR") that enacted a code regulating public advertising and, in the case of pharmaceutical products, applies exclusively to non-prescription drugs that may be advertised to the public in general. In fact, the CONAR code has a chapter specifically directed at the advertising of non-prescription medicines. CONAR's code applies to any advertisement in Brazil, even if the advertiser is not a member of the council.

As a rule, decisions from self-regulatory bodies are not made public, but competent authorities and the judiciary may (and do) use decisions issued by self-regulatory bodies as a basis for their decisions, if these decisions are brought to their attention.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

ANVISA defines the advertising/publicity of pharmaceutical products in Resolution RDC 096/2008, as: "the array of information and persuasive techniques and activities with the objective of publicising knowledge, making a product or trademark more widely known or the object of prestige, aiming to influence the public by means of actions intended to promote and/or induce the prescription, dispensing, purchasing and use of a medicinal product".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Initially, it is important to keep in mind that advertising of prescription drugs to the lay public is prohibited in Brazil. That said, as a rule, information will usually be seen as "advertising" if it includes products' trade marks and standard promotional messages.

The category of "information" includes disease awareness campaigns, related leaflets and other information (including electronic information), directed to patients and/or to the general public, which are widely used in Brazil. This includes health-related campaigns by private industries and does not qualify as advertising.

In fact, Brazilian health authorities implement several campaigns each year especially related to vaccines, AIDS prevention, hepatitis, influenza, COVID-19, and tropical diseases. In disease awareness campaigns, it is prohibited to mention any specific trade mark or name of a medicinal product. The campaigns must simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for vaccinations.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are allowed in Brazil and widely used. Although there is no specific legislation regulating this issue, in some cases, health authorities have argued that some releases (or articles published in lay media) were, in fact, disguised "advertising". Because of that, in preparing press releases the use of trade marks or trade names should be avoided in favour of using the name of the active ingredient.

2.4 Comparative Advertising for Medicines

Comparative advertising is allowed and RDC 096/2008 sets forth the rules to guide authorised comparisons.

Price Comparisons

Price comparisons are only allowed between medicines considered as interchangeable under applicable law and regulations. As a rule, only reference products and generics would be interchangeable. In the case of Brazil, even though "similar products" (generics bearing trade marks) must demonstrate bio-equivalence to the reference product, the use of comparative advertising is still the subject of some discussion.

Comparative Advertising

Comparative advertising, in general, must also abide by several different pieces of legislation and regulations, including:

- the Industrial Property Law;
- the Class Associations' Codes of Ethics; and
- the National Code of Self-Regulation in Advertising.

Self-Regulation and the Code of Conduct

CONAR's National Code of Self-Regulation in Advertising states that all comparative advertising must focus on objective aspects of the products and that the advertiser must be able to prove the conclusions of the comparisons. Also, it is forbidden to deprecate the compared brand or to create confusion between the products.

The INTERFARMA Code of Conduct, for instance, prohibits comparative advertising using third-party brands without their prior consent. However, it does allow comparisons between active ingredients even if indirect identification of brands could be possible. Any decision to engage in comparative advertising must be carefully evaluated.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The provision of information about unauthorised medicines and/or unauthorised indications (off-label) are, as a rule, not allowed in Brazil. Some information may be provided in medical events or through press releases but, as mentioned, the use of trade marks should be avoided.

3.2 Provision of Information During a Scientific Conference

Information on unauthorised medicinal products and/or off-label information can only be published as scientific information. That said, in order to avoid allegations of disguised advertising, if the product already has a trade mark, its use should be avoided. The INTERFARMA Code of Conduct sets forth that information on unregistered products or off-label indications may only be used in the context of medical and scientific information at congresses, symposiums or other scientific events.

If any company does disclose information on unauthorised medicines, the audience must be duly and previously informed that the product is not yet available in the market and that its use has not been approved by the regulatory authorities. There are no specific rules for international conferences.

3.3 Provision of Information to Healthcare Professionals

Although Brazilian pharmaceutical legislation and ancillary regulations strictly prohibit the advertising of medicinal products that have not been registered by ANVISA, products that have not yet been authorised may be discussed at scientific events (congresses, symposiums, etc), whether the event is sponsored solely by the company responsible for the product or not. These discussions must be restricted to technical information, eg, important findings in ongoing clinical studies, and should not use product trade marks to avoid being perceived as an inducement to prescribe.

It should be noted that the legislation does not mandate a previous request from the healthcare professional for such information. However, the INTERFARMA Code of Conduct states that this type of information, in principle, can only be sent if requested by the professional.

The same rules apply to off-label information. In this case, too, it is advisable not to use the trade mark of the product, but rather just the name of the active ingredient.

3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

3.5 Information About Early Access or Compassionate Use Programmes

There is no specific regulation on the publication of the availability of compassionate programmes.

It is important to say that while the production, distribution and sale of medicinal products that are not yet registered by ANVISA are prohibited, it is possible for an individual to import non-registered products for their own use, independent of previous authorisation. For this, it is only necessary to provide the importer with a specific prescription from a medical doctor duly registered to practise medicine in Brazil.

Importation for groups of patients can only be made through "compassionate use" or "expanded access" programmes that depend on ANVISA's previous authorisation but, as a rule, no public information is released. These types of programmes are mainly used in relation to patients who have participated in clinical studies, for access to the study drugs after the end of the study, while the product is undergoing registration.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Only over-the-counter (OTC) pharmaceuticals can be advertised to the general public in Brazil. Prescription-only products can only be advertised to prescribing professionals. While no restrictions apply for OTC medicines, advertising guidelines must be followed.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisement of medicinal products to the public in Brazil must always include the following generic warnings: "If the symptoms persist, consult a doctor", and "This is a medicinal product, and its use involves risks. Consult with a doctor and a pharmacist. Read the insert/leaflet".

The above-mentioned warnings must be included. Additional warnings regarding a specific active ingredient may be required by health authorities in relation to any product.

Restrictions on Advertising Non-prescription Medicinal Products

The following restrictions also apply to the advertising of non-prescription medicinal products:

- there can be no use of expressions such as "shown in clinical studies" or "scientifically proven";
- the advertising piece cannot suggest that the product would make healthy habits and visits to doctors unnecessary;
- there can be no use of celebrities stating or insinuating that they make use of the product;
- the piece cannot use language that relates the product to excessive intake of alcohol or food;
- there may be no language relating the use of the product to physical, intellectual, emotional or sexual performance or to a person's looks/complexion, except if the product has been approved by ANVISA for these specific properties;
- the piece cannot present visual representations of changes in the human body caused by illnesses or lesions in an abusive, frightening or misleading way; and
- the piece cannot include messages, symbols or images of any nature directed at children or teenagers.

Restrictions on Advertising to Professionals

Even considering that advertising of a medicinal product can only be made to prescribing professionals, the advertising cannot:

- foster indiscriminate use of medicinal products;
- suggest or stimulate diagnosis; and/or
- suggest that a medicinal product is tasty, yummy or delicious.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is very little legislation and/or ancillary regulation on the subject but, as a rule, direct interaction with patients is not allowed (except for through "call centres" or "access/adherence programmes"), while interaction with patient organisations is allowed. The INTERFARMA Code of Conduct, unlike the legislation, does expressly address the issue. For instance, the code expressly prohibits the industry from interfering with the administration of the organisation or participating in it. The code also prohibits an industry from being the sole contributor to any organisation.

Because of the high level of judicialisation of health treatment in Brazil, health authorities have been keeping a close watch on the relationship between the industry and patient associations.

Authorities believe, and in some cases found it to be true, that some donations made to patient support groups were being used to pay legal fees and the expenses necessary for patients to sue the government in order to receive treatment (medicines or medical treatment) not yet available in the public system or not yet registered in Brazil. Note that under the interpretation of the constitution by the courts, the government is obliged to provide medicines, for free, for those that cannot pay for them.

Most police investigations made over the past decade ended without finding hard evidence on the alleged financing of patient associations for the purpose of subsidising judicialisation, but a

few cases are still ongoing. Most of these cases refer to "high-cost" and "high-complexity" medicines.

The judicialisation of health is a big issue in Brazil.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

This is regulated under RDC 096/2008. The required information in advertising to healthcare professionals is:

- brand name;
- name of the active ingredient as it appears in the Common Brazilian Denomination – "DCB";
- ANVISA product registration number;
- indications;
- contraindications;
- warnings related to adverse reactions and interactions with other substances;
- dosage;
- prescription and dispensing classification; and
- date of printing.

Where a promotional piece on a prescription drug highlights the benefits of the product, the piece must also highlight at least one contraindication and one frequent drug interaction.

For vaccines, the advertisement must convey the necessary number of doses for complete immunisation.

Products containing substances under special control, as defined in Ordinance 344/98 (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**), are subject to further regulation.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising to prescribing professionals may contain information related to data held on file or to clinical studies that have not been included in the registration package, or even phase 4 studies. The information, however, must conform to the information (indications, dosage, etc) already approved by ANVISA and must be available for consultation if requested by healthcare professionals or by the authorities. Information that does not conform to the registration package will be deemed as promotion of unauthorised use (off-label).

5.3 Advertising of Combination Products

Pharmaceutical products in Brazil may only be promoted for the indications that are approved by ANVISA, and such indications are those included in the registration package. That said, for it to be possible to promote any product, even in combination with another product, it would be necessary to amend the product registration to include this "combined use indication" in the product registration package and have it approved by ANVISA. Advertising of these combined products is subject to the same standard regulations.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

These are generally considered as scientific information and, as such, reprints may be distributed to healthcare professionals. There are no specific restrictions, but the reprint should not come in a format that resembles a promo-

tional piece. For the distribution of reprints, a company must have the authorisation of the author or of the media, as the case may be.

5.5 Medical Science Liaisons

There are no specific regulations related to medical science liaisons (MSLs) who – in Brazil – are under the same rules applicable to pharmaceutical representatives. Although most MSLs are themselves healthcare professionals, they cannot discuss unauthorised medicines or off-label indications.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

No prior authorisation applies to advertising of medicines. However, RDC 096/2008 sets forth that the organisers of scientific events at which the advertising and promotion of medicinal products will take place, must inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event. There are no specific regulations regarding medical science liaisons' (MSLs') reporting lines.

6.2 Compliance With Rules on Medicinal Advertising

There are no arrangements or standard operating procedures (SOPs) required by law or regulation in Brazil, in relation to advertising or promotional activities.

Companies are free to establish these according to their own policies. Companies are also free to not even implement any SOPs to guide their promotional activities.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The internet is regarded as just another form of media and, as such, the same legislation and regulations that apply to the advertising of medicinal products in traditional media in Brazil also apply to advertising on the internet, meaning that only advertising of OTC medicines is allowed.

If companies have internet sites that carry or include any type of promotion or advertisement of medicinal products, they need to ensure that advertising and promotion of prescription products can only be accessed by prescribing professionals.

RDC 096/2008 has only a few regulations that are specific to internet advertising. These regulate, for example, how warnings must appear (even indicating the type of font or requiring the use of bold fonts and capital letters in some specific cases).

In addition, CONAR recently issued its Digital Influencer Advertising Guidelines and a Guide of Good Practices for Digital Advertising for Minors, which are also applicable to advertising of any medical product using digital influencers or digital platforms, mainly regarding its clear identification as an explicit advertisement.

It should be stressed that ANVISA does monitor the health-related sites of pharmaceutical companies, pharmacies, distributors, clinics, etc, to make sure these rules are followed. However, exercising control over the content of internet sites is difficult as they exist in vast numbers and most of them contain a lot of information and

countless different pages and/or links. That said, it is not common to see violation notices or fines applied for non-compliance with internet rules.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As the promotion/advertising of prescription medicines can only be made to healthcare professionals, any website containing adverts of these products must have access controls and restrictions.

7.3 Provision of Disease Awareness Information to Patients Online

Online disease awareness campaigns are allowed and, in fact, are very common in Brazil. The Brazilian health authorities are among the more common users of these campaigns and implement several of them each year especially related to vaccines, AIDS, hepatitis, influenza, and tropical diseases. These campaigns can be found on the internet sites of the Ministry of Health, the State Health Department and even municipal health departments.

Note that in online disease awareness campaigns, and/or material provided through this channel, no specific medicinal product or trade mark should be mentioned. The campaigns should simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for diagnosis or vaccination.

7.4 Online Scientific Meetings

The rules applicable to scientific meetings or congresses also apply to online events. Although there are no specific rules issued to online scientific meetings in Brazil, the sponsor should implement the same filters and controls required at presential events of the same nature. That said, these online meetings may or may not be considered international depending on their scope and content. No previous authorisation is needed.

In the same manner applicable to the online advertisement of prescription-only drugs, access to online materials must be subject to appropriate controls and restrictions during and after the online meeting or congress. No specific regulation applies to the use of social media by pharmaceutical companies' employees.

7.5 Use of Social Media

See **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

There is no anti-bribery/anti-corruption legislation or regulations specifically applicable to the interaction between pharmaceutical companies and healthcare professionals/organisations, or to the pharmaceutical industry in general.

In Brazil, bribery and corruption are regulated by:

- the Penal Code, as amended by Federal Law 10.467/2002;
- Federal Law 12.846/2013, which penalises actions against national or foreign public administrations (penalties apply to both individuals and organisations); and
- Federal Law 8.249/1992, applicable specifically to public workers/agents.

Anti-bribery/anti-corruption authorities will only investigate breaches related to advertising of pharmaceutical products to the extent that the breach constitutes an action of corruption or bribery.

8.2 Legislative or Self-Regulatory Provisions

As per applicable regulations, especially Resolution RDC 96/2008, pharmaceutical companies are not allowed to grant, offer, promise or distribute gifts, benefits and advantages to:

- professionals who prescribe or distribute medicines;
- those who directly sell medicines to consumers; and
- the public in general.

The rules apply to both individuals and/or organisations.

INTERFARMA also expressly regulates the issue in basically the same way as RDC 96/2008. Violation of the INTERFARMA code will subject the company to administrative penalties, eg, suspension or exclusion from the association and a pecuniary penalty that may be extremely steep.

It should be noted that the Federal Medicine Council, which regulates the medical profession in its Code of Conduct and Resolution 1.939/2010, prohibits physicians from participating in any advertisements or promotion of medical information for any promotional purposes and, also, to register patients or enrol them to participate in promotional actions, such as discount programmes.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Companies may offer gifts to healthcare professionals. However, as per the applicable regulations, only gifts of nominal value can be offered and these gifts must be of an "institutional" nature, meaning they cannot bear marks or signs that link them to any specific product. Some class associations like INTERFARMA, also require that the gifts:

- be related to the medical practice, which excludes all kinds of office supplies and gifts of a personal-use nature that are not considered directly related to the medical practice;
- are of a symbolic value (around USD50); and
- are limited to three per year per doctor.

9.2 Limitations on Providing Samples to Healthcare Professionals

Samples may be provided to healthcare professionals, with a few exceptions:

- samples of non-prescription products;
- biological products; and
- products prepared in compounding pharmacies.

The procedures related to the distribution of samples are clearly regulated in RDC 096/2008 and RDC 060/2009. Products containing substances under special control, eg, narcoleptics, which are included in Ordinance 344/1998 (controlled substances) are subject to additional regulations.

A free sample package must contain 50% of the quantity of an original package. However, in the case of products for chronic diseases and a few others, like contraceptives, samples

must have the same quantity of the registered original. Samples of antibiotics must contain a complete treatment for one patient. Applicable regulations require that free sample packages are clearly and indelibly marked with the words "free sample".

The distribution of free samples is limited to ambulatories, hospitals, medical doctors' offices, and dentists' offices. The prescribing professional receiving the samples must sign a document indicating receipt of the samples.

Regulations on samples, especially RDC 060/2009, require that holders of the product registration must keep on file, for a minimum of two years after each lot's expiry date, all documents related to the production, distribution, and pharmacovigilance data of the free samples, even if not distributed, and must send ANVISA, annually, information on the production and distribution of free samples.

9.3 Sponsorship of Scientific Meetings

The sponsorship of scientific events by pharmaceutical companies is allowed and is also regulated under RDC 096/2008, although there is no direct or specific regulation that directly mentions hospitality.

The INTERFARMA Code of Conduct is more detailed than the ANVISA regulation and does indicate that locations of primarily touristic appeal are not permitted. No approval from the local affiliate is required.

There is no specific threshold applicable, but the venues and activities must not be excessive or inappropriate for a healthcare event. Under the INTERFARMA Code, events should take place in the country where the organiser is located, except if the choice of a foreign country is justifiable for reasons of security or logistics.

It should be noted that payment or any type of remuneration, direct or indirect, for the time invested in participation cannot be made to participants. Also, payments for travel, accommodation, food, etc, are limited to the participant and cannot be extended to family members or other invitees of the doctor.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are allowed to organise and sponsor cultural, sports and other events, provided they are under the corporate trade marks of the companies concerned. These types of events cannot be organised using the names or trade marks of prescription-only drugs.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

There is no specific regulation in Brazil with direct and clear wording on this.

However, throughout the applicable legislation and ancillary regulations it is made very clear that promotional actions towards prescribing professionals should not be (or be understood to be) in exchange for prescriptions of any product. In this case, also, it is advisable that grants and donations are regulated by contracts indicating the reason for the grant or donation.

In relation to healthcare institutions, these donations must also be of an institutional nature. In addition, they must clearly not be linked to any requirement or for the effect of serving as an incentive for the recipient institute to promote, advertise or standardise the use of any medicinal product of the donor.

Donations should be covered by contracts that should have a specific clause to make this as evident as possible. The contracts may, and should, define the specific purpose of the donation and include clauses that give the donor the right to audit the use of the donations.

From a regulatory point of view, there is no difference between monetary or equipment donations. Some donations may be subject to taxation and specific rules will apply.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Usually, rebates or discounts are granted to distributors and retailers. The industry is allowed to grant discounts and rebates, provided they are within commercial market practices and in line with the rules set forth in RDC 096/2008.

9.7 Payment for Services Provided by Healthcare Professionals

Companies may hire healthcare professionals to render any reasonable and justifiable professional services such as consulting services and review of dossiers, etc. Payment for the services must be within market practices.

When hiring professional services from healthcare professionals, a contract should be executed clearly defining the services to be provided. If a healthcare provider is hired to give classes and/or presentations at the start of any such class or presentation, the doctor must indicate that they are receiving payment for that service as disclosure of potential conflict of interest.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Healthcare professionals linked to either government institutions or private companies must observe transparency and the conflict-of-interest norms set forth in their respective employment agreements and in the applicable law. Usually, government employees are prevented from rendering services to any private companies even if there is no apparent conflict of interest. Government employees may give speeches and/or presentations but cannot be paid for these. In some cases, prior authorisation or notification may apply, mostly for healthcare professionals, employed by private companies.

Furthermore, organisers of scientific events at which the advertising and promotion of medicinal products will take place, are also required to inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Resolution RDC 096/2008 requires that healthcare professionals disclose to events' organisers and participants any sponsorship by companies and/or eventual conflicts of interest.

There is no obligation to disclose the amount or details of any sponsorship. Speakers at events, symposiums, congresses, etc, must, however, disclose if they are sponsored by any compa-

ny at the start of their presentation and in the records of the event, if they exist.

It is important to point out that INTERFARMA's Code of Conduct recommends making the public the recipient of sponsorships and donations.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

See **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. In cases where the donor is a foreign company not subject to Brazilian Law, authorisations and notifications, if any, should be addressed by the grantee.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Enforcement of advertising rules is mainly exercised by ANVISA. The ANVISA department that holds the authority for supervising and judging advertising/promotional violations is located under the General Management in Charge of Sanitary Inspection and Supervision ("GGFIS").

As regulated by RDC 096/2008, the authorities also have the power to request that, if corrective statements are required, these will be issued and published by the companies.

Any final administrative decision, as per Brazilian law, may be submitted to the judiciary if the regulated entity/individual believes the administrative decision does not conform to the law. Enforcement may also be sought through class associations such as INTERFARMA, ABIMIP or SINDUSFARMA.

Finally, in the case of non-prescription medicines, enforcement may be sought through CONAR.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated ex officio by the regulatory authority, or by a competitor. Most of the time, the basis is some indication or evidence that the advertising rules have been breached by the accused party. Proceedings can be started before ANVISA and/or before any of the class associations mentioned.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Penalties imposed by ANVISA will range from:

- a warning;
- the prohibition of advertising; the obligation to provide a rectifying message; suspension from new advertisements; and/or
- the payment of a fine that may range from BRL2,000 to BRL1.5 million.

The penalties imposed will depend on ANVISA's evaluation of the gravity of the violation.

11.4 Relationship Between Regulatory Authorities and Courts

There is no relationship between the regulatory authority and the courts. However, the courts will tend to confirm decisions of the regulatory authority or class associations, as they realise that these bodies have a better technical knowledge of the field.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Recently, there has been a wave of comparative OTC advertisements and, given the speed necessary to block irregular advertising, CONAR has taken the lead in ruling these cases. The most significant decisions were about the veracity of the comparisons and the irregular use of trade marks in the advertisement (one leading case is: CONAR representation 240/19).

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The manufacturing, importation, distribution, and sales of veterinary medicines are regulated and supervised by the Ministry of Agriculture, Livestock and Supply. The advertising of veterinary products is very different from that of human medicines and is only marginally regulated by Law-Decree 467/1969, by Federal Decree 5.053/2004 and by the Brazilian Advertising Self-Regulation Code. These rules are enforced by the authorities by means of warnings, fines or cancellation of the company's registration.

Lopes Muniz Advogados is recognised as a multi-field action firm, known for solutions that grant security to its clients and give them the confidence they need to face their legal challenges. In the field of life sciences, the firm renders services in the areas of pharmaceutical and biological products, other health-related products (medical devices), food and food supplements. The firm's work model is based on specialised teams, led by one or more partners, that have hands-on participation in finding solutions and in determining strategies for each case, assuring high-quality legal advice. The firm's life sciences area is composed of a team of lawyers with recognised experience in regulatory and sanitary legislation.

Authors

Marcos Lobo de Freitas Levy is a senior partner at Lopes Muniz Advogados with over 40 years of experience working both in-house and as a legal consultant. He is a former director of legal and corporate affairs of MSD Brazil, legal director and associate general counsel of Pharmacia Brazil (Pfizer), and institutional relations director of Boehringer Ingelheim Brazil. He is widely published, including articles covering intellectual property, life sciences regulatory, and business ethics. Marcos is recognised as a leading legal practitioner in the area of life sciences in Brazil.

Mariana Carneiro Lopes Muniz is a partner at Lopes Muniz Advogados, where she is responsible for the corporate and contractual departments. She has over 15 years of experience working in the legal profession as a legal consultant. Mariana has extensive experience in the pharmaceutical area, especially in relation to clinical studies contracts. She has completed specialisation courses in corporate law and tax law. She has been regularly published on the topic of pharmaceutical advertising.

Julio Garcia Morais is a co-ordinator of the civil law department and of the regulatory department at Lopes Muniz Advogados. Julio has over 18 years of experience and his expertise covers civil and commercial litigation, including product liability, life sciences regulatory and other regulatory (advertising and telecommunications). He has taken specialisation courses and has extensive knowledge of civil law, medicine registration, digital law and data privacy law.

Contributed by: Marcos Lobo de Freitas Levy, Mariana Carneiro Lopes Muniz and Julio Garcia Morais,
Lopes Muniz Advogados

Lopes Muniz Advogados

Av. Brigadeiro Faria Lima
1656 – 5º andar
01451-001
São Paulo
SP
Brazil

Tel: +55 11 3038 0723
Email: mfl@almlaw.com.br
Web: www.almlaw.com.br

CHINA

Law and Practice

Contributed by:
Alan Zhou, Xuchun Huang, Xuan He and Qiuyan Dong
Global Law Office see p.101

Contents

CHINA

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Under the PRC legal system, advertising on medicines is subject to the following regulations.

- The Advertising Law serves as the foundation and was promulgated to regulate all types of advertising. It contains general principles and special provisions for pharmaceutical advertising. Regulators issue detailed measures for drug advertisements under the Advertising Law.
- The Drug Administration Law regulates the whole life cycle of a drug, including its advertising and promotional activities.
- The Anti-Unfair Competition Law prohibits unfair competition activities, including fraud, misleading promotions and commercial bribery. This general law applies to the pharmaceutical industry.

The major laws and regulations are:

- the Advertising Law (latest revisions effective in 2021);
- the Anti-Unfair Competition Law (latest revisions effective in 2019);
- the Law on the Protection of Consumer Rights and Interests (latest revisions effective in 2014);
- the Drug Administration Law (latest revisions effective in 2019);
- the Regulations on the Control of Advertisements;
- the Implementing Regulations of the Drug Administration Law (latest revisions effective in 2019);
- the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (the "Administrative Measures for Review of Drug Advertisements");
- the Provisions for Pharmaceutical Instructions and Labels;
- the Interim Measures for the Administration of Internet Advertising;
- the Administrative Measures for Online Drug Information Services (latest revisions effective in 2017);
- the Administrative Measures for Record-Filing of Medical Representatives (for Trial Implementation) (the "Administrative Measures for Medical Representatives");
- the Administrative Measures for the Receipt of Public Welfare Donations by Health and Family Planning Agencies (for Trial Implementation) (the "Administrative Measures for the Receipt of Public Welfare Donations");
- the Nine Criteria for the Incorrupt Practice of Staff of Medical Institutions (the "Nine Criteria");
- the Interim Provisions on Banning Commercial Bribery; and
- the Provisions for Supervision and Administration of Online Drug Sales.

In addition to the above laws and regulations, industrial associations and institutions also have their own codes of conduct to regulate members' promotion and advertising activities. These are normally referred to as "industry benchmarks". The major self-regulatory codes for medicine advertising include:

- the R&D-based Pharmaceutical Association Committee Code of Practice (the "RDPAC Code" – latest revisions (2022 revisions) will be effective from 1 April 2023) – the RDPAC is a member of the International Federation of

Pharmaceutical Manufacturers and Associations (IFPMA);
- the Pharmaceutical Industry Compliance Management Practices;
- the Code of Ethics for Pharmaceutical Enterprises in China;
- the Code of Ethics for Licensed Doctors in China;
- the Code of Professional Ethics for Licensed Pharmacists in China;
- the Guidance for Application of the Code of Professional Ethics for Licensed Pharmacists in China; and
- the Draft Code of Conduct for Chinese Medical Representatives (which has not yet been officially promulgated).

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes generally apply to the members of the relevant associations, including member organisations and/or individual members.

For example, the RDPAC Code applies to RDPAC's member companies (although the annotation of the RDPAC Code further notes that the Code covers all relevant company employees as well as subcontractors that carry out tasks on behalf of the company).

Other self-regulatory codes apply primarily to individual members. For example, the Code of Ethics for Licensed Doctors in China applies to licensed physicians, licensed assistant physicians, scholars and health administrative personnel, as well as healthcare institutions and certain other organisations.

None of these self-regulatory codes are mandatory. They are contractual in nature and reflect a certain level of industry consensus among a large group of market players. Some of these self-regulatory codes may reflect higher standards than laws and regulations. Others elaborate on issues with respect to which the law is silent, such as the scope of communications allowed with respect to off-label use of medicines and the level of substantiation required for promotional purposes.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The definition of advertising under the Advertising Law is broad. Advertising appears to cover any commercial activities whereby business operators or service providers directly or indirectly introduce and recommend products or services they are marketing by using certain forms of media.

The former State Administration for Industry and Commerce (SAIC), now reformed into the State Administration for Market Regulation (SAMR), and the Legislative Affairs Commission of the Standing Committee of the National People's Congress, summarise the characteristics of advertisements in their interpretations of the Advertising Law. They define an advertisement as a commercial activity that:

- is transferred through certain media (including both traditional media and new media), rather than directly between individuals or groups of individuals (eg, speech to specific audiences in a conference; one-to-one oral introduction to patients in a pharmacy);
- points to a specific commodity or service of a business operator as the identifiable beneficiary (the advertiser); and

- is for-profit and promotional purpose, ie, its purpose is to influence the public's attitude towards the commodities or services.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

For the purposes of this section, "information" in the narrow sense refers to the factual description and introduction of products and services. Under the Law on the Protection of Consumer Rights and Interests, consumers are entitled to know the correct information about the products and services, such as the price, place and date of manufacture, and term of validity.

Advertising, however, is about making recommendations for products or services. Its main purpose is to generate a positive attitude in the audience towards the products or services being presented.

Law Enforcement Perspective on Advertising

From a law enforcement perspective, the "information" part of an advertisement is not subject to legal scrutiny under the Advertising Law. For example, when reviewing the content of an advertisement, the SAMR tends to carve out the information that is required by laws and regulations to be provided to consumers, and will only scrutinise the rest of the advertisement as a "commercial advertisement".

Qualifying Events as Advertising

Whether disease awareness campaigns may qualify as advertising depends on whether the event is promotional in nature. If a disease awareness campaign simply provides general disease awareness information, then it is not likely to be regarded as advertising. If the information provided can be either individually or collectively viewed as pointing to a specific product, such information may be considered "drug information" and the campaign may be considered promotional in nature and may fall into the scope of advertising. Under the Administrative Measures for Review of Drug Advertisements, "drug information" may include drug names, diseases to which the drugs are applicable (functions and indications) or other drug-related content.

A disease awareness campaign may be aimed at healthcare professionals, patients or the general public, and there is no legal difference based on the type of audience. In practice, however, if a disease awareness campaign targets the general public, product-specific information is generally not allowed to be mentioned; otherwise, law enforcement is more likely to regard the campaign as advertising. Other compliance requirements are discussed in **7.3 Provision of Disease Awareness Information to Patients Online**.

2.3 Restrictions on Press Releases Regarding Medicines

The law in China does not prohibit press releases regarding medicines, but the promotion of medicines in the disguised form of press releases without prior regulatory approval is restricted. In practice, press releases are only allowed if they contain a strictly factual description of the medicine, such as the completion of clinical studies, the obtainment of relevant market approval, or the launch of a new product in a new jurisdiction. If the content of the press release exceeds such limited scope and includes elements of advertising/promotion, then it may fall into the scope of advertising and become subject to the Advertising Law.

There are generally no differences between press releases available in the specialised trade press and press releases in mainstream media.

2.4 Comparative Advertising for Medicines

The Advertising Law explicitly prohibits comparative advertising for medicines with respect to the medicine's efficacy and safety.

Comparison may nevertheless be allowed if the underlying activity is considered to be outside the scope of advertising. Under the RDPAC Code, comparison with other pharmaceutical products is generally allowed if the comparison is based on relevant and comparable aspects of the products and is capable of substantiation. Comparative claims, where possible, must not be misleading.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

PRC laws do not expressly prohibit the provision of information on unauthorised medicines or unauthorised indications but this is nonetheless prohibited under the Advertising Law if the sharing or provision of such information constitutes advertising. Under the Advertising Law:

- almost all drug advertisements are subject to the pre-approval of the local counterparts of the National Medical Products Administration (the NMPA; formerly known as China Food and Drug Administration) before release; and
- only advertisements of authorised medicines can be approved by the local NMPA (advertising may not refer to anything that is inconsistent with the medicine's instructions as approved by the authorities).

Therefore, in absence of the marketing authorisation, advertising on unauthorised drugs is unlikely to be approved and permitted by the local MPA.

As mentioned at **2.1 Definition of Advertising**, the definition and concept of "advertising" is broad. Pharmaceutical companies in China are cautious about providing information on unauthorised medicines or unauthorised indications to avoid what could constitute illegal advertising. Benchmark practice discourages this activity. For example, the RDPAC Code states that no pharmaceutical product may be promoted for use in China until the requisite marketing authorisation for such use has been given by the NMPA.

Also, under the RDPAC Code, in one-on-one visits with healthcare professionals, medical representatives are not allowed to provide information on unauthorised medicines or unauthorised indications without the supervision of medical experts (see **3.3 Provision of Information to Healthcare Professionals**).

3.2 Provision of Information During a Scientific Conference

There is no direct legal prohibition against providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals.

According to the RDPAC Code, off-label promotion is prohibited, but the prohibition is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. Also, the Code is not intended to restrict the full and proper exchange of scientific information concerning a pharmaceutical product.

However, if the information is promotional in nature, law enforcement may easily view it as prohibited advertising, especially if there is a large audience.

3.3 Provision of Information to Healthcare Professionals

Under the Administrative Measures for Medical Representatives, medical representatives are prohibited from misleading doctors on the usage of drugs, exaggerating or misleading the curative effect, concealing known information on adverse drug reaction and the information on adverse drug reaction reported by healthcare professionals. The pharmaceutical company as the marketing authorisation holder of the medicines is required to promptly correct any aforesaid wrongdoing by the medical representatives.

Therefore, when medical representatives are discussing scientific information on unauthorised medicines or indications with healthcare professionals, such information must conform with the aforementioned requirements. It is also advisable to have the competent department of the company review such information in advance to ensure the accuracy of the contents. The RDPAC Code states that pre-approval of off-label communication with healthcare professionals, whether in oral or written form, should be conducted by or under the supervision of medical experts instead of personnel with commercial functions.

3.4 Provision of Information to Healthcare Institutions

Public healthcare institutions in China generally do not procure drugs on their own initiative. Procurement is organised by the government through bidding performed on bidding platforms (including the recent volume-based procurement). Thus, public healthcare institutions usually do not have direct access to information on unauthorised medicines or unauthorised indications for the purposes of preparing budgets.

3.5 Information About Early Access or Compassionate Use Programmes

The concept of compassionate use programmes is only generally mentioned in the Drug Administration Law as a form of early access for patients. The draft measures regulating the use of medicines in extended clinical trials for compassionate use have not yet been promulgated.

PRC laws do not expressly prohibit the publication of compassionate use programmes; however, if the information on a programme that is released to the public cannot be proved necessary for the purpose of an expanded clinical trial for compassionate use, it might constitute advertising, which is not allowed to provide information on unauthorised medicines or unauthorised indications, as discussed in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Not all categories of medicines can be advertised to the general public. The Administrative Measures for Review of Drug Advertisements strictly prohibit advertising for several special categories of medicines such as:

- narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs;
- pharmaceutical precursor chemicals and medicines for drug rehabilitation treatment;

- drugs specially needed by the military and preparations made by military medical institutions;
- pharmaceutical preparations made by healthcare institutions; and
- drugs prohibited from production, sale or use by law.

Advertising of all other prescription-only medicines is only permitted in professional pharmaceutical or medical journals jointly designated by the Ministry of Health and the NMPA. Specifically, the Administrative Measures for Review of Drug Advertisements forbid the use of the names of prescription-only medicines to sponsor/title various activities for advertising, and also prohibit the use of any trade mark or trade name identical to the name of a prescription drug to publish any advertisement in a disguised manner in any media other than professional pharmaceutical or medical journals, or the use of such trade mark or trade name in the title of any activity for advertising.

Therefore, only over-the-counter medicines may be advertised to the general public, and such advertising must comply with substantive and procedural legal requirements. Under the Advertising Law, the Drug Administration Law and the Administrative Measures for Review of Drug Advertisements, advertisements for medicines are subject to review and approval from the drug regulatory department of the provincial-level government where the company is located (ie, the local MPA), which is more fully discussed in **6.1 Requirements for Prior Notification/Authorisation**.

Format and Medium of Medicine Advertising

There are also certain restrictions with respect to the format and medium of medicine-specific advertising. For example, medicine-specific advertising cannot be disguised as programmes introducing knowledge about health and well-being and such advertising may not be published in media that targets minors.

Medicine-specific advertising must comply with all the requirements that apply to advertising in general. For example, the Advertising Law states that advertising cannot contain national symbols, words such as “national”, “supreme”, or “best”, or obscene, violent or discriminatory language. Statistical citations and patent references must be true and accurate. In addition, advertising cannot degrade the goods and services of others.

Certain restrictions also apply to the format and medium of advertising in general. All advertisements published through mass media must be prominently marked as “advertisement”, and a distinction must be made by the advertiser between “advertisement” and “non-advertisement information”, so as not to mislead consumers. For example, advertising cannot be broadcast or published in the form of news reports.

Outdoor advertisements cannot be placed on military facilities or traffic signs, or in certain areas controlled by national institutions, cultural heritage sites and scenic spots. Without prior consent or request, advertisements cannot be sent to people’s residences or placed on transportation devices, or sent via electronic messages. Electronic messages must contain the sender’s identity, contact information and ways to unsubscribe from the messages.

Endorsements

Under the Advertising Law, no endorsement can be made in advertising for medicines, not even by a healthcare professional or a celebrity. The Administrative Measures for Review of Drug

Advertisements further prohibit the use of the names or images of experts, scholars, physicians, pharmacists and clinical nutritionists as a recommendation or endorsement.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

As mentioned at **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**, advertising directed at the general public can only be for over-the-counter medicines. All advertisements must be true, lawful and must not contain any false or misleading content. Advertisers are responsible for the veracity and legitimacy of the content.

Under the Advertising Law and the Administrative Measures for Review of Drug Advertisements, pharmaceutical advertising of a drug must include contraindications, adverse reactions and the drug advertisement approval number. For over-the-counter medicines, the advertisement should clearly use the abbreviation "OTC" and the following language: "Please follow the instructions for the drug or purchase and use it under the guidance of a pharmacist". For required content, fonts and colours must be clearly visible and legible. When released on TV, films, the internet and display screens, such content must be continuously displayed in the advertisement (rather than for only five seconds as required by previous regulations).

Also, pharmaceutical advertising cannot contain:

- assertions or guarantees of efficacy and safety;
- specifics about the cure rate or efficacy rate;
- comparisons with other drugs;
- endorsement by a spokesperson; or
- anything else that is inconsistent with the approved instructions.

Items Prohibited in Pharmaceutical Advertising

The Administrative Measures for Review of Drug Advertisements prohibit all of the following in pharmaceutical advertising:

- either openly using or using in disguised form the names or images of state organs, functionaries of state organs, military entities or military personnel, and the use of military equipment, facilities, etc for advertising purposes;
- using the names or images of research institutes, academic institutions, industry associations or experts, scholars, physicians, pharmacists, clinical nutritionists, patients and others for recommendation or as endorsement;
- using express or implied statements, contrary to valid science, that the product can cure all diseases, adapt to all symptoms and all groups of people, or that it is necessary for normal life and disease treatment;
- including content that induces unnecessary anxiety and fear among the public about their health status and the diseases they suffer from, or that lead to public misunderstanding that they will suffer from a certain disease or the disease will worsen if they do not use the product;
- the use of words and expressions like "safe", "safe, non-toxic and with no side effects" and "minor toxic side effects"; or expressed or implied statements that the ingredients are "natural", thus ensuring safety;
- including content that induces purchase, such as "hot sales", "rush to buy or use on a trial basis", "family necessities", "free treatment" and "free gifts"; comprehensive evalua-

tion such as "evaluation, ranking, recommendation, designation, selection and awards"; or content such as "refund if not effective" and "insurance with insurance companies" that encourages consumers to arbitrarily and excessively use drugs, health food and formula food for special medicinal purposes; or
- including content such as the name, address, contact information, service items and service methods of the medical institution, as well as such medical services as free treatment, medical consultation hotline, special outpatient service, etc.

Bullet points two to five might also trigger false advertising claims and subject the advertiser to strict penalties, as discussed in **11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe**.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

PRC law is silent on interactions between patient organisations and the industry, such as whether companies can sponsor patient organisations' meetings.

The latest RDPAC Code emphasses that the independence of patient organisations must be respected. No member company may require that it be the sole funder of the patient organisation or any of its programmes. If member companies wish to provide financial support or in-kind contribution to patient organisations, they must have written documentation setting out the nature of the support. Further, the primary purposes of such meetings or activities funded by member companies should be professional, educational, and scientific in nature, or otherwise support the mission of the patient organisation. In addition, any meals or refreshments provided must be modest as judged by local standards.

Regarding the direct distribution of drugs to patients under the Provisions for Supervision of Drug Distribution, prescription-only medicines and a sub-category of over-the-counter medicines are generally prohibited from being offered to patients for free, as in "buy one, get one free", or other quantity-related promotions. Donating prescription-only medicines to patients in a charity activity is not explicitly regulated under current Chinese laws and regulations. However, it is widely understood that patient aid programmes (PAPs) are, by nature, a charity activity that aims to provide drug assistance to financially burdened patients seeking to obtain drugs that are critical to their lives. Offering free prescription-only medicines is not prohibited under charitable PAPs conducted by qualified persons.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Both over-the-counter medicines and prescription-only medicines can be advertised to healthcare professionals (other than the categories for which advertising is entirely prohibited under PRC law). For prescription-only medicines, the advertising should be marked "This advertisement is for medical and pharmaceutical professionals only" in a prominent position.

Otherwise, the requirements and prohibitions for advertising directed at healthcare professionals are similar to the requirements and prohibitions for advertising directed at the general public that were discussed in **4.1 Main Restrictions**

on Advertising Pharmaceuticals to the General Public and 4.2 Information Contained in Pharmaceutical Advertising to the General Public.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under the Advertising Law and the Drug Administration Law, drug advertising may not refer to anything that is inconsistent with the medicine's instructions (similar to the summary of product characteristics in Europe) as approved by the authorities. The Administrative Measures for Review of Drug Advertisements specify that, where a drug advertisement involves a drug name, indications or major functions, pharmacological effects, etc, it may not go beyond the scope of approved instructions. Therefore, advertising may not refer to data on file or other clinical studies that are not already included in the instructions.

5.3 Advertising of Combination Products

Information on combination products needs to be included in a medicine's instructions (similar to the summary of product characteristics in Europe) under PRC law on the grounds that all usage information is legally required to be specified in a medicine's instructions. Therefore, in principle, there should be no information on combination products that is not included in the medicine's instructions, and advertising of such information is prohibited in that it is inconsistent with the medicine's instruction, as discussed in 5.2 Reference to Data Not Included in the Summary of Product Characteristics.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

The law in China does not prohibit companies from providing reprints of journal articles to healthcare professionals. Although generally allowed under the RDPAC Code, quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable regulations or administrative rules, in which case, it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

5.5 Medical Science Liaisons

Medical science liaison (MSL) is not a legal term under PRC law. However, medical representatives as professional personnel may assume some similar functions to those of MSLs as defined in the Administrative Measures for Medical Representatives, such as transmitting relevant information about medicines to healthcare professionals, assisting healthcare professionals in the rational use of the medicines, collecting and giving feedback on the clinical use of drugs and information on the demands of hospitals. The marketing authorisation holder (MAH) is required to file the information of its medical representatives and the medical representatives from contract sales organisations.

Although the law does not expressly prohibit medical representatives from discussing scientific information on unauthorised medicines or indications with healthcare professionals, according to the Administrative Measures for Medical Representatives, medical representatives are prohibited from undertaking drug sales targets, misleading doctors on the usage of drugs, etc.

As discussed in detail in 3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications and 3.3 Provision of Infor-

mation to Healthcare Professionals, in practice, pharmaceutical companies in China are cautious about providing information on unauthorised medicines or unauthorised indications to avoid what might be constituted as illegal advertising.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

As discussed at **4.1 Main Restrictions on Advertising Pharmaceuticals to the Public**, drug advertisements should be reviewed and approved, and obtain an approval number for the drug advertisement. The validity period of the approval must be consistent with the shortest validity period of the medicinal product registration certification or the manufacturing permit, and if no valid period is prescribed in such documents, the valid period for the approval will be two years.

After the approval is granted, the local MPA will file the approved advertising with the NMPA for record. Approved advertisements may be published nationwide in accordance with the PRC law.

6.2 Compliance With Rules on Medicinal Advertising

There is no legal requirement to adopt standard operating procedures (SOPs) or employ specific personnel. However, according to the RDPAC Code, a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. Alternatively, a senior company employee could be made responsible provided that they receive scientific advice on such communications from adequately qualified scientific personnel. In practice, large and medium-size pharmaceutical companies normally have their own SOPs guiding companies' advertising practices in order to guarantee legal compliance. Legal and/or compliance teams or external counsel may be involved to conduct compliance reviews of certain advertisements.

If the company entrusts an advertising agency to provide advertisement design or production or agent services on a commission basis, the Advertising Law requires advertising agencies and advertisement publishers to inspect and verify the relevant certification documents, and check the advertising contents in accordance with the law and administrative regulations.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Under the Interim Measures for the Administration of Internet Advertising, internet advertising may take various formats such as text, images, audio, video, or other forms on websites, web pages, or in applications (such as WeChat). In addition to all the requirements and restrictions regarding advertising in general (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**), a few additional requirements apply to internet advertising. For example, internet advertising cannot interfere with people's normal use of the network. Online pop-ups should be clearly marked with a closing sign to ensure a one-click closure. Advertisers may not deceive users into clicking on the advertising content. No advertisement or advertisement link may be attached to the emails sent by advertis-

ers or their agents without the recipient's prior permission. It is also prohibited to publish advertisements for prescription drugs on the internet.

In addition, the entity providing information on pharmaceuticals to online users via the internet is subject to the Qualification for Internet Drug Information Services issued by the competent local MPA according to the Administrative Measures for Online Drug Information Services. It is also prohibited to publish product information on narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, medicines for drug rehabilitation treatment, and pharmaceutical preparations prepared by healthcare institutions on such websites that provide online pharmaceutical information.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

The law in China does not explicitly require companies to include access restrictions on websites containing advertising or other information intended for healthcare professionals. In practice, many companies do have this arrangement in place, such as asking whether the user is a healthcare professional or conducting an identification verification before the user can access the contents on specific web pages or columns publishing scientific information on diseases and prescription drugs, to avoid being perceived as advertising prescription drugs to the public on the internet.

7.3 Provision of Disease Awareness Information to Patients Online

Provision of disease awareness information and/or materials to patients online is not legally prohibited but might be regarded by law enforcement as advertising if the information provided can be viewed as being promotional in nature or pointing to a specific product, as discussed in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

According to a summary of the relevant laws, provision of disease awareness information and/or materials to patients online, or in other ways to the general public, must be compliant with the following requirements:

- firstly, the provision should not include information on drugs, otherwise such provision will constitute advertising subject to approval for pharmaceutical advertising;
- secondly, the provision should not constitute retailing of pharmaceutical products without a distribution licence; and
- thirdly, other general rules on patient education also apply, including diagnosis and treatment not being included, not discrediting competitors, and not constituting false promotion.

7.4 Online Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor online scientific meetings or attendance by healthcare professionals of these online events. As with sponsoring of off-line scientific meetings, bribery in any form, such as provision of a participation subsidy, is strictly prohibited (see **9.3 Sponsorship of Scientific Meetings**).

PRC law is silent on the criteria required for an online meeting to be viewed as an "international" event. In practice, this generally depends on where the speakers and attendees come from. With reference to the RDPAC Code, it defines an "international" event as a scientific meeting where a significant proportion of the speakers and attendees come from countries other than the country in which the meeting takes place.

PRC law does not explicitly require prior authorisation in relation to healthcare professionals' participation in online scientific meetings, while in practice, pharmaceutical companies normally require doctors to obtain prior consent from their working hospital to ensure healthcare professionals are permitted to participate. Under the RDPAC Code, healthcare professionals should be informed of the details of the intended medical interaction programmes in advance, especially for online interactions through push email, social media, etc.

Separately, there are no special statutory requirements on (i) sharing handouts, materials, etc, during an online conference; or (ii) accessing conference recordings, materials, etc, after the date of the conference. For handouts and materials of an advertising nature, see **5. Advertising to Healthcare Professionals**. Also see **3.2 Provision of Information During a Scientific Conference**, which discusses providing information on unauthorised medicines or unauthorised indications.

7.5 Use of Social Media

The Interim Measures for the Administration of Internet Advertising cover advertising on social media as part of "internet advertising". Therefore, advertising on social media is generally allowed to the extent that internet advertising is allowed. Both pharmaceutical companies and their employees need to comply with the relevant medical advertising regulations as specified herein when publishing pharmaceutical advertisements on social media. If a pharmaceutical company or its employees illegally advertise drugs in social media articles, live streams or WeChat Moments, they will be punished.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery legal system includes laws at both the administrative and criminal levels.

Administrative Law

At the administrative level, the legal framework regulating commercial bribery is set out by the Drug Administrative Law, the Anti-Unfair Competition Law, together with the Interim Provisions on Banning Commercial Bribery, and a number of replies by the former SAIC on the handling of commercial bribery acts. The Drug Administrative Law states that:

- pharmaceutical companies and healthcare organisations may not offer or accept any kick-backs or improper benefits;
- pharmaceutical companies may not offer any improper benefits to healthcare professionals or other related staff in any healthcare organisation which uses their drugs; and
- healthcare professionals and related staff of a healthcare organisation may not receive any improper benefits from the pharmaceutical companies.

The key provision under the Anti-Unfair Competition Law states that business operators may not resort to bribery, by offering money or goods or by any other means, to any of the following entities or individuals, in order to seek a transaction opportunity or competitive advantage:

- any employee of the counterparty to a transaction;

- any entity or individual entrusted by the counterparty to a transaction to handle relevant affairs; and
- any entity or individual that is likely to take advantage of powers or influence to affect a transaction.

Penalties for violation include fines, confiscation of illegal gains and revocation of business licences in serious cases. The legal representative, main person-in-charge and directly responsible staff may be prohibited from engaging in drug production and distribution activities for life.

Public Healthcare Institutions

In practice, with respect to public-funded healthcare institutions, law enforcement takes the view that the purchasing of medicines "pierces" through the healthcare institution and should actually be viewed as transactions that take place between the pharmaceutical industry and the patients/medical insurance fund. Under this theory, the patients/medical insurance fund becomes the counterparty to the transaction, and both healthcare institutions and healthcare professionals, with their power to prescribe medicines to patients, fall into the scope of entities and individuals having the power or influence to affect a transaction. As a result, the general anti-bribery rules apply to benefits provided to healthcare professionals and benefits provided to public healthcare institutions.

Adverse Records

Other than an administrative penalty, a pharmaceutical entity that conducts commercial bribery may also be discredited with an adverse record of commercial bribery by the provincial health commission. In this case, public medical institutions or medical and health institutions that receive financial funds from local government in that provincial region may not purchase medicines, medical equipment or medical supplies from such pharmaceutical entity within two years after the publication of the adverse records. If a pharmaceutical entity has adverse records of commercial bribery two or more times within five years, no public medical institutions or medical and health institutions that receive financial funds across the country can purchase medicines, medical equipment or medical supplies from that pharmaceutical entity. In addition, under the Guiding Opinions of National Healthcare Security Administration on Establishment of the Creditworthiness Evaluation System for Drug Pricing and Procurement by Bidding, if the pharmaceutical entity takes part in commercial bribery, it will have an adverse credit and may be subject to negative treatment such as a warning, automatic risk heads-up in centralised procurement, and even suspension of listing or procurement, tendering and delivery of drugs.

Criminal Law

At a criminal level, the Criminal Law prohibits both individuals and entities from bribing several types of recipients. These include:

- state functionaries;
- the close relatives of or other persons closely related to a state functionary;
- a former state functionary or close relatives of or other persons closely related to the former state functionary;
- state agencies, state-owned enterprises, public institutions or people's organisations;
- employees of a company; and
- foreign individuals performing official duties or officials of an international public organisation.

Penalties for individuals include fines or confiscation of property and criminal detention or

fixed-term imprisonment ranging from three years to life imprisonment. For entities, penalties include fines and criminal detention or fixed-term imprisonment for up to five years for the responsible individuals.

8.2 Legislative or Self-Regulatory Provisions

The Drug Administration Law prohibits drug marketing licence holders, drug manufacturers, distributors and their agents from providing any property or other improper benefits to the responsible person, the procurement personnel, physicians, pharmacists and other relevant individuals of a health institution that uses their drugs. The listed categories of individuals are also prohibited from receiving these benefits.

Under the RDPAC Code, if a member company engages healthcare professionals to serve as the company's consultants or advisers, one of the requirements for such an engagement is that the hiring of the consultants or advisers to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine.

In regulatory practice, benefits provided to healthcare organisations for inducement to prescribe may be deemed as improper benefits and are therefore also forbidden. See **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals** for further detail.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The Interim Provisions on Banning Commercial Bribery promulgated by the SAIC permit gifts of "small value" to be provided in the course of customary business practice and would not consider these to be commercial bribery. However, there is no legal guidance on the maximum amount of "small value".

Gifts (such as sporting or entertainment tickets, social courtesy gifts) for the personal benefit of healthcare professionals, either directly or through clinics and institutions, are prohibited under the RDPAC Code. Providing or offering cash, cash equivalents or personal services is also prohibited.

However, promotional aids of minimal value (not more than RMB100 in value per item) and minimal quantity may be provided or offered to healthcare professionals solely for the promotion of over-the-counter medicines if relevant to the practice of the healthcare professional. Similarly, items of medical utility to enhance the provision of medical services and patient care are also conditionally permitted under the RDPAC Code with a limit of RMB500 per item. Even if each individual item is appropriate, such offering should not be made on more than an occasional basis.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to the RDPAC Code, samples of a limited quantity of a pharmaceutical product may be supplied directly to healthcare institutions so healthcare professionals can familiarise themselves with the product, but these should be delivered through a qualified third party. Samples should be marked so that they cannot be resold or otherwise misused. Member companies should have adequate systems of control and accountability for samples provided to healthcare professionals through healthcare

institutions with respect to the distribution, delivery and acceptance of samples.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are generally allowed to sponsor scientific meetings and the attendance by healthcare professionals.

Under the Administrative Measures for Review of Drug Advertisements, the sponsored event cannot be titled the same as the name of any prescription-only medicine and cannot be titled the same as a trade mark or trade name that is identical to the name of a prescription-only medicine.

Under the RDPAC Code, member companies may sponsor healthcare professionals to attend medical interaction programmes if such sponsorship complies with the following requirements:

- the programme itself complies with the requirements in the RDPAC Code;
- the sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- no payments are made to compensate healthcare professionals for time spent attending the programme;
- under no circumstances should a company make any payment or transfer any sponsorship funds directly to a healthcare professional or a hospital department; and
- any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Under the Interim Provisions on Banning Commercial Bribery promulgated by the SAIC, commercial bribery includes both monetary bribery and other means, where "other means" refers to non-monetary benefits, such as tours and field trips in China or abroad.

Similarly, under the RDPAC Code, no entertainment or other leisure or social activities may be provided or paid for by member companies. Cultural, sports or other non-scientific events in relation to scientific conferences may easily fall into the scope of "entertainment or other leisure or social activities" and, therefore, are generally prohibited by the RDPAC Code.

Moreover, under the Nine Criteria, healthcare professionals are prohibited from participating in entertainment activities arranged, organised or paid for by pharmaceutical manufacturers, distributors or their agents.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide grants or donations to healthcare institutions in accordance with the Administrative Measures for the Receipt of Public Welfare Donations. However, pharmaceutical companies are not allowed to specifically appoint the healthcare professionals from the healthcare institutions as the recipients of donations.

Under the above Measures, the recipient institutions are encouraged to use a third-party agency to confirm the value of non-monetary donations, and the ways in which recipient institutions can spend the donations differ depending on the type of donations.

Additionally, in practice, donations of equipment or services may be higher risk than monetary donations because, in addition to potentially violating the Measures, a wrongful donation of equipment or services may also be seen as offering equipment or services in connection with the sale of medicines under the prohibited buy-one-give-one model, thus violating the Provisions for Supervision of Drug Distribution.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

As discussed in **3.4 Provision of Information to Healthcare Institutions**, the procurement of drugs in China is organised by the government through bidding on bidding platforms. The Drug Administration Law explicitly prohibits drug marketing licence holders, pharmaceutical manufacturers, distributors and healthcare institutions from giving or receiving rebates or other improper benefits in the purchase and sale of drugs.

Moreover, under the Nine Criteria, healthcare professionals are prohibited from accepting any rebate offered by pharmaceutical manufacturers, distributors or their agents in any name or form.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay for services provided by healthcare professionals at fair market value under certain circumstances. For example, companies may invite healthcare professionals to give lectures or to serve on the company's advisory boards and attend board meetings.

The RDPAC Code sets out a large number of restrictions on the amount of payment allowed. Chief among these restrictions are: the hiring of the healthcare professional to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine, and the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Companies' SOPs may set out more specific restrictions on the amount of speaker fees, consultation fees and relevant expenses for meals and transportation, and may require employees to provide documents to prove the services provided by the healthcare professionals.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The law in China does not explicitly require prior authorisations or notifications in relation to gifts, hospitality, congresses and related payments described in this section. In practice, however, employers often do require that employees obtain prior consent from their employer before engaging in such activities.

In particular, doctors employed by medical institutions cannot practise outside the registered medical institution without due record-filing, and their personal activities are more closely managed by the registered medical institutions. Their activities in relation to gifts, hospitality, congresses and related payments described in this section will likely require the employer's prior consent.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The law in China does not provide explicit disclosure requirements for pharmaceutical companies.

The RDPAC Code states that if material relating to pharmaceutical products and their uses, whether promotional in nature or not, is sponsored by a member company at medical interaction programmes between member companies and healthcare professionals, that material should clearly indicate by whom it has been sponsored. Medical interaction programmes hosted or sponsored by member companies, whether promotional in nature or not, should clearly indicate by whom they have been hosted or sponsored. If a member company sponsors medical interaction programmes organised by a third party, the above disclosure should be made subject to the knowledge and consent of the organiser.

Under the Administrative Measures for the Receipt of Public Welfare Donations, the recipient institution must establish a publication system for donation information and must publish donation receipt information to the society in an authentic, accurate, timely and complete manner via their web portals or local major news media.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

There are no explicit legal transparency requirements targeting foreign companies. As self-regulatory codes are contractual in nature, if a company undertakes to be bound by certain self-regulatory codes, it will be subject to the same transparency requirements regardless of whether the company is domestic or foreign and regardless of whether its products are already on the market.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The SAMR

Until 2018, the SAIC and its local branches were responsible for enforcing the rules on advertising and the rules on inducement. Since the government restructuring in 2018, the SAIC has become part of the SAMR which, together with its local branches, is responsible for enforcement actions. The restructuring enabled the SAMR to combine the SAIC's enforcement mechanism and the NMPA's familiarity with the pharmaceutical industry, as a result of which, supervision of this industry has been strengthened.

The RDPAC Code

The RDPAC Code has also created its own dispute resolution system, providing member companies with the opportunity to file complaints against competitors and to request that the association enforce its rules through the established panel review, mediation or sanction procedures.

The People's Court

In the event that a pharmaceutical advertisement is recognised as false advertising, causing damage to the legitimate rights and interests of consumers, the consumers may file a lawsuit with the People's Court and claim for damages.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Companies can initiate proceedings against competitors in court for advertising infringements on the basis of the Anti-Unfair Competition Law and the Civil Procedure Law. Companies may also file complaints against competitors with the SAMR or its local branches in accordance with the provisions in the Law on Administrative Penalty. Additionally, member companies may also initiate panel review or meditation procedures as established by the RDPAC Code.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The penalties or measures for violating medicines advertising rules are mainly found in the Advertising Law and the Administrative Measures for Review of Drug Advertisements. The penalties and measures include ordering the cessation of the publishing of the advertisement, ordering the advertisers to eliminate negative impact, imposing fines, confiscating advertising fees and revoking business licences and approval documents for the advertisement. The penalties can be imposed on the advertiser, the advertising agency or the advertising publisher. The penalties imposed are listed in the National Enterprise Credit Information Publicity System for public notification.

For example, in the case of false advertising, law enforcement will order that the advertisement be stopped and that the advertiser eliminate the negative impact. The advertiser may be fined, and its business licence may be revoked; further, the local MPA may revoke the advertisement's review and approval document and not accept applications from the advertiser for one year.

In serious cases, there may also be criminal responsibilities. For example, false advertising may result in criminal detention or fixed-term imprisonment of up to two years for advertisers, advertising agencies or advertising publishers. Criminal fines may also be imposed separately or concurrently.

With regard to inducements to prescribe, if a case involves commercial bribery, then the penalties under the Anti-Unfair Competition Law and the Criminal Law discussed at **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals** will become relevant.

11.4 Relationship Between Regulatory Authorities and Courts

There is no direct relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by the courts. The former is not a prerequisite for the latter. Specifically, regarding the RDPAC Code, there has yet to be any case where a court has considered a decision under the RDPAC Code as a basis for the court's decisions.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

From 2017 to date, an increasing number of cases have been investigated and penalised by the law enforcement authorities. This might be relevant to the 2018 government restructuring discussed in **11.1 Pharmaceutical Advertising: Enforcement Bodies**. It is anticipated that cases related to pharmaceutical advertising might increase after the Administrative Measures for Review of Drug Advertisements have been implemented for a longer period of time and before the advertisers become familiar with the new rules, because they impose new require-

ments on advertisers and clearer guidance to law enforcement officials.

In practice, the main reasons that penalties are imposed on illegal pharmaceutical advertising include:

- the pharmaceutical advertising is published without approval;
- the pharmaceutical advertising of prescription-only drugs is publicly published on media other than the pharmaceutical or medical journals designated by the Ministry of Health and the NMPA;
- the pharmaceutical advertising does not list contraindications or adverse reactions and goes beyond the scope of its instructions; and
- the drugs advertised are not permitted to be advertised, eg, narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs.

In a recent high profile law enforcement case, an over-the-counter pharmaceutical company published its pharmaceutical advertising three times on a popular domestic variety show and was fined RMB900,000 for the reasons specified in bullet points one and three above. In March 2021, a branch of the SAMR in Shanghai imposed a fine of RMB200,000 on a pharmaceutical entity for the reasons specified in bullet points one and two above because the pharmaceutical entity had published an article via online media recommending a prescription-only drug.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

In China, veterinary medicine advertising should also comply with the Advertising Law. In addition, the Regulations on the Administration of Veterinary Medicines and the Regulations on the Review and Publication of Veterinary Medicine Advertisements also stipulate the contents, publication and supervision of veterinary drug advertisements.

Veterinary medicine advertisements also need to be reviewed before they can be published. Veterinary medicine advertisements that are published in key national media shall be reviewed and approved by the veterinary administrative department under the State Council, and veterinary medicine advertisements that are published in local media shall be reviewed and approved by the provincial veterinary administrative department. The SAMR is responsible for the supervision and management of veterinary medicine advertising.

According to the laws and regulations in China, the following veterinary medicines may not be advertised:

- veterinary narcotic drugs, psychotropic drugs and veterinary drug preparations prepared by veterinary medical units;
- the types, contents and names of a veterinary drug's ingredients that do not conform to the national standards for veterinary drugs;
- veterinary drugs that have toxic side effects beyond the prescribed clinical application; and
- veterinary drugs that are prohibited by the administrative department of agriculture and animal husbandry under the State Council, or that have not obtained the approval number of veterinary drug products or have not obtained the "Registration Certificate for Imported Veterinary Drugs".

In terms of the content, veterinary medicine advertisements must not:

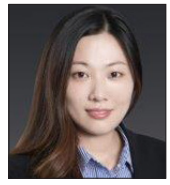
- contain assertions or guarantees indicating efficacy or safety;
- use the name or image of scientific research units, academic institutions, technology promotion institutions, industry associations, professionals and users as recommendations and proof;
- explain the efficiency;
- use text, language or pictures that violate safe use regulations;
- disparage similar products and compare the efficacy and safety with other veterinary medicines;
- use absolute expressions, such as "most advanced technology", "most advanced science", "most progressive method", "curing all diseases";
- contain comprehensive evaluation content such as evaluation, ranking, recommendation, designation, selection and award;
- use a picture that directly shows the symptoms and pathology of the disease, or make promises such as "invalid refund" and "insurance company insurance";
- claim that the scope of use exceeds the provisions of the national veterinary drug standard; or
- feature other content prohibited by laws and administrative regulations.

If a company violates the relevant regulations, it will be required to stop publishing such advertisements, eliminate the impact, and will be fined or have its business licence revoked.

Global Law Office was one of the first law firms in the PRC, dating back to 1979, and is one of the largest, with around 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. The life sciences and healthcare (L&H) practice group is one of the leading advisers in China, providing "one-stop" legal services for every area of the L&H industry, including drug R&D, clinical research organisations, pharmaceuticals, life sciences, biotechnology, medical devices, supply producers and distributors, hospitals and other healthcare providers, as well as various investment funds in the L&H sector. Global Law Office advises clients on challenging L&H legal issues, such as regulatory compliance, structuring transactions and contractual arrangements, realisation of pipeline and geographic expansions, capital raising and project financing, M&A, reorganisations, IP protection, licensing and distribution arrangements, settlement of disputes involving adverse effects in clinical trials and medical treatment.

Authors

Alan Zhou is the leading partner in the life sciences and healthcare (L&H) team at Global Law Office, with a strong background in L&H practice. He focuses on M&A, private equity/venture capital, regulatory compliance and general corporate. Alan has routinely represented multinational corporations, such as Sanofi, Siemens, AstraZeneca, GSK, Boehringer Ingelheim and Novartis, as well as local L&H companies. As a participant or external counsel, he has been engaged by local authorities and industrial associations to advise on legislation and industrial standards in the L&H industry, on topics including online hospitals, digital marketing, medical insurance reform, medical representative management and other compliance matters.



Xuchun Huang (Charlene) is a partner at Global Law Office. She specialises in cross-border acquisitions and foreign investment, and has in-depth experience advising multinational companies in general corporate, cybersecurity and data management. Her clients are in the healthcare industries and her transactions include greenfield foreign investment in the form of joint ventures or wholly foreign-owned enterprises, acquisitions of equity interests in Chinese state-owned or private companies, the restructure or integration of China-based businesses of multinational companies, and strategic co-operation. Charlene has given day-to-day advice and worked on substantial projects for Abbott, Align Tech, Boehringer Ingelheim, Eli Lilly, GE, the HRC, among others.

Xuan He (Samantha) is a partner at Global Law Office. Her practice is primarily focused on the life sciences industry, and she has represented a number of major life sciences companies on compliance and regulatory matters and corporate issues. Through her significant experience in the life sciences industry, she has acquired insights into the evolving legal and regulatory landscape in China. She advises clients on regulatory matters across a range of sectors, including drugs and biologics, medical devices, and e-health products and services. Samantha also counsels clients on regulatory and compliance issues, including advertising, anti-corruption and bribery, medical affairs, manufacturing and distribution.

Qiuyan Dong (Sylvia) is an of counsel at Global Law Office. Her main practice covers general corporate, M&A, private equity/venture capital and the capital market, and she is especially focused on the life sciences industry. She has represented well-known clients in various domestic and cross-border transactions, strategic investments and collaborations, as well as securities offerings and bond offerings. She has rich experience in investment, licence deals, business collaborations, general corporate and compliance in the life sciences and healthcare industries.

Global Law Office

36th Floor
Shanghai One ICC
No 999 Middle Huai Hai Road
Xuhui District
Shanghai 200031
China

Tel: +86 021 2310 8288
Fax: +86 021 2310 8299
Email: alanzhou@glo.com.cn
Web: www.glo.com.cn

环 球 律 师 事 务 所
GLOBAL LAW OFFICE

Trends and Developments

Contributed by:
Hans She, Qian Luo and Jasmine Zhang
Fangda Partners see p.108

China – the Regulation of Pharmaceutical Advertising in 2022

Following the amendments to the PRC Advertising Law in 2021 (with harsher penalties put in place), in China, 2022 was a year of generally smooth transition in respect of the legislation and regulation on pharmaceutical advertising. Meanwhile, newly emerging forms of advertising have turned out to be more active in the pharmaceutical area, bringing more tension and uncertainties regarding the legality of such new forms.

Developments in Legislation and Regulation

In general, 2022 provided no significant changes from the perspective of legislation or government supervision for pharmaceutical advertising in China. That said, some minor updates were still seen, along with the enactments of various implementing rules.

For example, the State Administration of Market Regulation (SAMR), aligned with other national ministries and commissions, released the Guideline on Further Regulating Celebrities' Endorsements in Advertising on 31 October 2022. Specifically, with regard to pharmaceutical advertising, these guidelines provide that celebrities are not allowed to endorse medical treatment, drugs or medical devices, which serves as a re-emphasis of the regulation of pharmaceutical advertising under the PRC Advertising Law.

Additionally, starting from 20 June 2022, the district level of the health committee in Shanghai is delegated by the municipal health committee to review and grant approval on pharmaceutical advertising, in accordance with the decision of the Shanghai municipal government on Delegating a Batch of Administrative Review and Approval Matters (Hu Fu Gui (2022) No 1) and the Notice on Delegation of "Pharmaceutical Advertisement Review and Approval" (Hu Wei Yi Bian Han (2022) No 94) issued by the municipal health committee. The authority for reviewing pharmaceutical advertising has thus transitioned from the municipal level to the district level of the health committee.

Newly Emerging Forms of Pharmaceutical Advertising – Case Studies from a Regulatory Perspective

In light of the quarantine policy and travel restrictions imposed on China throughout much of 2022 due to the COVID-19 pandemic, online business has become increasingly popular, which has bred multiple new forms of activity – including online health-educational articles or TV programmes, online lectures, short videos/films, coupons, and even consumer reviews – that may likely fall within the scope of "advertising", a concept of specific denotation under Chinese law.

According to Article 46 of the PRC Advertising Law, if any of the aforementioned newly emerging forms of activity is considered an advertisement, such promotional content will be subject to pre-screening procedures by the approval authority before formal launch. Given the unorthodox nature of these forms, it is likely to be difficult, and sometimes controversial, to identify whether they should be regarded as advertisements.

Some examples of these new forms of activity are discussed and analysed below in order to diffuse confusion, and this article is intended to help navigate these advertising-related "grey areas".

Articles or TV programmes introducing health knowledge

As revealed from an administrative judgment by the Dalian Intermediate Court, for articles released on the official website of a hospital, if introducing a patient case with information on drugs and treatment for a specific disease, such article would be considered as mainly for promotional purposes and should thus constitute advertising. In this connection, if the hospital fails to go through the pre-approval procedures for pharmaceutical advertising, administrative penalties would be imposed.

Additionally, in accordance with a judgment by the Shashi District Court in Jinzhou City, if a TV programme broadcasts health or wellness lectures and actually provides specific drug information, such "lectures" would be considered advertisements. Failure to obtain the authority's pre-approval would lead to administrative penalties being imposed on the relevant TV station.

Short films inserted into TV or online programmes

Short films which are inserted into a TV or online programme, with specific content promoting a drug, are also vulnerable to being penalised if the advertiser fails to go through the procedures of administrative pre-approval.

For example, a pharmaceutical company was fined by the Shanghai AMR after promoting its products in a short film that was inserted into a popular online talk show programme (the Roast Meeting). In the short film, the actors in the talk show programme orally introduced an ointment product, with promotional language including "colourless, tasteless and refreshing, this is really good and it can relieve itching quickly". Such short films are considered advertisements and thus give rise to the aforementioned administrative penalties.

Pay-per-click advertising provided by online search engines

Pay-per-click (PPC) advertising, if involving pharmaceutical products or medical services, is also subject to regulatory requirements for pharmaceutical advertising.

This was indicated in an administrative decision by the AMR of Guangzhou City, where a company providing search engine services was punished for its PPC advertisements service.

In this case, a company purchased the keywords of "reducing blood sugar" from an online search engine to promote its medical treatment service. The promotional content retrieved from the said keywords included "the feedback from patients: blood sugar has dropped steadily", which were ruled to be false advertisements. Additionally, the search engine company offered PPC advertisement services for pharmaceutical advertisements, in which the content actually released was inconsistent with that approved by the local health committee.

The AMR of Guangzhou City held that the search engine service provider was obliged to review the targeted advertising to be released (including to check whether it was false advertising or compliant with other applicable laws from a regulatory perspective) before providing its PPC advertising services. Since the search engine company failed to do so, the AMR of Guangzhou

City decided to confiscate its illegal gains, and imposed a fine.

Links directing to sales pages of pharmaceutical products or medical treatment

Links directing to specific sales pages of pharmaceutical products or medical treatment are under the supervision of pharmaceutical advertising.

In accordance with an administrative decision of the AMR of Dongcheng District, Beijing Municipality, a company that was engaged in providing online video-on-demand (VOD) song request systems and the relevant operation of interstitial advertisements, was fined for displaying an on-screen link directing to sales pages of cosmetology services when a song was paused. The linked pages contained wording such as "photon skin rejuvenation full mode", "whitening", "spot lightening", and "skin rejuvenation", thus rendering the activity as being regarded as pharmaceutical advertising.

The AMR found that the VOD provider violated the law for failing to obtain pre-approval for pharmaceutical advertising. Moreover, as the price information contained in the directed link was inconsistent with the price information shown in the following pages for online purchasing, the advertisement was further found to be confusingly misleading. The VOD provider was subjected to an administrative fine of CNY300,000.

Coupons relating to pharmaceutical products or services

Providing coupons and/or promotional information for specific pharmaceutical products or services risks being considered as advertising by the relevant authority in certain scenarios.

As ruled by an administrative decision of the AMR in Haishu District, Ningbo City, promotional information relating to pharmaceutical services provided by a social media account through an article and the corresponding in-built applet would be subject to the regulation of advertisements.

In this case, the company operated a WeChat official account titled "Ningbo You Dian Niu" (meaning "Ningbo City is a little bit awesome") and a relevant in-built applet. The company co-operated with a dental clinic to promote the relevant dental services, by means of:

- releasing an article introducing the dental clinic together with photos featuring its dentists, consultation rooms and equipment, as well as displaying several service packages with corresponding prices; and
- providing a link in the article which directed to the in-built applet for purchasing specific coupons.

The local AMR considered that the aforementioned content should be regarded as advertising. Given such content failed to be pre-approved by the health committee, the AMR imposed an administrative fine on the company.

Additionally, there was a case where provision of coupons for medical treatment services (even without specific accompanying promotional language) was taken to be advertising activity. As opined by the AMR in Xiaoshan Disctrict, Hanghzou, if the relevant medical institution provided coupons and promotional vouchers (indicating specific items of medical cosmetology with corresponding prices, and contact information of the medical institution) at conferences or lectures in the relevant industry, such activity would constitute advertising, and failure to obtain pre-

approval from the health committee would be subject to administrative punishment imposed by the relevant authority.

Monetary incentives for positive consumer reviews

Consumer reviews towards specific goods or services are unlikely to be considered as advertisements in normal circumstances. That said, if the consumer reviews are made under monetary incentives provided by the sellers or service providers, it is possible that such reviews or comments would be regarded as advertisements, and thus be subject to regulation of applicable laws.

For instance, an aesthetic and medical company, by means of executing a "Diary Cashback Agreement", entrusted its patients to publish a post-operative diary on the Soyoung platform (a popular forum and platform for communication of beauty and medical cosmetology in China), so as to generate positive publicity for the medical institution –whereby the institution would provide the patients with cash in return. Under such arrangement, a patient (Ms Huang) posted seven "diaries" within one year. The authorities in Shenzhen took the view that such patient reviews had actually fallen within the definition of advertising. Since the law prohibits hospitals from exploiting the names or images of patients in proving their medical services, such arrangement constituted a violation of the regulations in respect of pharmaceutical advertising.

Additionally, there have also been cases in Nanjing and Shanghai where operators in the medical cosmetology industry fabricated consumer reviews by engaging vendors in an illegal manner. Such activities were considered as misleading advertisements and violated the PRC Anti-unfair Competition Law. The cases were listed as the representative cases in the medical cosmetology field by the State Administration of Market Regulation (Third Batch) in 2021.

Observations

In light of what has been discussed in this article, the authors believe that it is critical for pharmaceutical companies and related advertising publishers to show initiative and adopt internal compliance protocols to review whether the aforementioned online health-educational articles or TV programmes, online lectures, short videos/films, coupons, and even consumer reviews will constitute advertising under the PRC Advertising Law.

In practice, two scenarios are worth heeding for internal regulatory protocols:

- if the materials are published by a pharmaceutical company per se, a key element to be considered is whether the content is directly connected to specific goods, services or promotional materials, and if so, the PRC Advertising Law is likely to be applicable; and
- if the materials are released by a third party, an element to be considered is whether the publication is based on entrustment or intention of entrustment by the pharmaceutical company, and if so, the PRC Advertising Law will likely apply.

However, given that the intention of entrustment is implicit, the Chinese regulatory authorities will in any case have to check and identify whether the released content is directly connected to specific goods, services or promotional materials.

In general, if the information released by a third party is directly linked to the aforementioned content, a high possibility that the pharmaceuti-

cal company intends to entrust the third party with publishing advertisements can be inferred, and the authorities may investigate along this line to check whether such entrustment exists via verification of contracts or other communication records. In fact, if the newly emerging forms of materials are obviously false or misleading, or disparage the goods or services of competitors, the possibility of being reported and punished by the authorities will further increase.

Fangda Partners was founded in 1993, and is a full-service law firm advising on PRC and Hong Kong laws. Fangda Partners has approximately 700 lawyers in its five offices in Beijing, Guangzhou, Hong Kong, Shanghai and Shenzhen. The firm has been at the forefront of the development of commercial law practice in China for over two decades, advising on notable matters including: the first initial public offering by a Chinese company involving an international underwriter; the first domestic listing by a company incorporated outside the PRC; the formation of the first open-end mutual fund in China; the first foreign acquisition of a controlling stake in a Chinese public company; the first FRAND litigation in China; representation of a claimant in obtaining the first injunction in an intellectual property litigation under Chinese procedural law; and the first public-interest environmental litigation brought by an NGO against a multinational company in China.

Authors

Hans She serves as a partner of the dispute resolution group at Fangda Partners. He specialises in high-profile intellectual property (IP), and has represented dozens of overseas IP holders in various legal proceedings in China. He also has abundant experience in advising clients in a wide range of IP-related issues, regulatory and advertising matters, and supporting clients' business operations and commercial growth in China and overseas by delivering practical and comprehensive solutions.

Qian Luo serves as a counsel of the dispute resolution group at Fangda Partners. He specialises in commercial dispute resolution, advertising, compliance, and administrative investigations. He has extensive experience in advertising, corporate disputes, contract disputes, tort disputes, compliance, and administrative disputes.

Jasmine Zhang serves as an associate of the dispute resolution group at Fangda Partners. She works on a wide range of IP-related matters in China, including trade mark infringement, copyright infringement and unfair competition litigations. She also has experience in non-contentious matters, advising clients on various IP-related, franchising and advertising matters.

Fangda Partners

24/F, HKRI Centre Two
HKRI Taikoo Hui
288 Shi Men Yi Road
Shanghai 200041
China

Tel: +86 21 2208 1166
Fax: +86 21 5298 5599
Email: email@fangdalaw.com
Web: www.fangdalaw.com

FANGDA PARTNERS
方達津師事務所

DENMARK

Law and Practice

Contributed by:
Jacob Ørndrup and Louise Bertelsen Forman
Loeven Law P/S see p.135

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DENMARK

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The following regulate advertising of medicinal products in Denmark:

- Chapter 7 of the consolidated Danish Medicines Act No 99 of 16 January 2018 (the "Act"); and
- Executive Order No 849 of 29 April 2021 on Advertising of Medicinal Products (the "Advertising Order"), as amended by Executive Order No 134 of 25 January 2022.

The Advertising Order is supplemented by Guideline No 9400 of 20 April 2022 on Advertising on Medicinal Products (the "Guidelines") (collectively, the "Legislation"). The Danish Medicines Agency (the "Agency") and the Danish Ministry of Health (the "Ministry") monitor compliance with the Legislation.

In addition, the consolidated Danish Marketing Practices Act No 866 of 15 June 2022 (the "Marketing Practices Act") sets out the general standards for advertising in Denmark and authorises the Danish Consumer Ombudsman to monitor advertising activities and sanction non-compliance with the Marketing Practices Act.

The self-regulatory body within the pharmaceutical industry in Denmark is the Ethical Committee for the Pharmaceutical Industry (ENLI). ENLI has issued the Pharmaceutical Industry's Code of Practice on Advertising, etc of Medicinal Products aimed at Healthcare Professionals (the "Promotion Code"). The provisions in the Promotion Code are in line with the Legislation, although in some cases the Promotion Code provides for stricter requirements. The Promotion Code is supplemented by guidelines (the "Promotion Code Guidelines").

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The Promotion Code applies to:

- members of the Danish Association of the Pharmaceutical Industry (LIF);
- members of the Danish Generic Medicines Industry Association (IGL);
- members of the Danish Association of Parallel Distributors of Medicines;
- the Danish Association of Parallel Distributors of Pharmaceuticals; and
- a number of other companies that have voluntarily agreed to comply with ENLI's rules.

The rules thus apply to the majority of pharmaceutical companies on the Danish market, and from a compliance perspective the legal importance of these rules is quite high.

The provisions of the Promotion Code are only applicable with respect to activities that are partially or fully directed against Danish healthcare professionals. However, the provisions also apply to activities that are exclusively directed towards foreign healthcare professionals, provided that these activities are held in Denmark.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The term "advertising" in the context of medicinal products is defined in Section 1 of the Advertising Order as follows:

"Advertising of medicinal products means any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products."

The definition in the Advertising Order is thus identical to the definition in Article 86(1) of 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 (the "Directive").

The Promotion Code incorporates the same definition of advertising by direct reference to the Advertising Order.

In line with case law from the European Court of Justice (eg, case C-421/07, Frede Damgaard), the term "advertising" is interpreted broadly under Danish law. Thus, all types of advertising regardless of media used (eg, written materials, direct mails, activities by employees, use of the internet and social media, electronic media, videos, brochures, product samples, gifts and hospitality) are covered by the definition.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The Advertising Order specifically lists a number of areas where the provisions regarding advertising do not apply; see its Section 2. By default, these areas are found to be "informational" rather than "promotional":

- labelling of medicinal products and package leaflets;
- individual correspondence that responds to a specific query about a specific medicinal product;
- necessary specific information or documentation that serves safety and not advertising purposes;
- price lists, product catalogues, etc;
- informative material on health and disease provided there is no direct or indirect reference to specific medicinal products;
- patient information leaflets accompanying a prescription as part of prescribing a medicinal product or supplied by the pharmacy when dispensing medicinal products (which only contain factual information of importance to patients and their relatives);
- press releases (provided that certain requirements are fulfilled – see **2.3 Restrictions on Press Releases Regarding Medicines**); and
- unedited and unabbreviated reproduction of a package leaflet, the officially approved product summary or publicly available evaluation report (see Section 72(1) of the Act) or an image of a medicine package, provided that the information is made available in such a way that users have to search actively for this information.

From these exemptions it can be seen that the rules on advertising of medicinal products do not apply to information material regarding health and diseases, assuming there is no direct or indirect reference to specific medicinal products. Accordingly, disease awareness activities and other patient-facing information do not qualify as advertising, provided they are not deemed to be indirectly "designed to promote" a medicinal product.

In addition to the above, scientific exchange with healthcare professionals at congresses in Denmark is also exempted from the definition of advertising, provided that certain criteria are fulfilled (see **3.2 Provision of Information During a Scientific Conference**).

Other examples of communication exempted from the definition of advertising are advisory board activities and other consultancy arrangements based on legitimate needs.

The Promotion Code incorporates the same exemptions by direct reference to the Advertising Order; see Section 2(2) litra c.

2.3 Restrictions on Press Releases Regarding Medicines

According to the Advertising Order, Section 2(7) (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**), the rules on advertising of medicinal products do not apply to press releases to the extent that these:

- contain objective (*saglig* in Danish) and brief information regarding a medicinal product;
- have general news value;
- have the press as the target group; and
- are sent or made available to a multitude of journalists and media with a view to journalistic assessment and processing prior to publication.

Thus, under Danish law, press releases are seen as information exempted from the rules on the advertising of medicinal products provided they comply with the above and do not contain advertising of medicinal products. Whether the latter is the case will depend on a case-by-case assessment. Recent Danish case law indicates that the courts interpret Section 2(7) narrowly and that each of the above-mentioned requirements must be clearly met if the press release is not to be seen as advertising.

If a pharmaceutical company has paid for a press release in the media, the press release will not fall under the "press release exemption" but rather be seen as advertising. According to the Guidelines, a pharmaceutical company is only allowed to make a press release available in its online news section for approximately three weeks. Following this period, but subject to requirements under, for example, Danish financial securities legislation, the press release will typically no longer be covered by the exemption.

2.4 Comparative Advertising for Medicines

Comparative advertising for medicinal products is allowed, but is subject to a number of restrictions. According to Section 16 of the Advertising Order, comparative advertising must clearly state which medicinal products the comparison concerns. The comparison must only concern medicinal products that are relevant to compare (as a rule, medicinal products that share the same indication(s)), and the comparison must be made on the basis of the information in the products' Summary of Product Characteristics (SmPC).

Further, comparisons relating to price must always include the current prices of the products, cf Section 63 of the Act. With respect to a comparison concerning prices of pharmacy-only medicinal products, the comparison can be made based on the prices published on medicinpriser.dk.

As a rule, a comparison is only permissible if it covers all generic (and any parallel imported) medicinal products that do not differ in therapeutic form or strength, or that do not differ substantially in pack size. Medicinal products with an insignificant market share can be excluded from the comparison. A market share of up to 2–3% is generally considered as insignificant.

Section 16(2) of the Advertising Order provides that comparative advertising must be prepared on the basis of the information appearing from the SmPCs of the products being compared – in so far as the SmPCs include information about the particulars being compared.

When comparing over-the-counter (OTC) products in advertising directed towards the general public, it is not legal to give the impression that the effect of a product is better or just as good as the effect of another product, cf Section 16(3) of the Advertising Order.

In addition to the above, comparative advertising will also be subject to the general provisions of the Legislation, the Promotion Code (Section 8 concerning comparative advertising) and the Marketing Practices Act (for example, the prohibition against misleading and/or disparaging advertising).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

According to Section 64 of the Act and Section 3(1) of the Advertising Order, it is prohibited to advertise for medicinal products which are not sold or dispensed in Denmark. A new medicinal product cannot be sold or dispensed until it has been approved by means of a marketing authorisation granted by the Agency or the European Commission.

Additionally, anyone placing a pharmacy-only medicinal product on the Danish market must notify its price to the Agency no later than 14 days prior to the price's effective date, cf Section 77(1) of the Act. Thus, the price can be notified earlier than 14 days before the price is to take effect. For some non-pharmacy medicinal products, it is required that their available pack sizes have been notified to the Agency, also at 14 days' notice, cf Section 78(1) of the Act.

Based on these provisions, and considering that the term "advertising" is interpreted broadly, providing information on unauthorised products or unauthorised indications will often be seen as illegal pre-launch advertising or off-label advertising. The permissibility must in any case be assessed on a case-by-case basis.

The Promotion Code also contains a prohibition against pre-launch and off-label advertising, and ENLI has also issued a guide on pre-launch to aid in the assessment of whether the mention of a medicine that has not been authorised will be considered as illegal pre-launch advertising or neutral information (eg, scientific mentioning).

3.2 Provision of Information During a Scientific Conference

The Legislation does not regulate this separately. ENLI has, however, issued a guideline regarding participation of pharmaceutical companies in international congresses in Denmark which in many ways also reflects the Agency's practice in this area.

When providing information during scientific conferences, the critical point will be to distinguish between "advertising" and "scientific information". In previous cases, both the Agency and ENLI have clarified that not all references to a medicinal product will be seen as advertising and may be permissible, for example in the context of company-sponsored symposia including presentations of scientific data in a

scientific forum (eg, on an international congress for healthcare professionals).

The Agency and ENLI consider that such a symposium may be seen as scientific, if the following criteria are fulfilled:

- the symposium is a part of the congress programme;
- the content of the symposium is approved by an impartial congress committee; and
- the external speaker has compiled the content, the formulation and angle to the subject/subjects in the presentation.

Moreover, it may be of importance how the symposium is branded as this can lead to it being seen as promotional.

Exhibition stands are considered as commercial areas. Information on unauthorised products available in exhibition stands can therefore very easily be seen as illegal pre-launch promotion.

Mention of scientific studies and data to healthcare professionals relating to Phase I and II studies is generally seen as scientific information, as it is by no means certain that the development will lead to a marketing authorisation for a specific medicinal product. To avoid this being seen as advertising, the information must, however, be presented in a neutral and non-promotional way.

As mentioned, ENLI has issued a guide on pre-launch, according to which each of the following factors may indicate that specific material will be seen as unlawful pre-launch advertising:

- the pharmaceutical company has published the results of Phase III studies;
- the pharmaceutical company has submitted its application for marketing authorisation to the relevant authorities;
- the pharmaceutical company has obtained a "positive opinion" from the European Medicines Agency/the Food and Drug Administration (FDA) – if the product is approved by the FDA, mentioning this product in Denmark will be seen as advertising for a product not yet approved in Denmark/the EU;
- the pharmaceutical company knows the results from Phase III studies and/or has positive interim results; and/or
- the pharmaceutical company is working on an indication expansion study on an already approved product.

3.3 Provision of Information to Healthcare Professionals

A pharmaceutical company's unsolicited/proactive approach to a healthcare professional regarding medicinal products or its indications will typically be seen as advertising. If the products and/or indications in question are unauthorised, this will in itself constitute illegal advertising (pre-launch or off-label advertising). Further, unsolicited contact with a healthcare professional without prior consent may also, depending on the circumstances, constitute a violation of the Marketing Practices Act.

As mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, individual correspondence (accompanied by documents of a non-promotional nature, if necessary) that responds to a specific query about a medicinal product is exempted from the advertising rules. Therefore, in the case of a reactive reply to a question from a healthcare professional, the company could be allowed to answer – in writing – a specific question relating to, for example, off-

label use. However, it must be ensured that the answer does not go beyond the question asked as this could constitute advertising (including unlawful advertising claims for off-label use). Also, the correspondence must be "individual" and the exemption will therefore not cover, for example, emails to several recipients, replies given in a forum of healthcare professionals, or the company's response to queries made on the internet in a blog or similar forum (as such correspondence may be accessed by anyone). The Agency has stated that the exemption does not apply to verbal queries and responses.

3.4 Provision of Information to Healthcare Institutions

As previously noted, initiating unsolicited contact with healthcare professionals regarding unauthorised medicines or unauthorised indications will generally constitute illegal pre-launch or off-label advertising.

Depending on the circumstances, the exemption regarding price lists set out under **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** may be relevant. According to this exemption, price lists, product catalogues, etc, containing no other information about the medicinal products besides their names, pharmaceutical form, strengths, pack sizes, prices and images of the product packaging will not be covered by the advertising rules.

Again, unsolicited contact with a healthcare professional without prior consent may also, depending on the circumstances, constitute a violation of the Marketing Practices Act. In any case, the Marketing Practices Act provides that prior consent is required before approaching anyone – including healthcare professionals – by means of electronic mail for the purposes of direct marketing.

3.5 Information About Early Access or Compassionate Use Programmes

In principle, it is permitted to publish the availability of compassionate use programmes. However, pursuant to Section 3 of the Advertising Order, it is not legal to promote a medicinal product sold or dispensed according to a compassionate use permit.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Pursuant to the Act, the advertising of prescription-only medicinal products towards the general public is prohibited. The "general public" is defined in the Legislation as anyone who is not a doctor, dentist, veterinarian, pharmacist, nurse, veterinarian nurse, pharmacologist, midwife, bio-analyst, clinical dietician, radiographer, social and healthcare worker, or a student within one of these professions.

Advertising of OTC products towards the general public is allowed subject to certain restrictions.

As a general rule, all advertising of medicinal products (prescription-only and OTC) must be complete and objective (*saglig* in Danish) and must not be misleading or exaggerate the qualities of the product. Furthermore, information in advertising material must be in accordance with the SmPC, cf Section 63 of the Act.

It is prohibited to advertise towards the general public medicinal products that are inappropriate for use unless the patient has first consulted a

doctor with a view to diagnosis or monitoring of the treatment, cf Section 66(1)(2) of the Act. Furthermore, it is prohibited to advertise towards the general public medicinal products that are covered by the Danish Act on Euphoriant Drugs, cf Section 66(1)(3) of the Act.

Section 10(1) of the Advertising Order further sets out a number of specific restrictions as to the content of advertisements to the public. An advertisement must not:

- give the impression that it is unnecessary to consult a doctor;
- give the impression that a surgical operation is unnecessary;
- give the impression that the effects of taking the medicinal product are guaranteed, are without adverse reactions or are better than or equivalent to the effect of another treatment, including a medicinal product;
- give the impression that general health can be enhanced by taking the medicine;
- give the impression that health could deteriorate by not taking the medicinal product;
- be directed exclusively or principally at children;
- include recommendations by health professionals, scientists or other persons, associations of persons, institutions, companies, etc, who by virtue of their prestige could encourage the consumption of medicinal products;
- compare the medicinal product with a foodstuff, cosmetic or other consumer product;
- give the impression that the safety or efficacy of the medicinal product is due to the fact that its active substances are natural;
- be such that it might lead to erroneous self-diagnosis;
- contain exaggerated, alarming or misleading claims of recovery; or
- use, in exaggerated, alarming or misleading terms, visual representations (pictures, illustrations, etc) of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

Pursuant to the Advertising Order, it must be clear from the advertising towards the general public that the communication constitutes advertising (ie, disguised advertising is prohibited) and it must be clear that the advertising concerns a medicinal product.

The specific requirements regarding mandatory information which must be provided in connection with advertising of OTC medicinal products towards the general public are described in more detail in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

The Promotion Code does not apply to promotion to persons who are not healthcare professionals – eg, patients and citizens, cf Section 2(2) of the Promotion Code.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising material directed towards the general public must, as a rule, contain the following:

- the name and international non-proprietary name (INN) of the medicinal product;
- information on the size of the packaging;
- references to an up-to-date price on medicinpriser.dk, if it is a pharmacy-only medicinal product;
- the indication(s), as specified in the SmPC;
- side effects;
- dosing;

- a request to read the information on the package leaflet or the package; and
- other information deemed necessary in relation to correct and proper use of the product.

It is at the discretion of the marketing authorisation holder to determine which particulars are necessary to include to enable consumers to form a correct and adequate picture of the medicinal product and its use, cf section 63 of the Act.

In general, any contraindications, special precautions for use, drug interactions, relevant overdose risks and special warnings that are mentioned in the SmPC should be included. Information which, based on objective criteria, is considered irrelevant to give to the public can be omitted. If requested by the Agency, the marketing authorisation holder must explain why one or more particulars from the SmPC have been omitted.

Specific information requirements apply in relation to outdoors advertising and advertising in movies, on the radio and on television, cf Sections 6–7 of the Advertising Order.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

The relationship between pharmaceutical companies and patients is not specifically regulated by the Legislation, but is covered by the provisions regarding advertising to the general public (patients are part of the "general public"). For example, it is not legal to provide any type of hospitality, accommodation or the like when advertising medicinal products to the public, cf Section 20 of the Advertising Order.

As previously mentioned, the Promotion Code covers only the interaction between a pharmaceutical company and healthcare professionals and is, therefore, not relevant in relation to patient interaction.

The term "patient organisations" is defined in the Advertising Order, Section 1(7) and the Act, Section 71d, and covers organisations of patients and relatives that have the purpose of catering for a group of patients' interests. However, the Ethical Rules for the Collaboration between Patient Organisations, etc and the Pharmaceutical Industry issued by ENLI (the "Patient Organisation Code") apply to a wider scope of patient and consumer organisations.

Regarding the pharmaceutical industry's interaction with patient organisations, it follows from Section 21 in the Advertising Order that a patient organisation must disclose all funding or benefits in kind that the organisation receives from pharmaceutical companies. Accordingly, funding can be provided to such patient organisations.

The Patient Organisation Code lays down various provisions on contract terms and transparency. Contracts under which the organisations provide any type of services to pharmaceutical companies are permitted only if such services are provided for the purpose of supporting healthcare or research. Also, it is permitted to engage organisations as experts or advisers for services; for example, in relation to participation at advisory board meetings and/or speaker services. This requires, however, that the form and content requirements in the code regarding the contract as such are fulfilled.

Specific restrictions apply in relation to financial support from pharmaceutical companies to patient organisations. In principle, support can

be granted for all types of activities, projects and purposes within the sphere of the organisation's work, provided that "professional activities" are the main intention of the collaboration and that any services to be provided are proportionate to the compensatory measures. Support must not be made conditional upon the organisation taking specific stands regarding professional or political topics. The company must naturally also not require organisations to favour specific products and no exclusivity agreements may be concluded. Organisations are thus always free to collaborate with other pharmaceutical companies and pharmaceutical companies may collaborate with one or several organisations. The Patient Organisation Code also sets out provisions on disclosure of support as well as levels of accommodation and hospitality.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Provisions on obligatory information in advertising for healthcare professionals are contained in the Advertising Order. Advertising material directed at healthcare professionals must include the following information:

- the name and the INN of the medicinal product;
- the name of the marketing authorisation holder;
- indication(s) as specified in the SmPC (in advertising material exclusively directed at a limited group of healthcare professionals, the indication text may be reduced to the extent relevant to the group concerned);
- contraindications;
- adverse reactions and risks;
- dosage;
- pharmaceutical forms;
- pack sizes;
- reference to the current price on medicinpriser.dk, if it is a pharmacy-only medicinal product;
- dispensing group;
- reimbursement status; and
- the date on which the advertising material was generated or last revised.

A similar provision regarding compulsory information is contained in Section 5 of the Promotion Code. However, according to this section the name and address of the pharmaceutical company or its representative must also be included.

According to Section 7(6) of the Promotion Code, words that indicate that the medicinal product is "safe" may not be used to describe the product. Likewise, words that indicate that a medicinal product is "new" may not be used to describe a product or packaging that has been generally available or for a therapeutic indication for which there has been widespread use of advertising measures for more than one year. Also, it is not legal to state that a medicinal product has no adverse reactions, no toxic effects or no risk of addiction.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Claims regarding a medicinal product that are not substantiated by the SmPC can be made only by reference to scientifically substantiated research, cf Section 13(4) of the Advertising Order and Section 7(5) of the Promotion Code. The research must have been published in established and independent Danish or foreign professional journals or similar. Further, the

research must, prior to publication, have been subjected to an independent assessment (peer review). References such as "data on file", posters and abstracts normally do not satisfy these requirements and consequently cannot be used as documentation.

That said, the Guidelines provide that data on file that has been made subject to an independent review similar to the review undertaken prior to acceptance by a recognised scientific journal and that has been acknowledged as credible in peer review may be used as documentation until comparable information has been published, publication of the information has been rejected or new information has disproved the scientific validity of the material.

ENLI has issued a guide on information material and documentation which sets out the requirements for documentation, including examples of what is considered as permissible documentation.

5.3 Advertising of Combination Products

As previously noted, advertising for medicinal products must always be in accordance with the SmPC. Thus, advertising for use in combination with another product must be in accordance with the SmPC. However, reference to another product in advertising may be permissible if supported by scientifically substantiated research, provided that it is not inconsistent with the SmPC.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Pursuant to the Guidelines, it is not regarded as advertising when a pharmaceutical company provides scientific articles to a healthcare professional on request, provided that such articles are sent without comment and without supplementary materials, and provided that the articles have already been published in a recognised, independent Danish or international journal.

The important distinction is whether the reprints are distributed based on the pharmaceutical company's or on the healthcare professional's initiative, as the company's unsolicited distribution of scientific articles will normally be considered advertising. In such cases, the advertising must be in accordance with the SmPC and the materials distributed must be enclosed with the compulsory information mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**.

It must also be considered whether the reprint will be seen as a gift (ie, value to be clarified according to applicable rules). Typically, supplying reprints to a healthcare professional is permitted on condition that this is directly relevant for the practice of the healthcare professional and directly benefits patients. Overall, reprints must also be of an insignificant value (see **9.1 Gifts to Healthcare Professionals**).

5.5 Medical Science Liaisons

The term "Medical Science Liaisons" is not used in the Legislation. However, the Advertising Order uses the term "medical sales representatives", meaning persons who provide information about and promote medicinal products to healthcare professionals on behalf of pharmaceutical companies.

The Advertising Order provides that medical sales representatives must have completed adequate training and possess sufficient scientific knowledge enabling them to give precise and adequate information about the products they promote.

Essentially, the activities of medical sales representatives must observe the general rules concerning advertising of medicinal products. Any unsolicited/proactive approach to a healthcare professional on behalf of a pharmaceutical company regarding medicinal products or its indications will highly likely be seen as advertising. If the products and/or indications in question are unauthorised, this will constitute illegal advertising (pre-launch or off-label advertising).

Further, dissemination of materials of a promotional nature to healthcare professionals must observe the requirements described in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, meaning, inter alia, that the advertising must be in accordance with the SmPC and that the materials distributed must be enclosed with the mandatory information.

However, as previously mentioned, it is permitted to engage organisations as experts or advisers for services; for example, in relation to participation at advisory board meetings. This requires that the form and content requirements in the code regarding the contract as such are fulfilled.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

The Legislation does not contain any requirements concerning prior notification of or approval from the authorities as regards advertising for medicinal products.

However, pharmaceutical companies that are subject to the Promotion Code are obligated to notify the following activities to ENLI:

- activities that are organised or co-organised by a pharmaceutical company (eg, meetings, congresses, conferences, symposia, courses, etc) and that are partially or fully directed against Danish healthcare professionals;
- activities where a pharmaceutical company provides financial support (sponsor support) to a third-party event that is fully or partially directed against Danish healthcare professionals or to the participation of Danish healthcare professionals; and
- activities where a pharmaceutical company buys an exhibition stand at a congress in Denmark.

Further, pharmaceutical companies are obligated to report all kinds of printed advertising material (printed leaflets, handouts, website material, etc) aimed at healthcare professionals on the Danish market.

Notification deadlines for each of the above are set out in Section 21 of the Promotion Code. The company is obligated to file a report online via ENLI's website using a standard form, and is obligated to ensure that the notification is complete and that all relevant documentation is submitted.

A pharmaceutical company seeking a pre-publication vetting of an activity and its compliance with the Promotion Code may also apply for a pre-approval. Applications are submitted online and are subject to a fee.

6.2 Compliance With Rules on Medicinal Advertising

Pursuant to Section 68 of the Act, the pharmaceutical company must store a copy (printed or digital) of any marketing material for a medicinal product for at least two years.

Pursuant to Section 17 of the Advertising Order, the following additional information must also be stored:

- the target group;
- the means/method of distribution;
- an overview of the media where the advertising has been shown; and
- the period of time where the advertising has been used.

Accordingly, even though there is no specific requirement to adopt standard operating procedures or similar internal policies, pharmaceutical companies must be able to handle the collection of relevant material and the storage thereof, as documentation must be presented if requested by the authorities.

The Advertising Order Sections 18 and 19 set out certain requirements for consultants and sales representatives of pharmaceutical companies. For example, such consultants and sales representatives must have received appropriate training and possess the knowledge to be able to provide precise and complete information on the medicinal products in question.

The Promotion Code Section 20 contains similar provisions regarding consultants and lists additional information and requirements applicable to such employees. In addition, pharmaceutical companies to which the Promotion Code applies must also appoint one senior employee to be responsible for ensuring that a company and its subsidiaries comply with the Promotion Code (see Section 20 of the Promotion Code). Further, a "scientific service" in charge of information about its medicinal products must be established. The scientific service must include a medical doctor (or, if appropriate, a pharmacist) who will be responsible for approving any advertising material before release. This employee is responsible for certifying that:

- they have reviewed the final form of the advertising material;
- it is in accordance with the requirements of the applicable Legislation and industry regulations;
- it is consistent with the SmPC; and
- it is a fair and truthful presentation of the facts regarding the medicinal product.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Danish provisions that apply to advertising "on paper" apply equally to internet advertising, cf Section 9 of the Advertising Order. The provisions should, however, be interpreted with due consideration to the special nature of the internet.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As advertising on the internet will usually be considered advertising to the general public, access restrictions are required if the website contains advertising of prescription-only medicinal products. According to Section 9(3) of the Advertising Order, the access must be restricted in an "effective manner" via user identification (ie, unique

username, authorisation number or similar) and an individual password. A password that is similar for all users is not sufficient.

ENLI has issued a guide regarding the use of digital media in advertising activities (the "Digital Media Guide"). The Digital Media Guide provides different example of effective access restriction methods.

7.3 Provision of Disease Awareness Information to Patients Online

As previously mentioned, disease awareness activities that do not contain any direct or indirect reference to specific medicinal products do not qualify as advertising (provided they are not deemed to be indirectly "designed to promote" a medicinal product). Thus, websites that exclusively provide disease awareness information will not be deemed advertising.

However, the Digital Media Guide provides that the pharmaceutical company should carefully consider the purpose of the website in question. Whether or not the website will be considered advertising will depend on a case-by-case assessment, taking into consideration the entire website.

Furthermore, the Digital Media Guide provides that a website containing permissible disease awareness information may change into an advertising website due to users' interactions on the website. Therefore, the company should monitor any activities on the website carefully. In ENLI's view, the company that is responsible for the creation of the website will – as a starting point – also be responsible for all communication on the website, including third-party communication.

7.4 Online Scientific Meetings

As a starting point, the rules on advertising for medicinal products apply to both physical and virtual meetings or congresses. As described in more detail under **9.3 Sponsorship of Scientific Meetings**, pharmaceutical companies can sponsor relevant (online) scientific meetings or congresses and/or attendance by healthcare professionals.

The Guidelines provide that scientific meetings or congresses held in Denmark are considered "international" when several participants or speakers come from abroad.

ENLI has issued a guide regarding the participation of pharmaceutical companies in international congresses held in Denmark (the "International Congresses Guide"). The International Congresses Guide provides that pharmaceutical companies may live-stream scientific meetings or congresses and have on-demand solutions where the presentations can be made available provided that the web access to the presentations does not contain advertising for medicinal products.

7.5 Use of Social Media

It is legal for pharmaceutical companies to use social media for advertising purposes, provided that the content is gated in an effective manner so that it can only be accessed by healthcare professionals if the advertising relates to prescription-only medicinal products. Also, it is a requirement that the content complies with the applicable requirements on advertising materials – eg, the requirements regarding compulsory information. Companies must generally be cautious due to the challenges and risk of non-compliance within this area.

It follows from the Guidelines that employees have a special connection to the pharmaceutical company and that the affiliation is relevant for the assessment of whether an employee has advertised for the company's medicinal product. In recent years there have been several cases against employees concerning illegal advertising on social media (eg, about liking and sharing posts on social media containing positive mention of a medicinal product).

The Guidelines and ENLI's Digital Media Guide provide helpful guidance when companies may wish to use social media in marketing activities.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Section 299(2) of the consolidated Danish Criminal Code No 1360 of 28 September 2022 (the "Criminal Code") prohibits bribery in the private sector. This provision applies to any person who receives/requests/accepts a gift or benefits in kind contrary to their duty in relation to the management of the property matters of another. The person who provides/promises/offers such gift or benefit in kind is also liable, and the sanction for the "recipient" and the "provider" is a fine or imprisonment of up to four years.

Under the Criminal Code, a legal entity can also be made subject to a fine to the extent that a crime has been committed by the legal entity in question and this crime can be attributed to one or several persons employed in the company. The rules on bribery will apply to benefits provided to individuals and organisations (to the extent that such organisations are seen as "legal entities").

In addition to the Criminal Code's provision on bribery, the question of public servants receiving gifts and other benefits is regulated by general principles in Danish administrative law and by a guide on good behaviour in the public sector issued by the Danish authorities in collaboration with the Danish Regions.

According to the Marketing Practices Act, businesses must comply with good marketing practices. Providing bribery to induce the sale of medicinal products is contrary to such good marketing practices and will thus also be illegal under the Marketing Practices Act.

8.2 Legislative or Self-Regulatory Provisions

As described in more detail under **9.1 Gifts to Healthcare Professionals**, it is not permitted to supply, offer or promise any healthcare professionals gifts or financial benefits except as specifically provided for in the Legislation. The reasoning behind this prohibition is that such gifts or benefits could be seen as inducements to prescribe certain medicinal products and such inducements would be illegal.

Similarly, the overall purpose of the Promotion Code is to create a framework for collaboration between the pharmaceutical industry and healthcare professionals. This collaboration must be made in such a manner that professional standards and ethics are paramount and that pressure opportunities and dependency between the parties are excluded.

In addition, ENLI has issued ethical rules for dialogue and negotiations with decision-makers (the "Lobby Code") that applies to pharmaceuti-

cal companies' dialogue and negotiations with politicians and authorities. According to Section 12 of the Lobby Code, there must never be any kind of financial dependency between pharmaceutical companies and the decision-makers. Similarly, company representatives must not act in a way that may cause suspicion of bribery.

Additionally, the purpose of ENLI's Patient Organisation Code is, among other things, to ensure that the collaboration between the parties is conducted in such a way as to exclude any possibility of pressure or dependency. ENLI's Donation Code also sets out that donations, grants and benefits in kind to institutions or organisations, comprised of healthcare professionals and/or that provide healthcare or conduct research (not otherwise covered by ENLI codes), are only allowed if, inter alia, they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

As a starting point, the supply, offer or promise to healthcare professionals of gifts or financial benefits is prohibited, cf Section 22(1) of the Advertising Order.

However, according to Section 22(2) of the Advertising Order it is legal to provide gifts if these are of an insignificant value and can be used by the healthcare professional in their practice. According to the Guidelines, the term "insignificant value" is interpreted as DKK300 per calendar year. This limit is not based on the price paid by the company, but is to be calculated on the basis of what the healthcare professional should have paid for the item if they were to purchase it on the market. Items that can be used in the practice of the healthcare professional include, for example, pens, clinical thermometers and calendars, but not art, lamps, radios or similar.

Additional specific exemptions to the prohibition against providing gifts are set out in the Advertising Order; for example, pursuant to Section 24 it is permitted to provide healthcare professionals reasonable payment in return for their consultancy services, and pursuant to Section 26 it is permitted to provide payment for healthcare professionals' professional training and information. Further, specific rules apply to rebates and samples (see **9.2 Limitations on Providing Samples to Healthcare Professionals**).

In the Promotion Code, the prohibition against providing financial benefits and gifts is set out in Section 12(1). These provisions are generally stricter than the corresponding provisions in the Legislation and generally do not even allow for the provision of inexpensive office supplies such as pens or calendars. However, in 2014 it was clarified that certain gifts of practical relevance (for example, paper and pens at professional symposia, congresses or the like) are acceptable if the items comply with the requirement to be of insignificant value.

According to Section 14 of the Promotion Code, the transmission of informational or educational materials to healthcare professionals is permitted, provided it is inexpensive, directly relevant to the practice of medicine or pharmacy business and directly beneficial to the care of patients. Such material or items must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. In addition, medical equip-

ment aimed directly at the education of healthcare professionals and patient care can legally be provided to the extent that it is inexpensive and does not influence the business practices of the recipient. Similar to the Advertising Order, the term "inexpensive" means that the total value of gifts to an individual healthcare professional must not exceed DKK300 per calendar year.

Other exemptions to the prohibition against providing gifts are also set out in the Promotional Code, for example:

- in Section 13 regarding the payment of healthcare professionals' professional training and information, and organising or sponsoring of specific events; and
- in Section 15 on payment of healthcare professionals in relation to consultancy services.

See also **9.3 Sponsorship of Scientific Meetings** and **9.7 Payment for Services Provided by Healthcare Professionals**.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to the Executive Order on the Provision of Samples of Medicinal Products No 1244 of 12 December 2005 (the "Sample Order") and the Guidelines, samples can be provided for free only if certain requirements are fulfilled:

- samples can only be provided to doctors and dentists, and only to the extent that they are certified to prescribe the product (provided that this is legal as part of their practice);
- samples can be supplied only in response to a written request – the request must be dated and signed by the doctor or dentist;
- only one sample a year can be provided to each doctor or dentist;
- the product must not be larger than the smallest package marketed;
- the sample must be marked "Free sample – not for sale";
- a sample must always be provided following a written (dated and signed) request from the recipient in question;
- the sample must only be provided by the owner of the marketing authorisation (or its representative) and provision must not be made via the pharmacy;
- every sample must be escorted by the SmPC; and
- no samples covered by the Act on Euphoriant Drugs must be provided.

The marketing authorisation owner must keep accounts of samples provided and such documentation must be stored for at least two years.

The Promotion Code incorporates the Sample Order and sets out a few additional requirements regarding the supply of samples of medicinal products. For example, samples must not be supplied for more than two years after the date of introduction (meaning the date on which the medicinal product is placed on the market for the first time), cf Section 19(1)–(2).

9.3 Sponsorship of Scientific Meetings

Pursuant to Section 26 of the Advertising Order, pharmaceutical companies can sponsor relevant scientific meetings or congresses and/or attendance by healthcare professionals to these events. Pharmaceutical companies can also provide or offer a healthcare professional:

- hospitality in the form of payment of direct costs for food, travel, accommodation, etc, in connection with advertising for and professional information on medicinal products; and

- professional information and training in the form of payment of direct costs of professional relevant courses, conferences, training, etc.

Specific requirements apply regarding the level of hospitality and accommodation.

If the event takes place abroad, pharmaceutical companies can only pay for the healthcare professional's participation if substantial reasons (eg, practicable or economic circumstances) for having the event in other countries can be identified, cf Section 26(4) of the Advertising Order.

As mentioned, the Promotion Code generally provides for stricter regulation than the Legislation when it comes to the prohibition against gifts and the exemptions thereto. Detailed guidance can be found in the Promotion Code Guidelines.

For companies to which the Promotion Code applies, it is possible to give or offer a healthcare professional training and professional information in the form of payment of direct expenses in connection with professional relevant courses, conferences, training, etc, in which the healthcare professionals participate or arrange, cf Section 13(1) of the Promotion Code.

The pharmaceutical company may also either:

- organise/co-organise events directed at healthcare professionals; or
- sponsor events organised by a third party responsible for the professional content.

Sponsorships must not be subject to the pharmaceutical company influencing the professional content of the programme.

All advertising, scientific or professional meetings, congresses, etc, that are organised or sponsored by, or on behalf of, a pharmaceutical company must take place at appropriate venues that are conducive to the main purpose of the event. It is, for example, not legal to use venues that are known for their extravagance or entertainment facilities, cf Section 13(3) of the Promotion Code.

Hospitality may only be offered when relevant. However, all forms of hospitality offered to healthcare professionals must be on a reasonable level and be strictly limited to the main purpose of the advertising or professional event, cf Section 13(7) of the Promotion Code. Any hospitality extended must be limited to travel, meals, accommodation and genuine registration fees, and must only be extended to the healthcare professional (eg, not the wife, spouse, children or similar). Companies must keep within the following thresholds if providing meals (food and beverages) to healthcare professionals, cf Section 13(8) of the Promotion Code:

- DKK450 for lunch;
- DKK850 for dinner; or
- DKK1,400 covering all meals at all-day meetings/conferences.

These thresholds apply to meals in Denmark, but if providing meals in other European countries, the thresholds laid down by the pharmaceutical industry associations in such countries prevail.

Similar to what is provided for under the Legislation, the Promotion Code, Section 13(4) sets out that no pharmaceutical company may organise or sponsor any events that take place outside the pharmaceutical company's home country, unless:

- most of the invitees come from abroad and it makes significantly more logistical sense to

hold the event in another country (eg, considering the countries of origin of most of the invitees); or
- given the location of the relevant resource or expertise relevant to the event, it makes significantly more logistical sense to hold the event outside Denmark.

Section 13(12) of the Promotion Code provides that in the case of international events where a pharmaceutical company is sponsoring the participation of a healthcare professional, any funding provided to such healthcare professional is subject to the rules of the jurisdiction where such healthcare professional carries out their profession (and not the rules of where the international event takes place). To the extent that Danish legislation is applicable, such provisions must, of course, still be abided by.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Hospitality by a pharmaceutical company in relation to scientific congresses (organised or sponsored events) must not include organisation or sponsorship of entertainment or other non-scientific events.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

As a starting point, a pharmaceutical company may not provide donations and grants to individual healthcare professionals or groups of healthcare professionals, cf Section 22(1) of the Advertising Order, unless specifically regulated (eg, in the case of gifts of insignificant value, cf Section 22(2)) or in relation to representation and sponsorships, cf Section 26.

Pursuant to Section 4 of ENLI's ethical rules for the pharmaceutical industry's donations and grants (the "Donation Code"), donations, grants and benefits to hospitals, hospital wards, private clinics or institutions and organisations comprised of healthcare professionals and/or that provide healthcare or conduct research are allowed if:

- they are made for the purpose of supporting professional activities;
- they are documented and kept on record by the donor/grantor; and
- they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

The Donation Code defines "grant" and "donations" as any kind of support given for projects, activities, equipment, units, etc.

According to Section 4(2), support for individuals is not allowed. The matter of financial contributions or sponsorships, the granting of payments in kind for services, the sponsoring of participation in congresses or other educational professional activities are not regulated by the Donation Code but by the Promotion Code.

According to the Promotion Code, donations and grants to individual healthcare professionals or groups of healthcare professionals (even for professional purposes, including distributing material or making a treatment database) is, as a rule, not legal. Explicit exemptions must also be found here to legally provide grants or donations – eg, in Section 13 (see **9.3 Sponsorship of Scientific Meetings**) or Section 14. According to the latter, the donation of medical equipment aimed directly at the education of healthcare professionals and patient care can legally be provided to the extent that it is inexpensive and does not offset the business practices of the healthcare professional.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The general prohibition on gifts mentioned in **9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions** will, as a rule, ensure that rebates and discounts cannot be provided to healthcare professionals.

However, under Section 37 of the Advertising Order, it is permissible for a supplier (eg, a pharmaceutical company) to provide rebates to a purchaser of medicinal products (eg, a pharmacy) to the extent that the rebate is based on a cost saving on the side of the supplier and the rebate is a direct consequence of a purchase behaviour by the recipient that deviates from the supplier's standard terms (eg, if fewer deliveries are made or more products are being ordered). Such rebates are referred to as "rebates based on costs" (*omkostningsbegrundede rabatter* in Danish).

Rebates based on costs must be proportionate in relation to the cost saving and a supplier must use similar principles of calculation of rebates to recipients who have the same purchase pattern. Rebates based on costs must further not be provided if they are:

- calculated on the basis of the supplier's cost price, or calculated with the supplier's cost price as an element in the calculation;
- based on cost relief as a consequence of rationalisation internally with the supplier; or
- based on rebates provided by others to the supplier.

It follows from Section 38 that rebates based on costs can be made only in the form of a rebate in the retailer's cost price.

The supplier must store certain information regarding the rebates (as described in detail in Section 40 of the Advertising Order) for three years. Also, the supplier is obligated to provide a statement of warranties and representations (*ledelseserklæring* in Danish) regarding the legality of the rebates provided, cf Section 42.

9.7 Payment for Services Provided by Healthcare Professionals

It is permitted to use healthcare professionals as consultants or advisers (in groups or individually) in relation to the following, cf Section 24 of the Advertising Order and Section 15 of the Promotion Code:

- professional services such as speaking at and chairing meetings;
- in clinical trials or training services; and
- participation in advisory board meetings or market research, and also when this participation involves remuneration and/or travel activity.

According to the Promotion Code, a prior written contract must be entered into between the pharmaceutical company and the healthcare professional, specifying the nature of the services and the basis of payment for these services.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Pursuant to Section 202(a) of the Danish Health Act (Consolidated Act No 210 of 27 January 2022) and Section 43(b) of the Medicines Act, collaboration between a healthcare professional and a pharmaceutical company concerning education or research and development must be notified to the Agency. A similar notification requirement applies to ownership by the health-

care professional of shares of up to DKK200,000 in the pharmaceutical company.

Other collaborations, or ownership by the healthcare professional of shares above DKK200,000 require approval from the Agency.

Executive Order No 716 of 24 May 2022 on Healthcare Professionals' Affiliation with Pharmaceutical and Medical Companies, etc (the "Disclosure Order") contains quite detailed requirements regarding notifications and applications for approval, and regarding publication of notifications and approvals.

Section 202(b) of the Health Act and Section 27 of the Advertising Order provide that if a healthcare professional receives payments from a pharmaceutical company to attend professionally relevant activities abroad, the person must notify the Agency. Such notifications will be published by the Agency on its website, cf Section 202(c). In this connection, a pharmaceutical company that has an authorisation under Section 7(1) or 39(1) of the Act, and that is undertaking the payments, is obligated to inform the healthcare professional about this notification duty, cf Section 43c of the Act.

The rules on transparency in connection with transfer of value are further described in **10. Pharmaceutical Companies: Transparency**.

In addition, under the Promotion Code, companies are obligated to notify the following activities to ENLI:

- activities that are organised or co-organised by the company (meetings, congresses, conferences, symposia, courses, etc), partially or fully directed against Danish healthcare professionals;
- activities where the company provides financial support (sponsor support) to a third-party event; and
- activities where the company buys an exhibition stand at a congress in Denmark.

Further, as mentioned, pharmaceutical companies are obligated to report all kinds of printed advertising material (leaflets, handouts, website material, etc) aimed at healthcare professionals on the Danish market.

Notification deadlines for each of the above are set out in Section 21 of the Promotion Code. The companies are obligated to notify online using a standard form.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Pursuant to the Disclosure Order, there are specific requirements applicable regarding transparency when it comes to pharmaceutical companies' affiliations with healthcare professionals.

While the main obligation to disclose information on the affiliation between the pharmaceutical companies and healthcare professionals is placed on the healthcare professionals (cf Chapter 61a of the Danish Health Act and the Disclosure Order), pharmaceutical companies have an obligation to report certain affiliations and transfers of value to the Agency and an obligation to inform the relevant healthcare professionals of such reporting (the Disclosure Order, Section 17–19). The rules apply to companies with permission subject to Section 7(1) (mar-

keting authorisation) or Section 39(1) (company authorisation) of the Act.

When a pharmaceutical company has established a relationship and is affiliated with a doctor, dentist or prescribing and proprietary pharmacists, the pharmaceutical company must notify this to the Agency, cf Section 17 of the Disclosure Order and Section 43b of the Act. Such notification must take place via the Agency's website once a year (by January 31st).

The pharmaceutical company must at the same time inform the individual healthcare professional in question about the notification made. Additional information regarding specific affiliations can be requested by the Agency.

Pharmaceutical companies are also obligated to inform the healthcare professional in question about their obligation to notify or apply for permission (in accordance with the rules set out in Sections 202a–202c of the Health Act and Sections 27 and 28 of the Advertising Order). The companies must also inform the healthcare professional that the Agency will publish information about the affiliation on its website.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The Disclosure Order's provisions regarding notification and information apply to pharmaceutical companies that have a marketing authorisation (cf Section 7 of the Act) and companies that have an authorisation from the Agency to, inter alia, produce, import, export, store and trade medicinal products (as set out in Section 39(1) of the Act).

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The Agency oversees compliance with the Legislation. Decisions made by the Agency can be brought before the Ministry via a complaint, and decisions made by the Ministry can be brought before the Danish courts.

As a self-regulatory authority, ENLI and its Investigator Panel (as first instance) can impose penalties on a member company if the company notifies any advertising activities that are considered to be in breach of the Promotion Code or if ENLI otherwise becomes aware of such activities; for example, via a complaint. Decisions from ENLI's Investigator Panel can be brought before the Board of Appeals.

Cases regarding non-compliance of the bribery provision in the Criminal Code will be investigated by the police and may result in a criminal case before the Danish courts.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Pharmaceutical companies can file a complaint against a competitor with the Agency on the basis of alleged non-compliance with the Legislation. Decisions made by the Agency can be appealed to the Ministry.

In the case of alleged non-compliance with the Promotion Code, pharmaceutical companies can file a complaint with ENLI's Investigator Panel (provided the competitor is bound by ENLI's rules). Such decision can be appealed to the Board of Appeals.

Pharmaceutical companies can also request that the Danish Consumer Ombudsman takes up a case on the basis of alleged non-compliance with the Marketing Act (cases can also be taken up ex officio). Decisions made by the Consumer Ombudsman cannot be appealed to another administrative authority.

Companies also occasionally initiate proceedings before the Danish courts against competitors for alleged non-compliance with the advertising rules. Such proceedings include interim injunction proceedings. The Danish courts have issued interim injunctions against violations of the rules on advertising of medicinal products in a limited number of cases.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The penalties that can be imposed due to non-compliance of the advertising rules specified in the Act are a fine and imprisonment of up to four months, cf Section 104(1) of the Act. Further (and depending on the specific basis of non-compliance), it can be required that the advertising activity is ceased, that a decision is published and/or that correction notices are issued, cf Section 69 of the Act.

Non-compliance with the provisions in the Advertising Order can be punished by a fine. For non-compliance with the Legislation, sanctions for companies can be imposed as set out in detail under the Criminal Code, Chapter 5.

Non-compliance with the Promotion Code or any of the other codes under ENLI's control (such as ENLI Penalties and Fees Regulation) can result in any of the following penalties:

- a reprimand;
- a fine; or
- a public reprimand.

ENLI may also require a pharmaceutical company to:

- rectify incorrect information;
- withdraw illegal advertising material;
- cease further use of illegal advertising materials;
- issue a corrective statement; or
- cancel or change a scheduled event (conferences, courses, etc).

11.4 Relationship Between Regulatory Authorities and Courts

Procedures initiated with ENLI can be filed in parallel with any proceedings before the Agency/Ministry. However, in such cases, ENLI will often suspend the case to wait for a decision from the Agency.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

As mentioned, under the Promotion Code, pharmaceutical companies must report all kinds of promotional material to ENLI. In 2021, ENLI carried out spot checks in 39 pct of the reported cases. Further, ENLI's focus areas have included preventative activities which, among other things, have been carried out by preparing and updating ENLI's numerous guidelines that elaborate the interpretation of ENLI's rules.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Chapter 7 of the Act applies to advertising of all medicinal products, including veterinary medicinal products. At the beginning of 2022, the new Regulation (EU) 2019/6 of the European Parlia-

ment and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC came into force. As a result, a new Executive Order No 130 of 25 January 2022 on the advertising of veterinary medicinal products (the "Advertising Order on Veterinary Medicinal Products") was issued. Further, the Agency issued two updated guidelines on advertising of medicinal products: one for medicinal products for human use and one for veterinary medicinal products.

Although advertising for veterinary medicinal products is regulated separately from medicinal products for human use (ie, in the Advertising Order on Veterinary Medicinal Products and the updated guideline on advertising on veterinary medicinal products), the rules are in many ways similar in Denmark.

Loeven Law P/S is a Danish law firm established by attorneys with experience from the largest Danish law firms. While maintaining the highest professional and ethical standards, Loeven's attorneys use their commercial understanding and international network to deliver uncompromising, effective and value-adding solutions to the firm's clients. Loeven's vision is to be a strong and dependable law firm that provides high-quality legal advice in all the industries and sectors it serves. The firm's main focus areas are life sciences, corporate and M&A, litigation and arbitration, intellectual property, media and entertainment, and IT law. Loeven's life sciences team comprises one of the strongest and broadest life sciences practices in Denmark. Loeven is domiciled in Frederiksgade in the heart of Copenhagen, a few steps from the Marble Church and Amalienborg Palace, the winter residence of the Danish royal family.

Authors

Jacob Ørndrup is widely recognised in Denmark and abroad as a leading expert in pharmaceutical law and healthcare law, and in R&D agreements and licence agreements. He has advised clients in cases concerning medicinal products, medical devices, biotechnology, food products, cosmetics and chemical products for more than 25 years. Jacob also has extensive experience in intellectual property law and litigation, including patents, trade marks and know-how infringement cases, and in preliminary injunction proceedings. Jacob joined Loeven Law Firm P/S on 1 January 2022. Previously, he worked with Gorrissen Federspiel as an attorney from 1998 to 2022, and as a partner from 2003 to 2022. He was admitted to the Danish Bar in 1995 and obtained right of audience before the Danish Supreme Court in 2002.

Louise Bertelsen Forman is a leading legal expert in the Danish life sciences sector. She has advised clients in cases concerning medicinal products, medical devices, health, food products, cosmetics and chemical products for more than ten years, with particular focus on advertising of medicinal products and cases concerning pharmaceutical law, healthcare law, R&D contracts, market access, GxP and regulatory matters. Louise teaches courses at Atrium under the Danish Association of the Pharmaceutical Industry, on the advertising rules on medicinal products in Denmark. Louise joined Loeven Law Firm P/S on 1 June 2021. Previously, she worked as an attorney in H Lundbeck A/S, a global pharmaceutical company with headquarters in Copenhagen.

Loeven Law Firm P/S

Frederiksgade 19
DK-1265
Copenhagen
Denmark

Tel: +45 70 60 50 26
Email: jo@loevenlaw.dk
Web: www.loevenlaw.dk

Trends and Developments

Contributed by:
Jacob Ørndrup and Louise Bertelsen Forman
Loeven Law P/S see p.142

Use of Climate and Environmental Claims in Marketing Materials

Use of climate and environmental claims in marketing materials has become widespread in recent years as sustainability becomes an even more important competitive parameter. This trend has also moved into the pharmaceutical industry.

Under Danish law, climate and environmental claims must not be misleading and must not make consumers believe that a product is more environmentally friendly and sustainable than it really is. Such misleading commercial practice is known as "greenwashing".

The general prohibition against misleading advertising is laid down in the Danish Marketing Practices Act No 866 of 15 June 2022 (the "Marketing Practices Act"). A similar prohibition against misleading advertising is found in the specific legislation on advertising for medicinal products (in particular, Chapter 7 of the consolidated Danish Medicines Act No 99 of 16 January 2018 and Executive Order No 849 of 29 April 2021 on Advertising of Medicinal Products, as amended by Executive Order No 134 of 25 January 2022), and in the Danish industry rules issued by the Ethical Committee for the Pharmaceutical Industry (ENLI) (in particular, the Pharmaceutical Industry's Code of Practice on Promotion, etc of Medicinal Products aimed at Healthcare Professionals (the "Promotion Code")).

In Denmark, the Danish Consumer Ombudsman (DCO) monitors compliance with the Marketing Practices Act, including the general requirement of fair marketing practices. In 2022, the Danish Parliament granted the DCO an additional DKK7 million each year until 2025 specifically in order to strengthen the DCO's work against greenwashing. The number of greenwashing cases within the DCO's office has increased significantly over the past year.

The DCO has issued guidelines regarding use of environmental and ethical claims, and a "quick guide" regarding environmental claims aiming to guide companies on the use of climate and environmental claims in their marketing.

The DCO's quick guide regarding environmental claims provides, among other things, that factual information used in marketing materials must be substantiated and that marketing materials in general must not be misleading. This means that climate and environmental claims must be factually correct and easy to understand for the average consumer. Further, where a company uses such claims in their marketing materials, the company must be able to document and substantiate the claims. Pursuant to the Marketing Practices Act, the DCO may require that all relevant information is submitted to the DCO, including documentation for climate and environmental claims.

The above-mentioned criteria are well-known from the standpoint of regulation of advertising for medicinal products and, therefore, are not new to the pharmaceutical industry. However, according to the Danish advertising rules, the information used in advertising for medicinal products must, as a minimum, supplement the

information in the medicinal product's summaries of product characteristics (SmPC) and this may have an influence on the use of climate and environmental claims and, ultimately, the contents of the advertising. Further, the DCO has stated that in general companies should not market their products as "sustainable", as this may indicate that the manufacture of the products in question does not have an impact on the environment, which is most likely factually incorrect.

The use of climate and environmental claims has also been at the top of the agenda for ENLI – ie, the self-regulatory body within the pharmaceutical industry in Denmark. In ENLI's view, the use of climate and environmental claims may be acceptable in advertising for medicinal products provided that the advertising in general is in accordance with the rules on advertising for medicinal products in the Promotion Code. However, the use of climate and environmental claims must only constitute secondary and supplementary information to other professional, relevant information about the therapeutic value of the medicinal product, including the effects of the medicinal product, safety profile, etc.

It follows from the Promotion Code that pharmaceutical companies can organise professional events for healthcare professionals (eg, professional relevant courses, congresses, training, etc) with the purpose of providing professional information and education. Up to this point, ENLI has interpreted the concept of professionalism strictly by assessing that events about climate and the environment did not meet the requirements for professional healthcare content. However, this has been modified in a recent decision from ENLI's Appeals Board, which ruled that presentations on climate and environmental aspects may be used during professional and educational events, provided that specific requirements are met. In the Appeals Board's view, the requirement for professionalism must reflect the current focus on sustainability and climate-friendly solutions due to the global climate crisis.

ENLI has subsequently stated that presentations on climate and environmental aspects of relevance for healthcare professionals may be part of professional, educational events if such presentations:

- ensure that healthcare professionals are presented with relevant facts with a view to a better understanding of climate effects for healthcare work;
- do not mention specific medicinal products; and
- can neither directly nor indirectly be perceived as advertising for medicinal products.

Thus, ENLI has recently expanded its interpretation of the concept of professionalism when it comes to conducting professional events and education. ENLI expects to update its guidelines supplementing the Promotion Code as soon as possible so that the new interpretation is reflected. However, ENLI has stated that companies can already rely on the above interpretation.

The topic of climate and environmental claims in advertising will likely receive increased attention in the future, as sustainability is of the highest interest for both healthcare professionals and end users, and as sustainability has become an integrated part of tender and procurement processes.

Employees' Activities on Their Own Social Media

In 2022, the Danish Medicines Agency (the "Agency") issued updated Guidelines No 9400 of 20 April 2022 on Advertising on Medicinal Products (the "Guidelines") which supplement the Danish legislation on advertising of medicinal products. The Guidelines specify the liability of employees of pharmaceutical companies for breaching the advertising rules in connection with the employees' activities on their own social media such as Twitter, Facebook, LinkedIn and other platforms. The Guidelines' regulation of such activities reflects the Agency's recent practice in several cases against employees and companies regarding activities on social media.

It follows from the Guidelines that any affiliation to a pharmaceutical company is relevant for the assessment of whether an activity is considered advertising of medicinal products. Therefore, if an employee likes or shares a post on social media containing positive mentioning of the pharmaceutical company's medicinal products, this may, depending on the circumstances, be considered advertising of the products, even if the employee is acting on their own.

However, the Guidelines also explicitly provide that employees are allowed to share (objective and factual) information about a medicinal product when promoting their own professional competencies on social media (eg, LinkedIn). Such mentioning will not be considered advertising for a medicinal product as the purpose of the mentioning is promotion of the employee's professional competencies rather than promotion of the medicinal product. Additionally, employees are allowed to like and share posts on social media containing general company branding.

Advertising on the internet and on social media is regarded as advertising towards the general public as this is accessible to everyone. Therefore, advertising on social media must be in compliance with the advertising rules to the public, meaning, among other things, that it cannot for example contain information on prescription medicine only and that it has to contain certain mandatory information. The rules on advertising to healthcare professionals only apply to web pages that are restricted in an effective manner by an individual password (eg, authorisation ID) without access for the general public.

There have been several cases in Denmark involving employees of pharmaceutical companies who have potentially breached the advertising rules by liking and sharing posts on social media containing positive mentioning of a pharmaceutical company's medicinal products. Most such cases have involved employees liking and sharing press releases or articles about the pharmaceutical company's medicinal products on social media, and the material breaches have mainly been related to this, resulting in pre-launch promotion, illegal advertising for prescription medicines towards the public or off-label promotion.

In connection with these cases, the Agency has assessed whether pharmaceutical companies can be made responsible for their employees' actions on social media. In such cases, the Agency will consider whether the pharmaceutical company has encouraged the employees' actions on social media. Furthermore, the Agency will look at whether the pharmaceutical company has appropriate guidelines in place regarding the employees' private use of social media, and whether it is stated in the guidelines that the employees must not like or share posts on social media mentioning the pharmaceuti-

cal company's medicinal products. Whether the pharmaceutical companies conduct appropriate training of the employees may also be a factor, as well as whether such training is mandatory for the employees. The position of the involved employees within the pharmaceutical company may also be taken into account.

Virtual Challenges

The COVID-19 pandemic had (and still has) a direct impact on scientific interactions and activities. During the pandemic, scientific international meetings or congresses had to be conducted virtually, which posed a challenge to the regulation of international meetings and congresses, including the choice of law.

In Denmark, choice of law in matters regarding electronic commerce is governed by Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (the "E-commerce Directive"), implemented in Danish Act No 227 of 22 April 2002 as amended by Act No 569 of 10 May 2022 (the "E-commerce Act"). Accordingly, the E-commerce Act applies to Danish pharmaceutical companies' advertising of medicinal products on the internet.

Pursuant to the E-commerce Act, a "sender country principle" applies to electronic commerce. Therefore, if marketing materials are made available by a Danish pharmaceutical company during an international virtual meeting or congress, the advertising for medicinal products must, as a rule, comply with the Danish advertising rules. Further, a "mutual recognition principle" applies, meaning that if, for instance, a German pharmaceutical company advertises for medicinal products during the same international meeting or congress, the German pharmaceutical company must comply with German advertising rules (and the German Code of Conduct), even though the advertising has Denmark as the target group.

The rules and principles laid down in the E-commerce Directive and the E-commerce Act are not new. Nevertheless, in the wake of the COVID-19 pandemic it became evident that the regulation of choice of law posed a challenge, as there may be variations in the applicable law depending on whether the scientific interactions and activities are carried out virtually or physically. For example, if a Danish pharmaceutical company physically attends a scientific meeting or congress in another country, then it is the hosting country's advertising rules that will apply according to the territorial principle.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has together with other global industry bodies issued a joint guideline on virtual and hybrid international medical congresses impacted by COVID-19 (the "Joint Guidelines"). It follows from the Joint Guidelines that pharmaceutical companies should consider the Code of Conduct of the region from which a majority of the participants are expected to come, based on past experience.

However, in Denmark, the authorities and industry bodies follow the principles laid down in the E-commerce Act (and the E-commerce Directive). Therefore, if advertising for a medicinal product is sent from Denmark, it will likely be Danish law and the Danish industry rules that apply to the activities.

The Agency's New Online Transparency Form

Pursuant to Danish law, healthcare professionals' affiliation with pharmaceutical companies is subject to specific transparency requirements. Both healthcare professionals and pharmaceutical companies have an obligation to disclose information on affiliations and transfers of value to the Agency. Some affiliations even require prior approval from the Agency. Notifications or submissions for approval must take place via the Agency's website by using a specific online transparency form.

In recent years, healthcare professionals and pharmaceutical companies have had to use different transparency forms depending on whether the healthcare professional or pharmaceutical company needed to disclose information about an affiliation or an economic benefit. In practice, this has caused problems as many affiliations and transfers of value were not properly notified to the Agency.

In 2023, the Agency is planning to launch a new "dynamic" transparency form via the Agency's website. With this new transparency form, it will be possible for healthcare professionals and pharmaceutical companies to notify the Agency about affiliations and transfers of value by using the same online transparency form.

However, the new transparency form does not change the obligations of the healthcare professionals or of the pharmaceutical companies laid down in Danish legislation.

The authors understand that the Agency expects the new transparency form to be available on its website by mid-2023.

Contributed by: Jacob Ørndrup and Louise Bertelsen Forman, **Loeven Law P/S**

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Authors

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Contributed by: Jacob Ørndrup and Louise Bertelsen Forman, **Loeven Law P/S**

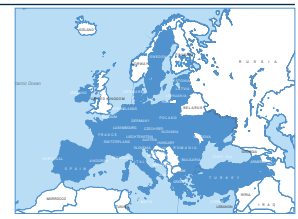
Loeven Law Firm P/S

Frederiksgade 19
DK-1265
Copenhagen
Denmark

Tel: +45 70 60 50 26
Email: jo@loevenlaw.dk
Web: www.loevenlaw.dk

Law and Practice

Contributed by:
Robin Blaney, Raj Gathani and Rosa Oyarzabal
Covington and Burling LLP see p.171



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EU

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In the EU, the advertising of medicinal products is regulated by laws at both the EU and national level, together with industry self-regulatory codes.

Law

Directive 2001/83/EC (the "EU Medicines Directive") sets out an overarching legal framework for regulating medicines in the EU. Articles 86 to 100 specifically regulate the advertising of medicines.

The EU Medicines Directive does not apply directly in EU member states, but must be transposed by member states into their respective national laws. There can be nuances in how countries have carried out this transposition, leading to differences in regulation at the EU member state level. Enforcement of the rules also principally takes place at the member state level.

A body of case law from the European Court of Justice interprets and builds upon the advertising provisions of the EU Medicines Directive.

The following EU legislation can also affect pharmaceutical advertising:

- Directive 2005/29/EC, concerning unfair business-to-consumer commercial practices in the internal market, which regulates advertising to consumers;
- Directive 2006/114/EC, concerning misleading and comparative advertising;
- Council Directive 2010/13/EU, concerning the provision of audio-visual media services; and
- Regulation (EU) 2017/2394, on co-operation between national authorities responsible for the enforcement of consumer protection laws.

Self-Regulation

To a large degree, medicinal advertising is regulated in the EU through industry self-regulatory codes. These industry codes generally apply to companies who are members of the relevant industry body or who voluntarily choose to comply.

These codes are often considerably more detailed and can be more restrictive than applicable EU and national laws. At the EU level, the Code of Practice of the European Federation of Pharmaceutical Industries and Associations (the "EFPIA Code") governs the promotion of prescription-only medicines to healthcare professionals. The EFPIA Code aligns with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice.

Most EU member states have national equivalents to the EFPIA Code. Please see **1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines** for further discussion.

There is no direct equivalent to the EFPIA Code for advertising non-prescription or OTC medicines, although there are self-regulatory codes that apply to such products at the national level.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The EFPIA Code has no force of law but is binding upon the members of EFPIA as a condition of membership. The principal members of EFPIA are research-based pharmaceutical companies, developing and manufacturing medicinal prod-

ucts in Europe for human use ("Member Companies"), and organisations representing pharmaceutical manufacturers at a national level whose members include research-based companies ("Member Associations"). Member Associations operate local-level codes in their respective markets in a manner consistent with the EFPIA Code. If a company commits to adherence to the EFPIA Code, it must also adhere to all applicable equivalent national codes.

Each EFPIA Member Company must either:

- be a member of the Member Association in each country where it conducts business covered by the EFPIA Code; or
- agree in writing with each such Member Association that it is bound by such Member Association's National Code (including any applicable sanctions that may be imposed).

Separate entities belonging to the same multinational Member Company are deemed a single company and therefore must also comply with the EFPIA Code and applicable national codes.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The EU Medicines Directive defines "advertising" as: "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products" (Article 86(1)).

The definition expressly includes the following activities within the remit of "advertising":

- advertising medicinal products to the general public and to healthcare professionals;
- visits by medical sales representatives to healthcare professionals;
- the supply of samples of medicines;
- the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;
- the sponsorship of promotional meetings for healthcare professionals; and
- the sponsorship of scientific congresses attended by healthcare professionals including the payment of their related travelling and accommodation expenses.

The EU Medicines Directive excludes several activities from this broad scope, which are discussed in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

Case Law

Case law from the CJEU has developed the definition of "advertising" under the EU Medicines Directive. In particular, the following are worth noting.

- Courts construe the term "advertising" very broadly in the pharmaceutical context. The term is not limited to the examples cited in the EU Medicines Directive, and can apply to various other modes of communication. These include the dissemination of promotional content over the internet.
- Case law highlights the existence of "promotional intent" as the fundamental defining feature of advertising (as opposed to the communication of non-promotional information). The existence of such intent requires a case-by-case assessment of the facts (MSD Sharp & Dohme GmbH v Merckle GmbH (CJEU, Case C-316/09) (MSD v Merckle)).

Promotional intent can therefore be inferred from the content and context of communications.
- "Advertising" may include communications that indirectly promote medicines, without necessarily naming products. The promotion of unspecified medicinal products (groups of medicines or medicines in general) may in certain circumstances also fall within the legal definition of "advertising medicinal products" (CJEU, Case C-530/20) ("Euroaptieka").
- "Advertising" may include the dissemination of information by a third party acting on their own initiative and independently of the manufacturer or seller of a medicine. That might include situations where the information being disseminated highlights the therapeutic or prophylactic properties of the product (CJEU, Case C-421/07) ("Damgaard").

The EFPIA Code

The EFPIA Code does not further define "advertising." However, it provides the following definition of "promotion":

"Any activity undertaken, organised or sponsored by a [pharmaceutical company], or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its [medicine(s)]."

This is a more holistic definition than that of "advertising" in the EU Medicines Directive, though it is consistent with the approach taken by the courts in construing advertising very broadly.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The EU Medicines Directive distinguishes advertising from the legitimate provision of certain types of non-promotional information, namely:

- the labelling and package leaflets of a medicine;
- correspondence, accompanied by non-promotional material, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims; and
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

In principle, these exclusions from the definition of advertising enable companies to:

- provide certain factual, non-promotional reference materials for members of the public, provided there are no product claims; and
- carry out health or disease awareness campaigns, provided these are not directly or indirectly linked with a particular product or group of products.

In MSD v Merckle, the ECJ recognised that the Directive's definition of advertising "does not, in principle, preclude publications or dissemination which include only objective information from being regarded as advertising." The Court distinguishes between messages "designed to promote the prescription, supply, sale or consumption of medicinal products", which are

considered advertising, and "material which is purely informative, without promotional intent", which remains out of the scope of the Directive.

The Court indicates that it is for national courts to determine whether a message or information has a promotional objective, based on "a detailed examination of all the relevant circumstances of the case." According to the Court, key factors for this assessment include the following.

- Purpose of the communication – this "constitutes the fundamental defining characteristic of advertising, and the decisive factor for distinguishing advertising from mere information" (paragraph 31).
- Identity of the sender – the Court clarifies that "although it is undeniable that the manufacturer of that medicinal product has a financial interest in marketing its product, the fact that the manufacturer disseminates such information itself cannot, as such, lead to the conclusion that it has an advertising purpose." There will be a difference between communications sent by, for example, the medical function of the company or marketing (paragraph 34).
- Content selectivity – the Court also holds that "the faithful reproduction of the packaging of the medicinal product, […] and in a literal and complete reproduction of the package leaflet or the summary of the product's characteristics" does not constitute promotion, provided that it is not accompanied by additional statements. This is not the case when the information is "selected or rewritten by the manufacturer, since such manipulation of information can be explained only by an advertising purpose" (paragraphs 43–44).
- "Pull" vs "push" dissemination – the Court distinguishes between so-called pull services, which require active research steps to obtain the information, and push services, where a user is confronted with information without searching for it (eg, "pop-ups"). According to the Court, for pull services, "communicating information with the assistance of a passive presentation platform is not, in principle, intrusive and does not impose itself unexpectedly on the general public." This is not the case for push services, "from which situation a strong presumption of advertising must, by contrast, be inferred" (paragraph 47).

2.3 Restrictions on Press Releases Regarding Medicines

The EU Medicines Directive does not expressly regulate press releases.

The EFPIA Code explicitly excludes from its scope of application any non-promotional or general information about Member Companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a Member Company and its Medicinal Products ("Scope" of the EFPIA Code). In principle, this permits press releases about medicines, provided they are genuinely non-promotional and are directed to individuals who have a legitimate interest in the company and its corporate activities.

2.4 Comparative Advertising for Medicines

In principle, the comparative advertising of medicines is permitted, subject to various general compliance requirements. However, national rules can be more restrictive, setting the compliance bar high and/or banning certain types of comparative advertising altogether.

At the EU level, comparative advertising must comply with generally applicable medicinal advertising rules (discussed throughout this survey) as well as particular rules governing comparative claims.

Comparative advertising is subject to Directive 2006/114/EC (the "Comparative Advertising Directive"). Article 4 of this Directive allows comparative advertising, provided that it:

- is not misleading;
- is only made between products that meet the same need(s) or are intended for the same purpose;
- makes objective and unbiased comparisons of one or more material, relevant and representative features of the product; and
- can be substantiated and verified with the information available.

These requirements are reflected in Section 3.05 of the EFPIA Code, which states that:

"Any comparison made between different medicinal products must be based on relevant and comparable aspects of the medicinal products. Comparative advertising must not be misleading or disparaging."

In practice, comparative advertising of medicines is subject to various additional rules at the national level, which can vary from country to country.

- In many EU countries, the comparative advertising of non-prescription products to the public is banned altogether. This is to avoid potentially misleading or confusing a non-expert audience.
- Some countries, such as Germany, require that comparisons made in HCP-facing advertising must only be based on head-to-head clinical studies.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Article 87(1) of the EU Medicines Directive prohibits the advertising of unapproved medicines (ie, unlicensed or pre-approval promotion) and advertising unapproved indications or uses (ie, off-label promotion). The EFPIA Code also incorporates this prohibition (Article 1).

There are certain well-established exceptions, which permit certain limited forms of non-promotional communications about unapproved medicines or indications. These include:

- non-promotional information given in response to a specific and unsolicited request (see **3.3 Provision of Information to Healthcare Professionals**);
- legitimate scientific exchange, for example at scientific conferences (see **3.2 Provision of Information During a Scientific Conference**); and
- factual, informative corporate announcements (eg, in press releases) (see **2.3 Restrictions on Press Releases Regarding Medicines**).

3.2 Provision of Information During a Scientific Conference

Legitimate Scientific Exchange

The IFPMA Code provides that the prohibition against pre-approval promotion:

"[…] is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences […]" (Clause 3).

Although "legitimate scientific exchange" is not expressly mentioned in the EU Medicines Directive or in the EFPIA Code, it is a concept generally recognised and respected both at the EU and national level. In general, to fall within the definition of "legitimate scientific exchange":

- the information/material communicated must have legitimate scientific or educational value;
- the content and context must be non-promotional; and
- there must be a genuine exchange.

Nonetheless, the parameters of what constitutes legitimate scientific exchange can vary at the national level and, ultimately, regulators are likely to take a case-by-case approach to assessing whether communications are legitimate or otherwise unlawful promotion. The involvement of a pharmaceutical company in sponsoring or preparing content that relates to its own pipeline product can, in some countries, create a presumption of promotional intent.

International Conferences

International conferences can be subject to specific rules. Although EU law is silent on this point, the EFPIA Code allows the sharing of promotional materials about unauthorised products or indications during international conferences, provided:

- any such promotional material is accompanied by a suitable statement indicating the countries in which the medicinal product or indication is authorised;
- the material makes clear that the medicinal product or indication is not registered locally; and
- the material referring to the prescribing information authorised in the countries where the product is registered is accompanied by an explanatory statement that explains that registration conditions differ in other countries (Section 8).

This is subject to many more restrictive requirements at the national level, and some countries, such as Denmark, prohibit the promotion of unauthorised products in all conferences.

3.3 Provision of Information to Healthcare Professionals

Proactive Information

As a general rule, in the EU, proactively giving HCPs information about unauthorised medicinal products or unauthorised indications is likely to be considered off-label or pre-approval promotion, and therefore unlawful.

The only real exception to this is the concept of legitimate scientific exchange (see **3.2 Provision of Information During a Scientific Conference**), though that envisages a dialogue between scientific peers rather than the proactive dissemination of content.

Reactive Information

In certain circumstances, it may be possible to provide HCPs with information about unauthorised medicinal products or unauthorised indications on a reactive basis.

Both the EU Medicines Directive and the EFPIA Code expressly permit "correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product" (Art 86 (2) EU Medicines Directive and under the "Scope" of the EFPIA Code).

If an HCP asks a specific question about an unauthorised medicine or unauthorised indication, the information a company provides in response may be protected from being classified as unlawful advertising (as it is not considered advertising per se).

3.4 Provision of Information to Healthcare Institutions

Neither EU law nor the EFPIA Code expressly regulates the provision of information to healthcare institutions (HCOs). Rules can exist at the national level enabling companies to communicate certain information to HCOs on a "need to know" basis. For example, where a product is close to launch and may need to be factored into HCO budgets, companies might be permitted to send advance budget-relevant information.

3.5 Information About Early Access or Compassionate Use Programmes

EU law and the EFPIA Code do not specifically regulate the provision of information about early access or compassionate use programmes.

As the medicinal products in question would be unlicensed, the products themselves cannot be promoted. The extent to which a company may raise awareness of the programme (rather than the product to which the programme relates) is subject to variable national rules. In some countries, the rules are silent. In Spain, there is a prohibition against advertising programmes. In Germany, the programme may be promoted, provided all communications are product-agnostic and no product is promoted.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Prescription-only Medicines

The EU Medicines Directive prohibits the advertising of prescription-only medicines to the general public (Article 88). This prohibition also applies to medicines containing psychotropic or narcotic substances.

As an exception, vaccination campaigns approved by the government or competent authority of the relevant member state can be promoted to the general public.

Reimbursed Products

The EU Medicines Directive also empowers member states to ban the advertising to the general public of any medicines that may be reimbursed nationally (Article 88(3)). Some countries have implemented this ban (eg, Spain) while others have not.

Samples

The direct distribution of samples of medicines to the public for promotional purposes is also banned.

Over-the-Counter Products

Medicines that are not "prescription only", so-called over-the-counter (OTC) medicines, may lawfully be advertised to the public.

A number of restrictions and requirements apply to the advertising of non-prescription-only medicines to the public. The disguised promotion

of medicines is prohibited. Any advertising of medicinal products must:

- relate to a product with a marketing authorisation;
- comply with the particulars listed in the summary of product characteristics (SmPC);
- encourage the rational use of the medicine, presenting it objectively and without exaggeration of its properties; and
- not be misleading (Article 87 EU Medicines Directive).

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Under Article 89 of the EU Medicines Directive, advertising directed at the general public must clearly indicate that it is an advertisement and identify the medicinal product, while containing the following minimum information:

- the name of the medicinal product, including any common name if the medicine contains a single active substance;
- any information necessary for the correct use of the medicine; and
- an express, legible invitation to carefully read the instructions accompanying the medicine on its package leaflet or outer packaging.

As an exception to this rule, member states may decide that, if the advertising is intended solely as a reminder, it may include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trade mark.

In addition, member states may decide to require more information. For instance, in both Belgium and Spain, respective national laws require that pharmaceutical advertising includes the name (or, in the case of Spain, logo) of the marketing authorisation holder for the advertised medicine.

Article 90 of the EU Medicines Directive requires that advertising to the general public not contain material which:

- implies that a medical consultation or surgical operation is unnecessary;
- suggests the medicine's effects are guaranteed effects, have no adverse reactions, or are better or equivalent to those of another medicine;
- suggests that taking the medicine enhances patient health;
- suggests that the health of the patient could be affected by not taking the medicine (although this does not apply to vaccination campaigns);
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, HCPs or celebrities;
- suggests that the medicine is a foodstuff, cosmetic or other consumer product;
- suggests that the safety and efficacy of the medicine is due to the fact that it is natural;
- could lead to erroneous self-diagnosis;
- refers in improper, alarming or misleading terms to claims of recovery; or
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicine on the human body.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Law

The EU Medicines Directive does not specifically regulate interactions between patients or patient organisations and industry.

The EFPIA Code

For the purposes of the EFPIA Code, a patient organisation (PO) is a non-profit organisation whose address or primary place of operation is in Europe and which is "mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers". PO representatives are defined as persons "mandated to represent and express the collective views of a PO on a specific issue or disease area".

POs and their representatives are treated as members of the general public, rather than HCPs. As such, the promotion of prescription-only medicines to POs is prohibited. The EFPIA Code contains specific principles in relation to the interactions of pharmaceutical companies with POs only, including:

- ensuring the independence of POs;
- basing all interactions between POs and EFPIA Member Companies on mutual respect, with their views having equal value;
- not requesting POs to undertake promotion of a particular prescription-only medicine;
- ensuring transparency of the objectives and scope of any collaboration; and
- welcoming broad funding of POs from multiple sources (Section 21.01 EFPIA Code).

In addition, companies must put in place a written agreement when providing financial support or significant indirect or non-financial support to POs, stating both the amount of funding and the purpose (eg, unrestricted grant, specific meeting or publication, etc) and including a description of any such significant indirect or non-financial support. There must also be a written agreement for all sponsorships, donations and grants to POs.

Companies must not influence the text of PO material which they sponsor in a manner favourable to their own commercial interests.

Gifts for personal benefit as well as providing or offering cash, cash equivalents or personal services to PO representatives are also prohibited (Section 11.01). Likewise, providing or offering a non-monetary promotional aid or donations and grants to PO representatives is prohibited (Sections 11.02 and 12 EFPIA Code).

Companies must also abide by the applicable national code(s) governing the criteria for the selection and support for PO representatives to attend events, and no payment must be offered to compensate for time attending events (Section 13.01 EFPIA Code).

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Law

Article 91 of the EU Medicines Directive requires advertising to "persons qualified to prescribe or supply such product", including HCPs, to include the following information:

- essential information compatible with the SmPC; and

• the product's supply classification.

Individual member states may require that advertising to HCPs includes the selling price or indicative price of the various presentations and any reimbursement conditions. Member states may also decide that in advertising intended solely as a reminder, the advertising of a medicinal product to HCPs may include only the product's brand or international non-proprietary name, or the trade mark.

Self-Regulation

The EFPIA Code mirrors the Directive in terms of the information required in promotional communications with HCPs, stating that, subject to all applicable national laws, promotional material must include:

- essential information consistent with the SmPC, specifying the date on which such essential information was generated or last revised;
- the supply classification of the medicinal product; and
- when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies (Section 2.01).

The Code adds that, where an advertisement is intended only as a reminder, the above requirements need not be complied with, provided the advertisement includes no more than the name of the medicinal product or its international non-proprietary name, where this exists, or the trade mark (Section 2.02).

The EFPIA Code also provides that the word "safe" must not be used to described a medicine without proper qualification. Similarly, the word "new" must not be used to described any medicine or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than one year. Companies must not state that a medicinal product has no side effects, toxic hazards or risks of addiction or dependency (Article 3).

Other restrictions will depend on the specific national laws, regulations and applicable code(s) in each member state.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The EU Medicines Directive provides that "all parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics" (Article 87(2)). This requirement is mirrored in the EFPIA Code, which states that promotion must be consistent with the particulars listed in the SmPC (Section 1.02).

However, the inclusion of information beyond the SmPC is not expressly precluded. Rather, as the Court of Justice decided in the case of Novo Nordisk AS v Ravimiamet (CJEU, Case C-249/09), advertisements may include information supplemental to that in the medicine's SmPC, provided that this information:

- confirms or clarifies, is compatible with, and does not distort the information in the medicine's SmPC;
- is presented objectively, without exaggeration and in a manner that is not misleading and encourages rational use of the product;
- is accurate, up-to-date, verifiable and sufficiently complete so as to enable the recipient to form their own opinion on the product's therapeutic value; and
- is faithfully reproduced and the source of quotations, tables and other illustrative matter

taken from medical or scientific journals is precisely indicated.

5.3 Advertising of Combination Products

Drug-Drug Combinations

Any advertising of or for a medicinal product must be consistent with the relevant medicine's SmPC. Where a combination of medicines is advertised, this is likely to be viewed by regulators as the products being individually advertised, thus necessitating consistency with both products' SmPCs.

In a scenario in which two medicinal products are both separately approved treatments for the same disease, but neither product's SmPC references its use in combination with the other, the analysis will be highly fact-specific and dependent on the contents of the SmPCs and applicable national requirements. There can be situations in which advertising a medicine in combination with another is inconsistent with one or both of the medicines' SmPCs due to, for instance, the fact that one or both of the SmPCs indicates that the medicine is a monotherapy or contains other contraindications to the use of the specific combination of medicines. If this is the case, advertising the combination of the medicinal products would constitute prohibited off-label advertising.

Drug-Device Combinations

With combinations of separate medicines and in vitro diagnostic medical devices (IVDs), such as companion diagnostics, advertising must comply with both pharmaceutical advertising rules and IVD advertising rules.

Regulation (EU) 2017/746 (the "IVDR") states that advertising of IVDs must not mislead with regard to the device's intended purpose, safety and performance by:

- ascribing functions and properties to the device which the device does not have;
- creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- failing to inform the user or patient of a likely risk associated with using the device for its intended purpose;
- suggesting uses for the device other than those stated as the intended purpose for which the device is conformity-assessed.

The promotion of an IVD must be consistent with its instructions for use. Before being placed on the market, an IVD must undergo a conformity assessment procedure, which will vary depending on the classification of the device. For companion diagnostics, the notified body conducting the conformity assessment must consult the EMA or national medicines regulatory before the name of the medicine may be included in the instructions for use.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Neither the EU Medicines Directive nor the EFPIA Code specifically regulate the provision of reprinted journal articles to HCPs by companies.

The proactive dissemination of scientific articles that refer directly to a medicinal product would, in principle, be considered "advertising" or "promotion" within the meaning of Article 86 of the EU Medicines Directive and the EFPIA Code, and therefore subject to the relevant EU rules on advertising medicinal products to HCPs (see **3. Advertising of Unauthorised Medicines or Unauthorised Indications**).

5.5 Medical Science Liaisons

Neither EU law nor the EFPIA Code provide for specific rules applicable to medical scientific liaisons (MSLs).

MSLs are generally regarded as scientific experts within a pharmaceutical company, who act as a liaison between the company and HCPs. As such, they are subject to the same rules applicable to any other employee of a pharmaceutical manufacturer. MSLs would in principle not be permitted to proactively discuss scientific information on unauthorised medicines or indications with HCPs, but may respond to unsolicited requests.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Pharmaceutical advertising is not subject to prior authorisation at the EU level. Specific prior authorisation or notification requirements will depend on the relevant national rules.

6.2 Compliance With Rules on Medicinal Advertising

Law

The EU Medicines Directive requires that the marketing authorisation holder for a particular medicinal product establish a scientific service in charge of information about the medicinal product (Article 98).

Marketing authorisation holders must also:

- retain a sample of all their advertisements together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;
- ensure that advertising complies with the relevant provisions of the EU Medicines Directive;
- verify that their medical sales representatives have been adequately trained;
- supply the competent authorities with any information and assistance required; and
- ensure full and immediate compliance with decisions taken by the competent authorities.

Self-Regulation

Under Section 20.01 of the EFPIA Code, the following applies for Member Companies.

- They must establish a scientific service in charge of information about their medicinal products and the approval and supervision of non-interventional studies (NIS).
- Companies are free to decide how best to establish such a service, but must include a medical doctor or pharmacist, where appropriate, to certify the final form of any promotional material before release, confirming that it is:
  - (a) in accordance with the requirements of the applicable code(s) and any relevant laws and regulations,
  - (b) consistent with the SmPC; and
  - (c) a fair and truthful presentation of facts about the product.
- The scientific service must include a medical doctor or, where appropriate, a pharmacist responsible for overseeing any NIS, to certify that the protocol relating to the NIS is in accordance with the requirements of the applicable code(s) and any relevant laws and regulations.
- They must appoint at least one senior employee to be responsible for supervising the Member Company and its subsidiaries in

ensuring that the standards of the applicable code(s) are met.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Law

The advertising requirements of the EU Medicines Directive apply equally to materials and information distributed online. There are no specific provisions in the Directive relating only to online materials, but there are in the national laws of some EU member states. For example, France has adopted its own digital advertising rules.

Self-Regulation

EFPIA has issued several guidelines on the use of digital channels, social media and virtual meetings.

Digital Channels

The EFPIA Code provides several principles for the use of digital channels at Annex 2 (which is non-binding), beginning with the statement that "laws and regulations applicable to other platforms and media also apply to digital media". Building on this, in September 2022, IFPMA and EFPIA published joint guidelines concerning the use of social media and digital media channels by pharmaceutical companies (the "Joint Digital Guidelines") updating the principles enshrined in the EFPIA Code.

The Joint Digital Guidelines specifically provide that Member Companies are responsible for all content disseminated via a digital channel where the content is initiated, branded, and/or sponsored by the Member Company or a third party acting on its behalf. Member Companies are thus required to establish processes for digital channels owned by them to review, monitor, moderate and/or, where appropriate and possible, to delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes.

According to the Joint Digital Guidelines, the main factors that companies should consider when assessing the appropriateness of digital channel content are the:

- objective of the communication;
- content made available on the digital channel;
- intended audience;
- channel standard set-up; and
- modalities by which the content is reviewed, approved and maintained including by the company.

Social Media

The general rules that apply to digital channels also apply to social media. In addition, the Joint Digital Guidelines contain specific principles applicable to "digital channels for interaction in social networks" (eg, Facebook, LinkedIn, Twitter, YouTube, Instagram) (see **7.4 Online Scientific Meetings** for further details).

Virtual and Hybrid Meetings

In April 2022, EFPIA, IFPMA and the Pharmaceutical Research and Manufacturers of America (PhRMA) published the Joint Guidance on Virtual and Hybrid International Medical Congresses. This guidance aims to detail specific principles applicable to virtual and hybrid international medical congresses (see **7.5 Use of Social Media**).

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Law

There are no specific EU-level restrictions on access to websites containing advertising intended for HCPs.

That said, companies should take all the necessary measures to ensure that the general public does not access promotional material intended for HCPs. They must ensure that any information disseminated through websites complies with the general rules applicable to advertising medicines (to HCPs and to the general public) described in the previous sections (see **7.1 Regulation of Advertising of Medicinal Products on the Internet**).

Self-Regulation

The EFPIA and IFPMA Joint Digital Guidelines detail principles applicable to websites containing advertising intended for HCPs.

The Joint Digital Guidelines state that websites are considered channels that reach the general public, unless verification (such as a pop-up for identification, or a password) is required to access the website – eg, for HCPs. Since many website visits result from the use of search engines, companies need to ensure that the use of keyword optimisation is appropriate for the intended audience.

If Member Companies sponsor website material to be produced by a third party, the role of the company must be made clear. The company will very likely be liable for the contents of the website if the company is:

- initiating the material, or the concept for it;
- influencing the content of the material in any way; or
- selecting or directly paying the authors.

In addition, companies should be careful with the pages or websites they link to their own websites. For example, a website directed to the general public must not link to content promoting prescription-only or unauthorised medicines.

7.3 Provision of Disease Awareness Information to Patients Online

There are no specific EU-level laws regulating disease awareness information online, provided that there is no reference, even indirect, to the medicinal product (see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**).

Self-Regulation

For disease awareness websites and the dissemination of information through social media, the principles explained in **7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals** and **7.5 Use of Social Media** apply.

7.4 Online Scientific Meetings

There are no specific EU-level laws for online meetings in relation to pharmaceutical products.

National rules may establish more detailed requirements for online meetings.

Self-Regulation

The IFPMA, EFPIA and PhRMA *Joint Guidance on Virtual and Hybrid International Medical Congresses* sets out specific principles applicable to virtual and hybrid international congresses. It applies to all virtual and hybrid international congresses organised by medical associations/societies involving HCPs from multiple coun-

tries, and activities organised by companies at these congresses (eg, exhibition stands, satellite symposia).

In particular, the Joint Guidance sets out several attendee identification and access requirements, including that:

- there should be a process to confirm participants' status as HCPs or non-HCPs (eg, patient advocates, journalists, industry representatives, etc);
- the congress's virtual platforms should allow for participant categorisation and companies should make reasonable efforts to restrict access to promotional material to HCPs only, where required – where the medical association's platform does not have a categorisation capability, Member Companies should consider alternative mechanisms to enable attendee classification for their promotional section; and
- if it is impossible to restrict access to HCPs only, Member Companies should clearly state to the attendees that the materials/communications are designed and intended for HCPs only.

Restrictions on non-HCPs are not applicable to industry company representatives or third parties engaged by industry.

The principles set out in the Joint Guidance complement the provisions of Article 10 of the EFPIA Code providing the applicable requirements to in-person meetings and events. These principles apply similarly to virtual and hybrid meetings and require that support and attendance be based on the event's educational value, considering the educational programme, overall cost, nature of the audience, cybersecurity and privacy arrangements, with attention paid to the overall impression given by all the various arrangements.

7.5 Use of Social Media

The advertising requirements of the EU Medicines Directive apply equally to materials and information distributed via social media. There are no specific provisions in the Directive relating only to social media, but there are in the national laws of some EU member states.

Self-Regulation

The IFPMA and EFPIA Joint Digital Guidelines establish specific rules for social media advertising, updating the principles already detailed in the EFPIA Code Annex 2.

Member Companies are responsible for their own social media page(s) and the content posted there. There is a strong presumption that the intent of dissemination through social media is promotional. For instance, any mention of a prescription-only medicine is likely to be considered promotion of that medicine to the public and prohibited.

Member Companies are also responsible for information disseminated by Member Company employees on their private social media channels, including when the employees:

- can reasonably be perceived as representing the Member Company; and
- are instructed, approved or facilitated by the Member Company to do so.

Member Companies should thus ensure that employees receive training appropriate to their roles for responsible conduct on social media.

Member Companies should also respect the rules relating to the social media audience. When

a social media channel is an "open" channel (ie, it is open to the general public), the relevant laws, rules and principles regulating interacting with the general public must usually be complied with (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**). On the contrary, when the social media channel is "closed" (ie, its access is restricted to a targeted audience), Member Companies should comply with the relevant law, regulations and principles regulating information directed to HCPs (see **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**).

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Generally, anti-bribery rules applicable to interactions with HCPs exist at a national, rather than EU, level.

However, there are anti-inducement rules under the EU Medicines Directive and the EFPIA Code which specifically regulate interactions between pharmaceutical companies and HCPs or HCOs, and which govern the offering of benefits, gifts and other inducements to HCPs and HCOs by pharmaceutical companies, as set out in **8.2 Legislative or Self-Regulatory Provisions**.

8.2 Legislative or Self-Regulatory Provisions

Law

Where medicines are being promoted, Article 94 of the EU Medicines Directive prohibits the provision of gifts, pecuniary advantages or benefits in kind being supplied, offered or promised to persons qualified to prescribe or supply such medicines (ie, HCPs), unless the gifts, pecuniary advantages or benefits in kind are inexpensive and relevant to the practice of medicine or pharmacy. The monetary limits for what constitutes "inexpensive" are set at a national level.

The Directive expressly permits hospitality to be provided to HCPs only at both promotional events and scientific events, provided that the hospitality is strictly limited to the main purpose of the event.

Self-Regulation

The EFPIA Code prohibits gifts for the personal benefit of HCPs, HCO members or PO representatives. The scope of this prohibition is broader than in the Directive, as it covers persons qualified to prescribe but also members of the general public. The prohibition also extends to providing or offering:

- cash, cash equivalents or personal services; and
- promotional aids (defined as "non-monetary items given for a promotional purpose") to HCPs, HCO members or PO representatives in relation to a prescription-only medicine (Article 11).

Informational or educational materials may be supplied to HCPs by pharmaceutical companies, provided such materials are:

- inexpensive;
- directly relevant to the practice of medicine or pharmacy; and
- directly beneficial to the care of patients (Section 17.01).

National codes determine what is considered "inexpensive".

Items of medical utility aimed directly at the education of HCPs and patient care may also be provided if they are inexpensive and do not offset the routine business practices of recipients (Section 17.02 EFPIA Code).

The provision of these materials and items must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer a medicine (Section 17.03). They may include a company's name, but must not be product-branded, unless the medicine's name is essential for the correct use for the material or item by the patient (Section 17.04 EFPIA Code).

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Law

Please see **8.2 Legislative or Self-Regulatory Provisions**.

Self-Regulation

Please see **8.2 Legislative or Self-Regulatory Provisions** on the prohibition of gifts. In addition, the EFPIA Code sets out key rules relating to events and hospitality (Article 10) applicable to interactions with HCPs, HCOs and POs.

In particular, when organising events and hospitality for HCPs, HCOs and POs, Member Companies must ensure the following.

- Event venues are appropriate and conducive to the main purpose of the event.
- They do not organise or sponsor an event that takes place outside the pharmaceutical company's home country unless it makes greater logistical sense to hold the event in another country because:
  - (a) most of the invitees are from outside its home country; or
  - (b) the relevant resource or expertise that is the object or subject matter of the event is located outside the country.
- Hospitality offered to HCPs, HCO members or PO representatives is appropriate and compliant with the provisions of any applicable code(s).
- Hospitality in connection with events is limited to travel, meals, accommodation and genuine registration fees.
- The value of any meal provided to a HCP, HCO member or PO representative does not exceed the monetary threshold set by the relevant EFPIA Member Association in its national code.
- Hospitality is only extended to persons who qualify as participants in their own right.
- All forms of hospitality offered to HCPs, HCO members or PO representatives are reasonable in level and limited to the purpose of the event.
- Hospitality does not include sponsoring or organising entertainment events.

Companies must also abide by the applicable national code(s) governing the criteria for the selection and support of HCPs or PO representatives to attend events and no payment must be offered to compensate for time attending events (Section 13.01 EFPIA Code).

9.2 Limitations on Providing Samples to Healthcare Professionals

Law

The EU Medicines Directive regulates the distribution of free samples to HCPs (Article 96). Samples may only be provided on an exceptional basis, and only to persons qualified to prescribe them, on the following conditions:

- the number of samples for each medicine each year on prescription must be "limited";
- any supply of samples must be in response to a written request, signed and dated, from the HCP;
- those supplying samples must maintain an adequate system of control and accountability;
- each sample must be no larger than the smallest presentation on the market;
- each sample must be marked "free medical sample – not for sale" or words to that effect;
- each sample must be accompanied by a copy of the SmPC; and
- no samples of medicinal products containing psychotropic or narcotic substances may be supplied.

Member states may define what is considered "limited" supply, and may also place further restrictions on the distribution of samples of certain medicines.

Self-Regulation

Article 19 of the EFPIA Code reflects the EU-level law, providing that:

- samples should be given only on an exceptional basis;
- samples must not be given to HCPs as an inducement to recommend and/or prescribe, purchase, supply, sell or administer medicines, and must not be given for the sole purpose of treating patients;
- samples should be provided only so that HCPs may familiarise themselves with the product and acquire experience in dealing with it; and
- samples (except psychotropics and narcotics) can only be given in response to a written request, signed and dated, from an HCP qualified to prescribe the particular medicine.

The Code further adds that:

- the "limited" number of samples that each HCP may receive per year per particular product shall not exceed four medical samples – this applies for two years after the HCP first requested samples of each particular medicine;
- Member Companies must have "adequate systems of control and accountability" for medical samples, which establish the number of samples supplied to each HCP; and
- each medical sample must be no larger than the smallest presentation of the particular medicine in the relevant country, and each sample must bear the marking "free medical sample – not for sale" or similar wording and be accompanied by a copy of the SmPC.

9.3 Sponsorship of Scientific Meetings

Law

The EU Medicines Directive allows companies to offer hospitality to HCPs at events for purely professional and scientific purposes, but does not otherwise regulate the sponsorship of meetings or the attendance of HCPs at these events.

Self-Regulation

Please see **9.1 Gifts to Healthcare Professionals**. Pharmaceutical companies are generally permitted to sponsor scientific meetings and HCPs' attendance at such meetings under the EFPIA Code, provided they comply with certain requirements in the EFPIA Code (Article 10) and all applicable national-level codes (ie, those of the member state in which the meeting is held, regardless of where the sponsoring company is based).

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Law

Under the EU Medicines Directive, it is not permissible to sponsor cultural, sports and other non-scientific activities alongside scientific conferences, unless these constitute the main scientific objective of the conference.

Self-Regulation

The EFPIA Code reiterates the aforementioned point, setting out that the limited hospitality permitted for scientific conferences must not include sponsoring or organising entertainment events, such as sports or leisure (Section 10.08). Similarly, the Code explicitly names sporting or entertainment tickets as examples of prohibited gifts for personal benefit (Section 11.01).

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The EU Medicines Directive does not specifically regulate the provision of donations and grants to HCPs and HCOs.

The EFPIA Code defines donations and grants collectively as "providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return". Donations and grants to individuals are prohibited. The EFPIA Code allows donations and grants to HCOs and/or POs, provided that they:

- are made for the purpose of supporting healthcare, research or education;
- are documented and kept on record by the donor/grantor; and
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines (Article 12 EFPIA Code).

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Restrictions on rebates or discounts to HCPs and HCOs are primarily governed by the national law of EU member states.

However, the EU Medicines Directive provides that "existing measures or trade practices in EU member states relating to prices, margins and discounts" are excluded from the prohibition on gifts, pecuniary advantages and benefits in kind, the restrictions on hospitality, and the inducement prohibition (Article 94).

The criteria for establishing what constitutes a trade practice and the criteria for their application (eg, the date by which the trade practice must have existed) will vary between member states. Thus, to benefit from this exception, companies will have to first establish whether a rebate or discount contemplated constitutes an actual trade practice in the relevant member state(s).

9.7 Payment for Services Provided by Healthcare Professionals

The EU Medicines Directive does not specifically regulate the provision of services by HCPs.

Article 15 of the EFPIA Code allows Member Companies to contract HCPs or PO representatives as consultants for services such as:

- speaking at and/or chairing meetings;
- involvement in medical/scientific studies;
- clinical trials or training services;
- participation at advisory board meetings; and
- participation in market research.

To the extent relevant to the particular arrangement, companies must:

- ensure that a written contract is agreed in advance of the commencement of the services, which specifies the nature of the services and the fees payable;
- identify and document a legitimate need for the services in advance;
- ensure that the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate candidates against such criteria;
- ensure that the number of consultants retained and the extent of the services are not greater than reasonably necessary to achieve the identified need;
- maintain records concerning, and make appropriate use of, the services provided by consultants;
- ensure that the engagement of the consultant is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular medicine; and
- ensure that the remuneration for the services is reasonable and reflects the fair market value of the services provided.

The contract should include a clause requiring the consultants to declare their position as consultants whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to the Member Company.

The EFPIA Code excludes from the scope of these rules limited market research, including one-off phone interviews or email questionnaires, provided that:

- the HCP, HCO member or PO representative is not consulted in a recurring manner; and
- remuneration is minimal.

Where an HCP or a PO representative attends an event in a consultant capacity, the hospitality rules of Article 10 apply (please see **9.1 Gifts to Healthcare Professionals**).

The EFPIA Code also contains disclosure requirements in relation to transfers of value, which may occur through payment for services provided by HCPs. Please see **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value** for further details.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

This area is governed by the national law of the EU member states, with some member states having restrictions built into their healthcare systems that regulate what type of services can be provided and what approvals would be needed. For instance, in France, if the value of the benefits provided to an HCP under a contract with a pharmaceutical company exceeds a certain level, the contract must be authorised by the relevant competent professional body.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Law

The EU Medicines Directive does not provide disclosure rules in this area. However, some member states have adopted national disclosure

requirements. For instance, under the Belgian Law of 18 December 2016 on "various provisions on health" (the "Sunshine Act"), pharmaceutical companies are required to document and annually disclose premiums and benefits that were granted, either directly or indirectly, to HCPs, HCOs or POs.

Self-Regulation

The EFPIA Code requires pharmaceutical companies to disclose transfers of value (ToVs) to HCPs, HCOs and POs.

The Code defines "ToVs" as "direct and indirect ToVs, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of [medicinal products] exclusively for human use." Direct ToVs are those made directly by an EFPIA Member Company for the benefit of a recipient HCP, HCO or PO. Indirect ToVs are those made on behalf of a Member Company for the benefit of a recipient, or those made through a third party and where the Member Company knows or can identify the recipient that will benefit from the ToV.

The Code requires the disclosure of donations and grants, sponsorship to events, and fees for services and consultancy for HCPs and HCOs (Section 23.05).

Disclosures must be made by each EFPIA Member Company within six months of the end of the relevant reporting period, and the information disclosed must remain in the public domain for a minimum of three years after it is first disclosed unless, in each case:

- a shorter period is required under applicable national laws or regulations; or
- the relevant data protection legal basis (eg, the legitimate interest ground, a legal duty or the recipient's consent relating to a specific disclosure) is no longer applicable (Section 22.01 EFPIA Code).

As an exception, ToVs do not need to be disclosed where they:

- solely relate to OTC medicines;
- are not listed in Section 23.05 EFPIA Code (such as items of medical utility, meals, and medical samples); or
- are part of ordinary course purchases and sales of medicines by and between a company and an HCP or an HCO (Section 23.03).

The EFPIA Code provides a template for these disclosures in Annex A. It explains that disclosure should be made either on the relevant company's website or on a central platform, such as one provided by the relevant government, regulatory or professional body (Section 23.04 EFPIA Code).

ToVs related to research and development in each reporting period must be disclosed by each company on an aggregate basis.

Each EFPIA Member Company must also disclose a list of POs to which it provides financial support and/or significant indirect/non-financial support, or with whom it has engaged to provide contracted services for that company (Article 24 EFPIA Code). This disclosure must include a description of the nature of the support or services that allows the reader to understand the nature of such without the need to reveal confidential information.

Disclosure must be done on the company's website on an annual basis, and each reporting period covers a full calendar year.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The disclosure requirements of the EFPIA Code apply to all Member Companies, defined in the Code as "research-based companies, developing and manufacturing medicines in Europe for human use".

These can be companies based outside the EU, provided they are developing and manufacturing medicines in Europe. There is also no requirement for Member Companies to have products on the EU market, needing only to be "developing and manufacturing" medicines. The Code also applies to affiliate Member Companies, defined as "companies specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry".

The Code specifies that separate entities belonging to the same multinational Member Company are deemed to constitute a single company and will therefore also be subject to the EFPIA Code. Even if a parent company is based outside the EU and is not a Member Company, any national subsidiary companies within member states will be expected to comply with the EFPIA Code if they are members of national EFPIA Member Associations, as they will be required to comply with the applicable national codes implementing the EFPIA Code.

As such, these would also be subject to the transparency requirements of the Code.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Law

Enforcement of EU pharmaceutical advertising laws is devolved to member states. Under Article 97 of the EU Medicines Directive, member states must:

- ensure that there are adequate and effective methods of monitoring pharmaceutical advertising, including legal provisions allowing those with a legitimate interest in preventing non-compliant advertising to take legal action against such advertising, or bring it before an administrative authority; and
- confer on courts or administrative authorities the power to order the cessation or prohibition of advertising, or, if misleading advertising has not yet been published but will be imminently, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication.

At the national level, enforcement rules vary from one member state to another. In Germany, for example, litigation before courts is very common. If a company violates a provision of the German Medicines Law, such violation is considered an act of unfair competition that is pursued among competitors through civil litigation. In other countries, such as Spain, enforcement will typically take place through self-regulatory bodies.

Self-Regulation

The EFPIA Code provides that its Member Associations must enforce the provisions of the Code within the current applicable national laws and regulations (Article 25 EFPIA Code). Under the

Code, if a breach of the applicable national code is established, each Member Association shall require the offending company to immediately cease its breaching activity and sign an undertaking to prevent recurrence.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings for advertising infringements are regulated at the national level by the relevant national laws and self-regulatory code(s) implementing the EFPIA Code applicable in each member state.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Applicable penalties and/or measures for violating pharmaceutical advertising rules depend on specific national laws, regulations and self-regulatory code(s) applicable in each member state.

Under the EFPIA Code, Member Associations should be able to order the immediate cessation of non-compliant activities and require companies to sign undertakings to prevent the recurrence of breaches.

11.4 Relationship Between Regulatory Authorities and Courts

This area is governed by national laws and self-regulatory code(s) applicable in each member state.

The relationship between regulatory authorities and courts may differ from one member state to another. In Germany for example, a competitor is free to bring action before a civil court and/or an arbitration body of a self-regulatory association. By contrast, in Spain, companies that adhere to the national self-regulatory code must file their claims before the self-regulatory body before raising the issue before a competent court.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

During the past two years, European regulators have increasingly concerned themselves with online and virtual activities, and MSLs.

Digital and Social Media

Digital communications and the use of social media have become hot compliance topics for the pharmaceutical industry in Europe. The COVID-19 pandemic and the reach of social media have pushed companies to increasingly try to find ways to use their social and digital platforms in a compliant way with the little guidance available both at a national and EU level (see **7.1 Regulation of Advertising of Medicinal Products on the Internet**). The COVID-19 pandemic has also led to transition from in-office visits and face-to face congresses to virtual and hybrid engagements to maintain scientific exchange with the medical community (see **7.4 Online Scientific Meetings**).

As a result, the number of enforcement cases related to advertising rules online has increased during the past two years.

MSLs

MSLs are regarded as scientific experts within a pharmaceutical company, who act as a liaison between the company and HCPs (see **5.5 Medical Science Liaisons**). They have greater knowledge and a more sophisticated understanding of scientific aspects of the product. Their intermediate position between the company and HCPs places them in a grey area. Due to the sensitive nature of their position, these professionals are the object of increasing interest from authorities.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

On 28 January 2022, Regulation (EU) 2019/6 on Veterinary Medicinal Products (the "VMPR") entered into force. Prior to that, the advertising of veterinary medicines was mainly unregulated at the EU level, principally governed instead by national self-regulatory codes. Today, manufacturers of veterinary medicines are faced with a complex landscape of directly applicable EU rules and national rules guidance that may not always match.

Articles 119 to 122 of the VMPR set out a detailed legal framework for veterinary medicines advertising, while allowing for some national leeway.

Similar to the EU Medicines Directive, the VMPR restricts advertising to authorised products, subject to any national exceptions (Article 119).

As a minimum, the VMPR requires that advertising of veterinary medicines:

- makes clear that it aims to promote the supply, sale, prescription, distribution or use of the product;
- is not formulated in a manner that suggests the medicine could be a feed or biocide;
- complies with the SmPC for the relevant medicine;
- does not include information which is misleading or could result in the incorrect use of the medicine;
- presents the medicine objectively and without exaggeration, thereby encouraging its responsible use; and
- does not take place during any suspension of marketing authorisation for the medicine.

In line with the EU Medicines Directive, the advertising of prescription-only veterinary medicines to the general public is prohibited. Such products may only be advertised to veterinarians or persons permitted to supply veterinary medicinal products in accordance with national laws (Article 120). In addition, member states may permit prescription-only veterinary medicines to be advertised to professional keepers of animals under the following circumstances:

- where the advertising is limited to immunological veterinary medicines; and
- where the advertising includes an express invitation to the professional animal keepers to consult the veterinarian about the product.

However, the VMPR prohibits the advertising of inactivated immunological veterinary medicines manufactured from pathogens and antigens obtained from animals in an epidemiological unit and used for the treatment of those animals in the same unit or a linked unit (Article 120(3)).

The VMPR allows the distribution of small quantities of samples of veterinary medicines for promotional purposes (Article 119(8)), but these samples must be appropriately labelled to indicate that they are samples and are to be given only directly to veterinarians or other persons allowed to supply such products during sponsored events or by sales representatives during their visits.

In line with the EU Medicines Directive, the VMPR has introduced inducement rules. These provide that where products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons, unless they are inexpensive and relevant to the practice of prescription or sup-

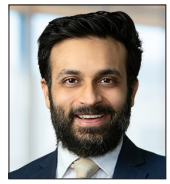
ply of medicines (Article 121(1)). Hospitality may be offered at events for purely professional and scientific purposes, provided it is strictly limited to the main objectives of the event.

Finally, Article 122 specifies that member states are allowed to lay down any other procedure they deem necessary for the implementation of the advertising rules in the VMPR.

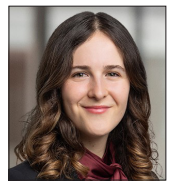
Covington and Burling LLP offers one of the largest and most comprehensive life sciences practices in the world. The firm's clients in the pharmaceutical industry range from start-up ventures to multinational corporations and trade associations, who for decades have trusted the firm with their most challenging business problems. Clients know that they can rely on Covington & Burling for practical, efficient solutions, rooted in a sophisticated knowledge of their business, the law and science, which only comes from deep immersion in the industry and decades of dedicated service. From the firm's offices in Brussels, Frankfurt and London, the tight-knit life sciences team offers advice on EU and national laws across the European continent.

Authors

Robin Blaney is a partner in the firm's life sciences practice. He advises pharmaceutical, biotechnology and medical device clients on a wide range of regulatory, compliance, transactional and legislative matters, including pharmaceutical advertising and communications strategies. Robin writes and speaks regularly on subjects such as medical device regulation, pharmacovigilance and clinical trials.



Raj Gathani is a senior associate at Covington & Burling LLP, based in London and Dublin. Raj specialises in pharmaceutical advertising matters both in Europe and the UK, and regularly publishes on this topic, both online and in print. He has advised and represented numerous clients both on compliance and in internal and external investigations regarding alleged breaches of advertising rules. He also advises pharmaceutical, medical device and healthcare clients in adversarial/complaint proceedings before regulatory and self-regulatory advertising bodies.



Rosa Oyarzabal is an associate in the life sciences team. She assists clients across a range of regulatory, legal and procedural matters in the pharmaceutical and food sectors, and her practice focuses on EU and Spanish regulatory advice. Rosa has acquired significant experience in the pharmaceutical advertising space, both at EU level as well in member states such as Spain and Belgium.

Covington and Burling LLP

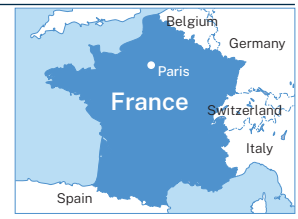
Manhattan Bolwerklaan 21
Avenue du Boulevard
B-1210 Brussels
Belgium

Tel: +32 2 549 52 50
Email: bvanvooren@cov.com
rgathani@cov.com
Web: www.cov.com

FRANCE

Trends and Developments

Contributed by:
Joyce Valencia
Valencia Avocat see p.182



The Legal and Regulatory Landscape for Advertising of Medicinal Products and Medical Devices in France

Laws and regulations from various sources govern the advertising and promotion of health products in France; indeed, there are both general and more specific rules applicable to health products.

The provisions of the French Consumer Code and the French Criminal Code prohibit and generally punish misleading commercial practices.

In addition, specific European regulations or directives, as well as French law (ie, the French Public Health Code (FPHC) and French Social Security Code (FSSC)), specifically regulate the promotion of health products. The FPHC, in particular, regulates health products such as:

- medicinal products for human use;
- medical devices (MDs);
- veterinary products;
- food supplements;
- cosmetics; and
- devices, objects and methods presented as beneficial to health.

In addition to the complex and extensive body of legislation, there are numerous – most not legally binding – recommendations, guidelines, charters or ethics codes governing advertising, to which health products operators may subscribe at the national, European or international level. The most important of these are listed below.

Authorities' charters, guidelines and recommendations

- Guidelines issued by the French National Agency for Medicines and Health Products Safety (ANSM):
  - (a) recommendations on advertisement of medicinal products, medical devices and in vitro medical devices, and objects and methods presented as beneficial to health; and
  - (b) the charter for the communication and promotion of health products (medicinal products and medical devices) on the internet and e-media.
- The charter for information by canvassing or prospection aiming to promote medicinal products, signed between the Economic Committee for Health Products (CEPS) and the French industry organisation representing pharmaceutical companies (Leem), applicable to operators marketing medicinal products reimbursed by the French health insurance scheme.
- The new charter for the quality of professional practices of persons responsible for presenting, providing information on, or promoting MDs for individual use, health products other than medicinal products and associated services which entered into force on 8 March 2022.
- Guidelines of the High Authority for Health (HAS) for the certification of activities relating to information gathered by canvassing or prospection aiming to promote medicinal products.

- General recommendations of the General Directorate for Competition, Consumer Affairs and Fraud Control (DGCCRF).
- Rules and recommendations of the professional code of ethics for general advertising issued by the French Professional Regulatory Authority for Advertising (ARPP).

Self-regulation guidelines and codes

- Guidelines and codes issued by industry organisations, such as EFPIA, MedTech, IFPMA, Leem and SNITEM (the French medical device industry association), along with reference documents, ethical professional provisions, and opinions.

Since 2011, there have been no major changes to the rules applicable to health product advertising.

However, some regulations have been completely overhauled in the last few years and have had an impact on the advertising of health products – eg, the early access scheme, the provisions of the new anti-gift act, and the EU regulation on medical devices.

The new charter for the promotion of MDs will drive the sector to anticipate, certify and track their promotional activities even more in-depth. The implementation of the new charter will require additional regulatory and organisational adaptations once the final certification reference framework (the "HAS referential") for these activities is published and effective. The last Social Security Financing Law (LFSS) for 2023 significantly increased MD regulation, which tends to show increasing similarities with the regulations applicable to medicinal products.

Moreover, a new bill is planned to be introduced in Parliament for examination by the end of March 2023 aiming to regulate e-media influencers' activities, and more specifically to ban advertising of certain health products by e-media influencers. Considering the actual restrictions, this bill, if adopted, may slightly impact advertising practices in the health products sector.

Promotion of Medicinal Products for Human Use

High-level overview of the French legal framework

Article 86 of EU Directive 2001/83 as implemented in the French Public Health Code (Article L 5122-1 and R 5122-1 et seq) defines the promotion of medicinal products for human use as being any form of information, including that derived from canvassing, prospecting or inducement, designed to promote the prescription, dispensation, sale or consumption of medicinal products, except for information provided by hospital pharmacists.

According to French law, the following are not considered as promotional materials or activities:

- information provided by hospital pharmacists (as stated above);
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual, informative announcements and reference material relating, for example, to packaging changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;
- information on human health or human diseases with no reference to a medicinal product; or

- institutional information (ie, information documents of a scientific, technical or financial nature, issued by the establishment or company, which are not intended to promote a medicinal product).

Companies should be aware that although some material may be presented as non-promotional or as part of the above list, any positive, complimentary or comparative information may convert it into promotional material and lead to a risk of sanction if the material does not comply with applicable rules.

For example, in the fifth case listed above (institutional information), when an advertisement for a pharmaceutical company mentions a medicinal product, it is automatically subject to promotional legal rules. Consequently, materials must be carefully analysed by internal advertising departments which are, by law, under the supervision and accountability of the pharmacist responsible.

France distinguishes between two different mechanisms depending on whether the targeted audience is the general public (GP) or healthcare professionals (HCPs).

In both situations, advertising is strictly limited to that authorised for marketing or to registered medicinal products for which no benefit/risk ratio reassessment is ongoing.

Promotion and advertising to the GP

Promotion and advertising of medicinal products to the GP is possible provided that the medicinal product is:

- not subject to medical prescription;
- not reimbursed by the French health insurance scheme; and
- not held back by a prohibition or restriction on advertising to the GP due to a possible risk to public health mentioned in the marketing authorisation or registration.

Notwithstanding the above conditions, regardless of their prescription or reimbursement status, advertising for vaccines and for smoking cessation products is authorised for public health purposes under certain conditions.

Advertising of medicinal products to the GP, including for the above-mentioned vaccines, is subject to prior authorisation (namely a "Visa GP") granted by the ANSM.

Promotion and advertising to HCPs

The promotion of medicinal products to HCPs (so-called "PM") is not limited regarding the product prescription or reimbursement status, but requires the pre-approval of the ANSM (in the form of a "Visa PM").

Unlike GP advertising rules, the provision of free samples of medicinal products to HCPs is permitted provided that certain legal requirements are met.

Advertising application process and periods

Applications to the ANSM for a Visa GP or a Visa PM for authorised products are carried out online and according to the respective filing periods (four periods for a Visa PM, eight periods for a Visa GP). In some cases, Visa applications may be submitted prior to the granting of the marketing authorisation or its amendment. In both situations, they can only be made during these periods.

The ANSM's decision dated 14 October 2023 sets out the timetable and submission periods for 2023 along with the form and content of

applications for approval of advertisements for medicinal products for human use.

Since 3 October 2022, application forms provided on the ANSM website have been updated along with the notice for applicants.

In the absence of a decision on a Visa application by the ANSM within two months of the day following the end of the filing period, the Visa application is deemed to be accepted.

Both the Visa GP and the Visa PM are valid for two years.

Updating of guidelines and recommendations

The ANSM guidelines for advertising have not undergone any major modification within the last year.

In fact, the only recommendation updated in 2022 by the ANSM was the recommendation on "minor changes that can be made to a material with a valid PM Visa".

However, the last working group session between the ANSM and the industry revealed some important information, as follows.

- The ANSM has announced its willingness to review its recommendations relating to the mentioning of price and reimbursement, and to consider the Early Access reform. To date, no timeframe has been disclosed.
- For advertising of medicinal products to the GP, the soundtrack used in a storyboard should also be submitted to the ANSM to avoid any risk of "guarantee by notoriety through a known tune or lyrics".
- To date, a podcast is not a permitted promotional material. This may change depending on future discussions.
- Clarification on claims of being "Made in France".

In addition, the HAS recently published its avenues of evolution to decrease the influence of health product canvassing on HCPs. This report is the result of an analysis of 199 studies and 12 systematic reviews published between January 2004 and December 2018 in more than 30 countries on the subject, and brings with it a very interesting description about the advertising practices in France.

Promotion of Medical Devices and In Vitro Diagnostic Medical Devices

High-level overview of the French legal framework

The FPHC (Article L 5213-1) defines the promotion of MDs and in vitro diagnostic (IVD) MDs as being any form of information, including canvassing, prospecting or inducement, designed to promote the prescription, dispensation, sale or use of devices, except information provided by hospital pharmacists.

Following the same path as for medicinal products, the following are not considered to be promotional materials or activities:

- labelling and instruction leaflets (IFUs) for MDs and IVD MDs;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular MD or IVD MD;
- information relating to warnings, precautions for use and adverse effects identified in the context of vigilance, as well as trade catalogues and price lists, provided they include no product claim; and

- information relating to human health or human diseases, if there is no indirect reference to an MD or an IVD MD.

Since 2011, the general advertising legal provisions set out by the FPHC for MDs and IVD MDs have not been subject to any major or significant modifications. Respectively, Articles L 5213-1 et seq and L 5223-1 et seq of the FPHC regulate the advertising and promotion of such devices.

Accordingly, promotion and advertising of medical devices is possible for the GP for both reimbursed Class I or IIa MDs and for MDs not reimbursed by the French health insurance scheme. Except for the derogation described below, prior authorisation is not required for such advertising. However, in any case, advertising Class IIb and III MDs is strictly forbidden for the GP.

The promotion of MDs to HCPs (which falls under PM) does not require any pre-approval by the ANSM, except in the cases described below.

The ANSM would eventually control the GP and PM promotion material. In this case, if the advertisement doesn't comply with the applicable requirements, the ANSM would be able to order the promotional material to be withdrawn after the fact, by following a specific administrative procedure.

By way of derogation in both GP and PM situations, prior authorisation is required for the promotion of MDs that present an important risk to human health. These MDs, listed in a decree dated 24 September 2012, include the following:

- for the GP – dermal depression fillers; and
- for the PM – implantable cardiac defibrillators and ankle, knee, hip and shoulder prostheses, etc.

The promotion of IVD MDs does not require prior authorisation, except in situations where their failure is likely to cause a serious health risk (eg, self-diagnosis IVD MDs for the GP and some specific reagents and reagent products for PM advertising, as stated in the decree dated 24 September 2012).

Where prior authorisation is required by law, the GP and PM Visas for IVD MDs and other MDs are granted for five years, provided that the CE marking is valid.

Unlike medicinal products, applications to the ANSM for promotional materials are not subject to a particular calendar.

What is new regarding MDs?

French Ordinance No 2022-582 adopted on 20 April 2022 to implement the MDR

The legal framework of MDs and IVDs has been reshaped by new Regulations (EU) 2017/745 and 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices and on in vitro diagnostic medical devices (the MDR and the IVD MDR, respectively), which became applicable as of 26 May 2021 and 26 May 2022.

An ordinance was adopted on 20 April 2022 by the French Parliament adapting French law to the MDR.

This ordinance has an impact on the FPHC advertising provisions, in particular as follows.

- The ANSM will carry out post-marketing surveillance and market surveillance for MDs and their accessories and for the products not intended for medical purposes listed in Annex XVI of the MDR. Accessories to MDs that present an important risk to human health are expressly subject to a prior authorisation for

their promotion. The violation of this provision, extended to accessories, constitutes both a criminal offence and an infringement under the terms of the draft ordinance subject to, respectively, a financial penalty and imprisonment, and an administrative fine.
- Advertisement to the GP of MDs and their accessories that are reimbursed, covered or financed (even partially) by the French health insurance scheme, except for reimbursed Class I or IIa MDs, constitutes an infringement under the terms of the draft ordinance.
- The ANSM will be competent to control after the fact, by all appropriate means, the advertising and promotion of products not intended for medical purposes, listed in Annex XVI of the MDR. According to the ordinance, the general power of control of the ANSM will be extended to those products listed in Annex XVI of the MDR, including the advertising activities related to them.
- Misleading conduct regarding promotional materials for MDs and their accessories and for those products listed in Annex XVI of the MDR will constitute an infringement subject to a financial penalty under the terms of the draft ordinance.

Accordingly, the ANSM and the DGCCRF will have a shared sanction power with respect to products regulated by the MDR (MDs and products listed in Annex XVI of the MDR).

To ensure constitutional sustainability of the ordinance, a draft ratification law was introduced before the French Parliament on 13 July 2022.

One notable point of 2023 is related to the DGCCRF investigation prerogatives, which have recently been highlighted by a procedure involving a MD operator that has led to a EUR6.6 million penalty for massive breach of the anti-gift law by an MD group.

EU Council vote on the MD Regulation extension

The proposed amendment has been formally adopted on 17 March 2023 by both the European Parliament and the Council with no modifications.

Accordingly, the delay for certifying medical devices under MDR rules is extended until 2027 or 2028 depending on the class of the MD and under specific conditions. This amendment aims to mitigate the risk of shortages.

The new charter dedicated to information and promotion of MDs, effective 8 March 2022

The LFSS for 2018 created Article L 162-17-9 of the FSSC which required the establishment of a new charter to ensure the quality of professional practices of persons responsible for presenting, providing information on, or promoting MDs for individual use, and for health products other than medicinal products and associated services.

Negotiations between the stakeholders – ie, relevant professional organisations and the CEPS – involved in the adoption of the charter were lengthy and not easy. In fact, these negotiations were ultimately unsuccessful, and the French Ministry of Health and Social Insurance was left to set out the terms of the MD charter. As a result, the long-awaited charter was eventually adopted by an order dated 4 March 2022, applicable as of 8 March 2022.

The charter aims to provide a better framework for commercial, promotion, presentation or information practices relating to all products and services mentioned in the reimbursement List of

Products and Services (LPP) referred to in Article L 165-1 of the CSS, whether or not they are subject to the regulations relating to CE marking, and which could otherwise be detrimental to quality of care, or lead to unjustified expenditure for the French health insurance scheme.

According to Article L 162-17-9 of the FSSC, a financial penalty can be imposed by the CEPS if a company does not comply with the provisions of the charter.

Under conditions to be determined by the HAS, a certification reference framework (the HAS referential) is to be established within one year from the publication of the charter (8 March 2023) to ensure that certified operators subject to the charter comply with its provisions. Pending the HAS referential, the charter cannot be completely implemented.

The certification bodies will be the recipients of any infringements observed and sanctioned by the CEPS, as well as of any financial penalties (up to 10% of turnover excluding tax) resulting therefrom.

According to the LFSS for 2023, the commitment of MD operators to complying with the charter is an essential condition for entering into an agreement with the CEPS.

Modification of Annex XVI of the MDR

An amendment of Annex XVI of the MDR reclassified certain active products without an intended medical purpose by way of derogation from Annex VIII to Regulation (EU) 2017/745, the impact of which shall be reassessed by operators to ensure compliance with promotion-applicable rules.

Updated guidelines

The ANSM recommendations have not been updated since the application date of the new MDR and IVD MDR.

Recent Developments and Points of Attention

ANSM financial and administrative penalties

The ANSM has the power to impose financial penalties on operators who do not comply with legal provisions.

The ANSM's decisions on this matter are published on the agency's website and are analysed by operators in the sector, as they provide information on the ANSM's doctrines.

In 2021, no financial penalties or injunctions related to promotion and advertising infringements were imposed on French operators.

According to the FPHC, infringements of advertising regulations can also be subject to financial penalties imposed by the CEPS. However, the provisional CEPS annual report for 2021, just published in December 2022, mentions no imposed penalties.

Pending the publication of the ANSM annual report for 2022, it cannot be determined whether the ANSM inspections focused more on the promotional activities of health operators.

New rules for influencers in the pipeline

A bill aiming to define the status of influencers, to regulate their practices and to ensure more transparency in their promotional activities was introduced for examination in the French Parliament in late December 2022.

Among other things, the bill proposes to prohibit influencers from promoting pharmaceutical products, medical devices and surgical proce-

dures on social networks unless the influencer is just relaying government public health campaigns.

However this bill was withdrawn on 9 February 2023, and is to be integrated into a broader bill that should be introduced in the French Parliament for examination by the end of March.

The MedTech code of ethics and its importance for MD operators

In 2015, the European trade association representing the medical technology industry (ie, in vitro diagnostics and medical device manufacturers operating in Europe) published the MedTech Europe Code of Ethical Business Practice (the "MedTech Code").

This code, which became binding for MedTech Europe corporate members on 1 January 2017, "regulates all aspects of the industry's relationship with healthcare professionals (HCPs) and healthcare organisations (HCOs), to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators, and – most importantly – patients".

In France, since 1 January 2022, all provisions of the MedTech Code are applicable to SNITEM member companies (ie, over 557 members with a significant position in France), which includes non-corporate members of MedTech Europe.

The MedTech Code lays down stricter rules than those governing interactions between HCPs/HCOs and IVD MD/MD operators in France.

Accordingly, relevant operators subject to the MedTech Code will no longer be able to provide direct financial support for individual HCPs to attend third-party organised educational events.

With the new French anti-gift scheme eventually coming into force pursuant to the publication of the long-awaited decree dated 1 October 2020, the IVD-MD and MD industries have had to anticipate every interaction, along with the expected delay, for the competent authority to authorise or respond to a declaration of interaction between HCPs and IVD-MD/MD operators.

It should be noted that the anti-gift law prevents companies manufacturing or marketing healthcare products or providing healthcare services from granting benefits, particularly to HCPs and HCOs. This framework has existed under French law since 1993 and was frequently updated, until being completely reshaped by Ordinance No 2017-49 of January 2017 (ratified by Law No 2019-774 of 24 July 2019). This new framework redefines the strict conditions under which certain benefits can be granted to HCPs and HCOs by healthcare companies. The regulation requires either a prior declaration or a prior authorisation to be submitted to the relevant professional board or relevant competent authority (regional health agency) depending on the amount of benefit to be provided to the recipients.

In any case, feedback from the authority is considered prior to the implementation of the regulated interaction.

The MedTech Code requirements represent a real challenge for operators subject to its provisions. The process for granting an indirect sponsor would need to start sooner, and the SNITEM estimates that the delay between the signature of the grant agreement with the third-party beneficiary and the event date is between four and eight months.

Detailed processes are required to be implemented internally within relevant operators in order to comply with all the ethical and legal requirements.

Conclusion

The regulatory environment of advertising of medicinal products and medical devices has been modified by direct and indirect changes affecting the applicable rules.

In 2022, MD operators are most affected by these changes, due to the implementation of the MDR, the charter dedicated to providing information on and promoting MDs, and the implementation of a restrictive framework for the provision of direct financial support of individual HCPs to attend third-party organised educational events. This has significantly modified the mindset and internal organisation of MD operators.

Valencia Avocat is a Parisian law firm that acts exclusively for companies in the field of life sciences and healthcare. The firm assists its clients on legal and regulatory matters relating to early access and market access, promotion and advertising, anti-gift and transparency, legal structuring, pharmaceutical activities and related agreements. The firm also assists clients in product liability cases and litigation against the French health administration. In addition, Valencia Avocat's practice is particularly focused on market access matters related to price and reimbursement of health products, and litigation against health authorities' decisions, such as early access decisions, withdrawals, modifications, suspension of marketing authorisations, refusal of inscription of medicinal products on reimbursement lists before the French Administrative Supreme Court, price set-up for reimbursed medicinal products, and health authorities' penalties. The firm works in English, French and Spanish.

Author

Joyce Valencia is the founder of Valencia Avocat. With over ten years of experience in the life sciences field, Joyce has extensive knowledge of the pharmaceutical industry environment. Her practice focuses on regulatory matters and, more particularly, on access to the French market (price and reimbursement) of health products. Her past litigation experience in the French Ministry of Health has led to her developing keen expertise in litigation relating to market access, French health authorities' decisions and product liability. Additionally, Joyce has developed specific and recognised skills on strategic negotiation with French authorities. She is an author of a French legal encyclopaedia on health law.

Valencia Avocat

173 rue de Vaugirard
75015 Paris
France

Tel: +33 970 444 404
Email: contact@valencia-avocat.com
Web: www.valencia-avocat.com

JAPAN

Law and Practice

Contributed by:
Michiru Takahashi, Benjamin Lang and Chizuru Yoshida
Jones Day see p.206

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JAPAN

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Japan is regulated by both Japanese laws and regulations as well as self-regulatory codes created by trade associations in the pharmaceutical industry. The main law that regulates pharmaceutical advertising is the Pharmaceuticals and Medical Devices Act (Act No 145 of 10 August 1960, as amended) (the "PMD Act"). The major self-regulatory codes include the codes created by the Japan Pharmaceutical Manufacturers Association (JPMA) and those created by the Japan Self-Medication Industry (JSMI).

Laws and Regulations

In Japan, the Act against Unjustifiable Premiums and Misleading Representations (Act No 47 of 19 May 1997, as amended) (UPMRA) provides some general rules concerning advertising. However, in the case of pharmaceutical advertising, the PMD Act, which is the main law that regulates drugs, has several special articles that regulate pharmaceutical advertisements.

PMD Act

Articles 66, 67 and 68 of the PMD Act provide for the following.

The prohibition of advertisements for unauthorised drugs

The PMD Act states that no person shall advertise the name, manufacturing process, indications or performance of a drug before obtaining the necessary marketing authorisation from the Japanese government.

The prohibition of false or exaggerated advertisements

The PMD Act states that no person shall, explicitly or implicitly, advertise, describe or disseminate the name, manufacturing process, indications or performance of a drug using false or exaggerated statements.

The prohibition of advertisements endorsed by a doctor

The PMD Act states that the advertisement, description or dissemination of statements giving the false impression of an endorsement by a medical doctor or other medical professional of the efficacy or performance of a drug shall be prohibited.

The prohibition of obscene statements or diagrams

The PMD Act states that no person shall use obscene statements or diagrams or those suggesting illegal abortions in connection with the advertisement of drugs.

The regulation of advertisements for drugs for designated diseases

The PMD Act states that no person shall advertise to the general public drugs intended for use in the cure of cancer, sarcoma or leukaemia, and that are likely to be highly dangerous if used without the direction of medical doctors or dentists.

Administrative fines

The PMD Act was amended on 17 November 2019 to introduce administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies to correct improper advertising, among other revisions. These amendments came into effect on 1 August 2021.

The MHLW Regulations

The Ministry of Health, Labour and Welfare (MHLW) is the competent governmental authority with regard to medicines in Japan and has promulgated the PMD Act Enforcement Ordinance, the PMD Act Enforcement Regulations and various other notices for the enforcement of the PMD Act. One example is the "Standards for Appropriate Advertising concerning Medical Goods" (Notification No 0929-4 of the Pharmaceutical Safety and Environmental Health Bureau of 29 September 2017) (the "MHLW Standards"), which were issued by the MHLW in the form of an official notice and which have as their central function the regulation of pharmaceutical advertising.

The MHLW Standards

The MHLW Standards prescribe the standards of conduct that must be adhered to by any person or entity when advertising drugs. The MHLW Standards consist of two parts: the first part relates to the interpretation of "False or Exaggerated Advertisements" under Article 66 (1) of the PMD Act, and the second part sets forth rules to prevent misuse, drug abuse and the deterioration of drug reliability.

Specifically, the first part of the MHLW Standards sets forth specific rules regarding:

- expressions related to product name;
- expressions related to manufacturing process; and
- expressions related to indication, dosage, administration and safety.

The second part of the MHLW Standards prescribes rules or restrictions regarding:

- the inducement of excessive use or abuse of drugs;
- advertising prescription-only medicines;
- expressions related to drug performance in advertising to the general public;
- drug addictiveness warnings;
- precautions;
- slander of other companies' products;
- endorsements by healthcare professionals;
- premium advertising;
- offensive advertising;
- email advertising;
- statements on television or radio programmes; and
- the use of drugs as cosmetics or food.

The Detailing Guidelines

In order to prevent the dissemination of inappropriate information during the course of promotion activities, the MHLW issued its new "Guidelines Concerning Detailing Activities of Ethical Drugs" (the "Detailing Guidelines") on 25 September 2018. The Detailing Guidelines took full effect on 1 October 2019 and include:

- basic principles for detailing activities;
- responsibilities of company management, including organisational measures (such as establishing independent supervisory divisions for monitoring activities), employee training and record keeping;
- responsibilities of individuals who conduct detailing activities; and
- guidelines on offering information on unauthorised drugs and off-label uses.

Self-Regulatory Codes

With regard to prescription-only medicines, a trade association of leading Japanese pharmaceutical research companies issues the major self-regulatory codes. In particular, the JPMA Code is the main regulatory code that regulates pharmaceutical advertisements. The JPMA Code has two chapters. The first chapter is the

Code of Practice (the "JPMA Code of Practice") and the second chapter is the Promotion Code (the "JPMA Promotion Code"). The JPMA Code establishes the rules that all member companies must comply with when promoting prescription-only medicines.

The JPMA has also issued several additional guidelines relating to pharmaceutical promotion. Among these are the Guidelines for the Drafting of Prescription Pharmaceutical Products Informational Material (the "JPMA Drafting Guidelines"), see **5. Advertising to Healthcare Professionals**.

With regard to advertising over-the-counter (OTC) medicines, the JSMI, a trade association of Japanese over-the-counter manufacturers, issued the Guidelines for Proper Advertising of Over-the-Counter Medicines (the "OTC Guidelines"). The OTC Guidelines apply to the advertising of non-prescription drugs to the general public. In particular, the OTC Guidelines regulate advertising through newspapers, magazines, television, radio, websites and other forms of mainstream media to ensure the appropriateness of publicity and advertising activities of non-prescription drugs.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes apply to the member companies of the particular trade association that created the code. For example, the codes created by the JPMA apply only to pharmaceutical companies that are JPMA member companies.

Conduct that violates self-regulatory codes does not necessarily violate Japanese laws and regulations; such conduct is only illegal if it independently violates Japanese laws and regulations. However, a violator may face sanctions under the self-regulatory codes, potentially damaging its reputation.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Notice No 148 dated 29 September 1998, issued by the Pharmaceutical Safety Bureau of the MHLW, defines "advertising" for the purposes of the PMD Act. This notice states that "advertising" has all of the following three characteristics:

- it has a clear intention to induce customers to make purchases;
- the product names of particular medicines are clearly expressed; and
- it can be seen by the general public.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Advertising and other information are distinguished by the above definition of "advertising". First, advertising must be clearly intended to induce customers to make purchases. For example, it is not likely that a book in a medical library describing certain drugs and targeted at researchers would have such an intention. The second requirement – the clear expression of product names – may be met even in cases where particular product names are not mentioned; this would be the case if the general public could recognise particular medicines from the pictures or descriptions of those medicines in the advertisement. Finally, the third requirement – the ability to be seen by the general public – would not be likely to be satisfied if the relevant information is, for instance, only provided to patients in a hospital, since the narrow scope

of its distribution would limit the potential for the information to reach the general public.

Disease-awareness campaigns and other patient-facing information do not qualify as "advertising" under the PMD Act unless they satisfy all three parts of the definition of advertising set out above. For example, if a disease-awareness campaign informs the public in a general way about a certain disease and does not name specific medicines, it is not considered "advertising" under the PMD Act. However, a disease-awareness campaign that provides patient-facing information concerning prescription-only medicines to the general public would run a risk of being "advertising" under the PMD Act. In this regard, the JPMA Code of Practice suggests that the content of disease awareness activities targeting ordinary citizens and patients be closely examined from the planning stages to ensure that they will not be considered prohibited advertising.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases regarding medicines are not prohibited. However, if a press release satisfies the three parts of the definition of advertising mentioned in **2.1 Definition of Advertising**, both the regulations concerning advertising under the PMD Act and the MHLW Standards will apply.

Generally, the restrictions under the PMD Act are more stringent when the target audience is the general public than when the target audience is healthcare professionals. For example, advertisements for pharmaceutical products used for cancer, sarcoma or leukaemia aimed at the general public are prohibited under Article 67 of the PMD Act.

2.4 Comparative Advertising for Medicines

Comparative advertising of medicines is not prohibited but is restricted by Japanese law and self-regulatory codes. According to the Commentary of Article 9 of the MHLW Standards, a pharmaceutical company's comparative advertising must only feature its own products and the advertising must specify the name of those products. Comparisons with competitors' products are prohibited. In addition, when a pharmaceutical company compares two of its own products, the company must ensure that it provides a sufficient explanation of the products.

Further, the JPMA Promotion Code stipulates that comparative advertising "shall be based on scientific data and, in principle, shall be made using generic names".

Finally, the Consumer Affairs Agency has issued general guidelines for comparative advertising. These guidelines suggest that a comparative advertisement shall be considered a "Misleading Representation" prohibited under the UPMRA if:

- it makes comparisons using unproven or unprovable facts;
- it emphasises unimportant matters as if they were important or makes comparisons based on an unfair selection of products; or
- it merely slanders or defames competitors' products.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Article 68 of the PMD Act expressly prohibits advertising unauthorised medicines or unauthorised indications. However, providing information on unauthorised medicines or unauthorised indications that falls outside the definition of "advertising" under the PMD Act is allowed.

Guidelines for Providing Information

The Detailing Guidelines include the following conditions for providing information on unauthorised medicines and unauthorised indications:

- separating information on unauthorised medicines and unauthorised indications from other promotion activities;
- providing such information only to individuals who have actually requested it;
- providing only accurate information that is based on scientific and objective evidence, without omissions, emphases, exaggerations or misleading summaries;
- providing information relating to a clinical trial involving a pharmaceutical company only if the research adheres to Good Clinical Practice, the Clinical Research Act or other equivalent rules;
- providing negative information such as information relating to adverse effects;
- clearly indicating that such indication, dosage or method of administration has not been approved; and
- preparing and maintaining records detailing information that has been provided on unauthorised medicines and unauthorised indications.

Cases Permitting Additional Information

The JPMA Promotion Code requires that member companies may only provide certain information, such as indication, dosage and administration, which may not deviate from the approved label for the relevant drug. However, the Commentary of the JPMA Promotion Code lists several cases in which the provision of other information is permitted if the information is provided for the purpose of promoting the right to know about scientific/medical advancements for both medical/pharmaceutical experts and the general public. These cases include:

- presenting research findings at scientific conferences or scientific journals;
- displaying exhibition materials at an international scientific conference (limited to unapproved drugs which have been approved in at least one country);
- supplying previously reviewed academic literature; and
- disclosing information to stockholders as required by law.

Moreover, the Commentary notes that, even if the activity consists of providing information as permitted above, the company must take special care not to be involved in any inappropriate promotional activities for its own commercial purposes.

3.2 Provision of Information During a Scientific Conference

The Commentary of the JPMA Promotion Code lists two cases in which providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals is allowed.

The first case is the presentation of clinical research results during a scientific conference. However, seminars sponsored by pharmaceutical companies are not covered by this exception.

The second case is the display, by a pharmaceutical company, of educational samples of an unapproved medicine at an exhibition during an international scientific conference held inside or outside Japan to the extent that Japanese medical professionals are in attendance. This only applies, however, when the unapproved medicine has been approved in at least one other country. If no countries have approved the product, the company may not display a sample of the product. In addition, the pharmaceutical company may not distribute samples of unapproved medicines and related scientific materials to anyone during the conference.

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the Detailing Guidelines provide certain conditions on providing information on unauthorised medicines or unauthorised indication and such conditions will also apply to the provision of information during a scientific conference.

3.3 Provision of Information to Healthcare Professionals

The Commentary of the JPMA Promotion Code allows the supply, by a pharmaceutical company, of peer-reviewed scientific journal articles, such as reprints of medical journals, upon the request of a medical doctor. However, companies shall not proactively induce a medical doctor to request such scientific journal articles.

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the Detailing Guidelines provide certain conditions on providing information on unauthorised medicines or unauthorised indication.

3.4 Provision of Information to Healthcare Institutions

There are no Japanese laws or self-regulatory codes that expressly regulate the sending of information on unauthorised medicines or indications to healthcare institutions to enable them to prepare budgets. Given that there are no laws or self-regulatory codes that permit such transmission of information, there remains a risk that such conduct would be considered a "promotional activity on unauthorised medicines or unauthorised indications", which is prohibited under Article 68 of the PMD Act.

3.5 Information About Early Access or Compassionate Use Programmes

Japan's compassionate use programme is intended to promote the expansion of clinical trials for patients who are interested in using unapproved products but are unable to join a clinical trial because they do not meet the inclusion criteria. This expanded trial system applies to investigational products that have gone through or are currently going through a clinical trial that is in the final stage of development; generally, clinical trials conducted to verify efficacy and safety after indications and dosage and administration have been established through a separate series of studies ("Main Trials").

In order to provide such patients with information on the ongoing Main Trials or expanded trials, the PMDA will publish on its website certain information, such as a description of the investigational product (investigational ingredient code), contact information for the trial sponsor, subject disease, and scheduled period of the tri-

al. Provision of such information by pharmaceutical companies is allowed "reactively" (ie, only upon actual request from healthcare professionals, patients, etc) and under strict compliance with all requirements stipulated in the Detailing Guidelines as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**. Accordingly, publication of such information by pharmaceutical companies is not permitted.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising Prescription-Only Medicines

Advertising prescription-only medicines to the general public is prohibited in Japan. Article 5 (1) of the MHLW Standards expressly prohibits such advertising. In addition, Article 67 (1) of the PMD Act prohibits advertising drugs for specified diseases and regenerative medicines to the general public.

Advertising Over-the-Counter Medicines

Advertising OTC medicines to the general public is not prohibited but is restricted by the PMD Act and the MHLW Standards, as well as by self-regulatory codes.

Advertising for OTC medicines is subject to the rules concerning advertising under the PMD Act and the MHLW Standards, which are described in **1. Pharmaceutical Advertising: Regulatory Framework**. In this regard, it should be noted that Article 6 of the MHLW Standards stipulates a particular restriction on advertisements to the general public concerning the efficacy of drugs for diseases that cannot be expected to be cured without a doctor's or dentist's diagnosis or treatment. This Article provides that any such advertisements targeted to the general public must not suggest that the diseases can be cured without such a diagnosis or treatment.

In addition, the OTC Guidelines regulate advertising through newspapers, magazines, television, radio, websites and other forms of mainstream media to ensure the appropriateness of the publicity and advertising activities for non-prescription drugs.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

There is no law or regulation that provides exactly what information must be included in pharmaceutical advertising aimed at the general public. However, under the PMD Act and the MHLW Standards, if advertising contains information as to the names of the products, their manufacturing process or their indication, dosage, administration or safety, the advertising must follow the following rules:

- companies shall use only authorised brand names, generic names or, for products that do not require marketing authorisation, names listed on the Japanese Pharmacopeia;
- companies shall describe the manufacturing process accurately and not in a way which could lead the general public to mistakenly believe in the superiority of the product;
- Article 3 (1) and (4) of the MHLW Standards prohibit companies from using expressions that are beyond the scope of or deviate from the authorised indication, dosage, administration or safety of the products (ie, "off-label promotion");
- for products that do not require marketing authorisation, Article 3 (2) and (4) of the MHLW Standards provides that companies

shall not use expressions beyond the scope of the product's efficacy, dosage, administration or safety as generally recognised in the field of medicine or pharmacy; and
- the MHLW Standards include several other relevant rules, including prohibitions on certain claims relating to efficacy or safety of products and prohibitions on slander and/or defamation of competitors' products.

Beyond the question of what information to include, the OTC Guidelines identify specific statements that are required or prohibited in advertisements for each category of OTC medicines. For instance, advertisements for cold medicines must use the phrase "relief of cold symptoms" but cannot include the statement "this will not make a patient sleepy". Also, advertisements for cold medicines on television or through streaming a video on the internet must display the statement "this product shall be used only after receiving an explanation from a pharmacist and after carefully reading the warning label" for one second or more with clear and distinct characters.

The price of the medicine can be mentioned in advertising aimed at the general public, although doing so is not required by laws or self-regulatory codes.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no laws or regulations that expressly impose restrictions on interactions between patients or patient organisations and industry.

The JPMA Code of Practice sets forth the rules concerning collaboration with patient groups. First, when a pharmaceutical company has any relationships or collaboration with patient institutions, the company must respect the independence of the institutions and the company's activities must meet a high ethical standard. Further, the company must make an effort to promote sufficient mutual understanding with patient groups regarding the purpose and scope of the collaboration.

Secondly, a disclosure of the sponsorship is required. Further, the purpose and scope of the sponsorship shall be agreed upon between both parties and shall be made in writing and recorded in order to ensure transparency. Finally, the member companies that are collaborating with patient organisations shall establish internal company guidelines based on the "Guideline on Collaboration with Patient Organisations" issued by the JPMA.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

There is no national law or regulation that explicitly provides which information must be included in pharmaceutical advertising directed at healthcare professionals.

However, if such advertising contains information relating to the names of the products, the manufacturing process, indication, dosage, administration or safety of or in relation to the drugs, as well as other relevant items, the advertising would be subject to the MHLW Standards, as described in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

As for self-regulatory codes, the JPMA Drafting Guidelines provides that advertising directed at healthcare professionals must contain the following information in principle:

- name of the product (both brand name and generic name);
- therapeutic category;
- regulatory classification;
- indications;
- dosage/administration;
- warnings/contraindications/precautions;
- presence on the National Health Insurance (NHI) reimbursement price list;
- name of marketing authorisation holder (contact and address for more product information);
- limitation of administration period;
- conditions for approval; and
- creation date of the advertisement.

Even if an advertisement is intended to promote only the name of a product, statements made in the advertisement shall contain at least the name of the product (both brand name and generic name), therapeutic category, regulatory classification, presence on the NHI reimbursement price list, and the name of the marketing authorisation holder (contact and address for more product information).

Specific Prohibited Statements

Beyond the question of which information to include, the JPMA Promotion Code identifies specific statements that may or may not be used in advertisements to healthcare professionals. For example, it prohibits stating that "there are few adverse reactions" without also citing the conditions of use or without providing a summary of relevant data, including the relevant adverse reactions, to back up such a safety claim. The JPMA Promotion Code also attempts to promote the quality and clarity of the information being presented. For example, the advertising materials must not only emphasise the efficacy of the product but must also include product safety information, including adverse reactions, in order to create a fair and balanced statement of the advertising. Further, the contact and address for seeking more information on the product must be described clearly.

Price

The advertising must mention whether or not the medicine is registered on the NHI reimbursement price list, rather than the price itself.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Reference in pharmaceutical advertisement to data on file or other clinical studies not included in the Summary of Product Characteristics is not prohibited. However, references to data on file or clinical studies are limited in certain ways by law and by self-regulatory codes.

First, the general rules on advertising (such as prohibition of false or exaggerated advertisements and advertising that recommends unapproved drugs or off-label uses) under the PMD Act will apply.

Secondly, references to data on file or other clinical studies shall be subject to the specific regulations provided by the JPMA Drafting Guidelines. For example, statements shall only concern indications approved in Japan. In addition, the study must be published in a peer-reviewed journal.

5.3 Advertising of Combination Products

In Japan, combination products are treated as one product (ie, pharmaceutical, medical device or regenerative medicine product) and will have one Summary of Product Characteristics. The

fact that a diagnostic is a companion diagnostic for certain drug must be included in the Summary of Product Characteristics. No specific rules exist for the advertising of medicines with companion or complimentary diagnostics.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints of journal articles for healthcare professionals are subject to the conditions set forth in both laws and regulations and self-regulatory codes. Major restrictions on reprints are as follows.

- The reprint must be authorised by the author(s) under copyright law.
- The contents of the journal article shall not violate the PMD Act. In particular, the contents of the journal article shall not be false or exaggerated advertising, advertising that recommends unapproved drugs or off-label uses or advertising that slanders and/or defames competitors' products.
- In principle, the reprint must be related to the company's own product and supplied in response to a request from a healthcare professional. In other words, a pharmaceutical company must refrain from actively inducing a healthcare professional to request such a reprint.

5.5 Medical Science Liaisons

There is no national law or regulation that specifically refers to or governs the activities of Medical Science Liaisons (MSLs) or Medical Affairs (MA) activities in Japan. However, in keeping with global practice, the number of pharmaceutical companies establishing MA sections and MSLs in Japan has been on the rise recently. Against this background, the JPMA issued a "Consensus Statement on Medical Affairs Activities" and "Consensus Statement on Medical Science Liaison Activities" ("JPMA MSL Statement") on 1 April 2019. In the JPMA MSL Statement, an MSL is defined as "a person who belongs to a division independent from the company's commercial divisions and whose main role is to interact with external experts in the field of medicine or science".

The JPMA MSL Statement also provides that MSL activities should not be aimed at promoting sales of the company's drugs. As the definition shows, an MSL's main role is to interact with external experts. However, this does not mean that MSLs are prevented from responding reactively to requests from other healthcare professionals, including requests for information on unauthorised medicines or indications. When MSLs provide any such information on unauthorised medicines or indications at the request of healthcare professionals, they must comply with the requirements under the Detailing Guidelines as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

In Japan, advertisements for medicines do not require prior authorisation from, nor notification to, any regulator. Management should establish a monitoring department within the company, independent of the department in charge of sales information provision activities, in order to ensure that these activities, including the MSL's activities, are being properly carried out.

6.2 Compliance With Rules on Medicinal Advertising

The Detailing Guidelines require that companies establish internal systems to ensure appropriate conduct with respect to promotion activities. This includes establishing a "promotion supervisory department" responsible for monitoring promotional materials and promotion activities, which must be separate from the company's sales and marketing division. Companies are also required to set up a "review and supervisory committee", which must include members who are independent of the company, to provide independent advice to the promotion supervisory department. In addition, the Detailing Guidelines require, among others:

- the preparation of standard operating procedures for promotional activities;
- the preparation and maintenance of business records (including records of any verbal explanations made during detailing activities);
- the prior review and approval of marketing materials by the promotion supervisory department based upon advice from the review and supervisory committee;
- periodic training for both employees and officers; and
- the establishment of a telephone tip-line to field complaints about promotional activities.

The JPMA Promotion Code also requires that JPMA member companies:

- establish internal systems to comply with relevant laws, regulations and industry self-regulations;
- appoint a promotional material officer; and
- establish an in-house oversight system so that only reviewed promotional materials and advertisements are used.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Generally, the same laws, regulations and self-regulatory codes concerning pharmaceutical advertising will also apply to advertising on the internet for medical products. In addition, the Commentary to the JPMA Promotion Code provides specific rules concerning access restrictions on internet-accessible information related to prescription-only medicines.

As advertising prescription-only medicines to the general public is prohibited, when a pharmaceutical company provides healthcare professionals with product-related information concerning prescription-only medicines through the internet, the company must restrict access to the relevant websites so that only healthcare professionals have access to such information.

The question, therefore, is: what is considered a sufficient access restriction? In this regard, the Commentary provides that if all the conditions set out below are satisfied, then an access restriction will be considered sufficient:

- the name of the pharmaceutical company is provided, the website states that the information is targeted at healthcare professionals and the person intending to access the information understands that the information is targeted at healthcare professionals;
- the information is appropriate for healthcare professionals; and
- if a company website targeting healthcare professionals links to an external website, the contents of the external website and the external website itself are appropriate for healthcare professionals and the owner or

author of the external website can be clearly verified.

As long as a pharmaceutical company uses a sufficient access restriction, it is not required to use any particular method of establishing passwords.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As mentioned in **7.1 Regulation of Advertising of Medical Products on the Internet**, pharmaceutical companies must include access restrictions on websites containing advertising or other information intended for healthcare professionals, since advertising prescription-only medicines to the general public is prohibited.

7.3 Provision of Disease Awareness Information to Patients Online

Generally speaking, the provision of disease awareness information and/or materials to patients online is subject to the same laws, regulations and self-regulatory codes as apply to those activities offline. As mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, the JPMA Code of Practice suggests that the content of disease awareness activities targeting ordinary citizens and patients be closely inspected from the planning stages so that they will not be considered prohibited advertising.

7.4 Online Scientific Meetings

There are no specific laws, regulations or self-regulatory codes in Japan that address online scientific meetings. As a result, online scientific meetings would be subject to the same laws, regulations and self-regulatory codes that apply to in-person scientific meetings.

7.5 Use of Social Media

Generally, the same laws, regulations and self-regulatory codes concerning pharmaceutical advertising will also apply to pharmaceutical advertising on social media. The JPMA Code of Practice, in particular, describes several issues to which pharmaceutical companies must pay close attention when advertising through social media.

The JPMA Code of Practice defines "social media" as media formed by interactive communication mainly through the internet, where the users, including individuals, send various information. The main feature of social media is that an individual can easily and promptly send information to the general public. Due to this characteristic of the medium, inappropriate information, including false information, may be broadly transmitted to the general public without any confirmation of the accuracy of the information. Therefore, the JPMA Code of Practice requires member companies to take all responsibility for such social media content and, before advertising on social media, the companies must confirm that all relevant subsidiaries, parent companies, affiliates, planning companies, agencies, employees, etc, comply with the JPMA Code.

Further, the JPMA Code of Practice requires that member companies pay special attention to the following:

- compliance with the PMD Act and the MHLW Standards;
- when a member company plans or supports social media activities, that company shall take responsibility for verifying the appropriateness of published content including content posted by third parties and shall take appropriate steps (including take-downs) in the event that inappropriate information

is posted, such as information relating to unapproved use, slander and/or defamation of other companies' products or information regarding adverse events;
- only information that has passed careful scrutiny by the appropriate department within the company shall be released; and
- when a company is acting as a sponsor, it shall clearly indicate its company name.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Anti-bribery rules generally applicable to pharmaceutical companies and healthcare professionals or organisations are provided in the Penal Code (Act No 45 of 24 April 1907, as amended). In addition, pharmaceutical companies are expected to comply with the National Public Service Ethics Code (the "Ethics Code"). Further, the Unfair Competition Prevention Act (Act No 47 of 19 May 1993, as amended) (UCPA) provides rules regarding bribery to foreign officials. These regulations apply only to benefits provided to recipients who are individuals (eg, public officers).

Penal Code

Article 198 of the Penal Code is the basic anti-bribery regulation that directly applies to officers or employees of pharmaceutical companies. Article 198 provides that any person who gives, offers or promises to give a bribe to a public official shall be punished by imprisonment with labour for not more than three years or a fine of not more than JPY2.5 million.

Bribery under the Penal Code is broadly defined. It covers not only money or goods but also any benefit (material or immaterial) sufficient to satisfy a person's desires. "Public Official" is also broadly defined. The term includes not only national or local government officials but also individuals deemed government officials under special laws.

National Public Service Ethics Code

The Ethics Code is a code established by the Cabinet based on the National Public Service Act for the purpose of maintaining the integrity of, and citizens' trust in, public service. The Ethics Code prohibits national public officials from receiving money or goods from interested parties. In some situations, pharmaceutical companies can be considered such "interested parties". The Ethics Code provides for some exemptions, including, among others:

- accepting gifts that are distributed widely to the public as promotional goods or as souvenirs; and
- accepting souvenirs at a large dinner party.

Pharmaceutical companies are expected not to participate in conduct that violates the Ethics Code in order to prevent illegal acts by national public officers.

Unfair Competition Prevention Act

Article 18 (1) of the UCPA prohibits any person from giving, offering or promising to give any benefit to a foreign public official to have that foreign public official act or refrain from acting in relation to the performance of their official duties, in order to make any illicit gains in business with regard to an international commercial transaction. An employee of a pharmaceutical company who violates Article 18 would face imprisonment with labour for up to five years and/or a fine of

up to JPY5 million. Further, the pharmaceutical company itself may also be subject to a fine of up to JPY300 million.

8.2 Legislative or Self-Regulatory Provisions

The UPMRA and the Fair Competition Code concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (the "Fair Competition Code") regulate offering benefits or other inducements to prescribe to healthcare professionals or organisations. The JPMA Promotion Code contains similar rules. These regulations apply to benefits provided both to individuals and organisations.

UPMRA

Article 4 of the UPMRA allows the Prime Minister to restrict the offering of premiums in various ways, including through a prohibition. Under Article 6 (2) of the UPMRA, the Cabinet issued a public notice entitled: "Restrictions on the Offering of Premiums in the Ethical Pharmaceutical Drugs, Medical Devices and Sanitation Inspection Industries". The notice prohibits pharmaceutical companies from offering articles, services or other premiums to healthcare institutions as a means of inducing unjust transactions beyond what is commercially reasonable for the usage or sanitary inspection of ethical pharmaceutical drugs.

Fair Competition Code

"Fair competition codes" are self-regulatory codes set up by the business associations of specific industries based on the UPMRA restrictions on the provision of premiums. Generally, fair competition codes will include UPMRA rules as well as supplemental rules not provided under the UPMRA depending on the nature of the products and transactions in the relevant industry. The pharmaceutical industry established the Fair Competition Code, which pharmaceutical companies are currently complying with.

The Fair Competition Code provides that pharmaceutical companies shall not offer premiums to healthcare professionals or institutions as a means of unjustifiably inducing drug transactions. If, however, based on standard commercial practices the offers of economic benefits are considered to be discounts, after-sale services or benefits in connection with the drugs, they are no longer categorised as offers of premiums. In addition, even if money, goods or economic benefits are considered premiums, there are some cases in which offering premiums is permitted (several examples are listed). In addition, if premiums are "small sum offerings", offering them will not violate the Fair Competition Code.

The JPMA Promotion Code

The JPMA Promotion Code has several provisions regarding offering benefits to healthcare professionals or institutions. It regulates, among other issues:

- the total amount of sample drugs that can be supplied;
- food, drinks, and gifts that can accompany lectures;
- gift-giving; and
- provisions of cash or its equivalent that may negatively affect the proper use of drugs.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The Fair Competition Code and the JPMA Promotion Code regulate offering gifts to healthcare professionals.

The Fair Competition Code lists several examples of permitted gift giving activities, including:

- offers of articles or services that are necessary for the use of or for enhancing the benefits of ethical pharmaceutical drugs;
- offers of medical or pharmaceutical information on ethical pharmaceutical drugs; and
- offers of articles or services not considered extravagant or excessive in relation to seminars, or the payment of expenses for individuals to attend such seminars, which are organised for medical or other similar institutions in order to promote the understanding of certain ethical pharmaceutical drugs.

The JPMA Promotion Code prohibits member companies from offering healthcare professionals and medical institutions, among other entities, any goods that could potentially negatively affect the appropriate use of drugs or damage drug credibility.

9.2 Limitations on Providing Samples to Healthcare Professionals

The Fair Competition Code and the JPMA Promotion Code impose limitations on providing samples to healthcare professionals.

The Enforcement Rules and the Operating Standards of the Fair Competition Code provide the basic rules for offering samples of drugs. In the case of product samples for reference the following rules apply:

- the number of units of the drug contained in one package must not exceed the maximum number allowed;
- the number of packages provided shall be the minimum necessary for the purpose of providing samples;
- if the drug is provided through a wholesaler, the destination medical institutions must be designated by the pharmaceutical company; and
- pharmaceutical companies must supply the relevant drug information to the recipient healthcare professionals.

Similar rules apply to the provision of clinical drug samples.

The JPMA Promotion Code states that member companies must provide only the minimum amount of samples and must also provide the relevant drug information.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events, but only in a limited capacity and in strict compliance with the Fair Competition Code and the JPMA Promotion Code.

With regard to a seminar for healthcare professionals concerning a pharmaceutical company's own drugs, the company can provide non-extravagant articles or services and can bear some related expenses. For example, companies may provide tea and snacks or lunch boxes, hold small social gatherings, cover transportation and accommodation expenses and compensate the lecturer. The seminar should be held in an appropriate place in light of its purposes it would be sensible to avoid a resort, a place for sightseeing or a location overseas for this reason (the JPMA Promotion Code expressly provides that pharmaceutical companies shall, in principle, hold such seminars in Japan). Even if such seminars are permitted to take place abroad, the payment of travel expenses must be limited to the travel expenses of healthcare professionals

who will provide information on the company's drugs to all participants.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The rules under the Fair Competition Code set forth the types of entertainment/hospitality that pharmaceutical companies may or may not provide to healthcare professionals. By way of example, providing entertainment such as karaoke or golf is prohibited.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharmaceutical companies may provide grants or donations to healthcare professionals or healthcare institutions subject to the restrictions under the Fair Competition Code and the JPMA Promotion Code.

Under the Fair Competition Code, pharmaceutical companies may not provide donations to healthcare professionals or healthcare institutions as a means of unjustly inducing drug transactions. The question of whether the donations have such a purpose is decided based on detailed criteria provided in the Operating Standards of the Fair Competition Code.

With regard to monetary donations, according to the Operating Standards criteria, pharmaceutical companies may make monetary donations to healthcare institutions within the bounds of standard commercial practice; such donations would not be considered a means of unjustly inducing drug transactions.

With regard to non-monetary donations, the Operating Standards criteria state that pharmaceutical companies may voluntarily provide their own drugs to healthcare institutions in the case of a disaster and to the medical faculty of universities as long as doing so meaningfully contributes to the students' lessons.

Under the JPMA Promotion Code, pharmaceutical companies shall not provide donations to healthcare professionals or healthcare institutions which may influence the appropriate use of drugs.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

In practice, pharmaceutical companies in Japan usually sell their drugs to wholesalers, who in turn sell the drugs to healthcare institutions. Thus, since pharmaceutical companies do not tend to sell directly to healthcare institutions, any rebates or discounts would mostly be provided to wholesalers rather than healthcare institutions. As to such rebates or discounts provided to wholesalers, the Anti-monopoly Act (Act No 54 of 14 April 1947, as amended) may prohibit certain conduct such as adjusting the discount or rebate amount in exchange for the wholesaler agreeing to follow a suggested price.

9.7 Payment for Services Provided by Healthcare Professionals

Under the Fair Competition Code, pharmaceutical companies may offer remuneration or expenses for research or certain studies. Also permitted are expenses for post-marketing surveillance for prescription-only medicines, as well as advertising fees for advertising drugs in journals. Such payments must meet the criteria provided in the Enforcement Rules and the Operating Standards of the Fair Competition Code. For instance, remuneration must be appropriate in light of the content of the relevant research.

The JPMA Promotion Code requires that any remuneration must be appropriate in relation to

the services provided. Pharmaceutical companies must not pay healthcare professionals to provide consulting services only as a way of covertly providing them prohibited monetary benefits.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior regulatory authorisations or notifications are required for the activities described in this section.

With regard to employer consent, pharmaceutical companies have internal company rules which regulate providing gifts, hospitality, donations or other payments/services to healthcare professionals and institutions. Such internal rules may require obtaining prior consent from or notification to the companies' compliance divisions.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The Clinical Research Act

The Clinical Research Act (Act No 16 of 14 April 2017), which took effect on 1 April 2018, requires that pharmaceutical companies and their subsidiaries disclose certain transfers of value to healthcare professionals and institutions in connection with specified clinical research. Clinical research includes human trials examining the efficacy or safety of pharmaceuticals but would not include a clinical trial for a new drug conducted under the PMD Act.

Specified clinical research is defined as clinical research funded by pharmaceutical companies, clinical research on unapproved drugs or clinical research concerning off-label use of a drug.

Transfers of value which must be disclosed under the Clinical Research Act include research funds for specified clinical research, donations provided during the term of or within two years after specified clinical research, and fees for writing, lectures or other services provided during the term of and within two years after specified clinical research. The recipients of payments covered by the regulation include healthcare providers involved in specified clinical research, healthcare institutions or other organisations to which a principal investigator belongs, and organisations managing the specified clinical research. The transfers of value for specified clinical research made in each fiscal year shall be disclosed the following fiscal year on the company's website.

The JPMA Transparency Guideline

The JPMA "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" (the "Transparency Guideline") requires that JPMA member companies disclose certain information regarding transfers of value made to healthcare professionals or healthcare institutions.

The Transparency Guideline further requires that each member company create its own internal "transparency policy" based on the Transparency Guideline. Therefore, each JPMA member company has established its own internal transparency policy and has been disclosing information on transfers of value it has made to healthcare institutions based on this internal policy.

Transfer categories

The Transparency Guideline creates five different categories of transfers of value (fees or expenses). For each category the relevant fees or expenses must be disclosed in detail. The five categories are:

- research and development expenses (such as those for clinical trials for new drugs);
- academic support expenses (such as donations to academic societies);
- manuscript/writing fees (such as fees for writing manuscripts containing scientific information regarding the pharmaceutical companies' own drugs);
- expenses related to the provision of information (such as expenses for lectures and seminars); and
- other expenses (such as for hospitality as a social courtesy).

The types of transfers of value to be disclosed include not only cash but also medicines, medical devices and other goods. Value transferred through a third party, such as a subcontractor or foundation, must also be disclosed.

Recipients and disclosure

The recipients of payments covered by the Transparency Guideline include:

- healthcare institutions (such as hospitals and pharmacies);
- research institutes (such as medical and pharmaceutical departments of universities);
- healthcare associations (such as medical associations and pharmacists' associations); and
- persons engaged in medical care and nursing care (such as doctors and nurses) and life-science researchers.

The transfers of value made in each fiscal year shall be disclosed the following fiscal year through the company's website.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

As the transparency requirements under the Clinical Trial Act would apply only to the marketing authorisation holder and its subsidiaries, the requirements would not apply to foreign companies or companies that do not sell products on the market in Japan.

The transparency requirements under trade association rules such as the Transparency Guideline (see **10.1 Requirement to Pharmaceutical Companies to Disclose Details of Transfers of Value**) only bind members of such trade associations. Accordingly, the transparency requirements under the self-regulatory rules will not apply to foreign companies and/or companies that do not yet have products on the market, unless such companies are members of trade associations with transparency requirements.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Each Japanese law has one or more government agencies that are responsible for enforcement (ie, the regulatory authority). With regard to the PMD Act, as well as the MHLW Standards, the MHLW and the competent prefectural governor are the regulatory authorities. In the case of the UPMRA, the Prime Minister, the Consumer Affairs Agency, the Japan Fair Trade Commis-

sion and the competent prefectural governor are the regulatory authorities.

The main role of courts in administrative law enforcement (including for the PMD Act) is to impose criminal penalties on companies and their employees that violate the law. In the case of a serious violation, the regulatory authority will ask the Public Prosecutor's Office to prosecute the company or its employee, and the Public Prosecutor's Office will file charges against the company. The court will then render a final judgment.

With regard to the enforcement of self-regulatory codes, the codes usually establish an organ that is in charge of enforcing the code. In the case of the JPMA Promotion Code, the JPMA Code Compliance Committee is responsible for enforcement. As for the Fair Competition Code, the Fair Trade Council of the Ethical Pharmaceutical Drug Marketing Industry (the "Fair Trade Council"), which consists of the pharmaceutical companies designated by the code, is responsible for the Code's enforcement.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In Japan, pharmaceutical companies may initiate civil litigation proceedings against their competitors before courts for certain types of advertising infringements of the UCPA.

Under the UCPA, a company whose business interests have been infringed or are likely to be infringed by a competitor's dissemination of information or advertising likely to mislead the public as to the quality, content or manufacturing method of its goods or services (UCPA Article 2 (1) (xiv)), or announcement or dissemination of a falsehood injurious to its business reputation (UCPA Article 2 (1) (xv)), may seek an injunction against the competitor suspending or preventing the infringement (UCPA Article 3 (1)).

The company may also claim damages to its business interests resulting from intentional or negligent infringement related to the above conduct.

For example, a pharmaceutical company may file a lawsuit in a Japanese court seeking an injunction and/or compensation of damages against a competitor if the competitor creates an advertisement containing falsehoods or slander regarding the pharmaceutical company's products.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Penalties or Measures Imposed by Regulators

In practice, Japanese regulatory authorities, such as the MHLW or the Prime Minister, will most likely issue an administrative "guidance" in the first instance against a pharmaceutical company found to be in violation, which is basically an official request to remedy the illegal conduct. If the company does not follow such guidance, the authority will then issue an administrative "disposition."

Under the PMD Act the MHLW or the competent prefectural governor may take the following administrative dispositions, among others:

- order a pharmaceutical company that violated the PMD Act to comply with a "business improvement order" (eg, an order to improve internal review systems for advertisements) (Articles 72-4);

- order a pharmaceutical company that advertised a pharmaceutical product before obtaining the necessary marketing authorisation (prohibited under Article 68) to take certain measures to prevent any such violation in the future (Article 72-5); and
- withdraw a pharmaceutical company's manufacturing and/or marketing licence or suspend all or part of its business for a certain period, as determined by the MHLW, for a company that violated the PMD Act (Article 75).

In addition, as mentioned in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the amendments of the PMD Act, which became effective on 1 August 2021, include administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies engaged in such improper advertising.

A company that has had its manufacturing and/or marketing licence withdrawn has the right to appeal such a disposition above under the Administrative Appeal Act (Act No 160 of 15 September 1962, as amended).

The JPMA Code Compliance Committee

The JPMA Code Compliance Committee may take actions against pharmaceutical companies that violate the JPMA Promotion Code to address the companies' violations in accordance with the "Rules of Actions against the Breach of the Promotion Code". Actions the aforementioned committee may take include, among others, serious warning, suspension of membership or expulsion from the JPMA.

The Fair Trade Council

The Fair Trade Council may order companies violating the Fair Competition Code to take certain measures. If the violator does not comply with such an order, the council may impose a penalty, including a fine of up to JPY1 million or expulsion from the council. The council may also request the Consumer Affairs Agency to take necessary actions.

Penalties Imposed by Courts

Courts may impose criminal penalties on pharmaceutical companies and/or on their officers and employees who violate the relevant laws. The major criminal sanctions for the violation of pharmaceutical advertising rules and rules on inducements to prescribe are as follows:

- false or exaggerated advertising and advertising for an unauthorised drug: imprisonment with labour for not more than two years and/or a fine of up to JPY2 million (PMD Act Article 85);
- advertising to the general public pharmaceutical products intended for use in the cure of cancer, sarcoma or leukaemia: imprisonment with labour for not more than one year and/or a fine of up to JPY1 million (PMD Act Article 86);
- violation of a cease-and-desist order from the Secretary General of the Consumer Affairs Agency: imprisonment with labour for not more than two years or a fine of up to JPY3 million (UPMRA Article 36);
- bribery of a public official: imprisonment with labour for not more than three years or a fine of up to JPY2.5 million (Penal Code Article 198); and
- bribery of a foreign public official: imprisonment with labour for not more than five years and/or a fine of up to JPY5 million (UCPA Article 21 (2) (vii)).

While only individuals are subject to criminal sanctions under the Penal Code, both individu-

als and companies may be subject to criminal sanctions under the PMD Act, the UPMRA and the UCPA (PMD Act Article 90 (ii), UPMRA Article 38 (1) and UCPA Article 22 (1) (iii)).

11.4 Relationship Between Regulatory Authorities and Courts

The procedures before and measures taken by the self-regulatory authority and the courts are conducted separately and independently.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The MHLW is strengthening its enforcement activities in relation to pharmaceutical advertising. In 2016, the MHLW began monitoring the advertising of ethical drugs in order to identify violations early, and encourage voluntary measures on behalf of the pharmaceutical companies and trade associations. This endeavour included the appointment of an anonymous healthcare institution to identify problematic items in advertisements and promotional information provided by pharmaceutical companies, including on their websites or in specialist journals.

On 1 October 2019, the MHLW expanded the monitoring activity above to include information from any healthcare institution on a voluntary basis. As a result of these monitoring activities, the MHLW identified 20 possible violations, including 26 problematic items, in 2021.

In addition, as mentioned in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the MHLW issued the Detailing Guidelines in 2018 and amended the PMD Act in 2019 to include administrative fines for violations of the regulations on false or exaggerated advertising as well as cease and desist orders against pharmaceutical companies engaged in improper advertising. As of 31 January 2023, there are no cases where such administrative fines were imposed.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

As veterinary medicines are included in the definition of "medicines" under the PMD Act, the same advertising regulations under the PMD Act apply to veterinary medicines. The difference is that for veterinary medicines, the regulatory authority is not the MHLW, but the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the competent prefectural governors. MAFF has issued "Standards for Appropriate Advertising concerning Veterinary Medicine" (Notification 12 Chiku A No 728 of the Livestock Industry Bureau of 31 March 2000). Similar to the MHLW Standards, the MAFF standards list prohibited expressions in advertisements, including language that is misleading as to the effectiveness of the medicine or that denigrates other companies.

While the regulatory body is different, enforcement measures that may be taken under the PMD Act by the MAFF in respect of veterinary medicines are the same as those taken by the MHLW for human medicines.

The views and opinions set forth herein are the personal views or opinions of the authors; they do not necessarily reflect views or opinions of the law firm with which they are associated.

Jones Day assists with all facets of clients' pharmaceutical marketing, promotion and advertising efforts by devising marketing strategies, developing packaging and labelling, obtaining internal and governmental approvals, and implementing compliant advertising campaigns, including print, radio and television advertising, website development and social media platforms. The firm's life sciences team helps clients to preserve their advertising position and challenge infringing competitors. Its lawyers provide assistance with pharmaceutical, medical device and biological regulations, including counselling and representation on diverse issues such as product development, product clearance and approval, clinical trials, biosafety, licensing agreements, facility and establishment registration, product listing, government inspections, product and ingredient notifications, recalls, corrective actions, regulatory and due diligence projects, and audits and compliance with good manufacturing practices and the quality systems regulation. The team has successfully defended clients against FDA enforcement actions, including warning letters, seizures, product recalls, inspections, civil monetary penalties, adverse agency determinations, consent decrees and corporate integrity agreements.

Authors

Michiru Takahashi is of counsel at Jones Day and has about 30 years' experience representing prominent clients in IP counselling and litigation. Her practice focuses on trade marks, unfair competition and copyright issues, including infringement litigation and trade mark prosecution. She also has significant experience in cross-border technology transactions, including life science licensing and development agreements. In addition to advising on intellectual property issues, Michiru frequently counsels clients on privacy and data security issues, and advises multinational clients on Japanese and other nations' personal information protection laws.

Benjamin Lang is a partner at Jones Day and leads its Tokyo life sciences practice. He has a wealth of experience advising Japanese and international clients on cross-border transactions. Having practised for more than 15 years in Tokyo and New York, Ben has advised on a wide variety of strategic and commercial transactions, including public and private M&A, divestitures, spin-outs, joint ventures and other investments. He focuses in particular on the life sciences industry, handling international co-development, licensing, distribution and other arrangements, and providing guidance to international clients on market entry and clinical trials in Japan.

Chizuru Yoshida is an associate of Jones Day based in Tokyo. She has experience in international and domestic business transactions and general corporate matters, with a particular focus on Japanese regulatory issues, including those in the life sciences and antitrust sectors.

Jones Day

The Okura Prestige Tower
2-10-4 Toranomon
Minato-ku
Tokyo 105-0001
Japan

Tel: +81 3 4595 3939
Fax: +81 3 5570 1520
Email: mtakahashi@jonesday.com
Web: www.jonesday.com

MEXICO

Law and Practice

Contributed by:
Gustavo Adolfo Santillana Meneses
Santillana Hintze Abogados, S.C. **see p.225**

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MEXICO

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In Mexico, the General Health Law (GHL) is the federal legislation that regulates advertising in connection with medicines as well as other medical products, including devices. This federal law is grounded in the Mexican Constitution (*Constitución Política de los Estados Unidos Mexicanos*); Article 4 of which establishes healthcare protection as a human right.

The Mexican healthcare law system is based on the principle that the protection of people's health is a human right. Provisions related and applicable to advertising on medicines are part of the GHL; this law has several similar regulations that apply to different aspects and issues related to healthcare (such as research, regulatory matters and healthcare services). Therefore, in addition to the dispositions of the GHL, there is a particular regulation on advertising of healthcare products (*Reglamento de la Ley General de Salud en Materia de Publicidad*). In certain cases, such as pricing, the provisions of Mexican consumer protection law might apply. Issues related to the accuracy of the information submitted to consumers are regulated by the Federal Law of Consumer Protection (*Ley Federal de Protección al Consumidor*).

The National Chamber of the Pharmaceutical Industry (CANIFARMA) groups pharmaceutical companies in Mexico. Its members must comply with several codes, including:

- the Ethics and Transparency Code;
- the Good Promotional Practices Code; and
- the Code of Interactions with Patient Associations.

Such regulations only apply to members of CANIFARMA, compliance with their terms is not binding, pursuant to the terms of Mexican legislation. They contain precise obligations with respect to advertising practices.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

CANIFARMA codes apply only to members of the chamber – their dispositions do not apply to healthcare professionals (HCPs), healthcare institutions or third parties that are not members of such association. CANIFARMA is a Mexican commerce and industrial chamber, affiliation with which is strictly voluntary. Pharmaceutical industry companies are not obliged to join it under the terms of Mexican law. In order to be admitted to such an association, the members must accept compliance with all its codes, including the ones applicable to ethics and good promotional practices.

CANIFARMA codes are not mandatory pursuant to the terms of the Mexican constitution, nor the GHL or any other legal provision. For Mexican pharmaceutical companies, being members of CANIFARMA is logical due to its visibility before the Mexican government as well as with other industries and sectors. CANIFARMA is the official link and representative of the pharmaceutical industry. With the above factors in mind, being a member and complying with the terms of its regulations is valuable to members. It is important to note that breach of such codes does not automatically represent a breach of Mexican legislation; however, one key provision of such codes is the members' duty to comply with the terms of Mexican law.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The regulation of the GHL includes two concepts. One is advertising and the other is the definition of advertising or "commercial".

Advertising

As defined by the GHL "advertising" incorporates the entire creation process, planning execution and diffusion of commercials in the media, with the purpose of promoting the sale and consumption of products and services.

Commercial

This is defined by the GHL as a message directed to the public, or to a segment of it, with the purpose of informing it of the existence or the characteristics of a product, service or activity for that product's commercialisation and sale or to create a reaction.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Under the terms of the GHL and its regulations, the difference between advertising and information is that information related to a healthcare product is considered advertising; conversely, information about healthcare in general and/or general awareness of illnesses is not considered as advertising. The regulations of the GHL clearly determine that information about healthcare products is considered promotional activity even if there are no advertising phrases and/or suggestions to use such products. Information about good healthcare practices or disease awareness are not considered advertising. The Mexican regulatory authority has interpreted information that mentions a product even by its generic name as advertising and therefore subject to the applicable legal terms and limitations.

Distinction between Target Audiences

There is a clear distinction about the advertising activities that may be performed depending on the target audience. Any information related to medicines that requires a medical prescription in order to be sold (Rx pharmaceutical products) can only be delivered to HCPs. This restriction includes the information that contains either the generic and/or the trade mark of the correspondent product. Advertising and information related to over-the-counter (OTC) products can be directed to the general public with a prior permit from the regulatory authority.

The specific law/regulation regarding promotional activities mandates that the same must be grounded and supported. No information on Rx pharmaceutical products could be used or released to the public. If a company owner of a pharmaceutical product launches a campaign to such general audience, it assumes full responsibility to comply with the terms of the applicable law, being the holder of the correspondent marketing authorisation. In the case of Rx, products can only be directed to an HCP.

Nowadays the use of social media platforms is common, if they allow access to the public, the only messages that could be performed are the ones related to OTC products.

PSPs

With respect to patient support programmes (PSPs), in Mexico in the past years several pharmaceutical companies have developed programmes to support patients during their medical treatment. These programmes are sensitive from a legal point of view, as well as for applicable self-regulatory codes, due to the following:

- the PSP must not advertise directly or indirectly Rx pharmaceutical products; and
- the only purpose of the PSP must be to provide support to the patient, including discounts, remainders of medical appointments, laboratory analysis, and coaching for a heathy life – subscription to PSPs must the proposed directly by HCP.

Finally, information about health and diseases is not considered as advertising, provided that the same does not directly or indirectly promote pharmaceutical products, or in any matter could be considered as subliminal information to provoke the use of pharmaceutical products.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are considered an advertising activity and are therefore subject to the applicable regulations; the specific law/regulation regarding promotional activities mandates that the same must have the scientific and technical information that support the message. No information on Rx pharmaceutical products can be used or released though press releases if the same are directed to the public and/or have public access, regardless of if the intention was only to refer to an HCP. If a company owner of a pharmaceutical product launches a campaign on social media, they assume full responsibility to comply with the terms of the applicable law, being the holder of the correspondent marketing authorisation.

The regulations on marketing of healthcare products defines broadcast or public medium (*medio de difusión*) as those means used to disseminate marketing adverts to the public including TV, movies, radio, press, magazines, public adverts on streets as well any other means of communication whether electronic or any other technology. If a social media platform is accessible by the public, the only messages that can be broadcast are ones related to OTC products, no matter if the message is made through a press release.

2.4 Comparative Advertising for Medicines

Even though comparative advertising for medicines is not specifically forbidden, making comparisons between medicines might be considered as a trade mark administrative infraction, since the intention of such an advert might be to damage the reputation and image of one of the products being compared.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Mexican law requires a marketing authorisation for a medicine to be manufactured, distributed and used. These activities include advertising. Due to the aforementioned, advertising of unauthorised medicines or new non-authorised indications is not permitted.

It is not allowed to provide information about an unauthorised medicine or unauthorised Indications.

3.2 Provision of Information During a Scientific Conference

As mentioned, Mexican law requires a marketing authorisation for a medicine to be manufactured, distributed and used. These activities include advertising; it is generally thought that if the medicine is not authorised the information

cannot be provided at a scientific conference of HCPs.

3.3 Provision of Information to Healthcare Professionals

As a general rule, if the medicine is not authorised, the information cannot be provided to HCPs.

3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

3.5 Information About Early Access or Compassionate Use Programmes

It is not allowed to publish the availability of compassionate use programmes. The same might be classified as advertising of a medicines and therefore subject to the terms of the GHL applicable to advertising of medicines.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Mexican legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx, products can only be directed to HCP. In the author's opinion if any media platform allows access to the public, the only messages that could be presented are the ones related to OTC products.

The classification of a medicine as an OTC product or a prescription-only medicine is given by the regulatory authority when analysing and approving a marketing authorisation.

Prescription Medicines

These fall into the following categories:

- controlled medicines where the prescription is special and issued by the Ministry of Health;
- controlled medicines where the prescription is retained by the pharmacy;
- medicines whose prescription is stamped three times and the last time it is retained;
- medicines that for their sale require a medical prescription that is not retained;
- antibiotics – following a ruling published in the Official Federal Gazette on 27 May 2010, the Ministry of Health determined that antibiotic medicines may only be sold after a medical prescription is presented, which will be retained by the pharmacy at the end of the treatment.

OTC Medicines

These fall into the following categories:

- OTC medicines sold only in pharmacies that do not require a prescription to be shown; and
- OTC medicines sold in establishments that are not pharmacies, which do not require a prescription to be shown.

Legal Principles of Advertising Medicines

The main legal principles of advertising of medicines pursuant to the terms of the GHL and the applicable regulation are as follows.

- The information that is provided in the advertising must be verifiable – the information about the security, efficacy and quality of a medicine must previously be approved by the healthcare regulatory authority.
- Advertising must be free of dialogues, texts, sounds, images and other descriptions that cause or could cause error or confusion

because they are deceptive or abusive and should not mislead.
- The content must be for guidance and education.
- Advertising must not attribute to medicines preventive, therapeutic, rehabilitative, nutritional, stimulant or other types of qualities that do not correspond to their function or use, as established in the applicable provisions or in the marketing authorisation granted by the authority.
- Advertising must not indicate or suggest that the use or consumption of a product is a decisive factor for changing people's behaviour.
- Advertising must refer to the real characteristics, properties and uses or those recognised by the Ministry, of the products, services and activities, in Spanish, in clear and easily understandable terms for the public to whom it is directed.

Purposes Requiring the Provision of Health Information

The following are compulsory when providing health information.

- Providing health information on the use of the products and the providing of services, which must correspond to any purposes indicated in the respective authorisation.
- Indicating the necessary precautions when the use, handling, storage, holding or consumption of the products may cause risk or harm to people's health. The HCP and/or the patient should be warned about the potential effects and risks involved in the use of the medicine.
- The assertions that refer to the benefits derived from the purchase, use or consumption of a product, would be obtained immediately or in a specified period, must have technical or scientific support that can prove them.
- Avoiding using categorical or superlative terms that encourage error or confusion for consumers with respect to the performance, characteristics or conditions of the advertised product. A categorical term will be understood as one that is asserted or denied absolutely. When upon using these terms, objective assertions are also used, or reference is made to studies, samples and/or tests, such information must be verifiable. Thus, avoiding the use of phrases such as "the best", "the only", "100% percent safe", or others of a similar nature.
- Avoid discrediting, by false assertions, other companies, products or industrial or commercial activity of any other person or company and its products, services, activities or circumstances or its brands, trade names or other distinctive signs through its content or in the form of presentation or dissemination.

Basic Legal Divisions

The advertising of medicines and dissemination materials is divided into two categories based on the target audience.

- Advertising directed to the public in general – medicines or other health products that for their sale do not require a medical prescription (ie, OTC medicines, protheses, orthoses, and medical device functional aides).
- Advertising directed to health professionals.

Medicines

OTC medicines:

- must comply with the marketing authorisation and authority prior specific permit to perform the advertising; and

- should not be deceptive, exaggerated or tendentious.

Prescription medicines:

- may only be advertised to health professionals;
- must comply with the terms granted within the marketing authorisation and the information to prescribe, approved by the Federal Commission to Prevent Sanitary Risks (*Comision Federal para la Protección Contra Riesgos Sanitarios* or COFEPRIS); and
- must contain a summary of the medicine's information known as information for prescribing (IPP is the acronym in Spanish).

4.2 Information Contained in Pharmaceutical Advertising to the General Public

The information that can be used in advertising of medicines is that included and approved by the regulatory healthcare authority during the process of the review and analysis of the correspondent marketing authorisation. Only the approved information and therapeutic indications of a medicine can be used in advertising.

The price of a medicine can be advertised. The information about the security, efficacy and quality of a medicine must have technical and scientific support, as well as be approved be approved by the Mexican healthcare authority. The key document for purposes of advertising activities is the marketing authorisation.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is not a specific legal restriction for interactions between patients, patients' organisations and industry. The limitations will be with public institutions as well as public servants.

With respect to the industry codes (CANIFARMA), there is one specifically referred to the interactions between industry and patient organisations. This code contains rules and certain limitations for such interactions, including:

- no promotion of Rx medicines to patients or their associations;
- keeping records of agreements, contributions and in general interactions with these organisations;
- having internal policies that regulate the interactions;
- no editorial participation in sponsored publications;
- when sponsoring meetings or seminars, these should take pace in adequate non-luxury sites not known for being only for entertainment purposes – such sponsorship should be reasonable; and
- paying the financial contribution to the association, not directly to a patient.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The information that can be directed to an HCP is the one approved by the healthcare authority and contained in the marketing authorisation, of which an important part is known as information for prescription. This data is submitted by the applicant for the marketing authorisation; the medicine will be approved together at the same time. Basically, the data is needed to prescribe the medicine and includes generic and trade

names, indications, manufacturer, formula, contraindications, possible adverse reactions and events.

The price of a medicine can be informed to the HCP. The information that cannot be provided to an HCP is that not approved by the authority, such as: non-approved indications and possible adverse reactions of a third product.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising needs to refer to the Summary of Product Characteristics (*SmPC/Información para Prescribir*). If clinical or scientific information is used, the same must coincide with the correspondent summary.

5.3 Advertising of Combination Products

It is not permitted to advertise combination products or companion diagnostics that are not included in the Summary or Product Characteristics, the company is only allowed to advertise the product itself with the indications that are approved by the Mexican regulatory authority in the marketing authorisation.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies can provide reprints of journal articles if the same contain information regarding diseases, general healthcare matters and medicines information, in this case, the same must be in accordance with the one contained in the SmPC.

5.5 Medical Science Liaisons

Medical science liaisons (MSLs) are not clearly included and regulated by the HCL or its regulations; however, they would follow the same pattern and principals of pharmaceutical advertising. Therefore, any information to be provided to HCPs even in scientific discussions must comply with the law, particularly, and be limited to the approved information in the marketing authorisation as well as in the information to prescribe. In the case of self-regulatory provisions, CANIFARMA includes terms and obligations for its members to not provide information related to unauthorised medicines or indications to healthcare professionals.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

The advertising approval system is as follows:

- for ads or materials related to OTC products a prior permit must be submitted; and
- if the material refers to Rx products, a notice will need to be submitted before the advert is published/broadcast.

The competent authority for all regulatory healthcare matters is COFEPRIS.

6.2 Compliance With Rules on Medicinal Advertising

Under the terms of the Mexican healthcare law, including GHL and its regulations, there are no legal requirements to have internal policies and/or standard operating procedures that regulate advertising activities.

In respect of these, the CANIFARMA codes contain certain obligations, including, for example: Written rules for the delivery of free samples, interactions with medical associations and control of promotional events.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

There is not a specific law/regulation for the use of advertising on the internet. If the internet is used for messages or adverts, the GHL and its regulations apply to information and publicity made with respect to goods, services and healthcare products that will be used by humans. This information should be accurate and not mislead the public, at the same time must be grounded and supported.

The regulations on marketing of healthcare products defines as broadcast and/or public mediums (*medio de difusion*) those used to disseminate marketing adverts to the public including TV, movies, radio, press, magazines, public adverts in streets as well any other mean of communication whether electronic or any other IT technology.

Such legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx products, they can only be directed to HCPs. If the IT platform allows access to the public, the only messages that may be broadcast are those related to OTC products; no information related to Rx products and their therapeutic indications should be published.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

If the information submitted is intended for HCPs, and is related to Rx medicines, the company must ensure that the websites contain solid restrictions to prevent access to the general public.

7.3 Provision of Disease Awareness Information to Patients Online

Companies are allowed to provide disease awareness information online, as long as there is no mention to the generic name and/or the brand of the Rx pharmaceutical product. If the company wants to provide disease awareness information in which the generic and/or brand of an OTC product is mentioned, the company needs prior authorisation that allows providing that information to the general public. Information related to RX products is forbidden.

Providing disease awareness information to the public is a sensitive matter, since it might be considered as advertising, therefore the same should not directly or indirectly promote pharmaceutical products, or in any way be potentially considered as subliminal information to provoke the use of pharmaceutical products. If a company plans to provide online disease awareness information, it is advisable to get a written ruling from the regulatory authority.

7.4 Online Scientific Meetings

There is no specific regulation for online scientific meetings in Mexico. Pharmaceutical companies are allowed to sponsor scientific meetings, provided the information to be presented is in the scope of the specific marketing authorisation as well as the authorised information for prescription. The handbooks and related information to be provided must only be the one approved by the health care authority as information for prescription. An event will be considered “national” if the same is organised and/or sponsored by a Mexican institution and/or company.

Online scientific meetings organisers must assure that all attendees are health care professionals, therefore each of them must provide with the correspondent information. Only health

care professionals can attend such meetings, due to the fact that the information to be provided is not allowed to be shared to the general public.

Online meetings under the terms of Mexican law are not considered as international events. If the same are organised by a Mexican institution or company, local regulations will apply.

There is no prior authorisation required, with the exception of online meetings organised inviting public servants that are health care professionals, in this particular case, the prior authorisation of the public institution where the professionals render their services is needed. There must be rules of access, such a pre-registration that assure the participation of only of health care professionals.

7.5 Use of Social Media

The same rules apply as to the internet. Such legislation allows only marketing adverts or information related to OTC pharmaceutical products. In the case of Rx products they can only be directed to HCPs. If the social media platform allows access to the public, the only messages that could be published are those related to OTC products. This includes Twitter, Facebook and WhatsApp. For legal purposes, social media is considered a broadcast medium (*medio de dufusión*).

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The Mexican anti-bribery legislation is contained in a group of laws that are known as the national anti-corruption system. Within this mechanism there is one federal law – the Federal Law of Administrative Responsibilities. This legislation prohibits giving any benefit, gift or retribution to a public servant and applies to HCPs working for public institutions. In addition, public servants need to avoid any relation that might represent a conflict of interest with their public duties. The concept of conflict of interest applies to both individuals and public organisations.

Under the terms of their provisions, CANIFARMA codes include the obligation of its members to avoid giving benefits, that is, contributions that might have the intention to get a benefit, in return, such as incentivising the prescription of a company's medicines. These anti-bribery rules apply to relations with HCPs or public or private sector organisations.

When dealing with HCPs in Mexico, an important division must be taken in consideration:

- HCPs working for public institutions; and
- HCPs with a private practice.

The private sector is considered to be made up of companies as well as business projects that do not draw on public funds – ie, the investment does not come from economic resources of any government institution.

8.2 Legislative or Self-Regulatory Provisions

After many years of debate and discussion, in 2015 and 2016, alongside the creation of new legislation, important amendments to the constitution were integrated into Mexican anti-bribery legislation to create a group of laws that are known as the national anti-corruption system. As mentioned, this mechanism has the specific purpose of preventing and prosecuting corrup-

tion. The Federal Law of Administrative Responsibilities prohibits giving any benefit, gift or retribution to a public servant. This limitation applies to HCPs working for public institutions. This law clearly establishes the concept of conflict of interest between the professional activities of an HCP and the relationship with the pharmaceutical industry.

In 2008 the Ministry of Health issued regulations that prohibited pharmaceutical companies directly giving any goods to public HCPs. The invitation to participate in scientific activities and congresses must be approved by the administrative authorities. In addition, public servants need to avoid any relationship that might represent a conflict of interest with their public duties. The concept of conflict of interest applies to both individuals and public organisations.

A clear conflict of interest will be considered if an HCP who has any interaction with the pharmaceutical industry participates in a decision-making process to approve a medicine. This applies also to a public procurement procedure or the analyses of its inclusion in a national formulary.

CANIFARMA codes include, under the terms of their provisions, the obligation for members to avoid giving benefits, that is contributions that might have the intention to get a benefit, in return, such as incentivising the prescription of a company's medicines. These anti-bribery rules apply to relations with HCPs or public or private sector organisations.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

As mentioned in the preceding paragraphs, the Federal Law of Administrative Responsibilities prohibit giving any benefit, gift or retribution to a public servant, this limitation applies to HCPs working for public institutions. In addition, public servants need to avoid any relation that might represent a conflict of interest with their professional activities and their interaction with companies of the pharmaceutical industry.

In 2008, the Ministry of Health issued regulations that prohibit giving any goods to public HCPs. The participation in scientific activities, including seminars, must be scrutinised and approved by the administrative authorities. In addition, public servants need to avoid any relationship that might represent a conflict of interest with their public duties.

In the case of HCPs who act in the private sector – ie, having their own medical practice – the CANIFARMA codes establish that it is possible to offer gifts that do not have a significant cost (ie, gimmicks).

9.2 Limitations on Providing Samples to Healthcare Professionals

In the case of public institutions, companies cannot directly provide samples to HCPs. The delivery must be made through the administrative authorities of the healthcare institution.

In the case of HCPs with private practices, CANIFARMA's codes mandate the following:

- not delivering free goods as an incentive or pressure to prescribe certain medicines;

- provide samples in reasonable amounts for the purpose of helping the HCP to get familiar with the product and to initiate a medical treatment;
- such samples must not be commercialised; and
- strong control policies should be created, as well as personnel, that keep records and monitor these samples.

9.3 Sponsorship of Scientific Meetings

Companies can sponsor scientific meetings as congresses, HCPs can attend. The main principle regulating these activities is to keep them for educational and scientific purposes, not with the intention to motivate the participants to benefit a pharmaceutical company and encourage the prescription of medicines in exchange for the participation in such events.

In the case of HCPs in private practice such events should take pace in adequate non-luxury sites not known for being for entertainment and must have a scientific purpose. The context and purpose of the event should be educational and not for the objective to entertain HCPs. The participation must be free of any influence or given as an incentive to prescribe medicines or benefit a company.

In the case of HCPs working for public institutions, the event should be authorised by administrative bodies of the institution and have the limits mentioned above. The participation must be free of any influence or given as an incentive to prescribe medicines or benefit a company in a public tender of public procurement procedure or to include certain product in a national formulary.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The cultural, sports or non-scientific events must not be the main objective and should not occupy more than 20% of the time conference.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Companies in the pharmaceutical industry can provide grants and donations to healthcare institutions. The key factor in both the public and private sectors is to avoid conflict of interest and to use the monetary, equipment or services contribution to get back a benefit, such as:

- prescriptions of medicines;
- benefits or advantages in public tenders or public procurement procedures;
- approvals of marketing authorisations; and
- inclusions in national formularies.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Such restrictions do not necessarily apply themselves, the legal issue will come if the discount is granted to an HCP with a potential conflict of interest, such as getting prescriptions of medicines in exchange.

In the case of healthcare institutions, it is valid to give rebates and discounts in compliance with antitrust regulations, for example, that the rebate is given under a free competition basis and not with the specific intention to damage a third party or obstruct the free access to goods.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to contract services to be rendered by an HCP. As mentioned for other cases, is important to establish the difference between

professionals from the public and the private sector.

In the case of an HCP of the public sector, is possible to contract for such services if there is not a conflict of interest that might illegally benefit a company, for example, services of an HCP who participates in the following decisions:

- to include a medicine in a national formulary;
- authorisation of a marketing authorisation; or
- granting a public contract to acquire a medicine or healthcare product.

In case of an HCP with a private practice, CANIFARMA codes allow getting these types of services and the correspondent payment. The purpose or intention must not be to benefit the company in an inadequate manner, such as:

- influencing the HCP to prescribe certain products;
- buying or recommending them; or
- damaging the image of a product of a third party.

The payment should have a fair market value and be related only to the service.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

In case of services to be contracted with public HCP, a previous authorisation of the superior is required.

Samples of medicines as well as gimmicks to be given to a public HCP will need to be delivered to the administrative authorities of the healthcare institution, not directly to the HCPs. This is a matter that implies that before performing this activity, the corresponding internal body will need to approve the same.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Legally, pharmaceutical companies are not required to disclose, under regular or periodic basis, details of transfers of value to HCPs. The GHL, and not its regulations, establish such obligations. The possibility exists that an administrative or judicial authority might request such disclosure in case of a specific legal procedure or litigation – such a request must be legally grounded and be precise and detailed request of disclosure. For example:

- the disclosure might be requested by the Secretariat of Public Function (in cases of corruption investigations);
- the Federal Economic Competition commission (in cases of antitrust investigations); and
- some requests based on a tax audit.

The CANIFARMA codes include transparency obligations, such as the obligation of companies to disclose upon request by the Ethics Council, contracts and payments or transfers of value to HCPs. In the author's opinion such requests must be grounded and be specific to the case, not being an open request for disclosure, nor an ongoing periodic obligation.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements from Mexican authorities apply to companies doing business

in Mexico and such requirements are not related to having products in the market and are linked to their commercial activities.

In the case of CANIFARMA their members already have products in the market; therefore, as members they are subject to the terms of the corresponding codes.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The Mexican regulatory authority with legal responsibility to enforce all the applicable regulations on advertising is COFEPRIS.

In cases that involve prices as well as claims that might affect directly the consumer, the Federal Consumer Protection Agency might have joint jurisdiction over an individual case, for example, advertising that is considered to mislead the consumer.

If a sanction is imposed, for example a fine and or a seizure or a product, a company will have the right to content the case before federal courts and the right to constitutional relief in the case of a constitutional violation.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

There are three scenarios:

- if the advertising infringements are any of regulatory healthcare provisions the company might file a complaint before COFEPRIS;
- if the infringement involves infractions to the Federal Law of Consumer Protection – ie, misleading advertising that might damage the consumer – an additional complaint might be filed before the Federal Consumer Protection Agency; and
- if, in addition to the above, the advertising might affect a trade mark or reputation of a company there is an administrative recourse to claim the infraction that could be filed before the National Institution of Industrial Property.

All the above proceedings have different instances that might end in litigation before federal courts, including constitutional reliefs.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The administrative authorities in charge of enforcing laws and regulation applicable to advertising of medicines might impose the following sanctions:

- administrative preventions;
- fines that might be from approximately USD5,200 to USD55,000 per infraction;
- temporary or definitive shutdown of the company;
- seizure of a product or entire stock;
- request to recall the correspondent products;
- in the case of an advertising campaign that might be considered to mislead the final consumer (ie, a deceptive ad), there could be a fine of up to 10% of the company's sales;
- media companies must ensure that the advertising transmitted has the corresponding permit or a notice has been filed with COFEPRIS; and
- COFEPRIS has the authority to order the media to immediately suspend, in 24 hours, the advertising of medicines that might be in breach of the GHL.

11.4 Relationship Between Regulatory Authorities and Courts

The procedures or measures taken by the self-regulatory authority and the procedures or measures taken by courts are not linked. Both types of authorities have their jurisdiction and forum. The Mexican Courts will act based on the terms of the Constitution; the GHL and its regulations as well as the consumer protection law. Their resolutions and final judgments will be binding to the sanctioned company.

In the case of a self-regulatory authority (CANIFARMA), the industry codes have procedures and sanctions that will be applicable only to members of such chamber. An infraction to the self-regulatory codes does not imply an action of Mexican federal courts or administrative authorities. At the same time, a final judgment of a court will not automatically imply the initiation of a procedure for sanction before the CANIFARMA's Ethics Council.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In recent years COFERPIS has issued a ruling that might be interpreted as an intention to allow advertising of Rx medicines to the general public; however, the law and the regulations must be changed, and the rules are currently still the same: advertising of Rx medicines can only be directed to HCPs.

The Mexican regulatory authority regularly prosecutes and sanctions advertising of medicines or products that pretend to be medicines – without having a marketing authorisation – which do not have the claimed therapeutic effects or in the worst case scenario are not medicines at all.

COFEPRIS as well as the Ministry of Health has the clear intention to combat so-called "miracle products" that are in the market pretending to be medicines or having non-proven therapeutic effects. In the past, TV broadcast companies have allowed advertising of these products, which poses an obvious danger to the consumer.

At the same time, the Federal Consumer Protection Attorney Office is active in preventing misleading advertising that might damage the consumer.

During 2021 there were no significant changes to the pharmaceutical advertising regulations in Mexico.

Restrictions on Marketing Agencies Monopolising Media and Advertising Space

On 3 June 2021, a new law was enacted, related to transparency and the combat of improper activities, when contracting publicity (*Ley para la Transparencia, Prevención y Combate de Prácticas Indevida en Materia de Contartación de Publicidad*). The purpose of this new law is to prevent marketing agencies and media companies improperly controlling marketing means and spaces. Due to the above, as of the enactment of this law, pharmaceutical companies (among others), must directly contract and hire media companies to market their products in the different means and marketing spaces (such as TV, radio, newspapers, internet and social media). The marketing agencies cannot directly buy such marketing spaces for purposes to resell the same. Such agencies could only act on behalf of pharmaceutical companies. It must be noted that this Law applies to any kind of advertising and not only to pharmaceutical products.

In January 2023, the Mexican Supreme Court of Justice, issued a final judgment in a particular case, declaring the unconstitutionality of this law, due to the fact that prohibiting marketing

agencies from contracting for marketing spaces directly with media companies limits their freedom to contract and develop their business. This judgment only applies to a particular case and at time of writing (March 2023) is not generally binding.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Advertising of Veterinary medicines is not part of the Mexican GHL, the particular legislation that applies to such products is the Federal Law of Animal Health (*Ley de Sanidad Animal*). The official standard that regulates this advertising is the "Specifications for Marketing of Chemical, Pharm chemicals, Pharmaceuticals, biological and food products for veterinary use" (NOM-059-ZOO-1997). This standard mandates that the information that is provided in the advertising must be verifiable, authentic and exact and correspond to the approved characteristics of the veterinary medicines.The information provided in the advertising will need to correspond to the approved label, following the labelling rules contained in two official standards (NOM-012-ZOO-1993 and NOM-059-ZOO-1997). This advertising will need to comply with the principles of the Federal Law of Consumer Protection (*Ley Federal de Protección al Consumidor*):

- the information submitted to consumers must be accurate and avoiding misleading them (ie, a deceptive ad); and
- the advertising must not discredit, by false assertions, other companies, products or industrial or commercial activities of any other person or company and its products, services, activities or its brands, trade names or other distinctive signs through its content or in the form of presentation or dissemination.

Santillana Hintze Abogados, S.C. is based in Mexico City. Founded 15 years ago, its areas of expertise include health law, regulatory, advertising, licensing, black market issues and prosecution, anti-bribery compliance and personal data protection and compliance. It advises life sciences companies involved in the pharmaceutical and medical devices industry, as well as industry associations, on legal matters related to biotechnology. The practice group consists of 20 lawyers specialising in healthcare law, with a team dedicated exclusively to administrative litigation matters, including advising and litigating on public procurement and public tenders of pharmaceuticals and medical devices. The firm's lawyers are experienced in health law, corporate law, personal data compliance, FCPA and competition matters, advising clients that are among the most prominent pharmaceutical and medical devices companies and demand highly specialised legal advice relating to the latest laws and regulations in this rapidly developing field.

Author

Gustavo Adolfo Santillana Meneses is the founding and managing partner of Santillana Hintze Abogados, and has 30 years' experience in the pharmaceutical and medical devices industries. He is a specialist in various practice areas, including M&A and the purchase and sale of portfolios in the pharmaceutical and medical device sectors, and advises on regulatory matters as well as advertising, veterinary products, and commercial transactions that involve healthcare products and animal care. Public procurement and anti-corruption are further areas of expertise. Gustavo Adolfo works with leading pharmaceutical and medical devices companies on advertising strategies and campaigns relating to both over-the-counter and prescription-only products, and litigates on these matters before administrative authorities and courts. He is a member of the administrative councils of various Mexican companies.

Santillana Hintze Abogados, S.C.

Ricardo Castro No. 54-302
Col. Guadalupe Inn
C.P., 01020
Mexico

Tel: +55 52 92 82 32
Email: gsantillana@santillana-abogados.net
Web: www.santillana-abogados.mx

Trends and Developments

Contributed by:
Carlos Díaz Sobrino and Javier Perez Moreno
Bello, Gallardo, Bonequi y García see p.233

Pharmaceutical advertising in Mexico can be categorised in terms of legal compliance, general compliance on consumer protection laws, and specific compliance due to the regulatory nature of pharmaceutical products and/or services.

However, before discussing the specific rules which may be applicable to such types of advertising, it is worth noting a fairly new pharmaceutical advertising topic due to a recently enacted law (currently being challenged) regarding paying for advertisements when there is an agency involved, and how the law intends to establish specific requirements and limitations on the manners for buying specific advertising products, such as pharmaceutical advertisements.

The Transparency Law

On 3 June 2021, the "Law for Transparency, Prevention and Combating Improper Practices in Advertising Contracting" (the "Transparency Law") was published in the Official Daily and became effective on 1 September 2021. As mentioned, the purpose of the law is to prevent certain commercial practices by publishers, specifically practices which involve monetary considerations to the agencies (hired by advertisers), for such publishers to gain more business with such agencies.

Although the law is aimed at publishing activities which are carried out in Mexico, it contains an express prohibition which may have extraterritorial effect, as it mentions that any advertisement in Mexico paid for outside Mexico by a foreign company is subject to compliance with the Transparency Law. However, in the authors' opinion, if there is an agreement not subject to Mexican law, or if the company is not a Mexican company and its services are understood to be provided through the internet, the Transparency Law would not be applicable.

A particular point of the Transparency Law is that sanctions due to breaches are imposed following an investigation procedure in accordance with Economic Competition Law procedures, and such investigation is also carried out by the Economic Competition Authority. The Transparency Law would thus be enforced taking into account economic competition procedures and principles, and breaches would only be investigated following a third-party claim.

The Transparency Law has become relevant considering there are no other specific laws which establish other contractual requirements for marketing/advertising activities in Mexico. Because of this, the Transparency Law has been challenged by many players through "amparo" suits. Such challenges have been ruled in favour of the companies, and recently, in January 2023, the Supreme Court ruled on a specific procedure, deeming the Law unconstitutional. Although this consideration of the Transparency Law as being unconstitutional only applies to such amparo challenges, this is a precedent which may be taken into account by other jurisdictional authorities in Mexico. The Telecommunications Institute has also challenged the Transparency Law, stating that it gives the Economic Competition Authority too much power in overseeing mat-

ters normally given to the Telecommunications Institute only.

Because of the aforementioned issues, and all amparo procedures and rulings currently being challenged, in the authors' opinion the Transparency Law will be ruled as unconstitutional by the Supreme Court, and will be requested to be repealed. Meanwhile, and until it is repealed, some of the rules and requirements established by the Transparency Law are worth noting:

- advertising spaces cannot be contracted by agencies on their own – such spaces should be contracted in the name and on behalf of the advertiser;
- a specific type of agreement must be executed, in which it is understood that a specific and specialised power of attorney is granted to the agency for the agency to contract on behalf of the advertiser for such advertising spaces;
- any rebate offered by the publisher to the agency must be replicated in the agreement between the advertiser and the agency;
- neither the agency nor third parties used by the agency to provide services to the advertiser can receive remuneration, commission or considerations by the publisher;
- an agency cannot provide services (simultaneously) to advertisers and to publishers;
- although the agency is the party paying the publisher, the publisher must bill the advertiser directly;
- an agency that buys programmatic digital advertising on behalf of the advertiser should inform the publisher of the identity of the advertiser and other information mentioned in the law after the broadcasting of the advertising;
- an agency must inform the advertiser of any financial relationships between them (or their group) and the publisher; and
- the economic sanctions arising from the Transparency Law may be 2% to 4% of the gross income of the infringer.

Consumer Protection for Pharmaceutical Advertising

It should be noted that there are no specific rules for the pharmaceutical advertising industry; however, the general rules regarding advertising are helpful for understanding how a pharmaceutical advertisement may be analysed or considered compliant by the Consumer Protection Agency (PROFECO) in charge of overseeing compliance with the Consumer Protection Law.

In general terms, pharmaceutical advertising must comply with the following rules:

- the information or advertising related to products or services must be truthful, verifiable, clear and free of texts, dialogues, sounds, images and other descriptions that induce or may induce error or confusion due to being misleading or abusive; and
- misleading or abusive information or advertising is that referring to characteristics or information related to a product or service that may or may not be true, and which induces error or confusion in the consumer due to the inaccurate, false, exaggerated, partial, artificial or biased manner in which it is advertised.

The authority of PROFECO in relation to advertising includes the following:

- requesting a service provider to suspend the advertising that breaches the provisions of

the Consumer Protection Law, wherever it is published;
- requesting correction of the advertising that breaches the provisions of the Consumer Protection Law; and
- imposing economic sanctions, in accordance with the law.

Economic sanctions may range from USD9,500 to USD260,000, and, depending on how severe the breach was, may go as high as 10% of the gross income of the infringer.

Economic sanctions imposed by PROFECO take into consideration the following:

- the damage caused to the consumer or to society in general;
- the intentional nature of the breach;
- whether it is a repeat offence; and
- the economic condition of the provider.

Since the definition of misleading advertising and the elements that qualify for it are established in a broad manner in the Consumer Protection Law, PROFECO has issued certain guidelines to help understand what is covered by unlawful advertising, and identifies specific types of advertising which are not allowed, as follows.

- Misleading advertising by action – texts, dialogues, sounds, images, trade marks and other descriptions that induce or may induce error or confusion.
- Misleading advertising by omission – advertising that is silent about characteristics of the good, product or service which are necessary for the consumer to have the appropriate information make a decision.
- Misleading comparative advertising – comparing goods or services must, for obvious reasons, not be misleading, and must be considered lawful, since it should aim to provide the consumer with additional (and better) information.
- Denigratory advertising – advertising that discredits a good, product or service of others. In this case, advertising will be unlawful or misleading when the information is not truthful, or is considered abusive since it will induce the consumer to change their consumption habits in an unlawful manner.
- Adhesive advertising – advertising that induces or is likely to induce confusion with the goods, products or services of other suppliers. This is a type of misleading advertising to the extent that it takes advantage of the prestige acquired by another supplier, in such a way that the message makes the consumer believe that the advertised good or service corresponds to the type (characteristics) of those advertised by a competitor, taking advantage of the prestige of others.
- Concealed advertising – a type of misleading advertising intended to hide its advertising nature, being hidden under an informative veil by means of which an attempt is made to make the consumer believe that they are being given an informative message of an objective nature, not vitiated by the persuasive and subjective interest that characterises the advertising message. The objective of this type of advertising is clear: to make the consumer/recipient of the concealed advertising give it the same credibility that they would give to an informative message, thus reducing consumer defences against advertising.
- Exaggerated advertising – this may be considered as misleading advertising, and is unlawful since it constitutes subjective information that cannot be verified and is normally used as a technique to exalt goods, products or services. It corresponds to civil fraudulent misrepresentation, and does not contain

objective information. Additionally, "over-promising" advertising which aims to surprise consumers and generate expectations is a classic example of the information provided with "miracle products".

PROFECO will look for the following to determine if a specific type of advertising is in fact unlawful:

- false information, when the information does not correspond to reality and may induce the consumer to make an erroneous decision, which they would not have made otherwise, as well as when the supplier does not deliver the good or perform the service in accordance with the terms and conditions offered or implied in the advertisement;
- inaccurate, imprecise information in relation to the characteristics or qualities of the product, good or service;
- exaggerated information which leads to deception of the consumer, where the consumer does not recognise such exaggeration at first sight and takes the advertising message seriously, and which may influence the consumer's decision to consume;
- partial information provided in an incomplete manner, where such omission relates to fundamental data required for a consumer's proper decision; and
- artificial or tendentious information where the advertising is intended to cautiously disguise the message sent – eg, inserting texts or legends that are not visible to the naked eye.

Rules for Pharmaceutical Advertising

For services and/or products of a pharmaceutical nature, there are two relevant laws establishing specific requirements and limitations: the General Health Law and the Regulations of the General Health Law on Advertising Matters. Their requirements and limitations as regards pharmaceutical advertising are discussed below.

Product advertisements

Cosmetic products cannot be attributed the same effects as medical products. The Ministry of Health must be notified when advertising cosmetic products, and advertising of any type of surgery must comply with all the requirements established in the General Health Law.

Any advertising related to health matters, disease treatments, rehabilitation of disabled people, health professionals and health products and services is subject to the prior authorisation of the Ministry of Health.

The advertising of raw materials for health, surgical materials, hygienic products and alcoholic beverages is also subject to the prior authorisation of the Ministry of Health.

The aforementioned advertising must adhere to the following principles:

- the information contained in the message regarding quality, origin, purity, conservation, nutritional properties and use benefits must be verifiable;
- the message must contain guiding and educational content;
- the elements comprising the message, if applicable, must correspond to the characteristics of the respective health authorisation;
- the message must not lead to behaviours, practices or habits which are harmful to physical or mental health, or imply a risk or threat to the safety, physical integrity or dignity of people, particularly women;
- the message must not undermine or contravene the principles, provisions or regulations established by the Ministry of Health in

prevention, disease treatment or rehabilitation matters; and
- the message must be drafted according to the applicable legal provisions.

Regulatory matters related to pharmaceutical advertising

Advertising must be consistent with the characteristics or specifications of the product or service, and it cannot:

- attribute to the product or service preventative, therapeutic, rehabilitation, nutritious, stimulative or other qualities that do not correspond to its function or use;
- indicate or suggest that the use or consumption of a product or service is a factor in determining a change of behaviour of individuals; or
- indicate or lead to believe, explicitly or implicitly, that the product has ingredients or properties which it lacks.

Advertising which attempts to put at risk the security or physical or mental integrity of people is forbidden.

Disclaimers or sanitary messages appearing in the advertisements of products, services or activities are subject to the following:

- written disclaimers in advertisements transmitted on TV should be shown for one quarter of the total length of the advertisement;
- the disclaimer should appear in a contrasted colour;
- the disclaimer should be located horizontally, with "Helvetic" font and in a size of 40 points per letter, proportional to a 14-inch TV screen;
- audible disclaimers should be pronounced in the same rhythm and tone as the advertisement; and
- for advertisements transmitted over the internet, the disclaimers should comply with the aforementioned obligations and principles.

Regulatory matters related to pharmaceutical products or services

For health services, the following applies:

- health services advertisements should inform on the characteristics and purposes of the services, and the means to access them;
- the advertisements cannot include techniques or treatments which are preventative, curative or rehabilitative, unless with the respective authorisation from the Ministry of Health; and
- health professionals (as doctors) should, when they advertise, include within the advertisement the university where they obtained their degree and their professional ID number.

For food, food supplements and non-alcoholic beverages, the following applies.

- Such advertising must not contravene the provisions on nutritional, hygienic and health education.
- Food, food supplements and non-alcoholic beverages cannot be advertised as stimulants or as though they are able to modify the physical or mental state of individuals, unless with the respective authorisation from the Ministry of Health.
- Advertising of food, food supplements and non-alcoholic beverages may not:
  (a) induce or promote harmful habits to health;
  (b) state that the product fulfils by itself the nutritional requirements of a human being;
  (c) attribute higher nutritional value to industrial food;
  (d) perform comparisons aimed at disparaging the properties of natural foods;

(e) express or suggest, through real or fictional characters, that ingestion of these products provides people with extraordinary abilities or characteristics;
(f) be directly or indirectly associated with the consumption of alcoholic beverages or tobacco; and
(g) declare properties that cannot be verified, or imply that the products are useful in preventing, alleviating, treating or curing a disease, disorder or physiological state.

- The advertising should include disclaimers about the condition of the products and messages promoting an equal alimentation and the promotion of healthy habits.
- Advertising of baby milk formulas should:
  (a) promote breastfeeding, for which they should clearly indicate the benefits thereof;
  (b) expressly indicate that the use of baby formula is recommended only in certain cases; and
  (c) include information on the correct handling of the formulas, their preparation and specific care.
- Advertising of food supplements should include a disclaimer indicating the relevant authorisation of such food supplement.

Health supplies

Regulations provide a series of restrictions and rules related to the following products, which are considered health supplies.

Medicines

- The advertising of medicines directed to the general population may include descriptions of human diseases, diagnosis, treatment, prevention or rehabilitation expressed in the terms of their sanitary registration and in language appropriate to the target public. These messages must always identify the issuer with the brand of the product or its corporate name.
- The advertising should be in a visual form for printed material, and in audible form for radio, with the legend "Refer to your doctor" as well as express the corresponding precaution when the use of the medicine represents any danger in the presence of any coexisting clinical or pathological condition.

Herbal remedies

- Herbal remedies should be limited to advertising a symptomatic effect based on the information expressed on the label, and should refrain from advertising them as curative.
- In addition to the "Refer to your doctor" legend, they should also include the following additional precautionary legend which the Ministry of Health determines, based on the health risk that the product represents: "This product has not been scientifically proven to have preventative or curative properties."

Generic exchangeable drugs

Only pharmaceutical specialties included in the Catalog of Interchangeable Generic Drugs referred to in the Regulation of Health Supplies may use the following legends, acronyms, denominations and adjectives in their advertising:

- the acronym "GE" (Generic Exchangable), its symbol or logo;
- the denomination "interchangeable generic drug", or the expressions "generic" or "interchangeable"; and
- any other expression, word, image or symbol whose purpose is to induce in the consumer the idea that the advertised medicine is a substitute for the original or innovative product.

Medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygiene products

The Ministry of Health authorises the advertising of these types of products in accordance with the characteristics and purposes for which they have been registered, and they shall be subject to the indications or uses approved by the Ministry.

- When granting or reviewing the registration of the product, the Ministry of Health shall specify in the advertising grounds whether it can be directed to the general population or only to health professionals or technicians.
- The advertising of the product should include messages that avoid self-treatment, when required due to their characteristics.
- Hygienic products may not be advertised when they:
  (a) promote practices that are harmful to health due to the inadequate use of such products; and
  (b) attribute preventative, therapeutic or rehabilitative qualities to the treatment of a certain disease, except in those cases where such circumstances have been fully proven.
- In general, all advertisements should:
  (a) be clear, concise and easily understandable for the sector of the public to which it is directed;
  (b) contribute, by means of the use of legends, to hygiene education; and
  (c) express in the precautionary message, if applicable, whether the use or consumption of the product represents a health risk.

It is important to mention that the following advertising always requires a specific advertisement permit issued by the Ministry of Health:

- provision of health services;
- food supplements and biotechnological products;
- medications and herbal remedies; and
- medical equipment, prosthetics, functional aids, diagnostic agents, dental supplies, surgical and healing materials, and hygienic products.

Conclusion

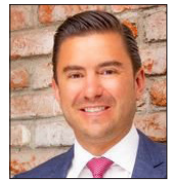
As can be seen from the topics discussed in this article, Mexico has strict regulatory requirements for pharmaceutical advertising. Because of this, it is always suggested that before carrying out any type of advertisement in this sector, the specific product and service is assessed in order to determine the relevant limitations and requirements.

Contributed by: Carlos Díaz Sobrino and Javier Perez Moreno, **Bello, Gallardo, Bonequi y García**

Bello, Gallardo, Bonequi y García was established in 2001 and has become a significant player in the Mexican legal market, meeting the growing need for specialised legal services. The versatility of its lawyers allows BGBG to provide personalised services in each of its practice areas, including technology, media and telecommunications (TMT). BGBG was created as a boutique law firm for TMT practice, and since its formation has been providing ongoing legal services to all types of companies within the TMT, technology, media, entertainment and communications industries. The firm's TMT practice, which handles all matters related to advertising and regulatory sectors, is one of the biggest standalone practices in Mexican law firms, and its team devotes almost all of its time to this specialised area. It has been recognised by independent national and international publications as a top-tier and leading practice.

Authors

Carlos Díaz Sobrino joined Bello, Gallardo, Bonequi y Garcia in 2012 and has over 13 years of experience in the technology, media and TMT sectors, as well as in privacy and data protection. He co-heads the TMT practice and also co-ordinates M&A expertise regarding the TMT sector. Since 2016, Carlos has been ranked by Chambers and Partners as "an associate to watch" and "up and coming" and as a highly recommended lawyer and partner in the TMT, media and technology practice areas. His key clients include technology companies looking for general legal and regulatory legal counsel for all different types of operations, such as e-commerce, technology, data privacy, content, media and cybersecurity.



Javier Perez Moreno joined Bello, Gallardo, Bonequi y Garcia in 2013, and assists clients in highly regulated sectors such as fintech, banking, insurance and healthcare. He advises national and international clients, including banks, insurance companies, financial technology institutions, and life sciences companies on complex regulatory matters, such as authorisation processes, design and implementation of compliance strategies.

Bello, Gallardo, Bonequi y Garcia

Downtown Santa Fe
Tower II
14 Floor Avenue
Santa Fe 428
Santa Fe
USA

Tel: +52 555 292 5232
Email: cdiaz@bgbg.mx
Web: www.bgbg.mx

NETHERLANDS

Law and Practice

Contributed by:
Robbert Sjoerdsma and Louise van de Mortel
Holla legal & tax see p.255

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NETHERLANDS

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In the Netherlands, the regulatory framework for pharmaceutical advertising is laid down in both international and national legislation and self-regulation.

Legislation

The EU rules on advertising and promotion of medicinal products as set out in Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended) have been implemented in Chapter 9 of the Dutch Medicines Act. Therefore, the Dutch Medicines Act is the primary national legislation governing pharmaceutical advertising.

In addition, the general rules on unfair commercial practices and on misleading or comparative advertising as laid down in Articles 6:193a-193j and 6:194-196, respectively, of the Dutch Civil Code (DCC) must be taken into account.

Self-Regulation

In the Netherlands, the self-regulatory landscape is diverse.

More detailed rules for pharmaceutical advertising are laid down in self-regulatory codes, such as the CGR Code of Conduct for Pharmaceutical Advertising (CGR Code of Conduct), which contains details on medicinal advertising, and the Code for Advertising Medicinal Products to the General Public (Code AGP), which is part of the Dutch Advertising Code and lays down the rules with regard to advertising of medicinal products to the general public.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

In the Netherlands, self-regulation is a system of private regulation which is in principle only binding on those who have subscribed to it.

The Dutch Advertising Code, which includes the Code AGP, is a self-regulatory instrument drawn up by representatives of advertisers, advertisement producers and distribution channels, consumer organisations, and civil-society actors. This code is non-binding; nevertheless, it is broadly supported and enforced.

The CGR Code of Conduct is drawn up by the Foundation for the Code for Pharmaceutical Advertising Commission. This foundation was established by various trade associations in the pharmaceutical industry. The CGR Code of Conduct is only binding on those parties who are members of the aforementioned trade associations.

However, Dutch courts have ruled that the CGR Code of Conduct is widely supported and have used (ie, through case law) the Code of Conduct to interpret relevant open norms in the Dutch Civil Code (DCC), and have held non-regulatees to the CGR Code of Conduct, meaning that the CGR Code of Conduct has generally binding force in practice.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Slightly different definitions of “advertising” are used in Directive 2001/83/EC, the Dutch Medicines Act, the Code AGP and the CGR Code of Conduct, respectively.

As the majority of cases involving pharmaceutical advertising are conducted before the CGR Code Commission, the following definition of "advertising" as included in the CGR Code of Conduct is worth mentioning: "any form of public and/or systematic, direct or indirect commendation of medicinal products and any services or images connected therewith, including offering or solicitation of goods or services in the interactions between authorisation holders and healthcare professionals" (Rule 3.1h CGR Code of Conduct).

It should be clear from this definition that the term "advertising" may be understood and interpreted very broadly.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Information or Advertising

Determining what should be considered information and what should be considered advertising is not easy. The objective of the communication is the decisive element in distinguishing advertising from mere information. If the objective is promotional in nature, then the communication will be qualified as advertising. If there is no promotional objective, the communication will be classified as mere information.

The question whether a communication concerns information or advertising must be determined on a case-by-case basis, in which connection the following factors are (or could be) taken into account (Rule 5.1.3 CGR Code of Conduct):

- the addressee;
- the content, presentation and design of the communication; and
- the context of the communication.

Disease Awareness Campaigns

Information relating to human health or diseases will not be considered advertising, provided that there is no reference, even indirect, to medicinal products. If there is such a reference, whether it qualifies as advertising or mere information will be dependent on the content of the communication.

Package Leaflets

Labelling and accompanying package leaflets for medicinal products are not considered advertising. This exemption only applies to the literal and complete reproduction of the labelling or package leaflet. When this information has been selected and rewritten by the authorisation holder, the information may be considered advertising.

2.3 Restrictions on Press Releases Regarding Medicines

As previously stated, every communication must be judged individually to determine whether it qualifies as advertising or mere information. Therefore, press releases, press conferences and interviews cannot, by definition, be considered as advertising.

However, a press release regarding a medicinal product would be regarded as an advertisement if the purpose of the message and the objective pursued is to promote the prescription, supply, sale or consumption of that medicinal product. If, in this case, the press release concerns a prescription-only medicinal product, the general prohibition on the advertising of prescription-only medicinal products to the general public would be breached.

2.4 Comparative Advertising for Medicines

Any advertising that explicitly or by implication makes reference to a competitor or competing medicinal products or substances is considered comparative advertising. According to both the Code AGP and CGR Code of Conduct, comparative advertising is in principle allowed, provided that certain conditions are satisfied, most notably that the comparison:

- cannot be misleading;
- cannot be detrimental to the value of the medicinal products in question;
- must be demonstrably scientifically correct and in line with the most recent state of the science (this must be demonstrated by means of one or more scientific studies); and
- must relate to all relevant characteristics of the medicinal products.

In the case of comparative advertising for over-the-counter medicinal products aimed at the general public, no brand names may be used (Rule 26 Code AGP). The use of brand names is allowed in comparative advertising for medicinal products aimed at healthcare professionals.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

A medicinal product is not authorised if no marketing authorisation has been granted for it. Use of an authorised medicinal product by a healthcare professional to treat a patient in a manner that is not covered by the marketing authorisation and is not described in the SmPC is considered "off-label" use.

In the Netherlands, advertising for medicinal products that have not been authorised and/or for off-label use of authorised medicinal products is in principle prohibited.

Information about unauthorised medicinal products, such as unauthorised medicinal products that have been prepared magisterially, is permitted. The same applies for information on off-label use, provided that the information is based on the latest state of scientific knowledge and practice and within the bounds laid down in the Dutch Medicines Act (Rule 5.7.1.a CGR Code of Conduct).

3.2 Provision of Information During a Scientific Conference

During scientific conferences directed at healthcare professionals, the same principles as discussed in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications** apply: information about unauthorised medicinal products and off-label use thereof is permitted, and advertising is not.

However, an exception applies in a strictly international context. Advertising for unauthorised medicinal products is permitted during a scientific meeting only if all three conditions below are satisfied (Rule 5.2.1.1b CGR Code of Conduct):

- the advertisement is published during a meeting which has a truly international nature in terms of organisation, and where a significant proportion of the speakers and participants are from countries outside the Netherlands;
- the advertisement is undeniably not targeting the Netherlands; and

- the medicinal product to which the advertisement refers is registered in at least one major industrialised country.

3.3 Provision of Information to Healthcare Professionals

In principle, it is permitted to provide information on unauthorised medicinal products and off-label use of authorised medicinal products to healthcare professionals, provided the information does not qualify as advertising.

Reactive correspondence, possibly accompanied by material of a non-promotional nature, and needed to answer a specific question about a particular medicinal product, qualifies as information. The same applies to *proactive* communication of frequently-asked questions (FAQs), provided that the questions and answers:

- concern the correct, safe and responsible use of medicinal products; and
- cannot be deemed to be advertising in view of their content, presentation and design.

3.4 Provision of Information to Healthcare Institutions

In the Netherlands, the government is responsible for setting the basic health insurance package, the maximum prices for authorised medicinal products and the available resources. Therefore, there is no reason to send information on unauthorised medicinal products and off-label use of authorised medicinal products to healthcare institutions for budget reasons.

3.5 Information About Early Access or Compassionate Use Programmes

In the Netherlands, the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*) can give permission for bringing a medicinal product on the market which has not (yet) been granted a marketing authorisation, if it involves a severe condition for which no alternative medicinal product is available on the market. This is known as a compassionate use programme.

In the assessment of the admissibility of the compassionate use programme within the framework of the advertising rules, the following three aspects are relevant:

- the rules for public advertising of prescription-only medicinal products – ie, to what extent the patient is involved in the programme;
- the rules for payment for services provided by healthcare professionals in the context of the implementation of the programme; and
- whether the programme promotes the rational use of the medicinal product in question.

As a result of the way the programme is set up, the following should be prevented:

- the relevant patients being confronted with advertising for prescription-only medicinal products;
- a financial relationship being entered into between the authorisation holder and the healthcare professional with the apparent object of promoting the prescription of the medicinal product; and/or
- the financial interests of patients negatively affecting the rational use of the medicinal product.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising of medicinal products to the general public is prohibited if:

- such products are exclusively available on prescription;
- such products are available without prescription, but contain psychotropic substances or narcotics as referred to in List I and II of the Dutch Opium Act; and
- the advertising message is not provided with a valid approval number, issued by the Inspection Board for the Advertising of Medicinal Products to the General Public (KOAG) (Rule 3 Code AGP).

Thus, only advertising for over-the-counter medicinal products is permitted. These are:

- over-the-counter medicinal products that may only be sold at a pharmacy (Pharmacy-only PH, *Uitsluitend Apotheek UA*);
- over-the-counter medicinal products that may be sold in pharmacies and drugstores (Pharmacy and Drugstore-only PDO, *Uitsluitend Apotheek of Drogist UAD*); and
- over-the-counter medicinal products that may be sold freely and, therefore, also in "standard" shops, webshops and supermarkets (General Sales GS, *Algemene Verkoop AV*).

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising for over-the-counter medicinal products to the general public must include the following information (Rule 8.1 Code AGP):

- the name of the medicinal product;
- the generic name of the active substance, if the product contains only one active ingredient;
- the indications and contraindications; and
- an explicit request to read the package leaflet or the text on the outer packaging.

Advertising for over-the-counter medicinal products to the general public may not mention the reimbursement status, as that might encourage people to not buy the product themselves, but to request prescription (Rule 12 Code AGP).

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

An authorisation holder is allowed to support an activity undertaken by a patient organisation in the form of grants or sponsorship, if the following is taken into account (Rule 6.6.2 CGR Code of Conduct):

- the support must relate to innovative and/or quality-improving activities and have as a goal the direct or indirect improvement of patient care or the advancement of medical science;
- direct or indirect advertising for one or more specific prescription-only medicinal products is prohibited; and
- the information on prescription-only medicinal products must comply with the requirements for information.

The support needs to be recorded in a written agreement, which includes the following (Rule 6.6.3 CGR Code of Conduct):

- a description of the object of the support;

- a detailed description of the rights and obligations of the patient organisation and the authorisation holder;
- the scope of the support (in cash or kind), expressed in euros; and
- the patient organisation's obligation to communicate that the relevant activity has been sponsored in whole or in part by the authorisation holder.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising for medicinal products aimed at healthcare professionals must state the following, in conformity with the summary of product characteristics (SPC) (Rule 5.4.1 CGR Code of Conduct):

- the name of the product;
- the name and address of the party responsible for marketing the product;
- the qualitative and quantitative composition of the active ingredients;
- the pharmaco-therapeutic group;
- the pharmaceutical form;
- the therapeutic indications;
- the principal adverse reactions;
- the principal warnings;
- the contraindications; and
- the classification of the medicine with respect to its dispensing.

Article 91(1) of Directive 2001/83/EC states that member states may also require advertising to, among others, indicate the selling price and/or the conditions for reimbursement by social security institutions. However, such a requirement has not been included in the Dutch Medicines Act or in the CGR Code of Conduct.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising of medicinal products must be consistent with the information contained in the summary of product characteristics (SPC) of the relevant medicinal product. An advertisement may not include claims that contradict the SPC of the relevant medicinal product (Rule 5.2.1.2 CGR Code of Conduct).

However, there is room for information about new developments, such as clinical studies that are not (yet) included in the SPC, provided that the information is compatible with the SPC (Rule 5.7.1 CGR Code of Conduct).

5.3 Advertising of Combination Products

There are no specific rules that govern the advertising of a combination of medicinal products. In principle, the advertising of a combination of medicinal products is permitted, if that combined use is included in the summary of product characteristics (SPC) and is in conformity with the other requirements for advertising.

In case law, the CGR Code Commission has ruled that where the combination is not included in the SPC, the advertising would falsely suggest that the combined use of the medicinal product has been assessed and permitted by the registration authorities and would thus amount to unlawful advertising of an unauthorised medicinal product.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

In principle, authorisation holders may provide reprints of journal articles to healthcare professionals. However, in most cases this will be

deemed a form of advertising, meaning that the content of the journal article (in addition to any accompanying materials) must conform with the applicable advertising rules.

For example, in one case where the reprint was used to provide more detail about the safety profile of a medicinal product, the provision of the reprint was allowed, as it communicated relevant information to healthcare professionals.

In another case, where in the reprint a medicinal product was compared on effectiveness with another medicinal product, the provision of the reprint by the authorisation holder to healthcare professionals was qualified as unlawful comparative advertising, as the article involved related to a study that, according to the CGR Code Commission, was incomprehensive, because the adverse reactions (in the long-term) were not assessed as well.

5.5 Medical Science Liaisons

Although the CGR Code of Conduct contains various rules regarding medical sales representatives (MSRs, *artsenbezoekers*), (the actions of) medical sales liaisons (MSLs) are not explicitly regulated.

As it is generally accepted that the actions of MSRs are (partly) aimed at the promotion of medicinal products and thus qualify as advertising, MSRs are limited to having on-label proactive discussions with healthcare professionals about the authorised medicinal products they support.

As MSLs are generally seen as non-promotional, reactively having in-depth scientific discussions with healthcare professionals, they are able to reactively discuss yet unauthorised (pipeline) medicinal products, as well as to have off-label discussions. However, it is also prohibited for MSLs to promote an unauthorised medicinal product or to promote an authorised medicinal product for off-label use. Therefore, proactive communication in this respect and/or the dissemination of such information in a promotional context (eg, during an event) should be avoided.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

A distinction should be made between advertising of prescription-only or over-the-counter medicinal products to healthcare professionals and advertising of over-the-counter medicinal products to the general public.

All advertising to the general public must be approved in advance by the Inspection Board for the Public Promotion of Medicines (*Keuringsraad KOAG*) (ex Rule 3 under c Code AGP).

In the case of advertising to healthcare professionals, it is the responsibility of the authorisation holder to ensure proper compliance with the relevant advertising rules.

6.2 Compliance With Rules on Medicinal Advertising

Each authorisation holder must establish a scientific service. The scientific service must include a medical doctor or a pharmacist who will be responsible for approving any promotional material before release.

The authorisation holder is further obliged to keep a detailed administration of all its advertising, including a sample of each advertising, an overview of the persons to whom it was

addressed, the method of distribution and the first date of dissemination. The administration must remain available for at least five years.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Internet Advertising

The rules that apply "offline" also apply "online". Therefore, websites which are accessible to the general public may not contain advertising of prescription-only medicinal products, as that would amount to unlawful promotion of prescription-only medicinal products to the general public. No specific rules apply for advertising on the internet of over-the-counter medicinal products.

Product Sites

So-called product sites, which are websites with a brand name of a prescription-only medicinal product in their URL addresses, and corporate websites which are accessible to the general public, are permitted, provided that only general technical user information about the prescription-only medicinal product and brief information of a subordinate nature about the relevant disease is provided there (Rule 5.8.12 CGR Code of Conduct).

Hyperlinks

Hyperlinks or banners on product sites and corporate sites to third-party websites are allowed, provided that:

- the link leads to the homepage/landing page of that third-party website;
- the content of the third-party website complies with the CGR Code of Conduct; and
- it is clear for the visitor of the website that the hyperlink or banner leads to a third-party website that is not the responsibility of the party whose website the visitor is leaving.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As advertising of prescription-only medicinal products to the general public is prohibited in the Netherlands, any advertisements of such products on websites intended for healthcare professionals may not reach the general public. In practice this will mean that such websites need to be password-protected, and the passwords should not be easily guessable or available for the general public. A password that consists of the (brand) name of the prescription-only medicinal product, for example, will therefore most likely not be enough.

7.3 Provision of Disease Awareness Information to Patients Online

Types of Information

A distinction should be made between two types of information on public health or human diseases:

- information that contains no reference, not even indirectly, to a prescription-only medicinal product; and
- information which refers, directly or indirectly, to a prescription-only medicinal product.

Targeted Public

Further, a distinction should be made between provision of such information to:

- the general public; and
- patients who have already been prescribed a prescription-only medicinal product.

The first type of information is generally allowed.

Consistent, Complete and Balanced Information

The CGR Code of Conduct only covers the type of information which refers, directly or indirectly, to a prescription-only medicinal product (Rule 5.7.1 CGR Code of Conduct). The provision of this type of information to the general public online is allowed, provided that the information does not qualify as disguised advertising and certain requirements have been met, most importantly that the information is consistent with the government-approved texts (such as the package leaflet and the SPC), is not misleading and is complete and balanced. The latter means that if information on different forms of therapies is given, all the relevant treatments must be mentioned.

Technical and Specific User Information

An exception to the main rule that information must be complete and balanced, and thus that all relevant treatments must be mentioned, applies for technical and specific user information on the relevant prescription-only medicinal product targeting patients who have already been prescribed that prescription-only medicinal product (Rule 5.8.10 CGR Code of Conduct). In this case, the alternative treatments do not have to be mentioned. However, there is a requirement that this information may not be generally available. For the internet, this means that this information must be placed behind a password.

7.4 Online Scientific Meetings

(Online) Scientific Meetings

The Netherlands does not have a specific set of rules that governs online scientific meetings. There is one set of rules that applies for physical as well as virtual/online scientific meetings (see also **9.3 Sponsorship of Scientific Meetings**).

Relevant Hospitality Costs for Online Meetings

There will be no recreational costs or travel or accommodation costs in the case of online scientific meetings. Relevant hospitality costs can be the registration costs, for example where physical course materials are sent to the participants. Where the course materials are distributed digitally, the associated costs cannot be individualised, and those costs do not then qualify as hospitality costs, but will then qualify as general organisational costs. The latter will also apply for other costs made for the development and offering of the online scientific meeting.

International Events

An online scientific meeting can qualify as an "international event" if it has a truly international nature in terms of organisation and a significant proportion of the speakers and participants are from countries outside the Netherlands.

Advertising of medicinal products which is communicated to participants of an online international event may refer to medicinal products which are not registered in the country where participating healthcare professionals are based, or which are registered under different conditions, as long as the advertising is accompanied by a suitable statement indicating the countries in which the medicinal product is registered and makes clear that the medicinal product or indication is not registered locally (Rule 5.2.1.1 CGR Code of Conduct).

7.5 Use of Social Media

As previously mentioned, the main rule is that all which applies "offline" also applies "online" (Rule 5.5.1 CGR Code of Conduct).

Aimed at the Dutch Public

As the reach of social media knows no national borders, and as the CGR Code of Conduct only applies to expressions that are accessible in the Netherlands and are unmistakably aimed at the Dutch public, whether this is the case for each specific social media post must be ascertained.

General Requirements

The mere fact that the medicinal product the social media post is about is also available in the Netherlands is not decisive. The following aspects may be relevant:

- the language of the social media post;
- the nationality of the sender;
- the question whether and (if so) in what manner reference is made in national media to the social media post;
- the presence of references to the use, availability or price of the advertised medicinal product in the Netherlands; and
- the presence of a typically Dutch setting and/or other associations with the Netherlands.

Advertising of Prescription-only Medicines

Advertising for prescription-only medicinal products on social media is only possible if it is made certain that the advertising is only directed towards those healthcare professionals that have an interest in obtaining the information. Social media has technical possibilities for this purpose by means of pre-registration and/or the use of usernames and passwords. Use must be made of these technical possibilities.

Further, it is important to note that any information that the authorisation holder obtains via social media about the adverse effects of a particular medicinal product must be followed up according to the applicable pharmacovigilance rules.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

General Anti-bribery Rules

In the Netherlands, general anti-bribery rules are incorporated in the Dutch Penal Code. A distinction is made between bribery of public officials and bribery of others working under an employment contract or acting as an agent. Further, as there are two parties to a bribe – the briber (the one who offers the bribe) and the person being bribed (the one who has to do something in exchange) – a distinction is made between active bribery (bribing someone) and passive bribery (being bribed):

- general bribery – Article 328ter Dutch Penal Code (both active and passive bribery); and
- bribery of public officials – Article 177 (active bribery) and Article 363 (passive bribery) Dutch Penal Code.

Anti-bribery Rules Applicable to Healthcare Professionals

A healthcare professional can be affiliated with a healthcare institution, such as a hospital, on various legal grounds. The healthcare professional may have a civil service appointment, an employment contract or can also be self-employed.

A healthcare professional who has a civil service appointment, for example a healthcare professional working in a university medical centre, is also a public official. In this case, the above-mentioned articles applicable to bribery of public officials apply.

Where the healthcare professional is working under an employment contract, the above-mentioned article applicable to general bribery applies.

Where the healthcare professional is self-employed, technically none of the above-mentioned articles apply.

Sanctions

General bribery (both active and passive) is punishable by a prison term not exceeding four years or a fine of the fifth category (EUR90,000). Bribery of public officials (both active and passive) is punishable by a prison term not exceeding six years or a fine of the fifth category (EUR90,000).

8.2 Legislative or Self-Regulatory Provisions

The CGR Code of Conduct makes a distinction between inducements and other financial relations.

Inducement

Inducement is one of the means of influencing the behaviour of persons or organisations with the apparent goal of sales promotion. Inducement is defined as a "financial relation with the apparent object of promoting the prescription, supply or use of a medicinal product".

Exemptions

In general, inducements are prohibited by the Dutch Medicines Act (Article 94) and the CGR Code of Conduct (Rule 6.1.1). Specific exemptions for relations with healthcare professionals are provided for:

- inexpensive gifts that may be relevant to the practice of the healthcare professional (Rule 6.2.2 CGR Code of Conduct);
- discounts granted for the supply of medicinal products, if, in the case of discounts in kind, such discounts are awarded in the form of bonus supplies of the same medicinal product, or, in the case of cash discounts, if these discounts are recorded explicitly and in writing (Rule 6.2.3 CGR Code of Conduct);
- a limited number of free samples of medicinal products (Rule 6.2.4 CGR Code of Conduct);
- services that may be provided by healthcare professionals, or a grouping of healthcare professionals and/or an institute in which healthcare professionals participate or by which they are employed, to pharmaceutical companies, provided that the service agreement must be recorded in writing in advance and the services are subject to reasonable payment for the services provided (subsection 6.3 CGR Code of Conduct); and
- certain hospitality costs as part of meetings and manifestations (subsection 6.4 CGR Code of Conduct).

Other Financial Relations

Other financial relations that serve a healthcare interest and/or are considered to be normal in legal transactions do not fall under the definition of inducement. The CGR Code of Conduct distinguishes three types of "other financial relations":

- financial relations with parties other than healthcare professionals (Rule 6.5.2 CGR Code of Conduct);
- sponsorship of projects relating to innovative and/or quality-improving activities (Rule 6.5.3 CGR Code of Conduct); and
- (partly) making scientific awards for care-improving and/or medical scientific performances possible (Rule 6.5.4 CGR Code of Conduct).

Financial relations with parties other than healthcare professionals are not subject to the prohibition on inducements and are therefore permitted, in short, if there is no apparent goal of sales promotion (Rule 6.5.2 CGR Code of Conduct).

Sponsorship of healthcare activities and projects, and contributions to scientific awards, are permitted if it is determined that an apparent goal of sales promotion is lacking. It is presumed that there is no apparent goal of sales promotion if the relevant cumulative conditions, which are provided for by the CGR Code of Conduct for these categories, are met.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The guiding principle is that an authorisation holder must refrain from offering gifts to healthcare professionals. An exception is made for inexpensive gifts that are relevant to the practice of the healthcare professional (Rule 6.2.2 CGR Code of Conduct).

A gift is considered inexpensive if the value does not exceed EUR50, including VAT, with a maximum of EUR150 per year. These sums apply per healthcare professional and per authorisation holder.

9.2 Limitations on Providing Samples to Healthcare Professionals

In principle, no samples of medicinal products should be given, other than on an exceptional basis. For medicinal products containing psychotropic substances or narcotics, it is prohibited to provide samples altogether. For other medicinal products, healthcare professionals may not receive more than two samples of the same medicinal product per calendar year. After a period of two years after a healthcare professional has requested a sample, no new samples of the same medicinal product may be provided.

Authorisation holders must keep adequate records of the samples of medicinal products they have provided and of the healthcare professionals to whom they have provided the samples, and on which date and in what quantities. These records are subject to a retention period of five years.

If a medicinal product is assigned a new indication, this medicinal product is qualified as new and samples may be provided (Rule 6.2.4 CGR Code of Conduct).

9.3 Sponsorship of Scientific Meetings

Scientific meetings may be sponsored by authorisation holders, but only within certain limits. The most important rules regarding financial contributions by pharmaceutical companies are as follows (subsection 6.4 CGR Code of Conduct).

- Social/recreational costs (entertainment) may not be paid for.
- Restrictions apply for any costs that can be traced to an individual (these are “hospitality costs”); examples are registration fees, meals and drinks for participants, hotel stays and travelling expenses, as well as the costs of printing handouts, programme booklets and conference bags for participants. These hospitality costs must remain limited to what is strictly necessary for their participation in the event. In addition, the sponsoring of the hospitality costs of healthcare professionals may in no event exceed EUR500 per occasion (otherwise the participant must cover at least half of the hospitality costs) and EUR1,500 annually for every separate therapeutic class.

- In general, no limits apply for the sponsoring of general organisational costs, which are costs that cannot be individualised, such as the costs of hiring conference rooms, preparations, and the costs and expenses of the speakers.
- As a matter of principle, a surplus/positive balance without a specific destination is not permitted, if it is formed by the sponsoring of pharmaceutical companies. In any event such a surplus/positive balance may not be used for social/recreational activities. In order to judge whether sponsoring is permitted, a budget must be prepared before the scientific meeting and a final settlement must be made after the scientific meeting.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Any hospitality offered or provided by an authorisation holder may not include relaxation. This includes visiting museums and/or sport events.

However, certain hospitality may be offered or provided in relation to manifestations. If events do not qualify as (scientific) meetings and the programme still meets the information needs of healthcare professionals, then they will qualify as manifestations.

Hospitality in relation to manifestations should also be strictly limited to what is necessary for participation (Rule 6.4.8 CGR Code of Conduct), whereby:

- the costs incurred by the authorisation holder for the hospitality per healthcare professional may not exceed the amount of EUR75 per occasion and EUR375 per year; and
- the arrangements for the hospitality provided are laid down in a written agreement, in which the performance must be clearly defined – this requirement does not apply if the hospitality only concerns participation in a manifestation organised by the authorisation holder concerned, without reimbursement of travel and/or accommodation costs.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Under the CGR Code of Conduct, a "donation" or "grant" is considered "sponsorship". Sponsorship is understood to include all forms of support (monetary or in kind).

In principle, sponsorship may not benefit an individual healthcare professional. In such a case, an apparent object of promoting the prescription, supply or use of a medicinal product is assumed, making the sponsorship subject to the prohibition of inducement (Rule 6.5.3c CGR Code of Conduct).

Subject to certain conditions, such as that the sponsorship relates to innovative and/or quality-improving activities and has as a goal the direct or indirect improvement of patient care or the advancement of medical science, sponsorship may be awarded to collaborations of healthcare professionals, such as partnerships or other legal entities in which healthcare professionals are active (Rule 6.5.3c CGR Code of Conduct). This does not apply for Pharmacotherapeutic (Transmural) Consultation (*Farmacotherapeutisch (transmural) overleg*), for the reason that it is not considered desirable that FT(T)Os be sponsored by authorisation holders.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts in kind (provided they are given in the form of bonus supplies of the same medicinal products) or discounts in cash are permitted

(Rule 6.2.3 CGR Code of Conduct), provided the discounts are granted in a transparent way.

Giving 100% discounts on supplies of medicinal products is considered permissible in principle.

9.7 Payment for Services Provided by Healthcare Professionals

There is in principle no objection to the provision of services by health professionals to authorisation holders, on the condition that:

- such services are relevant to the practice of medicine, pharmacy, dentistry, nursing or midwifery – these services can be of a different nature, and may include lecturing, consulting or participating in pharmaceutical research;
- the service agreement is recorded in writing in advance; and
- the services are subject to a reasonable hourly rate and to payment of reasonable expenses.

For services provided by healthcare professionals, maximum hourly rates have been determined. These rates are indexed yearly. In 2023, the maximum hourly rates range from EUR87 (eg, for a nurse with a post-secondary vocational education (MBO)) to EUR267, for a professor.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

If the hospitality provided for by an authorisation holder relates to a meeting/manifestation taking place abroad, the meeting/manifestation must be submitted to the CGR Code Commission for prior approval.

Foreign meetings are exempt from this prior approval requirement where they are truly international in scope, have a significant proportion of speakers and participants from countries other than the Netherlands, and are organised by an association of healthcare professionals by a scientific organisation or other groups or bodies independent of the pharmaceutical industry, or the content of which has been classified as scientific by a scientific association or a body independent of the pharmaceutical industry and recognised by the profession concerned.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Transparency Register

Since 25 April 2013, financial relationships between healthcare professionals registered in the Dutch BIG Register (a legal, online and public register for Professions in Individual Health Care (*Beroepen in de Individuele Gezondheidszorg*)) and pharmaceutical companies must be disclosed in the online Dutch Healthcare Transparency Register (DHTR). Since 1 January 2015, financial relationships between patient organisations that are established in the Netherlands and pharmaceutical companies must also be disclosed in the DHTR.

The DHTR has no formal basis in Dutch law, but is the result of self-regulation. The DHTR is governed and operated by the Foundation Transparency Register Care (*Stichting Transparantieregister Zorg*).

Financial Relationships

A financial relationship is defined as a direct or indirect financial compensation in cash or in kind or otherwise, provided by an authorisation holder to a healthcare professional practising in the Netherlands, respectively, to a patient organisation that is established in the Netherlands.

All above-defined financial relationships must be recorded in written agreements. These written agreements do not need to be disclosed. Only the following must be provided for in the DHTR:

- the name of the healthcare professional involved (doctor, pharmacist or nurse), the partnership (eg, scientific association or partnership) or the institution (hospital, patient organisation);
- the name of the authorisation holder concerned;
- the nature of the financial relationship (eg, services agreement or sponsorship);
- the total amount or fee paid by the authorisation holder that year per individual financial relationship; and
- the year in which the financial relationship took place.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

As mentioned, the Dutch Healthcare Transparency Register (DHTR) has no formal basis in Dutch law, but is the result of self-regulation.

Currently, the affiliated organisations behind the following have joined the DHTR:

- the Foundation for the Code for Pharmaceutical Advertising (CGR);
- the Foundation for the Code of Conduct for Medical Devices (GMH); and
- the Code of Commendation of Veterinary Products (CAVP).

The above means that only the members of the CGR, GMH and CAVP have to disclose their relevant financial relationships with healthcare professionals practising in the Netherlands, respectively, with patient organisations established in the Netherlands in the DHTR, regardless of whether those members are foreign companies or already have products on the market.

It must be noted, though, that through memberships, the CGR, GMH and CAVP by and large cover the Dutch (veterinary) pharmaceutical and medical devices industry as well as healthcare professionals practising in the Netherlands.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

For supervision of the rules regarding pharmaceutical advertising, the Netherlands has a dual system: legislation and self-regulation.

Legislation

As previously stated (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**), the Dutch Medicines Act is the primary national legislation governing pharmaceutical advertising. Compliance with the Dutch Medicines Act is monitored and enforced by the Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*).

Self-Regulation

Compliance with the Dutch Advertising Code is monitored by the Advertising Code Committee (*Reclame Code Commissie*). There is also an

Appeals Board, which can assess complaints in the second instance. Compliance with the CGR Code of Conduct is monitored by the CGR Code Commission (*Codecommissie CGR*) and in the second instance by the Appeals Committee of the CGR Code Commission.

The Inspection Board for the Public Promotion of Medicines (*Keuringsraad KOAG*) is charged with the preventative supervision of self-regulation of advertising for (over-the-counter) medicinal products to the general public (ex Rule 3 under c Code AGP).

As the Code AGP is both a special code of the NRC and an integral part of the CGR Code of Conduct (ex Rule 5.6.1 CGR Code of Conduct), for *reactive supervision*, a complainant can turn to both the Advertising Code Committee as well as to the CGR Code Commission. Although the CGR Code Commission mainly focuses on pharmaceutical advertising aimed at healthcare professionals, the CGR Code Commission also handles complaints about allegedly prohibited advertising for prescription-only medicinal products to the general public.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

When confronted with a (competing) authorisation holder that infringes the rules for pharmaceutical advertising, in most cases, there are various bodies one can turn to and various sets of rules one can invoke.

The options include the following.

- Reporting the infringement of the Dutch Medicines Act to the Health and Youth Care Inspectorate, which can subsequently take action.
- Filing a complaint with one of the following self-regulatory bodies:
  (a) the CGR Code Commission for breach of the CGR Code of Conduct; or
  (b) the Advertising Code Committee for breach of the Code AGP and/or the NRC.
- Initiating civil proceedings before the Dutch courts against the authorisation holder for breach of the relevant rules on unfair commercial practices and/or on misleading or comparative advertising as laid down in the DCC. As, under Dutch law, the violation of a statutory provision only establishes civil liability for damage caused to another person if the statutory provision concerned aims to protect against the damage (Schutznorm-principle), and it is established in case law that the advertising rules of the Dutch Medicines Act do not aim to protect the (commercial) interests of competing pharmaceutical companies, those advertising rules cannot be invoked by an authorisation holder against a competitor, at least not directly.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The possible sanctions that can be imposed for violation of medicinal products advertising rules and rules on inducements to prescribe differ in nature and severity depending on the enforcement body dealing with the violation.

Health and Youth Care Inspectorate

In the case of a violation of the advertising rules included in the Dutch Medicines Act, the sanction can be an administrative fine, which is dependent on the size of the company (for a big company the maximum fine is EUR150,000) and on whether it regards a first offence or a repeated offence (for the third offence the maximum fine is EUR450,000).

Further, in order to prevent damage to public health, the public officials of the Health and Youth Care Inspectorate are authorised to seize medicinal products and/or suspend or terminate the trade of medicinal products.

It is, however, current practice for the Health and Youth Care Inspectorate to only impose a fine in the case of a violation of the medicinal products advertising rules.

Self-Regulatory Bodies

Where a complaint that is brought before the CGR Code Commission is ruled founded, the CGR Code Commission can impose the following sanctions:

- a reprimand;
- an order to immediately cease the act complained of and/or to (further) refrain from doing the act, or in the case of a challenged omission, to act in accordance with the CGR Code of Conduct;
- an order to take the measures necessary to guarantee compliance with the CGR Code of Conduct in the future;
- a rectification order;
- an order to recall distributed material; and
- publication of the decision on different media including the sanction or measure imposed.

A decision of the Appeals Committee of the CGR Code Commission qualifies as a binding advice (ex Article 7:900(2) DCC) between parties that:

- are members of an organisation belonging to the Foundation for the Code for Pharmaceutical Advertising (CGR); or
- have voluntarily submitted to the authority of said Appeals Committee.

The authors believe the same applies for a decision of the CGR Code Commission in the first instance, if said decision is not (timely) appealed.

The Advertising Code Committee can rule that a complaint is founded, unfounded or inadmissible. If the complaint is ruled as founded, a recommendation can be issued to the advertiser to refrain from advertising in the way that was found in breach of the rules. The Advertising Code Committee can also decide to provide non-binding advice or to issue a press release.

Dutch Courts

In proceedings on the merits, Dutch courts can, among others:

- render an injunction, for example to refrain from the contested advertising;
- award damages suffered by the claimant, for example as a result of the contested advertising by the defendant;
- render a declaratory judgment; and
- rule that compliance with the court order is subject to penalties (*dwangsommen*).

Dutch procedural law also provides parties with opportunities to request short-term measures (provisional remedies) in preliminary relief proceedings. The most common and significant provisional remedies issued in preliminary relief proceedings include the preliminary prohibitory injunction (*verbod in kort geding*), such as the order to refrain from the contested advertising, and the preliminary mandatory injunction (*gebod in kort geding*), such as a rectification order. These injunctions can be subject to a penalty, if so requested.

11.4 Relationship Between Regulatory Authorities and Courts

There is a difference in the binding power of the judgments rendered by courts and those rendered by self-regulatory bodies.

The Advertising Code Committee can only provide non-binding advice. Judgments by the CGR Code Commission (and its Appeals Committee) are only binding on those parties who have subscribed to it, through memberships of trade associations, who in turn are the member organisations of the Foundation for the Code for Pharmaceutical Advertising.

However, as the Dutch Civil Code contains various open (and as a result vague) norms – such as "misleading advertising" – that need to be filled in/developed in case law, which Dutch civil courts have not hesitated to do with the content of self-regulatory codes and/or the judgments of self-regulatory bodies, the scope of self-regulation is extended, so that it has generally binding force in practice.

There is already an example of a case concerning pharmaceutical advertising in which a non-regulatee to the CGR Code of Conduct was held to comply with its content, as the court held that the use of the code in the sector was so omnipresent that the court adopted the self-regulation as being the norm applicable in the pharmaceutical sector.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In 2021, two separate cases were brought before Dutch civil courts in proceedings between competing pharmaceutical companies regarding the use of refund schemes for medicinal products not (yet) included in the so-called basic package, meaning that the costs of those products were not (yet) reimbursed via the statutory health insurance in the Netherlands. The central question brought before the courts was whether such a refund scheme in itself qualified as unacceptable advertising. This question was answered in the negative.

In 2022, for the first time, a case was brought the CGR Code Commission regarding an advertisement about the carbon footprint of a medicinal product. One of the central questions to be answered was whether this type of advertising fell within the scope of the CGR Code of Conduct. This question was answered in the positive.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Prohibited Advertising

Advertising veterinary medicines that have no market authorisation is prohibited.

Advertising of prescription-only and Opium Act-listed veterinary medicines to the "public" is prohibited. Veterinarians, dealers in veterinary medicines and professional animal keepers are not regarded as "public".

Authority

The Royal Dutch Society for Veterinary Medicine (KNMvD) and the Association of Manufacturers and Importers of Veterinary Medicines in the Netherlands (FIDIN) have jointly established a code for promoting veterinary products and have set up a disciplinary committee to handle complaints about violations of this code, the Committee on the Promotion of Veterinary Products (CAVP).

Holla legal & tax is an independent Netherlands-based full-service firm with around 80 lawyers and tax advisers at its offices in 's-Hertogenbosch, Eindhoven and Utrecht. Holla's client base mainly consists of national and international large corporations and medium-sized enterprises. The firm houses legal specialists in the areas most relevant to these clients, such as corporate specialists, litigation specialists and regulatory experts. Holla also has a team dedicated to (pharmaceutical) advertising law.

Authors

Robbert Sjoerdsma is a partner at Holla legal & tax and specialises in (soft) IP and (pharmaceutical) advertising law. He is one of the few specialists in the Netherlands who regularly represents pharmaceutical companies in (pharmaceutical) advertising matters before the CGR Code Commission and before the Dutch civil courts.

Louise van de Mortel is an associate at Holla legal & tax. Her practice focuses on (soft) IP and IT law, and compliance and litigation in the pharmaceutical industry, assisting both international and domestic clients. She has significant experience in (pharmaceutical) advertising law.

Holla legal & tax

Dorgelolaan 30
5613 AM Eindhoven
PO Box 63
5600 AB Eindhoven
The Netherlands

Tel: +31 88 44 02 400
Fax: +31 88 44 02 300
Email: info@holla.nl
Web: www.holla.eu

PORTUGAL

Law and Practice

Contributed by:
Fernanda Matoso and Alessandro Azevedo
Morais Leitão, Galvão Teles, Soares da Silva & Associados see p.271

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PORTUGAL

Contributed by: Fernanda Matoso and Alessandro Azevedo,
Morais Leitão, Galvão Teles, Soares da Silva & Associados

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Legislative Acts

- Decree Law 176/2006 of 30 August, as amended, which establishes the legal regime applicable to medicines;
- Decree Law 5/2017 of 6 January, which establishes the advertising principles and a prohibition on National Health Service (NHS) hospitals from requesting and receiving benefits from the pharmaceutical industry and from other health technologies companies, except if such receipt is previously authorised by the competent authority (local regulatory authority) and does not harm their impartiality and neutrality; and
- Decree Law 330/90 of 23 October, as amended, which approves the Advertising Code.

Administrative Regulations

In addition, some specific matters are regulated by administrative regulations issued by the regulatory authority, the National Authority of Medicines and Health Products, IP (*Autoridade Nacional do Medicamento e Produtos de Saúde* or "Infarmed"), and the Secretary of State of Health.

Self-Regulatory Codes

The Portuguese Pharmaceutical Industry Association (*Associação Portuguesa da Indústria Farmacêutica* or "APIFARMA") approved the following self-regulatory codes:

- the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Health Organisations;
- the Code of Conduct for the Relations between the Pharmaceutical Industry and Patient Associations, Patients' Advocates, Patients' Experts, Patients and Caregivers; and
- the Code of Good Practice for Communication.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes identified in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines** are ethical standards and they are binding for the APIFARMA's associated members.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Advertising of medicines is defined in Article 150 (1) of Decree Law 176/2006 of 30 August, as amended, as any form of information, prospection or incentive which is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines in any of the following circumstances:

- before the public in general;
- before wholesale distributors and healthcare professionals (HCPs);
- through the visit of medical sales representatives to HCPs;
- through the provision of samples or commercial bonuses to wholesale distributors and HCPs;
- through the granting, offer or promise of pecuniary or in-kind benefits, except when their value is insignificant;

- through the sponsorship of promotional meetings attended by HCPs;
- through the sponsorship of congresses or meetings of a scientific nature attended/participated in by HCPs, namely, through the direct or indirect payment of the respective hosting costs; and
- through reference to the commercial name of a medicine.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Portuguese laws and regulations do not make a clear distinction between advertising and information. Therefore, the definition of information, for this purpose, must be understood as included in the definition of advertising, once the disclosed information corresponds to the criteria established in Article 150 (1) of Decree Law 176/2006 of 30 August.

However, Article 151, No 1-d) of Decree Law 176/2006 of 30 August foresees that information relating to human health or human diseases, provided it does not refer to or mention, even indirectly, a medicine, is not subject to advertising regulations, which is deemed to mean that this information does not qualify as advertising. Therefore, disease awareness campaigns and other patient-facing information, as long as they comply with the quoted Article 151, No 1-d), do not qualify as advertising.

In addition, APIFARMA's Code of Ethics, specifically Article 5, No 4, foresees the exclusion from the prohibition of advertising medicines not yet authorised, or off-label information, the right of pharmaceutical companies to inform the scientific community about advances in the field of medicinal products and therapeutics, therefore permitting the disclosure of the results of scientific research they are carrying out for that purpose. Therefore, it deems that data on the advances of scientific research in the field of medicinal products and therapeutics should also be qualified as information, instead of advertising.

Case-by-case analysis is strongly recommended.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are not specifically addressed by Portuguese law, regulations or self-regulatory codes. Therefore, press releases issued by pharmaceutical companies should comply with the general rules applicable to advertising activity, namely, concerning the respective content and the audience.

2.4 Comparative Advertising for Medicines

Comparative advertising of medicines can only be addressed to HCPs and is therefore prohibited from being disclosed to the general public. In accordance with APIFARMA's Code of Ethics, comparative advertising should be based on relevant and comparable aspects. It cannot be deceitful or defamatory, and the comparison of medicines should be based on the medicines' characteristics and specifications, instructions for use, technical documentation or credible clinical data, or objective features, such as the price of the medicinal products.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The advertising of unauthorised medicines or unauthorised indications (off-label advertising) is not permitted. However, as explained in **2.1 Definition of Advertising**, the dissemination of information on advances in scientific research in the field of medicinal products and therapeutics is permitted, since the constraints mentioned are met. Such information may solely be disclosed to, and accessible by, the scientific community.

3.2 Provision of Information During a Scientific Conference

The information mentioned in **2.1 Definition of Advertising** may be disclosed to HCPs in any context, as they are, for this purpose, part of the scientific community.

3.3 Provision of Information to Healthcare Professionals

See **3.2 Provision of Information during a Scientific Conference**.

3.4 Provision of Information to Healthcare Institutions

Taking into consideration the prohibition on advertising unauthorised medicines or indications (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), providing such information to healthcare institutions for the purpose of preparing budgets, etc, is not permitted.

3.5 Information About Early Access or Compassionate Use Programmes

Taking into consideration the prohibition on advertising unauthorised medicines or indications and the limits mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, the publishing of such information is not permitted. Compassionate use is solely permitted in the scope of clinical trials.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is forbidden to advertise the following to the general public: prescription-only medicines; medicines containing substances defined as drugs or psychotropic substances (at international conventions for drugs and psychotropic substances); and medicines under reimbursement by the state.

Advertising of other medicines to the public must be unequivocally identified as such, expressly indicating the specific medicine.

Comparative advertising of medicines to the general public is prohibited.

Regarding what information is mandatory and what is prohibited – in advertising to the general public – see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisements for medicines directed at the general public must contain, as a minimum, the following information:

- the name of the medicine, as well as its common name, if the medicine contains only one active substance, or the brand;
- essential information on the rational use of the medicine, including therapeutic indications and special precautions; and
- advice to the user to carefully read the information on the packaging and in the leaflet, and a warning about the need to consult a physician or pharmacist in case of doubt or persistence of symptoms.

Advertising to the public in general cannot contain any element that:

- leads to the conclusion that a medical consultation or surgery is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail;
- suggests that the effect of the medicine is guaranteed without adverse reactions or secondary effects, with superior or equivalent results in comparison to another treatment or medicine;
- suggests that the average health condition of a person may be harmed if the medicine is not used, except in the case of vaccination campaigns approved by the local regulatory authority;
- is exclusively or mainly targeted at children;
- refers to recommendations of scientists, HCPs or other individuals who could, because of their celebrity status, encourage the consumption of the medicinal products;
- treats the medicinal product as a food, cosmetic or body hygiene product or as any other product;
- suggests that the safety or efficacy of the medicine derives from it being a natural product;
- induces an incorrect self-diagnosis, by a description or detailed representation of a person's medical history;
- refers, in an abusive, daunting or misleading way, to statements or guarantees of recovery; and
- uses, in an abusive, daunting or misleading way, visual representations of human body changes caused by diseases or lesions, or by the effect of a medicine on a human body or parts of it.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Pharmaceutical companies may, as a general principle, interact with patient organisations. However, such interactions must occur within the limits and constraints established by Decree Law 176/2006 of 30 August and APIFARMA's Code of Conduct, which establish several rules on such interactions.

The limits and constraints are generally established to prevent interactions with patient associations that qualify as a form of information, prospection or incentive which is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines, in the terms ruled by Article 150 (1) of Decree Law 176/2006 of 30 August.

In this regard, it should be highlighted that APIFARMA's Code of Conduct prohibits the promotion of prescription-only medicines before

a patient association, but foresees that such medicines may be promoted to HCPs who assist or co-operate with patient associations. In the same sense, the events promoted by the industry in which patient association representatives participate, cannot be of a promotional nature. Furthermore, the partnerships, services supply and financial support granted by the industry must be under a written contract. Companies in the industry cannot be the sole financing entity of any of the activities and events promoted by a patient association.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising to HCPs must include, in a legible way in the respective advertising material, the following:

- the name of the medicine;
- the essential information compatible with the summary of product characteristics ("SmPC");
- the classification of the medicine concerning the dispensation regime of the same, namely, if it is a prescribed medicine, when applicable;
- the respective reimbursement regime; and
- the date of the issuance of the advertising.

The information contained in the advertising material must be accurate, updated, verifiable and sufficiently complete to allow the recipient to correctly assess the therapeutic value of the medicine. The references and the illustrative material of medical publications or scientific works used in advertising support must be correctly reproduced and should mention the respective source.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising material may refer to data or studies not mentioned in the summary of product characteristics, provided that the information complies with that mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, and no contradiction is found between the summary of product characteristics and the information provided on the data on file and on the clinical studies.

5.3 Advertising of Combination Products

Since combined advertising would be qualified as off-label advertising, which is prohibited as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, any reference to a combination of products or companion diagnostics not included in the summary of product characteristics is not admissible.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

In Portuguese law and regulations there are no specific rules regarding the reprinting of journal articles. However, assuming that the reprints are of scientific journal articles, it is believed that such reprints may be provided if referring to human health and diseases or to scientific information relevant to the practice of medicine.

In accordance with APIFARMA's Code of Ethics, promotional materials published in any printed or digital means of communication should not resemble independent editorial articles and should be clearly identified as being of an advertising nature (Article 5 (11)).

5.5 Medical Science Liaisons

The activity of medical science liaisons (MSLs) is not specifically regulated by Portuguese law or regulations. However, regarding MSLs, pharmaceutical companies should comply with the general rules applicable to the advertising activities already described.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

The market holders, or holders of medicine registers, are required to submit one sample of each advertising material relating to each medicine within ten days of respective distribution starting dates.

In the context of the sponsorship of congresses, symposiums or any actions or events of a scientific nature or aimed to directly or indirectly promote medicines, the sponsor company must communicate the sponsorship to Infarmed ten business days before the event.

Vaccination campaigns or promotional campaigns of generic medicines aimed at the general public are to be approved beforehand by Infarmed. If not, such campaigns could be classified as prohibited advertising activity.

6.2 Compliance With Rules on Medicinal Advertising

Pharmaceutical companies are not legally required to establish standard operating procedures (SOPs) governing advertising activities. However, they are required to have a scientific service responsible for the information related to medicines and for maintaining complete and detailed records of all the advertising of medicines with indications of the target audience, channel and date of first dissemination. The same scientific service must ensure that the advertising activities comply with all the obligations imposed by the law and codes, and that the medical sales representatives have appropriate professional qualifications.

The scientific service should keep advertising records for a five-year period and should make such records available for consultation or inspection by the local regulatory authority. The scientific service is also required to co-operate with this authority and other competent authorities, in all that is deemed necessary within the scope of the authorities' respective legal powers. The scientific service should be supervised by a qualified person (a physician or a pharmacist, as established by Article 4 (2) of APIFARMA's Code of Ethics).

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Decree Law 176/2006 of 30 August expressly addresses advertising on the internet. However, this should obviously follow the general rules applicable to advertising activities described previously.

In addition, a local regulatory authority issued two informative circulars establishing specific rules on advertising through the internet and other digital channels. Accordingly, pharmaceutical companies may publish information, accessible by the general public, in the following ways:

- exclusively on the respective institutional website and not on social media or on any other disclosure support; and
- the information to be disclosed, jointly and simultaneously, must solely contain the faithful reproduction of the packaging of the medicine and the literal and full reproduction of the medicine leaflet and/or of the summary of the medicine characteristics, as authorised.

Advertising on websites and social media of medicines containing substances defined as drugs or psychotropic substances at international conventions for drugs and psychotropic substances, is forbidden.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Access restrictions are not specified by the law or regulations, however, companies should take all the necessary measures to ensure that the general public has no access to advertising intended for HCPs and must ensure that the information disclosed complies with the general rules applicable to advertising medicines (to HCPs and to the general public) described in the previous sections.

7.3 Provision of Disease Awareness Information to Patients Online

Since disease awareness information is beyond the scope of the advertising activities regulation (see **2.1 Definition of Advertising**), companies may provide disease awareness information to patients online, as long as the general rules are met (namely, the absence of any direct or indirect reference to a medicine).

7.4 Online Scientific Meetings

Online scientific meetings are not specifically regulated under Portuguese law or regulations, but are subject to the general rules applicable to conventional scientific meetings and to the rules applicable to advertising activities in general.

Concerning the international or national nature of online scientific meetings, despite the lack of legislation, they are held in accordance with local practice and local regulatory authority understanding. If the promoter/organiser of such meetings is a national entity, the same should comply with the applicable local law and regulations on advertising and with the principles of conventional scientific meetings.

7.5 Use of Social Media

Pharmaceutical companies cannot use social media to advertise medicines (see **7.1 Regulation of Advertising of Medicinal Products on the Internet**).

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery rules applicable to the interactions between pharmaceutical companies, HCPs and healthcare organisations are, in general, the rules defined in the Portuguese Criminal Code and specific legislation on anti-bribery, applicable to both sectors: public and private.

8.2 Legislative or Self-Regulatory Provisions

According to Portuguese law, as a general rule (Article 158 (1) of Decree Law 176/2006 of 30 August), the marketing authorisation holder, the company responsible for the information or promotion of a medicine, and the wholesale distributor are prohibited from – directly or indirectly

– giving or promising HCPs or their patients, prizes, offers, bonuses or pecuniary or in-kind benefits, except if the same are cumulatively of insignificant economic value (under EUR60) and relevant for the medical or pharmaceutical practice (exceptions are defined in **9. Gifts, Hospitality, Congresses and Related Payments**). The same prohibition falls on HCPs, who are prevented from receiving such benefits under the quoted Article 158 (2).

In accordance with Article 9 of Decree Law 5/2017 of 6 January, public hospitals and services and bodies of the Ministry of Health cannot request, or directly or indirectly receive, any pecuniary or in-kind benefit from pharmaceutical companies or health technology companies that either impair or might impair their impartiality, except if previously granted with the specific authorisation of the local regulatory authority.

Any form of inducement to prescribe medicines is forbidden.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Following on from **8.2 Legislative or Self-Regulatory Provisions**, pharmaceutical companies may sponsor the participation of HCPs in scientific or educational events, promoted by pharmaceutical companies or by third parties. Such sponsorship is limited to the registration and hosting costs, ie, travel, lodging and meals.

According to APIFARMA's Code of Ethics, the support for such costs can only be granted to the HCP(s) who will attend the event concerned, and the costs are to be restricted to the main purpose of the event and cannot include entertainment events.

The length of stay covered cannot surpass a period of one day either side of the event and the event cannot be held in a location or tourist resort that is best known for its leisure, entertainment or sports facilities.

The cost of the meals within the national territory cannot exceed EUR60 per meal (EUR90 at international events, except when the legislation or the Code of Ethics in effect in a specific foreign country establishes a higher amount for the meal cost, which will therefore be applicable).

In addition to this, pharmaceutical companies may only give pecuniary or in-kind grants or donations to HCPs if the same are cumulatively of insignificant economic value (under EUR60) and relevant to the medical or pharmaceutical practice.

In accordance with APIFARMA's Code of Ethics, within the scope of the promotion of over-the-counter medicinal products, promotional gifts can be given to healthcare professionals provided they consist of benefits in kind, the value of which does not exceed EUR25, which are cumulatively relevant to their professional activity and/or involve a benefit for the patient (Articles 15 (2)).

9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is, under Portuguese law, subject to the following conditions:

- the number of samples provided each year to each HCP cannot be more than four, if the lowest number is not defined by the marketing authorisation;

- the samples are to be requested by the HCP in a written document, duly dated and signed;
- the samples cannot be larger than the smallest presentation of the medicine under commercialisation;
- the samples' packaging must contain the references "Free Sample" and "Prohibited Sale" or other similar words;
- the samples must be accompanied by a summary of product characteristics;
- the samples can only be provided within the two years following the start of the commercialisation of the medicine; and
- the provision of samples of medicines containing drugs or psychotropic substances is prohibited.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies may sponsor scientific meetings or congresses organised by third parties. However, even if the same take place abroad, the local regulatory authority must be informed of all granted sponsorships in the ten days before the event.

As established by Decree Law 176/2006, the sponsorship of congresses, symposiums or any actions or events of a scientific nature that directly or indirectly promote medicines, must be mentioned in the promotional documentation of such events, in the documentation to be provided to the attendees and in the documents and reports that might be published after the events. APIFARMA's Code of Ethics contains similar provisions in this regard.

The Code of Ethics establishes that the sponsored events should take place in premises suitable for the main purpose of the event or action, and that places and/or complexes which are known for their leisure, entertainment, sport, or luxury and extravagant facilities should not be chosen.

Pharmaceutical companies may also support HCPs' attendance of such events, limited to the registration and hosting costs, see **9.1 Gifts to Healthcare Professionals**.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The sponsorship or organisation of cultural, sports or other non-scientific events (even if in relation to scientific conferences) is expressly prohibited.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Besides those referred to in **9.1 Gifts to Healthcare Professionals**, no other grants or donations are permitted.

Regarding healthcare institutions, it is possible to provide support, both monetary and non-monetary, with the aim of supporting healthcare services, research activities or continuing medical education.

However, in accordance with Article 9 of Decree Law 5/2007 of 6 January, NHS hospitals cannot request or receive, directly or indirectly, pecuniary or in-kind benefits from pharmaceutical companies, health technology companies or from related companies where such actions may harm the impartiality and neutrality of the hospitals. When impartiality and neutrality are not at risk, a previous authorisation to receive the benefit should be requested by the NHS hospital's management bodies to the local regulatory authority (Infarmed).

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Price discounts or rebates are expressly considered as beyond the scope of the rules on advertising of medicines. However, Article 153 (6) of Decree Law 176/2006 expressly prohibits pharmaceutical companies from advertising discounts to the general public on medicines subject to medical prescription, medicines containing substances defined as drugs or psychotropic substances, and medicines under reimbursement by the state. Pharmaceutical companies can offer discounts to healthcare institutions in the context of an established commercial relationship, but not to HCPs, as the companies are prevented from executing sales to the same.

9.7 Payment for Services Provided by Healthcare Professionals

Pharmaceutical companies can enter into professional services agreements with HCPs in order to acquire expert services. HCPs can also be paid for acting as an active participant (speaker, moderator, etc) in a scientific or training event. However, the payments cannot constitute financial compensation for the prescription of medicines.

In accordance with APIFARMA's Code of Ethics, the payment of HCPs must be reasonable and must reflect the market value of the services to be provided by the same.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Sponsorships of congresses, symposiums or any actions or events of a scientific nature or aimed to, direct or indirectly, promote medicines must be communicated by the sponsor company to Infarmed ten business days before the event.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The entities under the scope of Decree Law 176/2006, among them pharmaceutical companies, must report to the local regulatory authority all benefits of EUR60 or above, granted to HCPs, healthcare organisations, patient organisations, workers of the National Health Service and bodies or services of the Ministry of Health or of the National Health Service.

Such report is to be filed via a specific transparency platform within 30 working days following the effectiveness of the benefit (payment of the benefit or granting of the benefit in the case of granting of goods or rights assessable in cash). The information to be reported is the following: name and data of the beneficiary, nature of the benefit and amount granted.

Beneficiaries will be asked via email by the local regulatory authority to validate – or not – receipt of the benefit. In the case of non-validation, the authority is to be informed of the reason. If the recipient remains silent, the benefit is considered tacitly accepted.

Benefits are defined in Article 159 of Decree Law 176/2006 of 30 August, as any advantage, value, good or right assessable in cash, regardless of whether in the form of a prize, sponsorship, subsidy, fee, subvention or any other form.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements apply to all market holders or to respective local representatives granting benefits to individuals and entities identified in **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. Hence, if the market holder is a foreign entity, the report on the granting of benefits to Portuguese HCPs, or to the entities identified in the previous point, is still required.

Companies that do not have any products placed on the market and are not operating under a wholesale distribution licence or register, do not fall under the legal provisions on transparency. Such companies are prevented from promoting medicines within the Portuguese market and therefore cannot grant benefits to the individuals or entities mentioned in the previous point.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The public competent authority for enforcing the rules on advertising is Infarmed.

The self-regulatory body is APIFARMA.

The competent court to decide on any issued related to the rules on advertising will depend on the specific claim under decision: as a general rule, the acts issued by Infarmed should be challenged before the administrative courts; however, if a sanction decision on the scope of an administrative offence procedure is at stake, it should be challenged before the Competition, Regulation and Supervision Court (according to the available jurisprudence). For civil liability lawsuits, if applicable, the civil courts are competent (see **11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements**).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated before any of the bodies identified in **11.1 Pharmaceutical Advertising: Enforcement Bodies**, depending on the specific violation and whether the respective requisites are met in each case:

- Infarmed is the authority responsible for punishing infringements of the law and public regulations;
- APIFARMA's Ethics Council may impose penalties on respective members for infringements of respective codes; and
- competitors may take action in relation to advertising infringements through civil liability lawsuits.

The same conduct may qualify as an infringement of the law and public regulations, and of APIFARMA's Code of Ethics provisions, in which case, proceedings may be conducted in parallel, making the respective decisions autonomous.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The fines range from a minimum of EUR2,000 to a maximum of 15% of the business volume of the infringer or EUR180,000, whichever is the lower maximum.

General accompanying sanctions may also be imposed (depending on the seriousness of the infraction and the level of fault):

- loss in favour of the state of illicit objects, equipment and devices;
- interdiction, for a maximum period of two years, of activity of the infringing company;
- deprivation of the right to participate in public tenders for a maximum period of two years; and
- suspension of authorisations, licences and other titles attributing rights for a maximum period of two years.

Accompanying sanctions specific to the case of infringement of advertising legal provisions may also apply:

- the decision on the imposing of fines may also determine the publication on social media of the essential elements of the condemnation;
- advertising of the relevant medicine may be suspended for a maximum period of two years;
- a procedure to exclude the relevant medicine from the reimbursement regime by the state may also be initiated; and
- the infringer's medical sales representative may be prevented from visiting public hospitals and services, in the case of violation of the legal regime of such visits.

11.4 Relationship Between Regulatory Authorities and Courts

There is no relationship between the procedures before, or measures taken by, the self-regulatory entity and the measures taken by the courts.

As the association of the pharmaceutical industry, APIFARMA has a supervisory function and enforces its codes upon its members. The procedures, decisions and penalties have a deontological nature and are completely independent of the ones taken by public entities (such as Infarmed or the courts).

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Infarmed and APIFARMA do not disclose their decisions on advertising or on any other topic concerning infringements of the applicable law and established rules. Therefore, there are no identifiable trends in relation to pharmaceutical advertising.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Advertising of veterinary medicines is regulated by Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 (the "Regulation"), on veterinary medicinal products.

Advertising of veterinary medicinal products is defined in Article 4 (40) of the Regulation as the making of a representation in any form in connection with veterinary medicinal products to promote the supply, distribution, sale, prescription or use of veterinary medicinal products, and comprising also the supply of samples and sponsorships.

The following rules apply:

- only veterinary medicinal products that are authorised or registered may be advertised, unless otherwise decided by the competent national authority;
- the advertising of a veterinary medicinal product will aim at promoting the supply, sale, prescription, distribution or use of the veterinary medicinal product;

- the advertising may not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide;
- the advertising must comply with the summary of the product characteristics of the advertised veterinary medicinal product;
- the advertising must not include information in any form which could be misleading or lead to incorrect use of the veterinary medicinal product;
- the advertising must encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties;
- the suspension of a marketing authorisation will preclude any advertising during the suspension period of the veterinary medicinal product;
- veterinary medicinal products may not be distributed for promotional purposes, except for small quantities of samples;
- the samples must be appropriately labelled as "samples" and are to be provided directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events, or by sales representatives during their visits; and
- antimicrobial veterinary medicinal products may not be distributed for promotional purposes as samples or in any other presentation.

The advertising of veterinary medicinal products that are subject to veterinary prescription will only be allowed when addressed exclusively to the following persons:

- veterinarians; and
- persons permitted to supply veterinary medicinal products in accordance with national law.

The advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link is prohibited.

Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefit in kind may be provided, offered or promised to such persons unless they are cumulatively inexpensive and relevant to the practice of the prescription or supply of medicinal products. On the other hand, persons qualified to prescribe or supply medicinal products may not solicit or accept any prohibited inducement.

This prohibition does not prevent the possibility of offering hospitality, directly or indirectly, in events with exclusively professional and scientific purposes, as long as this hospitality is strictly limited to the main objectives of the event.

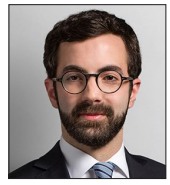
Although the advertising rules pointed out above address similar topics to those established for human medicinal products, for instance, in establishing prohibitions and constraints on the advertising of veterinary medicines (promotional actions, provision of samples, granting of benefits, and advertising of veterinary products), the legal framework on human medicinal products is much stricter and more detailed.

The General Directorate for Food and Veterinary Medicine is the enforcement authority for the advertising of veterinary medicines.

Morais Leitão, Galvão Teles, Soares da Silva & Associados (Morais Leitão) is a leading, full-service law firm in Portugal, with a solid background of decades of experience. Its reputation among both peers and clients stems from the excellence of the legal services provided. The firm's work is characterised by unique technical expertise, combined with a distinctive approach and cutting-edge solutions that often challenge some of the more conventional practices. Morais Leitão's team consists of over 250 lawyers spread between its headquarters in Lisbon and additional offices in Porto and Funchal. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola (ALC Advogados), Cabo Verde (VPQ Advogados) and Mozambique (MDR Advogados).

Authors

Fernanda Matoso is a partner at Morais Leitão and co-ordinates the life sciences practice. She is particularly focused on international pharmaceutical companies that market medicines and medical devices in Portugal, health technology companies and the medical cannabis industry and licensing. Fernanda has extensive knowledge of, and expertise in, the regulatory framework of pharmaceutical industry activity and the respective products (medicines, medical devices, cosmetics, food supplements and other health products); wholesale distribution activity; healthcare institutions; and associated topics, such as licensing, marketing authorisation, price regulation, state reimbursement/funding mechanisms, promotion/advertising activities, patient protection, data protection, compliance, and the marketing of health products.



Alessandro Azevedo joined Morais Leitão in February 2019. He is a member of the firm's administrative and public law team. He focuses his practice on several areas of administrative law, namely, public contracts and urbanism for both public and private entities in procedural matters and litigation. Alessandro is also experienced in life sciences regulatory practice, particularly in the pharmaceutical industry and its products (medication, medical devices, cosmetics and dietary supplements) and in controlled substances. On the academic circuit, he is an assistant investigator at the Administrative Law Investigation Centre of the Lisbon University Law School.

Contributed by: Fernanda Matoso and Alessandro Azevedo,
Morais Leitão, Galvão Teles, Soares da Silva & Associados

Morais Leitão, Galvão Teles, Soares da Silva & Associados

Rua Castilho, 165
1070-050
Lisboa
Portugal

Tel: +351 21 381 74 00
Fax: +351 21 381 74 99
Email: fmatoso@mlgts.pt
Web: www.mlgts.pt

Trends and Developments

Contributed by:
Francisca Paulouro and Ana Isabel Lopes
VdA see p.278

Introduction

While the previous few years were focused on how to deal with the COVID-19 pandemic, 2022 finally brought some sense of normality.

Gone, hopefully, are the days of prohibition or of severely restricted visits of sales representatives to healthcare professionals (HCPs) imposed by governmental measures. Events are steadily shifting from digital platforms to classic venues – although digital platforms have certainly come to stay, with hybrid events now making up part of day-to-day life, enabling an increasing proximity and availability which until very recently was not even realisable.

The industry is once more focused on new initiatives and projects, with more innovative ways of promoting products, creating value-added initiatives where healthcare is crucial, and engaging with both HCPs and patients with one key goal: delivering for patients.

Patients have assumed a new and more pronounced role and, now more than ever, are the purpose and the driver for change, in a push for access and affordable medicines. While traditional means of advertising are still present, the truth is that communication has gone digital. This was already the case before the pandemic, and is even more so following it. In the aftermath of COVID-19, pharmaceutical and medical device companies have understood that embracing the digital transformation is not optional – it is the only way forward.

As always, the world changes faster than legislation, and with it come new challenges. In the pharmaceutical sector, the key challenge is navigating a legal framework construed for a non-digital world. In the medical devices sector, in addition to this challenge, companies are faced with a non-harmonised regime at the European Union (EU) level where promotion is concerned.

Medicinal Products

The Portuguese legal regime applicable to the advertising of medicinal products stems from Directive 2001/83/EC (the "Directive"). Considering the extremely narrow margin of freedom given to member states in the transposition of the Directive, particularly concerning promotion rules, this might be expected to lead to a common legal framework; unfortunately, this is not the case for Portugal.

The Portuguese legislature has gone beyond what the Directive provides in specific matters, including with the notion of advertising and the prohibition on granting any kind of benefit to patients (similarly with the EU prohibition for HCPs). These aspects of the Portuguese legal framework significantly impact the activities of pharmaceutical companies in Portugal.

As an example, the disclosure of scientific information, a sensitive topic throughout the EU, faces additional hurdles in Portugal. Similarly, certain initiatives freely carried out by pharmaceutical companies throughout the EU are often barred from being implemented in Portugal, as is the case with patient support programmes.

Contrary to the Directive, the Portuguese regime does not require that the information, canvassing or inducing activity be "designed" to promote medicinal products, it being sufficient that it has such an effect. This constitutes a significant departure from the wording of the Directive, and a considerable challenge for pharmaceutical companies operating in Portugal, rendering the distinction between "informing" and "promoting" almost artificial, with very little room for the former.

Under Portuguese law, the underlying purpose of a given initiative developed by a pharmaceutical company is completely immaterial to its qualification as advertising. In other words, if an initiative promotes a given medicine, it will fall within the notion of advertising, even if this is not its intention. Should it be designed to promote a medicine, it is undoubtedly advertising. However, initiatives which are not intended as such, but which directly or indirectly have as an effect an increase in the purchase, dispensation or consumption of a medicinal product will also fall under the notion of advertising. The law provides for very few exceptions.

In line with the Directive, only the labelling and information leaflet, correspondence required to reply to a specific query, information related to packaging, warnings or adverse reactions, price lists and information related to human health or diseases – if these do not make any direct or indirect reference to a medicine – are excluded from the scope of promotion rules.

As a result of this extremely broad definition of advertising, any disclosure of information directly or indirectly related to a product made by pharmaceutical companies both to the scientific/medical community and to patients may result in the application of advertising rules.

This extremely thin line between information and advertising poses several challenges to pharmaceutical companies and is a relevant setback in the dissemination of information and knowledge.

One of the clearest examples of said challenges is the disclosure of information regarding ongoing clinical research or regarding medicines which are still undergoing regulatory approval, even if at early stages.

While the prohibition of off-label advertising is a common standard within the EU, in Portugal the possibility of pharmaceutical companies informing the scientific/medical community of research that is being carried out or of potential new therapies which could have a significant impact on the treatment of patients – even if made in an objective and balanced manner – is severely limited.

In fact, any communication of this nature can be considered off-label advertising, and therefore prohibited. Consequently, the debate regarding new medicines and ongoing clinical research is very often made behind closed doors and no incentive is given for a more public, comprehensive and transparent discussion on future available treatments within the scientific/medical community. Disclosure of scientific advances is therefore often severely compromised.

A further example of these challenges is related to the disclosure of information by pharmaceutical companies to the public. Another standard within the EU is the prohibition on advertising of prescription drugs to the public. Disclosing purely objective and educational information on a given prescription drug, such as educational material with precautions and/or instructions for the administration of the medicine, if not within the scope of a risk management plan, entails a

very significant risk of being condemned by the Portuguese regulatory agency.

Given patients' potential vulnerability and absence of knowledge that could enable them to "filter" information, the Portuguese regulatory agency has always been particularly cautious with patient protection, and described as somewhat conservative in its approach to promotion before the public, be it direct or indirect (as could be the case in disease awareness campaigns not strictly raising disease awareness).

However, the latest case law of the Court of Justice of the European Union (CJEU), rendered on 22 December 2022 in Case C-530/20 "Euroaptieka", may bring this into question and potentially suggest that such a position is to be followed across Europe.

Following a request for a preliminary ruling from the Latvian Constitutional Court, the CJEU was called to decide on a set of questions focusing on a national provision which forbade the inclusion of any information encouraging the purchase of a medicinal product on the basis of its price, special sale or bundle in the advertising of a given medicinal product before the general public. The questions put forward to the CJEU entailed, in essence, addressing two topics:

- the concept of advertising; and
- the boundaries of complete harmonisation in the field of advertising brought about by the Directive.

In its judgment, the CJEU clarified that activities that do not relate merely to dissemination to the public solely of information about medicinal products, but are activities which encourage the purchase of medicinal products, should be considered advertising even if not referring to a specific medicinal product but to unspecified medicinal products.

It is true that the court was called to analyse a very specific measure which arguably, by its very nature, is promotional. The question remains on how far the agencies of member states will apply the principles arising from such judgment, particularly as regards the following:

- the aim of safeguarding public health would be greatly compromised if an activity seeking to promote the prescription, supply, sale or consumption of medicinal products without making reference to a specific medicinal product did not fall within the concept of advertising; and
- patients do not necessarily have the specific and objective knowledge to enable them to evaluate the therapeutic value of prescription medicinal products, and therefore advertising may exercise a particularly strong influence on the evaluation and choice made by patients, both as regards the quality of the medicinal product and the amount to purchase.

While this discussion is not new, it has again gained relevance given the shift in patient behaviour. Patients are taking their place at the table and are eager to receive more and more information, and are now able to find such information very quickly through digital channels, social media and the internet. Patients are not only interested in knowing their treatment options but are also increasingly interested in knowing and publicly discussing topics such as the safety profile of medicinal products, their reimbursement statuses and even their approval processes.

Although this trend appeared prior to the COVID-19 pandemic, the health crisis undeniably emphasised it. Information on medicinal products and health technology was available everywhere, with no filters, and was directly provided to patients.

Understanding that the market has changed, pharmaceutical companies are trying to keep up the pace: even when engaging with HCPs, the focus is on patients and on reinforcing their presence on the internet and digital channels.

Naturally, as patients' interest in these topics grows, so does the need to protect patients. As the latest judgment by the CJEU has shown, the tendency is to increase control over the information shared with patients. While the Portuguese regulatory agency has not been very active in the past year concerning pharmaceutical advertising, there is no doubt it will continue to closely watch companies' activities and behaviour. The question is whether supervising the activities of the pharmaceutical industry will be sufficient for ensuring the protection of patients, especially considering that today patients can easily access information from all kinds of sources.

For now, pharmaceutical companies are left with a dilemma regarding how to comply with the rules while still engaging with patients and answering their demands for more transparent information, including from the pharmaceutical industry, without putting at risk the need to safeguard public health.

Medical Devices

Contrary to with medicinal products, the rules on advertising of medical devices were not addressed at the EU level, either under the former regimes scattered through different directives, or under the Medical Device Regulation and the In Vitro Medical Device Regulation (hereinafter the MDR and IVMDR, respectively).

The MDR and the IVMDR very timidly address this issue, stating solely that advertising cannot contain elements that may mislead the user or patient concerning the device's intended purpose, safety and performance. Such a principle would always arise from the general rules applicable within the EU both for consumers and for HCPs.

In the absence of harmonisation at the EU level, there are naturally different regimes throughout member states affecting cross-border activities.

While some member states have left the rules on advertising of medical devices subject to the general rules on advertising, others such as Portugal have approved a specific legal regime. This regime closely follows that provided for medicinal products:

- the notion of advertising is similar to that provided for medicinal products, covering any type of information, canvassing activity or incentive which is aimed at or that has as an effect the promotion of use, prescription, discharge, sale, purchase or consumption of medical devices;
- advertising of medical devices should be consistent with the instructions of use of medical devices and promote their safe use, doing so objectively and without exaggerating their properties;
- advertising of medical devices which were not subject to a conformity assessment and were not notified to the Portuguese regulatory agency is forbidden;
- advertising before the general public of medical devices whose use requires the mediation or decision of an HCP (including implantable

devices) is forbidden – the law does not provide for an exhaustive list of devices covered by this prohibition, although the Portuguese regulatory agency has recognised that devices that only require the mediation or decision of an HCP at a first stage and can be used by the patient after that without any further intervention of the HCP may be advertised; and
- in general, medical device companies are forbidden from providing any benefits to HCPs.

Such a regime was approved prior to the entry into force of the MDR and IVMDR, yet continues to apply.

Although a major departure from the existing rules is not expected, local legislation to be enacted to complement the regime provided for in the MDR and IVMDR would be a good opportunity to introduce tailor-made rules on the advertising of medical devices – as different from pharmaceuticals and covering an enormous range of realities – and to clarify exactly what can or cannot be advertised before the public.

In the absence of EU harmonisation, self-regulation arising from Medtech Europe and "transposed" by local industry associations plays a significant role and helps to create common standards.

While the rules provided for in self-regulation are quite detailed regarding the interaction between medical device companies, HCPs and healthcare organisations, there is still a significant gap concerning the interaction with patients and patients' associations. Aside from some specific guidance provided by Medtech Europe and the general principle that all advertising activity should prioritise patients, most rules do not address such types of interactions.

This is increasingly more relevant given that the market for medical devices has grown exponentially in the past few years. Medical technology is adding to this pace and new medical devices are available each day. These devices are not only intended for professional use, but also for laypersons. Medical devices made available through app stores or through online platforms are now common – proof that medical device software for patients is at its peak.

The industry has changed, and will continue to do so in a digital era where patients change with it and are at the centre of what is to come. As the medical devices legal framework is significantly altered, it will certainly be important to seize the opportunity to provide for a more adequate legal regime, which should be sufficiently flexible for catering to all types of devices, while still ensuring a high level of protection for patients.

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Authors

Francisca Paulouro joined VdA in 2002, and is of counsel and head of the life sciences practice. Francisca has devoted her career to life sciences and is a national reference for pharmaceutical companies both in day-to-day assistance and in complex matters. She is recognised by peers and clients for her clear, precise and sophisticated advice; her knowledge of the pharmaceutical and medical devices industry; her reliability and responsiveness; and her ability to oversee teams from different disciplines. Francisca regularly assists major multinational pharmaceutical companies operating in Portugal with promotional and advertising activities; marketing authorisations and renewals; regulatory data protection and marketing exclusivity; pricing, reimbursement and market access; manufacture and distribution; and clinical trials.

Ana Isabel Lopes joined VdA in 2016. She is an associate in the life sciences practice area, where she actively provides legal assistance to companies in the healthcare sector (namely to pharmaceutical and medical device companies). She assists these companies in their day-to-day activities, including with the rendering of legal advice on promotional initiatives and compliance matters, clinical trials, contract drafting and negotiation, and other regulatory matters.

Contributed by: Francisca Paulouro and Ana Isabel Lopes, **VdA**

VdA

Rua Dom Luís I, 28
1200-151
Lisbon
Portugal

Tel: +351 21 311 3400
Fax: +351 21 311 3406
Email: lisboa@vda.pt
Web: www.vda.pt

SPAIN

Law and Practice

Contributed by:
Jordi Faus, Anna Gerbolés and Claudia Alberdi
Faus Moliner see p.303

Contents

SPAIN

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Advertising of medicinal products in Spain is regulated by a combination of laws, guidelines of the regulatory authorities, and codes of conduct adopted on a voluntary basis by the pharmaceutical industry.

General Rules

General rules on advertising are comprised in General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition. The provisions related to the advertising of medicinal products contained in EU Directives have been implemented in Spain through Royal Decree 1416/1994. The Ministry of Health issued an Instruction in 1995 (Circular 6/1995, amended by Circular 7/99) regarding the interpretation of such Royal Decree.

In addition, Spanish autonomous regions (Spain is divided into 17 autonomous regions) are competent for the implementation of rules on advertising of medicinal products; in this regard, some autonomous regions have adopted guidelines reflecting the position of the regional authorities on the advertising of medicinal products (the most remarkable guidelines are those issued in the regions of Madrid and Catalunya). Furthermore, the Ministry of Health has issued a guide on the advertising of over-the-counter medicinal products (last updated version published in 2019). Royal Legislative Decree 1/2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, is also noteworthy as it sets forth the sanctions for breach of the rules on advertising of medicinal products.

Codes of Conduct

Spanish trade associations of different sectors of the pharmaceutical industry have adopted codes of conduct regulating interactions with healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, has issued a code of practice for the pharmaceutical industry (the "Code of Farmaindustria") regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs.

The Code of Farmaindustria was updated by a 2021 version, introducing some new aspects regarding areas such as social media and the digital environment, relationships between companies and HCPs, POs and the media. Conversely, AESEG, the Spanish generic medicinal products industry association, and ANEFP, the Spanish over-the-counter medicinal products industry association, among others, have also published their own codes of conduct on the promotion of medicinal products.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes of conduct apply and have binding effects on companies that are members of the trade association that issued them and on companies that have voluntarily adhered to a code. Companies subject to a self-regulatory code are also responsible for their affiliates and third parties acting on their behalf complying with the code when they perform promotional activities in Spain and/or they interact in any way with HCPs, HCOs and/or POs in Spain.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

According to Royal Decree 1416/1994, advertising of medicinal products includes any form of informative offer, commercial research or inducement designed to promote the prescription, dispensation, sale or consumption of medicinal products.

In particular, advertising of medicinal products includes:

- advertising directed to the general public;
- advertising directed to persons qualified to prescribe or dispense medicinal products;
- visits by medical sales representatives or informative agents of the companies to persons qualified to prescribe or dispense medicinal products;
- supply of samples of medicinal products;
- sponsorship of promotional meetings where persons qualified to prescribe or dispense medicinal products attend;
- sponsorship of scientific meetings attended by persons qualified to prescribe or dispense medicinal products, and, in particular, payment of their travel and accommodation expenses in connection therewith; and
- any inducement to prescribe or dispense medicinal products by granting, offering or promising any benefit, in money or in kind, except when its actual value is minimal.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Royal Decree 1416/1994 states that the following informative activities will not be considered as advertising of medicinal products and, therefore, are not subject to the rules that apply to such advertising:

- the labelling and the leaflet of the medicinal product;
- correspondence, together with any document of a non-promotional nature (for example, scientific articles) needed to respond a specific question about a particular medicinal product, provided that such correspondence/documents are true, not misleading and refer only to the question asked;
- information and documents specifically related to changes in packaging, adverse reaction warnings in the framework of pharmacovigilance, sales catalogues and price lists, provided that no other information on the medicinal product is included; and
- information regarding human health or diseases, provided there is no reference, even indirectly (for example, by mentioning its active substance), to the medicinal product.

In addition, the Code of Farmaindustria states that the following informative activities will not be considered as advertising of medicinal products:

- the SmPC;
- information provided by physicians to the patients on certain medicinal products that, due to the complexity of dosage, route of administration, etc, require providing additional information, and only if such information is intended to improve adherence to treatment;
- corporate advertising, meaning advertising which relates to the company, provided there are no references, not even indirect ones, to specific medicinal products;
- texts written and produced by journalists in their professional work, provided that there is

no contractual relationship between the firm responsible for editing or the author of the information and the owner of the medicinal product and/or its trade mark;
- reprints, literal translations of scientific articles and abstracts published in recognised scientific sources or in congresses, provided that they do not include any additional element, such as the name of the medicinal product of the company, regardless of the way in which it is included (link, additional paper, etc), highlights, and trade marks or promotional claims; and
- information on new lines of research mentioning the active ingredient and its properties provided to HCPs or patients, provided that its distribution is a condition mentioned in the authorisation of commercialisation, or that its distribution has been approved by the health competent authorities.

Finally, the description of research initiatives in corporate brochures or other informative documents accessible to the public is also commonly accepted as information by the Spanish authorities, as long as such description is objective and reasonable according to the usages of the sector and non-promotional in tone.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are a controversial issue in Spain and should be analysed on a case-by-case basis. According to the Code of Farmaindustria, and the rulings of the Jury of Advertising (a specialised body within an association for self-regulation in advertising called Autocontrol; the Jury of Advertising is responsible for hearing cases relating to the breach of provisions of self-regulatory codes, such as the Code of Farmaindustria), if the information on a medicinal product refers to a newsworthy event such as a relevant step in the research and/or authorisation process of such medicinal product, which is relevant for the financial performance of the company, is clearly directed to potential investors, shareholders and/or future employees, and has a non-promotional tone, then it may be considered as corporate information, and, therefore, may be published in non-scientific journals directed to the general public as it is not considered as promotion, but as information.

Determining Whether a Press Release is Advertising

However, if there is a contractual relationship between the company and the media where a press release is published, the press release will most likely be deemed to be an advertising material and would therefore be subject to the rules regarding this activity. On the contrary, Farmaindustria's Deontological Surveillance Unit has stated that it is not correct to interpret the Code of Farmaindustria as meaning that any text written by journalists in their professional work must always and in all cases be considered as advertising merely because there is a contractual relationship with the media, but that additional factors must be assessed.

These other factors to bear in mind to determine whether or not the press release has a promotional nature are mainly the following:

- whether the press release is aimed at promoting the consumption of a product;
- whether the statements contained in the article are made by experts hired by the company;
- whether the tone is laudatory; and
- in the case of various publications, if their content is very similar suggesting that the media did not add further journalistic content, then the chances of it being considered pro-

motional increase substantially (Ruling of Jury of Advertising of Autocontrol in Gilead v VIIV 2DR-JULUCA-DOVATO, dated 25 June 2020).

Guide for Interacting With the Media

The Code of Farmaindustria includes, as Annex III, a guide with a list of recommendations for companies when interacting with the media. When certain conditions are met as explained in this guide, press releases may be considered as having an informative nature (not promotional). For instance, it is recommended that the trade mark of the medicinal product, or its active ingredient, be only prudently and proportionately mentioned – ie, twice maximum and not in the headings.

2.4 Comparative Advertising for Medicines

Under Law 3/1991 and the Code of Farmaindustria, comparative advertising directed to HCPs is allowed provided that:

- the products or characteristics compared are comparable, essential and relevant;
- the comparison is objective, scientifically proven and verifiable from sources immediately accessible to the competitor; and
- the general tone of the advertisement is balanced and fair.

The competitor's brand name or trade mark can be used as part of the comparison, provided that such use is proportionate and is not made with the objective of taking an unlawful advantage of the reputation of the competitor's brand name or trade mark. However, there is no legal or deontological provision requiring an express reference to the trade mark of the medicinal product, as comparative advertising allows for referring to a competitor either explicitly or implicitly (Ruling of Jury of Advertising of Autocontrol in Sanofi-Aventis v Italfarmaco – Hepaxane, dated 8 January 2020).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Advertising of medicinal products which have not obtained a marketing authorisation is not allowed. In some specific cases, regulatory authorities, as well as the provisions of the Code of Farmaindustria, accept the possibility of companies making information available to HCPs and HCOs prior to the approval of the medicinal products if it is merely scientific information, instead of an advertising activity. However, it is advisable to take a rather restrictive approach regarding these activities, as any materials containing promotional statements will undoubtedly be considered as advertising.

Additionally, according to Royal Decree 1015/2009, which regulates the use of medicinal products in special situations, marketing authorisation holders must not distribute any type of information which may directly or indirectly stimulate the use of the medicinal product in conditions different from those approved in its SmPC.

3.2 Provision of Information During a Scientific Conference

Objective and non-promotional scientific information on unauthorised medicinal products or unauthorised indications may be provided during congresses or meetings organised by a prestigious scientific society, provided certain conditions are respected.

Conversely, regulatory authorities and the provisions of the Code of Farmaindustria accept that promotional materials on medicinal products authorised in countries other than Spain may be distributed during international congresses or meetings held in Spain, provided that:

- the congress or meeting is attended by numerous professionals from other countries;
- the materials are written in the language of the country where the product is approved or in English; and
- the materials include a clear warning indicating (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

Although the Code of Farmaindustria does not set a minimum font size for this warning, this is something that must be checked by comparing the letters used in the waring to those used in the rest of the messages. Including this warning as a footnote using a small font size is not enough (Ruling of Jury of Advertising of Autocontrol in Glaxosmithkline v Astrazeneca CD-PS 1/20 Symbicort, dated 7 July 2020).

3.3 Provision of Information to Healthcare Professionals

Any company may respond to specific requests for information from HCPs, provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met. Information must be provided reactively and not proactively. It is advisable to deal with these matters through the medical affairs department of the company rather than through its sales or marketing departments.

3.4 Provision of Information to Healthcare Institutions

There are no specific provisions in Spanish law or in the Code of Farmaindustria regarding the provision of information on unauthorised medicinal products or indications to HCOs. In practice, regulatory authorities and the provisions of the Code of Farmaindustria accept that objective information on a medicinal product may be provided to HCOs prior to its approval, in order to help prepare their budget, provided it does not contain promotional statements.

3.5 Information About Early Access or Compassionate Use Programmes

Advertising compassionate use programmes is prohibited under Spanish law. Royal Decree 1416/1994 prohibits any advertising of medicinal products which have not yet obtained a marketing authorisation. Also, even when referring to the access of a medicinal product authorised in another country (different than Spain), Royal Decree 1015/2009, regulating the use of medicinal products in special situations, expressly prohibits the holder of the marketing authorisation in the country of origin from any advertising on the use of the medicinal product.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising of prescription-only medicinal products and/or publicly financed medicinal products directed at the general public is prohibited under Royal Legislative Decree 1/2015, Royal Decree 1416/1994 and the Code of Farmaindustria.

On the contrary, non-prescription medicinal products which are not publicly financed may

be advertised to the general public. Furthermore, advertising of medicinal products to the general public for any of following therapeutic indications is not allowed:

- tuberculosis;
- sexually transmitted diseases;
- other serious infectious diseases;
- cancer;
- chronic insomnia; and
- diabetes and other metabolic illnesses.

According to Royal Decree 1416/1994, any advertising material directed to the general public must clearly indicate that it is an advertisement and that the product advertised is a medicinal product.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Messages must contain at least the complete name of the product, the name and/or logo of the marketing authorisation holder, the therapeutic indication of the product, the composition of the product, an invitation to read the instructions of the leaflet and to consult a pharmacist, and any additional recommendations that the Ministry of Health may determine in order to prevent risks and to promote the rational use of the product.

Additionally, Royal Decree 1416/1994 states that advertising to the general public must not contain any statement which:

- gives the impression that a medical consultation or surgical procedure is unnecessary;
- suggests that the effects of taking the medicinal product are guaranteed, do not have side effects or are better than, or equivalent to, those of another treatment or medicinal product – adjectives such as "perfect", "maximum", "unique", "safe" or "total" are expressly prohibited;
- suggests that a person's health may be improved by taking the medicinal product or that it could be negatively affected by not taking the medicinal product;
- suggests that the use of a medicinal product may enhance sports abilities;
- is directed exclusively or mainly to children;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product, or that the safety or efficacy of the medicinal product is due to the fact that it is a natural substance;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or by the action of the medicinal product;
- includes promises of a cure, exaggerated testimonies on the virtues of the product, or recommendations of scientists, HCPs or celebrities; or
- mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

Reminder advertisements, the purpose of which is merely to remind the target audience about the name of the medicinal product, are acceptable only for products sufficiently known and which have been promoted for at least two years, and can only include the name of the medicinal product. According to the guide on advertising of OTC medicinal products published by the Ministry of Health, a blurred image of the packaging is also acceptable in such advertising, provided that the only information clearly visible is the name of the product, the logo of the pharma-

ceutical company, and the identifying colours of the product.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no provisions in Spanish law regarding restrictions on interactions between patients or patient organisations and the pharmaceutical industry.

However, the Code of Farmaindustria states that any collaboration between companies and POs must be formalised in a written agreement, stating:

- the purpose of the collaboration;
- the activities to be performed by each of the parties;
- the financial amount of the collaboration; and
- a description of any relevant indirect support provided by the company and the sources and purposes of the support.

Additionally, companies must have an internal process for the approval of these collaborations, and must not be the exclusive sponsor of a PO or try to influence the content of the publications issued by a PO.

Meetings with patient support groups must be held at appropriate venues, avoiding those which are extravagant or renowned for their entertaining facilities. It is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain, or a relevant resource or expertise is located abroad. However, organising an event outside Spain due to a relevant resource being located at the place where the event is going to be held requires prior approval from Farmaindustria's Deontological Surveillance Unit.

Hospitality offered by the company must comply with the same requirements referred to in **9.1 Gifts to Healthcare Professionals**.

Hospitality must only be made available to accompanying persons if they attend as helpers of patients. Payment of such expenses must be made through the PO. Hospitality cannot include social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

Scientific Meetings

In the case of virtual meetings, all kinds of hospitality are forbidden.

It is forbidden to offer money to merely compensate for the time spent by patients to attend the meeting.

It is possible to pay a PO for expert services (for example, participating in advisory boards, acting as speaker/moderator at scientific meetings, educational activities, etc), provided that the following requirements are met:

- entering into a written agreement stating the nature of the services and the criteria to calculate the amount of payment;
- the purpose of the services must be co-operating with health assistance and/or research;
- the legitimate need for such services must be clearly identified;
- the criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates – the experts hired must be approved by the internal supervisor of the company;
- the number of experts hired must not exceed the number reasonably necessary to achieve the identified objectives;

- the company must keep documentary records of the services provided;
- the hiring of a PO must not be linked to their participation in a promotional event for a medicinal product;
- the hiring of patients must be carried out through the PO;
- the payment to a PO must not entail an inducement for the PO to recommend the medicinal products of the company;
- the remuneration paid must be at market prices and taking into account the hours of work and the responsibilities undertaken by the expert;
- payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit; and
- it is recommended that the agreement includes a clause by means of which the expert undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the company.

The Code of Farmaindustria

According to the Code of Farmaindustria, offering money or any kind of gift or services for personal benefit to patients or the representatives of POs is forbidden.

Also, the Code of Farmaindustria contemplates that any material or publication directed to patients must comply with the following requirements:

- it must help patients to get a better understanding of their disease development and improve their life quality – its content, therefore, must be related to patients' health, specific illnesses, hygienic-sanitary measures or healthy habits;
- it must expressly reflect whether they have been sponsored by a company;
- it must clearly and evidently prove that its main objective is to be a support tool for people affected by a certain disease; and
- it must be formative and informative and must visibly include messages that express that they are guidance and informative materials that cannot be interpreted as a substitute for the diagnosis or advice of an HCP.

Additionally, under the Code of Farmaindustria, companies must publish a list of the POs that the company supports, and the POs with which it has entered into a services agreement. Such publication must include a sufficiently detailed description of the support provided by the company to each PO and the amounts annually paid to each PO for their services.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

According to Royal Decree 1416/1994, advertising directed to HCPs legally entitled to prescribe or dispense medicinal products must include:

- the name of the product;
- the name and address of the marketing authorisation holder;
- the qualitative and quantitative composition of the product;
- essential data according to the SmPC, including complete clinical data, indications for use, cautions and relevant contraindications;
- the different dosages and pharmaceutical forms in which the product is available;

- the prescription and dispensation regime applicable to the product;
- the retail price and the conditions under which the product is publicly financed; and
- the estimated cost of treatment, if possible to determine.

Messages must be precise, balanced, honest, objective, based on adequate scientific evaluation, and sufficiently complete as regards the therapeutic value of the product.

Reminder advertisements, acceptable for products sufficiently known which have been promoted for at least two years, can only include the name of the medicinal product and the International Common Denomination if the product contains only one active substance, as well as the logo of the product and the company. No other statements may be included, but the regulatory authorities and the bodies in charge of enforcing the rules of the Code of Farmaindustria do accept including pictures of the packaging.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under Spanish rules, using data on file is not allowed for promotional purposes.

However, an advertisement may refer to studies not included in the SmPC of the product, provided that such studies do not contradict the information included in the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019). In any case, studies must be adequately reflected in the promotional material, in a way that its addressee may by themselves verify the truthfulness and accuracy of the information.

5.3 Advertising of Combination Products

Advertising the use of one medicinal product in combination with another is legally permitted as long as the advertising materials/message are consistent with the SmPC of both products. It is not required for the SmPC to include a specific reference to studies regarding the combined use of medicinal products, as long as such use is compatible with the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019).

Also, it is legally permitted to advertise medicinal products that include a medical device, provided that the advertisement is consistent with the SmPC of the medicinal product and with the intended purpose of the medical device.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies can provide reprints of journal articles to HCPs. However, under the Code of Farmaindustria, reprints cannot contain printed, stamped or electronically linked trade marks or trade names of medicinal products, advertising slogans, or other advertising materials related (or not) to the information.

5.5 Medical Science Liaisons

Medical science liasons (MSLs) must not proactively discuss scientific information on unauthorised medicines or indications with HCPs. MSLs can provide information to HCPs (provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met) in order to respond to specific questions asked by the HCPs. Information must be provided reactively and not proactively.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising directed to HCPs qualified to prescribe or dispense medicinal products does not need to be approved in advance by a regulatory or industry authority. However, companies placing an advertisement must send a copy of the advertisement to the health authority of the Spanish autonomous region where the company is located, assuming the responsibility for ensuring that only HCPs entitled to prescribe or dispense medicinal products have access to the relevant publication. The Ministry of Health may, in exceptional circumstances, make the advertising of a specific product subject to prior approval. Any decision of this nature must be duly justified and shall affect all products having the same composition.

Since July 2013, advertising directed to the general public does not need to be approved in advance by the authorities.

This is without prejudice of the fact that any advertising will be subject to control ex-post by the authorities and sanctions may be imposed if it does not comply with the provisions of the law. Additionally, according to Royal Decree 1416/1994, companies must send an annual index summarising all their advertising activities to the health authority of the Spanish autonomous region where the company is located.

6.2 Compliance With Rules on Medicinal Advertising

Royal Decree 1416/1994, as well as the Code of Farmaindustria, state that the marketing authorisation holder must have a scientific service in charge of the management of the information related to the medicinal products marketed by the company.

The scientific service of the company must fulfil the following obligations:

- revise and control any promotional materials in order to ensure that they comply with the legal requirements;
- ensure that the medical sales representatives and any personnel involved in the promotion of medicinal products or in interaction with HCPs, HCOs and/or POs have been adequately trained;
- compile all information regarding the medicinal products marketed, including the maintenance of a registry of the requests for and supply of samples; and
- supply the regulatory authorities with the information and assistance they require, and ensure that the decisions of the regulatory authorities on these matters are immediately and fully complied with.

Under the Code of Farmaindustria, companies are obliged to have a written procedure to monitor compliance with the Code. Additionally, the Code recommends that the different departments (marketing-sales, medical, regulatory, legal, finance-administrative) get involved in the committees, policies or internal procedures that the company implements on these matters.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Broadly speaking, advertising activities on the internet are subject to requirements identical to

activities performed through traditional channels.

As regards advertising directed to HCPs through the internet, the company must use valid channels within a context that is basically scientific or professional. Those channels must be intended exclusively for HCPs authorised to prescribe or dispense medicinal products, and those HCPs need to identify themselves in order to have access to the information. Pharmaceutical companies can also establish an HCPs status verification system in order for HCPs to have access to the information.

Companies will also be liable for the content of the websites accessed through links from the company's website.

Some provisions of Royal Decree 870/2013, which regulates the sale of OTC medicinal products through the internet, may also apply.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

The same rules applicable to other kinds of advertising apply to advertising through social media. In particular, advertising of prescription-only medicinal products on social media which the general public may access is not allowed.

The Code of Farmaindustria imposes on companies the obligation to adequately train its employees on how to behave in the digital environment. In this regard, pharmaceutical companies must have good-practice internal guides directed to their employees and any person acting on their behalf or under their control, or by virtue of an agreement. Companies must also train their employees to prevent them from posting inappropriate content on their personal social networks, such as comments on competitors' products or off-label promotion.

Also, under the Code of Farmaindustria, pharmaceutical companies must clearly and unequivocally inform HCPs and employees attending the meetings organised or sponsored mainly by the company about the prohibition on publishing promotional content related to the meetings on social media. It is advisable to include safeguards in the agreements entered with speakers and attendees.

7.3 Provision of Disease Awareness Information to Patients Online

According to Spanish law, a company must ensure that those parts of its website which contain promotional information about prescription-only medicinal products may only be accessed by HCPs entitled to prescribe or dispense such products. Conversely, it has been commonly accepted, following the guidance issued by the Pharmaceutical Committee, that the unmodified and unabridged publication on the website of information which has been authorised by relevant authorities (for example, the SmPC, the package leaflet, the public assessment reports, price lists) will normally not be considered as advertising and can, therefore, be openly published on the internet.

Under the Code of Farmaindustria, a clearly legible warning must also be included in those parts of the website directed to the HCPs only, indicating that the information is intended exclusively for the HCPs legally entitled to prescribe or dispense medicinal products and, therefore, that specialised training is required for the correct interpretation of the information. Persons who access the content must identify themselves as HCPs entitled to prescribe or dispense medicinal products. Pharmaceutical companies can also

establish an HCP status verification system in order for HCPs to have access to the information.

7.4 Online Scientific Meetings

Any information or material provided online to patients must comply with the requirements referred to in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry**.

7.5 Use of Social Media

Spanish law does not include any provision regarding online scientific meetings.

According to the Code of Farmaindustria, scientific online meetings must comply with the same requirements applicable to non-virtual meetings.

In addition, the Code of Farmaindustria provides some specific requirements applicable to online scientific meetings:

- it is forbidden to offer any kind of hospitality in online meetings, and this applies to meetings organised or mainly sponsored by the company, as well as to meetings organised by third parties; and
- notification of online scientific events to the Code of Practice Surveillance Unit is not compulsory.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Under the Spanish Criminal Code, companies may be subject to criminal liabilities for bribes offered or given by their employees, directors or other persons under their control to public officials or to private persons.

The penalties that may be imposed on a company for a bribe, which are independent from the penalties that may be imposed on the persons that have committed or participated in the bribe, may be as high as four times the amount of the profit obtained by the company.

However, a company may be exonerated from criminal liability if it demonstrates that prior to the bribe being offered or given, it adopted a compliance system that satisfied the conditions and requirements of the Spanish Criminal Code, and in order to offer or give the bribe the persons involved fraudulently eluded the compliance system and there was no serious breach of the supervision and control duties contemplated in the compliance system.

8.2 Legislative or Self-Regulatory Provisions

According to Royal Legislative Decree 1/2015 and the codes of conduct, it is prohibited for any person with a direct or indirect interest in the production, manufacture and/or placing on the market of medicinal products to directly or indirectly offer to HCPs involved in the cycle of prescription, dispensing and/or administration of medicinal products (or to their relatives or cohabitants) any kind of inducement, bonus, discount, reward or benefit, except for gifts, hospitality and discounts which fulfil the requirements set forth in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry**, **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals**, **9.3 Sponsorship of Scientific Meetings** and **9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions**. This prohibi-

tion will likewise apply when the offer is made to HCPs prescribing medical devices.

Offering benefits to HCOs and POs is acceptable, provided these benefits are not an inducement to buy, recommend and/or use the products of the company.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Gifts

According to Royal Decree 1416/1994, gifts to HCPs entitled to prescribe or dispense medicinal products may only be offered when the cost of the gift is insignificant and the gift is relevant for the practice of medicine or pharmacy.

The Code of Farmaindustria offers further guidance and provides that offering gifts to HCPs is only permitted provided that the items have stationary or professional use, are not related to a prescription-only medicinal product and have a market price that does not exceed EUR10. Moreover, such gifts may not be given to HCPs in the context of the promotional and informative visits made by sales representatives of companies, nor in the framework of a congress or meeting organised by a third party, if such visit or event relates to prescription-only medicinal products.

As an exception, it is permitted to give memory cards containing informative or formative material, provided their value does not exceed EUR10. Pens and notepads can be provided in meetings organised by the company, provided that they do not include information regarding prescription-only medicinal products and that their market price does not exceed EUR10.

Educational Materials

Educational materials and items of medical utility can be given as a gift provided that:

- they are relevant to the practice of medicine or pharmacy;
- they benefit patient care;
- they do not alter or modify the routine business practice of the recipient; and
- their market price does not exceed EUR60.

The offer to HCPs of such gifts is excluded from the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency**.

Hospitality

Except in the case of online events, hospitality may also be offered to HCPs at professional or scientific events, provided that it is reasonable and moderate, and strictly limited to necessary logistical means that allow HCPs to attend the event. Hospitality offered may only include payment of real costs of travel, registration and accommodation (hospitality may be only extended to the day after or before the event).

Payments for meals that cost more than EUR60 (taxes included) per person, as well as payments for five-star hotels, five-star grand luxury hotels, sports resort hotels, theme park hotels and/or winery hotels, are prohibited. Payment for cultural, leisure or entertainment activities is also prohibited.

The company must pay these expenses directly to the service providers. No monetary reimbursement can be made to the HCP attendees for expenses incurred to suppliers, except in the case of minor travel costs (taxis, mileage, etc) which are properly justified/evidenced. Hospitality may not be extended to persons other than the HCP attendees.

9.2 Limitations on Providing Samples to Healthcare Professionals

Royal Decree 1416/1994 states that delivery of free samples can only be made on an exceptional basis, and provided that the prior authorisation from the AEMPS is obtained. Authorisation by the AEMPS may be granted only for medicinal products which:

- have a new active substance;
- have a new pharmaceutical form, concentration dosage, or administration route which represents a therapeutic advantage; or
- have new therapeutic indications.

The following requirements/restrictions apply:

- supply of samples must be in response to a written request, signed and dated, from HCPs entitled to prescribe medicinal products;
- only a maximum of ten samples for each medicinal product each year per HCP, during a maximum period of two years after the granting of the marketing authorisation for the medicinal product, is allowed;
- companies must maintain an adequate system of control and accountability;
- samples must not be bigger than the smallest presentation of the product authorised in Spain;
- each sample must be marked "free sample – not for sale" and its reimbursement sticker must have been annulled; and
- a sample must be accompanied by a copy of the SmPC and by updated information on its price, conditions of reimbursement by the Spanish National Health System and, if possible, estimated cost of treatment.

No samples of medicinal products containing psychotropic or narcotic substances may be supplied.

The provision to HCPs of samples is excluded from the transparency obligations for the companies of Farmaindustria referred in **10. Pharmaceutical Companies: Transparency**.

9.3 Sponsorship of Scientific Meetings

According to Spanish regulations, companies may sponsor scientific meetings or congresses, as well as organise informative, professional and/or scientific meetings. Such sponsorship must be stated in all documents related to the event, as well as in any published derivative work.

It is also possible to pay necessary travel, accommodation and enrolment costs to HCPs attending such congresses or meetings. According to Royal Decree 1416/1994, hospitality must be reasonable in level (ie, it must not exceed what recipients would normally be prepared to pay for themselves) and remain subordinate to the main scientific objective of the event. Recipients must indicate the funds received and the source of financing in the publication of papers and lectures in the congresses and meetings. A company may be held responsible for the contents and hospitality arrangements for a meeting or congress if such event has been organised and/or mainly sponsored by such company.

The Code of Farmaindustria provides further guidance, as follows.

- Payments of HCPs travel, accommodation and enrolment costs must be made directly to the provider of these services, except for minor travelling expenses duly justified.
- No payment can be made for the time incurred by the HCP attending the event.
- Hospitality may be granted only for the duration of the event and one additional day.
- Scientific activities must cover at least 60% of an eight-hour working day.

- Tourist locations, sports resorts and the like should be avoided. In addition, it is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain or the congress or expertise object to the event is located abroad (prior approval by Farmaindustria's Deontological Surveillance Unit may be needed). In such cases, the company must abide by the rules of the code of conduct applicable in the country where the event is located.
- A limit of EUR60 (VAT included) must be established for meals and luncheons per guest.
- Hospitality must not be extended in any case to accompanying persons.
- Payment of reasonable fees and reimbursement of out-of-pocket expenses is possible for speakers and moderators.
- Companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency**.

The autonomous regions may place some additional organisational requirements as a consequence of the interaction of the visits made by the sales representatives with the public centres. For example, some regions require the company to submit its visit schedule for subsequent validation.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The hospitality offered to HCPs cannot include the organisation of social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

According to Spanish regulations, grants or donations to individual HCPs are strictly prohibited, except for gifts, samples and hospitality offered to HCPs, provided such gifts, samples and/or hospitality fulfil the requirements set forth in **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals** and **9.3 Sponsorship of Scientific Meetings**. Grants or donations to HCOs are acceptable, provided they are not offered as an inducement to buy, recommend and/or use the products of the company.

The Code of Farmaindustria provides specific rules as regards grants or donations to HCOs. The Code allows donations and/or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are HCPs and/or which provide services of sanitary, social or humanitarian assistance, research or teaching, subject to certain conditions, the most relevant of which are that the gift or donation:

- must not be offered as an inducement to prescribe, recommend or use any particular product;
- must be for the internal use of the institution in general, and not for the use of an individual (portable electronic devices are expressly excluded); and
- must be recorded in a document to be kept by the company.

It is advisable to show these transactions in a written agreement so that the terms under which the funding is awarded are explicit and transparent. Companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the offer of grants or donations to HCOs.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

For retail pharmacies, only reasonable volume-related discounts and discounts for early payment are acceptable, provided that such discounts do not induce the purchase of the product with prejudice to its competitors, and are reflected in the corresponding invoice. The reasonability of the discount must be analysed on a case-by-case basis. Companies must also keep a record, which has to be interconnected with the Ministry of Health, of all discounts offered to pharmacies for medicinal products that are financed by the National Health System.

For supplies to hospitals, discounts are subject to the public procurement system.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay HCPs for expert services (for example, participating in advisory boards, acting as speaker or moderator at scientific meetings, educational activities, expert meetings, etc), under the following conditions.

- Entering into a written agreement stating the nature of the services and the criteria to calculate the amount of payment.
- The legitimate need for such services must be clearly identified.
- The criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates. The experts hired must be approved by the scientific service of the company.
- The number of experts hired must not exceed the number reasonably necessary to achieve the identified objectives.
- The company must keep documentary records of the services provided.
- The payment to the HCP must not entail an inducement to promote the prescription, dispensation, sale or consumption of medicinal products.
- The remuneration must be at market prices and taking into account the hours of work or service actually employed and the responsibilities undertaken by the expert. Payments must be explicit and transparent, and a proper invoice must be issued by the HCP. Payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit.
- It is recommended that the agreement include a clause by means of which the HCP undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the company; and companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the payments made to HCPs related to said provision of services.

Annex IV of the Code of Farmaindustria includes a guide for action for companies when contracting services to HCPs and HCOs. Annex IV includes a list with some of the different kinds of services that may exist and the criteria that pharmaceutical companies must comply with.

In addition, this guide establishes a series of questions (23 in total) that companies must be able to answer affirmatively, to ensure that they comply with the provisions of the Code regarding these contracts. These questions are set out in line with IFPMA's "Guidance on Fees for Services".

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

According to the Spanish rules, HCPs which provide their services in HCOs depending on the public health system may be obliged to obtain an authorisation of their employer in order to accept the hospitality offered by a company or to provide a service for a company. HCPs are the ones affected by these obligations, and not the companies.

Under the Code of Farmaindustria, the companies must inform Farmaindustria's Deontological Surveillance Unit in the following cases:

- where the company organises the assistance to a congress or event of at least 20 people; and/or
- where the HCPs hired by the company for a given project number more than ten.

In the case of meetings or events that are part of projects that have already been notified by pharmaceutical companies, these do not need to be notified again in accordance with the principle of non-duplication.

Communication will be voluntary in the case of training activities or scientific meetings that are carried out virtually.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The Code of Farmaindustria has implemented the EFPIA rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs. Consequently, since 2015, companies are obliged to document and publish on their website (the first publication was actually made in 2016) all transfers of value made during the previous year – meaning any direct or indirect payment or grant, either cash or benefits in kind, and regardless of their purpose – whose recipient is an HCP or HCO. The only payments excluded from this obligation are:

- those associated with commercial transactions with distributors, retail pharmacies and certain transactions with HCOs;
- activities related to products or medicinal products that are not prescription-only medicinal products; and/or
- activities not detailed in Appendix I of the Code of Farmaindustria, such as the provision of gifts, samples, dinners or luncheons.

Disclosure must be made on an individual basis, except for transfers of value related to R&D. Spanish authorities on personal data protection have ruled that companies must inform an HCP on the disclosure of their personal data. However, there is no requirement that the HCP consents to the disclosure of their personal data.

AESEG has also implemented in its own code the Medicines for Europe rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs.

There are no exceptions regarding the disclosure obligation due to COVID-19 incidences.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The transparency requirements described in **10.1 Requirement for Pharmaceutical Compa-**

nies to Disclose Details of Transfers of Value apply to transfers of value to HCPs, HCOs and POs performed by companies associated to Farmaindustria/AESEG and/or which have voluntarily adhered to the Codes of Farmaindustria/AESEG. They also apply to transfers of value to Spanish HCPs, HCOs and POs performed by their affiliates, except in the case where such affiliates already publish such transfers of value in accordance with their national code of conduct. The fact that the company does not yet have products on the market is irrelevant for this purpose.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Except for those rules resulting from the industry codes of conduct, the responsibility for enforcing the rules on advertising and inducements lies with the health authorities of the Spanish autonomous regions and courts.

The Codes of Farmaindustria, AESEG and ANEFP are enforced by self-regulatory bodies in agreement with Autocontrol, an association for self-regulation in advertising.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Any advertising in breach of General Law 34/1988 on Advertising will be considered as an unlawful act under Law 3/1991 on Unfair Competition. The actions that may be taken before the courts for breach of the Law on Advertising and for breach of the Law on Unfair Competition (which may be taken individually or on a cumulative basis) have been unified in order to avoid any conflict between jurisdictions, as follows:

- action of cessation or prohibition;
- action of declaration of the unlawfulness of the advertising;
- action of removal of the effects produced by the unlawful advertising; and
- action of rectification of any deceitful, incorrect or false information contained in the unlawful advertising, including the publication of the court ruling.

This is without prejudice to the right to claim damages, if the advertiser has acted wilfully or negligently and/or for unlawful enrichment, if applicable.

The referred actions may be brought by any person or company who is affected by the unlawful advertising and, in general, those who have a legitimate interest. These actions may also be brought by consumer associations or other associations when the interests of their members are affected, but they will not have the right to claim damages.

The issues which have been discussed more frequently under these procedures involve the distinction between advertising and information on products, the conformity of advertising materials to the content of the SmPCs, and the conditions under which comparative advertising is fair. Another area on which various rulings have been adopted refers to the limits on hospitality that may be offered to HCPs.

Raising Issues

Under the Codes of Farmaindustria, AESEG and ANEFP, companies have agreed not to file complaints against each other directly before the ordinary courts or the health authorities without

first raising the issue with the bodies in charge of enforcing these codes.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The regulatory authorities are rather strict in scrutinising materials which companies notify to them, and they may suspend an advertisement if they consider it to be in breach of the rules. Furthermore, if the advertisement constitutes a risk for the health or security of consumers, the authorities may order the publication of the ruling and a corrective statement where the advertisement was published.

Failure to Comply

Failing to comply with the rules governing the medicinal products' advertising and/or inducements may also result in administrative sanctions. The general rule is that a breach of the law on this matter may result in a fine being imposed. The amount will depend on various factors including:

- negligence;
- whether the breach was intentional;
- whether there was fraud or connivance;
- whether a failure to comply with previous requests made by the authorities exists;
- the company's turnover;
- the number of persons affected;
- the damage caused; and
- the profits obtained from the infringement.

In some cases, criminal sanctions may apply.

Challenging Decisions

Decisions taken by regulatory bodies may be challenged through an administrative appeal and through judicial review. In some cases, the administrative appeal is compulsory and has to be filed within a month from the date on which the decision was notified. When the administrative appeal is only optional, the interested party may go directly to court within two months from the date on which the decision was notified. During the court case, an injunction may be sought. The chances of obtaining an injunction largely depend on whether the applicant shows that it will suffer irreparable harm in the event that the injunction is not granted.

Under the Codes of Farmaindustria, AESEG and ANEFP, the procedure may conclude with the declaration of the unlawfulness of the advertising, as well as with a fine, the amount of which will be set considering a variety of factors. The damage that a breach of the rules may cause to the image of the industry is one of the criteria to which the Code of Farmaindustria refers. The competent body to impose these measures and sanctions is the Jury of Advertising, a specialised body within Autocontrol. The rulings of the Jury of Advertising are made public through its website.

11.4 Relationship Between Regulatory Authorities and Courts

The Codes of Farmaindustria, AESEG and ANEFP state that, prior to raising the issue before the regulatory authorities or the courts, the companies adhering to these codes must first file their claims against the advertising practices of other companies before the bodies in charge of enforcing these codes of conduct.

Notwithstanding the foregoing, the regulatory authorities may investigate matters on their own initiative, even if they are being assessed by any self-regulatory body, and may also take up matters based on an adverse finding of any self-regulatory body. Conversely, the Jury of Advertising must refrain from assessing any issue which is

being or has been assessed by the regulatory authorities or the courts.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

During the last several years, there have been few cases regarding advertising of medicinal products in Spanish Courts and in Autocontrol. The last two rulings of Autocontrol under the Code of Farmaindustria were issued in 2020 and 2022.

On 30 June 2021, the High Court of Justice of the Basque Country issued a very interesting judgment clarifying, inter alia, that Spanish law does not prohibit the advertising of products which have been granted a marketing authorisation, even when their price and reimbursement decision is still pending from the Ministry of Health. Following this judgment, the Code of Farmaindustria changed its Q&A section (Question 10) by indicating that the advertising of a medicine in these circumstances is not against the Code provided that such advertising includes a warning in this regard and is aimed at HCPs.

One year later, on 17 June 2022, the High Court of Justice of Madrid issued a judgment on terms contrary to those upheld by the High Court of Justice of the Basque Country and ruled that medicinal products cannot be the object of promotion until a decision on their price and reimbursement has been issued, regardless of whether these products have obtained a marketing authorisation.

For more information about this judgment, and the context and conclusions in connection therewith, please refer to the accompanying **Trends & Developments** article.

At the end of July 2022, the Ministry of Health invited all interested parties to make their proposals regarding the preparation of the draft bill amending the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. The interested parties submitted the proposals, and the new draft law is currently under preparation. For more information about the aspects that will be amended with this new draft law, please see the **Trends & Developments** article.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The provisions related to the advertising of veterinary medicines are comprised in Royal Decree 1157/2021, which regulates industrially manufactured veterinary medicines. According to Royal Decree 1157/2021, advertising of prescription-only veterinary medicines is permitted only if addressed to veterinarians and persons authorised to dispense veterinary medicines. Regulations provide for an exception for immunological medicines, which can be advertised to persons in charge of animals.

Advertising of veterinary medicines addressed to the general public must abide by the following requirements:

- comply with the SmPC of the product;
- not include testimonials from HCPs or notorious persons, or expressions that provide assurances of healing; and
- not use claims on the fact that the product has been granted a marketing authorisation.

Also, the following information must be included in the advertising of veterinary medicines (except in the case of advertising for branding purposes) addressed to the general public:

- name of the medicinal product and number of the marketing authorisation;
- identification of the marketing authorisation holder;
- composition of active ingredients;
- indications for use and target species;
- contraindications, precautions and withdrawal periods, if applicable;
- additional indications required in the marketing authorisation; and
- a legend stating "If in doubt, consult your veterinarian".

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Authors

Jordi Faus is a founding partner of Faus Moliner and concentrates on regulatory matters, licensing and co-marketing agreements, pricing and reimbursement issues, advertising and antitrust. He has represented various Spanish and foreign companies and associations in a variety of matters, and also has substantial expertise in Spanish and international arbitration proceedings, both as counsel and as an arbitrator. Jordi is a member of the Health Law Section of the Barcelona Bar Association, the Spanish Association of Regulatory Affairs Professionals and the Spanish Association of Health Law.

Anna Gerbolés is an associate at Faus Moliner and is specialised in pharmaceutical and food law. Her experience in these sectors includes the provision of legal advice on issues related to regulation and advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has provided highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Claudia Alberdi is an associate at Faus Moliner and is specialised in pharmaceutical law and compliance for pharmaceutical companies. Her experience includes the provision of legal advice on issues related to regulation and advertising of medicinal products. Since becoming part of the Faus Moliner team in 2022, she has provided highly specialised advice to companies operating in the life sciences sector. Claudia is a member of the Madrid Bar Association.

Faus Moliner

Rambla Catalunya 135
3rd floor
2nd door
08008
Barcelona
Spain

Tel: +34 9329 22100
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

Trends and Developments

Contributed by:
Jordi Faus, Anna Gerbolés and Claudia Alberdi
Faus Moliner see p.310

The latest trends and developments in connection with pharmaceutical advertising in Spain concern the following matters:

- advertising of prescription-only medicinal products to healthcare professionals (HCPs) once they have received a marketing authorisation but before the price and reimbursement decision is issued by the Ministry of Health; and
- foreseeable legislative changes.

This article includes analysis of these matters, providing background information and relevant context when needed.

Advertising of Prescription-Only Medicinal Products to HCPs Before the Price and Reimbursement Decision is Taken by the Ministry of Health (MoH)

Relevant context

In Spain, prescription-only medicinal products cannot be placed on the market immediately once a marketing authorisation (MA) has been granted (either by the European Commission under the centralised procedure or by the Spanish Medicines Agency (AEMPS) under a national procedure, a mutual recognition or a decentralised procedure).

The consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, approved by Royal Legislative Decree 1/2015, states that prior to placing the product on the market, the MA holder or its local representative must offer such product to the MoH so that the MoH may decide whether to reimburse it or not. If in the affirmative, the MoH shall issue a decision (a "P&R Decision") also fixing the maximum price for the units of such product that will be reimbursed. Units that are not reimbursed (ie, private patients or other sales outside the National Health System) may be sold at the price notified to the MoH, provided the MoH does not oppose this on the grounds of protection of public interest.

The possibility of advertising a product after an MA has been issued but before a P&R Decision is adopted has been the subject of controversy in Spain, mainly due to the interpretation given by the Spanish authorities to certain provisions contained in Royal Decree 1416/1994 on promotion of medicinal products for human use.

Article 10.2 of Royal Decree 1416/1994 refers to the minimum information that must be included in any advertising of medicines aimed at HCPs. More precisely, Article 10.2 states that any advertising of medicinal products to HCPs must include information "about the price and reimbursement conditions and, whenever possible, about the estimated cost of the treatment". When referring to this requirement, Article 10.2 states that this information must be provided "if applicable".

Relying on this, some authorities in Spain have understood that advertising may not take place until a P&R Decision has been taken. In some cases, authorities have even stated that advertising cannot take place until the product is effectively placed on the market.

This position was also followed by the Jury of Autocontrol (a specialised body responsible for hearing cases relating to the breach of provisions of self-regulatory codes) when applying the Code of Farmaindustria. Farmaindustria is the Spanish innovative medicinal products industry association, which has issued a code of practice for the pharmaceutical industry regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs.

According to numerous rulings of the Jury of Autocontrol, for example in the case Cephalon Pharma, SLU v Prostrakan "Abstral", dated 8 October 2009, the advertising of authorised medicinal products for which a P&R Decision is pending is regarded as a breach of the Code of Farmaindustria.

Relevant trends – June 2021, first judgment in dispute

On 30 June 2021, an important judgment on the aforementioned matter was issued by the High Court of Justice of the Basque Country, in a case filed by Farmaindustria against an order governing visits by medical sales representatives to HCPs in the Basque Country. The appeal was filed because, inter alia, Farmaindustria considered that the order did not allow medical sales representatives to promote, at such visits, authorised medicinal products for which a P&R Decision was pending. The High Court rejected the appeal concluding that neither the order nor any other Spanish applicable law prohibit the advertising of products that have received an MA, even if a P&R Decision is pending.

Interestingly, the Court stated that when interpreting Article 10.2 of Royal Decree 146/1994, relevance must be given to the words "if applicable" contained in such provision, meaning that the information about the price and reimbursement conditions must be given only if such information is available when the advertising is made. The Court also stated that the absence of a P&R Decision cannot be an obstacle for authorised advertising of the medicinal product to HCPs.

Considering this judgment, Farmaindustria modified the Q&A section of its code of practice to include that advertising of authorised medicinal products to HCPs when the P&R Decision is still pending is possible, provided that such advertising includes a warning about such circumstance.

Relevant trends – June 2022, second judgment in dispute

The position maintained by the High Court of Justice of the Basque Country in the judgment of 30 June 2021, which encouraged Farmaindustria to modify its code of practice, was overshadowed by another recent judgment of the High Court of Justice of Madrid dated 17 June 2022.

In this case, the High Court of Justice of Madrid considered that until a P&R Decision has been taken, the requirements for the product to be promoted are not met because Article 10.2 of Royal Decree 1416/1994 imposes the obligation to include, in any advertising of medicinal products, data regarding the price of the product and the conditions of the pharmaceutical provision of the National Health System.

It is interesting to note that the High Court of Justice of Madrid does not state that Royal Decree 1416/1994 or Royal Legislative Decree 1/2015 prohibit promotion before the P&R Decision, but focuses its argument on the minimum content that promotional materials of medicinal products must respect under Article 10.2 of Royal Decree 1416/1994. Thus, in the opinion of the

Court, a medicinal product whose P&R Decision is pending cannot be promoted in compliance with Article 10.2 of Royal Decree 1416/1994.

The High Court of Justice of Madrid, therefore, overlooks the fact that Article 10.2, when referring to the minimum content in terms of price and financing conditions, states that such information must be included "if applicable".

It is also interesting to note how the judgment of the High Court of Justice of Madrid interprets the Basque Country judgment; this allows for a reading of the Madrid High Court judgment in somewhat more favourable terms.

According to the Madrid judgment, the High Court of Justice of the Basque Country examines the characteristics of visits by medical sales representatives, but the Madrid court states that the assimilation of this advertising regime with the documentary advertising of medicinal products should be avoided.

This can be interpreted as meaning that the prohibition on promoting medicinal products before the P&R Decision is taken would only refer to the documentary advertising that is actively made available to the HCP. Under this interpretation, only this documentary advertising would be obliged to include the information set out in Article 10.2 of Royal Decree 1416/1994. This minimum content would not apply to the information that the medical sales representatives can transmit to HCPs, which is what the ruling of the High Court of Justice of the Basque Country refers to.

Foreseeable future

The authors are not aware of the judgment of the High Court of Justice of Madrid being appealed before the Spanish Supreme Court, which is the court competent to revise a ruling issued by a regional High Court.

Consequently, at present two apparently divergent rulings coexist on the possibility for promoting medicinal products before the P&R Decision is issued.

However, the authors are aware that the health authorities of Catalunya have issued public statements and newsletters indicating that promotion before the P&R Decision has been issued is prohibited because such advertising would not comply with Article 10.2 of Royal Decree 1416/1994. These authorities also confirmed that medicinal products holding an MA and with a valid P&R Decision in force cannot be the object of advertising if commercialisation has not been notified to the authorities, since this advertising would be considered misleading.

As discussed further in the following section, Royal Legislative Decree 1/2015 is soon to be amended as a result of the initiative promoted by the MoH. The authors expect that this new version of the legislative decree will provide clarification as to whether a medicinal product whose P&R Decision is pending can be the object of promotion.

Foreseeable Legislative Changes

Amendment of Royal Legislative Decree 1/2015

In July 2022, the MoH opened a public consultation on the first draft of the law that will amend the current Royal Legislative Decree 1/2015. The document published by the MoH shows that the reform being considered will have three principal axes.

- Public financing of medicines – the MoH document refers to adopting new measures

to rationalise pharmaceutical expenditure and promote rational use of public funds. In this regard, it is proposed to modify the reference price system by introducing elements that increase competition and value the contributions that represent an incremental benefit in the use of medicines.

- The experience of the pandemic and the impact of new technologies – the pandemic has created great challenges related to the availability of medicinal products and medical devices. In this sense, the MoH aims to consolidate the non-presential dispensing of medicines for hospital dispensing and telepharmacy in the National Health System.
- Implementation of EU law – the text published by the MoH proposes to make the necessary amendments to incorporate the amendments and definitions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

Regarding objectives of the proposed amendment in the specific area of advertising, the MoH document states that the amendment to Royal Legislative Decree 1/2015 aims to clarify the competences of control over advertising activities for medicinal products, as well as to update the advertising regime for medical devices.

The process to approve this new law will be lengthy. After this public consultation period, the Spanish government will prepare a draft of the new law, and it will be put to a public hearing so that contributions can be made. After this, the government will send the draft law to the Spanish Parliament for the legislative amendment to be processed.

Amendment of Royal Decree 1591/2009 and Royal Decree 1616/2009

Regulation 2017/745 (EU) on medical devices is of direct application for member states; however, this regulation leaves certain issues to be further regulated at the national level. Consequently, those aspects of the national regulations that are not compatible with the EU regulation are subject to future amendment. In this context, in 2021 the MoH proposed a new draft on medical devices that would partially repeal Royal Decree 1591/2009 on medical devices and Royal Decree 1616/2009 on active implantable medical devices.

The derogation of these royal decrees is not complete. According to the proposed draft, whose final approval is still pending, the provisions of both decrees relating to promotion, incentives and sponsorship of scientific meetings, as well as the procedures before the notified body, will remain in force but will be subject to future amendment.

New Royal Decree on promotion of medicinal products and medical devices

Finally, according to the 2022 Annual Regulatory Plan (a document that includes the legislative or regulatory initiatives that the various ministerial departments plan to submit each calendar year to the Spanish Council of Ministers for approval), a new Royal Decree on the promotion of medicinal products and medical devices was expected for 2022. However, the MoH did not move forward with this proposal in 2022.

Among the objectives of this new Royal Decree, the Annual Regulatory Plan referred to:

- the need to update the regulatory regime of promotional activities with the technological evolution and predominance of digital media;

- the clarification of the control competences of the autonomous health authorities; and
- the need for a comprehensive regulation of the advertising of medicinal products for human use and medical devices, both to the general public and to health professionals.

At the time of writing this article, the Annual Regulatory Plan for 2023 has just been published and the proposed new Royal Decree on the promotion of medicinal products and medical devices has not been included as an initiative for 2023. The authors cannot exclude that the MoH has decided to abandon this particular initiative, as it may be regarded as being pursued through the amendment of Royal Legislative Decree 1/2015.

Contributed by: Jordi Faus, Anna Gerbolés and Claudia Alberdi, **Faus Moliner**

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Authors

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Contributed by: Jordi Faus, Anna Gerbolés and Claudia Alberdi, **Faus Moliner**

Faus Moliner

Rambla Catalunya 135
3rd floor
2nd door
08008
Barcelona
Spain

Tel: +34 9329 22100
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

SWEDEN

Law and Practice

Contributed by:
Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist
Advokatfirman Vinge KB see p.335

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SWEDEN

Contributed by: Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist,
Advokatfirman Vinge KB

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The Medicinal Products Act (2015:315) establishes the general requirements on advertising of medicinal products. Advertising must be in accordance with good marketing practice, be up-to-date, objective, balanced and must not be misleading. Further clarifications are found in the Swedish Medicinal Products Agency's (MPA) Regulation LVFS 2009:6 on the marketing of medicinal products for human use, which implements Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The Swedish Radio and Television Act (2010:696) contains limitations with regards to advertisements of medicinal products through, for example, teleshopping (which is prohibited) and sponsorships of TV advertisements.

Moreover, the Marketing Practices Act (2008:486) sets out general rules that are applicable on all products and services, including medicinal products. According to this Act, advertising must comply with good marketing practice and all marketing claims must be accurate and therefore not misleading. The Act also regulates matters relating to, for example, comparative advertisements and special offers.

Rules Pertaining to Medicinal Products

The Swedish Association of the Pharmaceutical Industry (LIF) has adopted the Ethical Rules for the Pharmaceutical Industry (the "LER Rules"), which govern advertising and information of medicinal products to healthcare professionals and to the general public. The Information Examiner Committee (IGN) and the Information Practices Committee (NBL) are the two regulatory bodies that supervise compliance with the LER Rules. The LER Rules, and the decisions from the IGN and NBL, are not legally binding, but are recognised by the pharmaceutical industry and should be seen as a complementing set of rules to current legislation, and will be considered by Swedish courts when assessing good marketing practice.

The LER Rules and decisions from the committees may also be considered by Swedish courts when determining, for instance, good marketing practice. The Code of Advertising and Marketing Communication Practice issued by the International Chamber of Commerce (the "ICC Rules") is also considered by Swedish courts when determining good marketing practice.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The LER Rules apply to members of the LIF as well as to the Association for Generic Pharmaceuticals and Biosimilars in Sweden (FGL) and the industry association for innovative smaller life-science companies (IML).

Only members may be subject to sanctions under the LER Rules (eg, penalty fees). However, the committees of the LIF can review matters relating to medicinal products from non-members, although these non-members cannot be subject to any sanctions.

The LER Rules are not legally binding. However, as stated in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the LER Rules are recognised within the pharmaceutical industry and may be applied by courts in order to determine, for example, good marketing practice.

Contributed by: Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist,
Advokatfirman Vinge KB

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

LVFS 2009:6 makes reference to Directive 2001/83/EC and cites the Directive's definition of advertising of medicinal products. Accordingly, advertising of medicinal products includes "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products".

Examples of what could constitute advertising under LVFS 2009:6 include:

- advertising of medicinal products to the general public or healthcare professionals;
- visits by sales persons to healthcare professionals;
- sponsorship of promotional meetings attended by healthcare professionals; and
- supply of samples.

It can be concluded from the expression "any form" that the definition of advertising of medicinal products is very broad.

The Marketing Practices Act defines marketing practice as "advertising and other measures in commercial activities which are intended to promote the turnover of, and access to, products, including a trader's acts, omissions or other measure or behaviour before, during or after the sale or delivery of products to consumers or traders".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

There is no sharp line between information and advertising. Information is part of a broader scope and may fall within the relevant marketing provisions. According to the preparatory works, where there is ambiguity on whether or not a statement is to be considered as advertising, the law should be interpreted in the light of Directive 2001/83/EC.

The decisive criterion for distinguishing between advertising and information (which, as a rule, does not fall under the advertising rules) is the purpose of the communication. The assessment of whether the communication has a promotional purpose should be based on an assessment of all the relevant circumstances, on a case-by-case basis. If the information does not have a promotional purpose or includes non-commercial information, it may fall outside the relevant marketing provisions.

For instance, the content in patient leaflets or information regarding patient support programmes may be considered as advertising if the information can be seen as an inducement designed to promote the prescription, supply, sale or consumption of medicinal products (ie, as having a promotional purpose).

Activities Not Covered by "Advertising"

In LVFS 2009:6, examples of activities that are not covered by the term "advertising" can be found. Correspondence or material of a non-promotional nature, which is necessary to answer a specific question regarding a medicinal product, is not considered as advertising. Neither are factual and informative announcements or material relating to pack changes, adverse-reaction warnings as part of general drug precautions or trade catalogues part of the term "advertisement", provided that this information does not include any claims of the medicinal product. Furthermore, information regarding human health or diseases (eg, disease awareness campaigns) are

not covered by the term "advertising", provided that the information does not include any direct or indirect reference to medicinal products.

Additionally, mere factual and informative messages on, for instance, product packaging are not considered as advertising provided there are no claims (eg, regarding effects) about the medicinal product and the information otherwise complies with relevant legislation.

Vaccinations

With regard to vaccinations of humans against infectious diseases, the LER Rules state that such campaigns are not regarded as marketing of a certain medicinal product provided the purpose is to provide the general public with necessary information regarding protection against infectious diseases through vaccination. Additional requirements are that the product name, logotype or similar distinctive mark or feature such as administration method are not included in the information.

Target Audience

The actual definition of advertising does not differ depending on whether the information is aimed towards the general public or towards healthcare professionals. However, lawfulness of the advertising does depend on whether the advertising is aimed towards the general public or towards healthcare professionals; see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**.

2.3 Restrictions on Press Releases Regarding Medicines

In general, Swedish legislation or self-regulatory codes do not set out any specific restrictions on what type of marketing activities are allowed. Irrespective of type and form, any advertisement must be in compliance with the applicable advertising rules, such as the Medicinal Products Act and LVFS 2009:6, the Marketing Practices Act and the LER Rules.

A press release may only be addressed to journalists – ie, it may not be sent or distributed to healthcare personnel or county council/region representatives. Both the IGN and NBL have in several cases concluded that press releases published by pharmaceutical companies, or that are made available by pharmaceutical companies, through a specific link targeting journalists, do not constitute advertising and thus fall outside the scope of the LER Rules. Whether or not a press release falls within the scope of the LER Rules is assessed on a case-by-case basis. The press release will likely fall outside the scope of the LER Rules if:

- it is of a scientific nature;
- it is presented in a clear and objective way;
- it does not promote the pharmaceutical company's own product; and
- it does not discredit another company's medicinal product.

2.4 Comparative Advertising for Medicines

Comparative advertising is allowed under Swedish law under certain conditions.

The Medicinal Products Act

The Medicinal Products Act includes general requirements that advertising must be up-to-date, objective, balanced and must not be misleading. These requirements must be considered when a medicinal product is compared with another medicinal product. According to LVFS 2009:6, it is not permitted, in relation to advertising to the general public, to claim that a

medicinal product is better, or equal to, another treatment or medicinal product.

The Marketing Practices Act

The Marketing Practices Act includes general provisions relating to comparative advertising between two traders. The Act implements Directive 2006/114/EC concerning misleading and comparative advertising. A trader can directly or indirectly refer to another trader or such trader's products provided that the comparison is not misleading, objectively relates to relevant, verifiable and distinguishing characteristics of the products, and does not discredit the other trader's business or product.

The LER Rules

The LER Rules contain specific rules regarding comparisons of medicinal product information towards the general public and healthcare personnel concerning, for example, effects, active ingredients and cost of treatment. Generally, the comparison must be performed in a fair way and be relevant, objective and truthful.

A comparison may not mislead the recipient. This entails that:

- the objects that are subject to the comparison should be specified and, if necessary, the name of the medicinal products and generic names of the compared products should be stated;
- the facts which the comparison is intended to highlight and the limitations with which the comparison is encumbered must be stated in such a way that the comparison cannot be misleading;
- the comparison of properties of synonymous medicinal products, or of medicinal products with the same indications, must provide a comprehensive and fair view of the compared properties; and
- the comparison of certain properties may not lead to incorrect or misleading conclusions regarding properties that are not subject to the comparison.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The Medicinal Products Act prohibits advertising of medicines or indications that have not been authorised for sale in Sweden. All advertising must correspond with the Summary of Product Characteristics (SmPC), as well as with the authorised indications, of the authorised medicinal product.

Distribution of information on unauthorised products or indications and which entails a promotional purpose may be considered as unlawful pre-launch advertising or off-label advertising – for instance, the IGN has concluded that a press release (which usually falls outside the LER Rules, see **2.3 Restrictions on Press Releases Regarding Medicines**) concerning a medicine candidate should be regarded as commercial information and, thus, as prohibited advertising of an unauthorised medicine.

3.2 Provision of Information During a Scientific Conference

As stated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is prohibited to advertise unauthorised medicines or indications, including during a scientific conference. However, if the

provided information has a purely informational purpose, without any references to, or claims regarding, a specific medicinal product, it may be permissible. In light of the broad interpretation of advertising, such provision of information should be performed with great care.

According to an opinion by the LIF, information regarding pipeline drugs (ie, drug candidates that a pharmaceutical company has under discovery or development) is not accepted within commercial areas, such as at exhibition stands at conferences.

It was previously possible, under certain circumstances according to the LER Rules, to refer to a medicinal product, authorised in another country than Sweden, at a conference taking place in Sweden (a "congressional exemption"). However, following a ruling in the Court of Appeal (Judgment No 546-21) on 27 September 2021, where the Court concluded that the congressional exemption is contrary to the Medicinal Products Act, the LIF decided to remove this exemption from the LER Rules.

3.3 Provision of Information to Healthcare Professionals

As previously stated, advertising of unauthorised medicines or indications is in general prohibited. This prohibition applies to advertising to healthcare professionals, as well as to advertising to the general public. Sending unsolicited information on unauthorised medicinal products or indications to healthcare professionals may thus constitute unlawful pre-launch or off-label advertising.

Individual correspondence, accompanied by material of a non-promotional nature if necessary, does not fall under the advertising provisions if it is required in order to respond to a specific query regarding a medicinal product. Accordingly, a pharmaceutical company may respond to a specific query from a healthcare professional concerning, for example, off-label use. The response may not go beyond the specific query.

3.4 Provision of Information to Healthcare Institutions

As previously stated, unsolicited communications with healthcare professionals may be deemed as unlawful pre-launch or off-label advertising.

However, LVFS 2009:6 provides an exemption concerning price lists, which may be of relevance. Under this exemption, factual and informative announcements and reference material relating to, for instance, trade catalogues and price lists, are not considered to be advertisements provided that they do not include product claims.

3.5 Information About Early Access or Compassionate Use Programmes

Compassionate use programmes (ie, allowing the use of an unauthorised medicinal product for patients who have a disease with no satisfactory authorised therapies) may be available in Sweden under strict conditions. The MPA is the competent authority.

There are no specific provisions relating to the publication of a compassionate use programme or other forms of early access. In the light of the broad interpretation of the term "advertising", information regarding a medicinal product's use in connection with a compassionate use programme may be deemed unlawful off-label or pre-launch advertising. This assessment must be made on a case-by-case basis.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

The Medicinal Products Act explicitly prohibits advertising of prescription-only medicines (except for vaccination campaigns on human infectious diseases) towards the general public. The prohibition also includes advertising of medicinal products or indications that have not been authorised for sale in Sweden, and advertising of medicinal products targeting children.

According to the LER Rules, information on prescription-only medicines can only be provided to the general public via the pharmaceutical specialities on Sweden's *Farmaceutiska specialiteter i Sverige* (FASS) website, to the extent the information complies with the requirements under Swedish legislation. It is also permitted to provide information through brochures if the information is intended to be handed to a patient by healthcare personnel to facilitate the patient's correct use of the medicine.

To ensure public access to this information, a pharmaceutical company may provide information regarding such products on a (pre-approved) website administered by a pharmaceutical company provided that pre-examination and pre-approval has occurred. This pre-approval system has been introduced by the LIF. Any pharmaceutical company that complies with the LER Rules may apply for a pre-approval. The company is not allowed to actively market the website; instead, the user must seek the information on their own.

Advertising of over-the-counter (OTC) medicines is allowed in Sweden but subject to comprehensive regulation. As a general rule, all advertising must be up-to-date, objective, balanced, must not be misleading and must correspond to, or be derived from, the SmPC.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

When advertising a medicinal product that addresses the general public, it must be made clear that the message is an advertisement and that the product is a medicinal product.

The content of the advertising must not be construed in a way that could result in the medicinal product being used in a harmful way or that could result in people not seeking appropriate care. Furthermore, the advertising must correspond to, or be derived from, the SmPC in all respects. Other information is permitted only to the extent that it supplements (by confirming or specifying) and is compatible with the information in the SmPC.

According to LVFS 2006:9 and the LER Rules, the advertising must at least contain the following information:

- the name of the medicinal product and the generic name if the medicinal product contains only one active ingredient;
- information that is necessary to facilitate the correct use of the medicinal product including any necessary warnings or limitations of use – such information can relate to the need for contact with healthcare personnel for a diagnosis before treatment or if the treatment does not have any effect within a certain time, limitations in treatment for children and pregnant women, or limitations with the duration of treatment;

- an explicit and easy-to-read invitation to take note of the package leaflet or the outer packaging, as the case may be;
- its dosage form;
- contact information of the manufacturer or applicable representative;
- information on the year of publication of the information or, if applicable, the date when the web page was last updated; and
- if the advertising concerns an OTC medicinal product that has an effect against a disease or symptoms of a disease, whether this requires contact with healthcare personnel for diagnosis or treatment, or a recommendation to consult a physician prior to the use of the product.

The price of a medicinal product may be disclosed in an advertisement, but this is not mandatory.

Prohibited Information in Advertising

According to LVFS 2009:6, advertising of medicinal products to the general public may not contain any information that:

- gives the impression that it is not necessary to consult a doctor or that a surgical operation is unnecessary;
- suggests that medicine effects are guaranteed, are without adverse reactions or are better than, or equivalent to, another treatment or product;
- suggests that a person's health can be enhanced by taking the medicine;
- suggests that a person's health may be affected without taking the medicine (with the exception of vaccination campaigns);
- refers to recommendations by scientists, health professionals or other persons, who, because of their celebrity, could increase the use of the medicinal product;
- suggests that the medicinal product is equal to any foodstuffs, cosmetics or other consumer goods;
- suggests that the safety or effect of the medicinal product is due to the content being derived from nature;
- could lead to a wrong self-diagnosis, for instance, by describing a case history;
- contains exaggerating or misleading claims of a cure; or
- contains exaggerating or misleading visual representations of changes in the human body caused by disease or injury.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interaction between pharmaceutical companies and patients is covered by the applicable advertising provisions targeting the general public (in which patients and all members of patient organisations are included). For instance, advertising of prescription-only medicines is explicitly prohibited, and a pharmaceutical company is not allowed to provide free samples to patients when advertising a medicinal product.

Co-operation and Collaboration

The LER Rules contain a comprehensive set of ethical rules with regard to co-operation between pharmaceutical companies, patients/the general public, user organisations and interest groups, such as disability and patient organisations. Collaboration can, for instance, take place around joint disease information activities (meetings, development of patient support programmes or information materials, etc) and joint opinion formation and advocacy work within the framework of a limited activity. In the event of collaboration, an organisation should, if relevant, be contacted or engaged in the first instance.

However, the rules also apply to collaboration with patients who are not members of or represent an organisation, as well as to collaboration with parties related to the patient. The term "related party" herein refers to persons such as the patient's family, relatives, partner, close friends, and others such as a voluntary support person (but not healthcare personnel in their role as service providers). These rules aim to ensure that collaborations, information and training are designed in a way that the parties' independence from each other is not jeopardised or doubted from a legal or ethical point of view. This entails that any collaboration project cannot consist of the main part of an organisation's business and/or economy.

The LER Rules regarding collaborations apply to pharmaceutical companies and comprise collaborations such as research, training, consultancy, information and educational material and market studies.

Transparency and contract

A collaboration between pharmaceutical companies and organisations should be regulated in a written agreement containing provisions regarding the purpose of the collaboration, financing, rights and obligations, etc. Such agreement must be signed by both parties before any collaborative activities are carried out. Any agreement should be kept available for third parties in a short version in the LIF's collaboration database. It is the obligation of the pharmaceutical company concerned to publish the information in the database in accordance with the relevant classification in the database, after the agreement has been signed by all parties and no later than the day the collaboration is carried out.

All projects are published for three years, before being automatically unpublished. All consultation with an individual patient or related party, such as a lecture, advisory board, or other consultation, in its role as a patient or related party, is published according to the same procedure, without any personal data.

Economic and other support

Economic and other support may only be provided to specified projects. A pharmaceutical company may not provide economic or other support that:

- intends to finance the organisation's daily and regular operations;
- results in an organisation's business being unable to continue after the termination of the collaboration agreement;
- causes circumstances of dependency between the parties; and
- exceeds the costs for the activities under the collaboration.

Travel and accommodation for meetings or conferences for individual participants may not be paid for by pharmaceutical companies or requested by individual participants or patient organisations. Participants in meetings may not be offered a fee by pharmaceutical companies and participants are not entitled to receive or request a fee for their participation. Pharmaceutical companies may only offer such meetings as are connected to the pharmaceutical company's areas of business.

Consultation

When a pharmaceutical company engages a representative of an organisation, a patient or a representative from the general public (eg, a related party) for consultation, the pharmaceutical company must ensure that there is a legitimate need for the assignment. The purpose shall be the exchange of knowledge and experience,

for instance that a personal medical experience is shared by the patient and/or related party, or that users who have tested a specific aid (eg, an app) or other patient support, provide feedback to the company about its functionality.

The purpose of a consulting assignment must not be to influence or train the consultant. Thus, it is important to note that the engagement may not constitute encouragement to promote a product or a pharmaceutical company. If the assignment concerns a lecture/patient story directed to health institutions or the general public, the consultant may only share the experience of their, or related ones', illness and possible care, not regarding specific medicines, treatments or vaccinations. Prior to the engagement, the enquiry must be made to the responsible persons within the organisation, who shall decide whether to accept the assignment.

A written agreement should be concluded between the organisation of the representative and the pharmaceutical company, regulating the remuneration for the assignment, which should be reasonable in relation to the performed work and time spent. The pharmaceutical company may pay for travel, boarding and accommodation relating to the consultation assignment provided that the costs are moderate. No other benefits, remunerations or gifts may occur. In relation to public announcements, the pharmaceutical company must announce that the representative is a consultant of the pharmaceutical company.

Information and educational materials

In aids and patient support programmes, no gift items may be provided, offered or promised to organisations and their representatives or patients/related parties. However, product-neutral information and educational materials and aids may be distributed provided that the material is:

- of a value not exceeding SEK450; and
- constitutes relevant information for the general public/patient (eg, regarding a disease).

Pharmaceutical companies may provide product-neutral patient support programmes of various kinds to patients, such as materials, applications, lectures and support, with the primary purpose of safeguarding patient safety and improving the patient's ability to manage their illness. A product-specific patient support programme for prescription-only medicines may only be provided to patients who have been prescribed the product, which may be ensured by information about the patient support programme being provided by the relevant healthcare institution.

General rules

The general rules for co-operation and collaboration must be transparent. In all information materials and invitations, it must be made clear that it is a collaborative project. These rules also apply to advertising or PR agencies.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The Medicinal Products Act and LVFS 2009:6 set out general rules for advertising of medicinal products to healthcare professionals. In particular, LVFS 2009:6 states that all advertising must include essential information that corresponds to the SmPC and the supply classification of the medicinal product. The documentation relating

to the advertising must include the date it was drawn up or last revised.

The advertisement must be accurate, up-to-date, verifiable and sufficiently complete in order for the recipient to form their own opinion about the product's therapeutic value. Furthermore, any quotations, tables or other illustrative material from medical journals or other scientific works that are used in the advertising must include the source.

The LER Rules contain slightly more detailed rules on what information advertising must include. Provided that the FASS catalogue text or the SmPC is not reproduced, the information must, as a minimum, encompass the following data according to the LER Rules:

- the product's name;
- its dosage form and, if required, its strength (it is required to include the strength if the product is offered in different strengths);
- its active ingredients, indicated by the generic name;
- a balanced statement of the product's characteristics, including particulars of the pharmacological group or other accepted group affiliations and indication/area of indications;
- warnings and restrictions in relation to the use of the product;
- name and contact information (address or telephone number or web address) of the manufacturer or of its representative who is responsible for the medicinal product information in Sweden;
- information on the year of publication or the date when the web page was last updated if advertising occurs on the internet;
- information regarding the date the SmPC was compiled or reviewed;
- the status of the product (whether it is a prescription-only or OTC medicine);
- whether the product is included in the Swedish benefits system, including any restrictions, and if it is included in the benefits system, the sales price for the subsidised package (it is, however, not necessary to state the price as such); and
- a reference to fass.se for further information.

Advertising directed to healthcare professionals that do not constitute licensed healthcare personnel has been considered incorrect in the IGN's review.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

As a rule, advertisements of medicinal products may not contain information, such as therapeutic indications, pharmacological properties or other characteristics, which conflicts with the SmPC.

However, according to a decision from the NBL, references to new studies not constituting the basis for the SmPC is allowed in accordance with the judgment from the Court of Justice of the European Union in case C-249/09, Novo Nordisk AS v Ravimiamet. In light of this judgment, claims in advertising may under certain conditions supplement the information in the SmPC. This is conditional on those claims confirming or clarifying – and being compatible with – the SmPC information and not distorting it. This possibility is limited to advertising that targets persons qualified to prescribe or supply medicinal products. The LER Rules have been updated accordingly.

Notwithstanding the above, advertising to persons with no specific medical knowledge must in all parts correspond to the SmPC. It is not necessary to have a literal conformity between

the advertising and the SmPC, but the advertising must have factual support in the SmPC.

5.3 Advertising of Combination Products

There are no explicit rules which address advertising of combination products or companion diagnostics. The general rule is that advertisements of medicinal products may not contain information such as therapeutic indications, pharmacological properties or other characteristics, which conflict with, or are not included in, the SmPC.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

As a main rule, information relating to human health or diseases, such as in the form of a reprint of a journal article, will not be considered as advertising, provided that there is no direct or indirect reference to medicinal products. The same applies to correspondence, accompanied with non-promotional material, which is required to respond to a specific query from a healthcare professional regarding a medicinal product. It should, however, be noted that journal articles concerning unauthorised medicinal products or indications may constitute unlawful pre-launch or off-label advertising.

Furthermore, the LER Rules contain rules regarding the distribution of information and educational material to healthcare professionals. Such material may be provided if it is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and of a direct benefit to patient care.

5.5 Medical Science Liaisons

The general rule is that advertising of unauthorised medicines or indications is prohibited. For instance, providing unsolicited information on unauthorised medicinal products or indications to healthcare professionals may constitute unlawful pre-launch or off-label advertising. Accordingly, the lawfulness of MSLs will depend on whether the discussion of scientific information is purely informational and does not have a commercial purpose. However, if the discussion is considered to be an inducement to, for instance, prescribe off-label use for a specific product, it will be deemed unlawful. This will be assessed on a case-by-case basis.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising of medicinal products is not subject to prior authorisation from or notification to public authorities. However, according to the LER Rules, for the IGN to perform its task as a supervising regulatory body, pharmaceutical companies are required to send new medicinal product information to the IGN, such as publications, advertisements, invitations, mailings or information on websites. This applies for information to both the general public and to healthcare professionals.

6.2 Compliance With Rules on Medicinal Advertising

There are no rules for arrangements or requirements regarding ensuring compliance with rules on medicinal advertising.

Contributed by: Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist,
Advokatfirman Vinge KB

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The same rules are applicable on advertising of medicinal products irrespective of the medium used – ie, the applicable provisions are technology-neutral in this respect. Accordingly, the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules will apply to advertising on the internet and social media.

Moreover, the LIF has adopted interpretative documents which provide guidance on how the LER Rules should be applied on advertising in digital media, such as through social media platforms, mobile applications and podcasts.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

There are no specific restrictions in relation to advertising of medicines in social media channels. Such advertising must always comply with the Medicinal Products Act, LVFS 2009:6, the Marketing Practices Act and the LER Rules.

It should be noted that social media, in its general use, is considered to target the general public. However, certain platforms provide the possibility to target the advertising against a specific group, such as healthcare professionals. For instance, closed groups can be used on Facebook and Sponsored InMail can be used on LinkedIn.

The LIF's interpretative documents highlight a few aspects that should be considered in relation to advertising on social media. For example, it is stated that posting texts regarding new findings may be unlawful pre-launch advertising. Furthermore, it is stated that a pharmaceutical company is responsible for the content on the applicable social media platform. This means that if someone is commenting on the company's post, the company is responsible for removing the comment if, for instance, it concerns information regarding a prescription-only medicinal product, which may target the general public. Also, if a pharmaceutical company uses "social influencers" in its advertising, it is stated that the company is responsible for the content in the influencer's communication.

Demands on Visual and Digital Advertising

A clickable "green box" enables advertisements for OTC medicines on smartphones, tablets, etc, in two steps. The main advertisement must contain mandatory information about reading the package leaflet and indication, and contain a reference to an extended field where other mandatory information is presented. In order to comply with these guidelines, the advertisement must have the following format:

- the advertisement must be marked with a green field in the entire width of the advertisement which should constitute at least one fifth of the total area of the advertisement;
- the green field must be marked with a standardised symbol, a white-coloured cross in a white circle, and the heading "Over-the-counter medicine", as well as the text "Read the package leaflet carefully before use";
- the green field must contain a clickable field or the possibility to scroll on to the remaining part of the mandatory information, marked, for instance, with the text "read more here"; and
- the advertisement and the mandatory information must appear together in a uniform manner and all text reproduced in the advertisement must be easy to read.

7.3 Provision of Disease Awareness Information to Patients Online

Currently, it is not a requirement to implement access restrictions. An identification request is adequate. However, it may be useful to include access restrictions to ensure that the advertising is not targeting the general public.

Further, if a restricted access website includes forum functionalities where website users can discuss a pharmaceutical company's medicines that are authorised for sale in Sweden, this may be associated with difficulties. If healthcare personnel, for example, start discussing off-label prescribing, this may constitute prohibited advertising, for which the pharmaceutical company is responsible.

A pharmaceutical company may not allow healthcare personnel to participate in medicine information and/or express themselves as a guarantor of a particular medicine or advocate a particular treatment. If a forum, for instance, contains too much information about a particular medicine, this may indirectly be interpreted as advertising. This implies that the pharmaceutical company would have to monitor the forum and remove any inappropriate posts, even if access is restricted.

7.4 Online Scientific Meetings

The same rules are applicable on advertising of medicinal products irrespective of the medium used – ie, the applicable provisions are technology-neutral in this respect. Information and/or materials regarding human health or diseases, such as disease awareness campaigns, are not covered by the term "advertising" and are thus allowed provided that the information and/or materials do not include any direct or indirect reference or claim regarding medicinal products.

7.5 Use of Social Media

Online scientific meetings are not separately regulated in Sweden. The regular provisions regarding scientific meetings in the LER Rules apply in relation to restrictions and requirements for sponsorship; please refer to **9.3 Sponsorship of Scientific Meetings**. In relation to information materials, etc, provided during an event, the general rules apply; thus, it is not permitted to offer gifts to healthcare professionals. However, information and educational material may be provided only if the material is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and of a direct benefit to patient care.

Further, advertising of unauthorised medicines or indications is in general prohibited.

This prohibition applies to advertising to healthcare professionals, as well as advertising to the general public. Sending unsolicited information on unauthorised medicinal products or indications to healthcare professionals may thus constitute unlawful pre-launch or off-label advertising. Pharmaceutical companies should include a statement explaining to participants when entering their event to help them understand the context by which the material was developed and to highlight that the content may not be applicable to their country.

National/International Events

Depending on whether the event is marketed exclusively in Sweden or internationally, and whether invitations are sent to Swedish healthcare professionals only or even to international professionals, an online conference may be considered a national or international event. As stated in **3.2 Provision of Information during a Scientific Conference**, during an international event, it is possible to refer to a medicinal

product authorised in another country besides Sweden. It is thus recommended that organisers enable attendee classification for their events.

Prior Authorisation or Approval

No prior authorisation requirement is applied, neither is the new (as of January 2021) requirement from the EFPIA for international congresses to be approved through the e4Ethics system, before a sponsorship is carried out (the requirement applies to physical congresses with more than 500 participants and from more than five countries). It is the responsibility of the pharmaceutical company (if the meeting is arranged by such company) to ensure that content presented at the company's meeting complies with the LER Rules. Ways to ensure this in advance include briefing lecturers and supervising presentation material.

If lectures are recorded to make the information available afterwards, there is also a responsibility to control the material and remove any parts that would be contrary to the LER Rules (for instance, off-label topics that appear through questions in the discussion part).

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Anti-bribery rules are set out in Chapter 10 of the Swedish Penal Code. Under these rules, it is unlawful for an employee or person performing an assignment to receive, accept a promise of or demand an undue benefit for the performance of their employment or duties (bribe-taking). Conversely, it is unlawful for a person to provide, promise or offer an undue benefit to any of the aforementioned persons (bribe-giving). It should be noted that it is not relevant whether the bribe is of any benefit to the receiving person.

Bribe-taking and bribe-giving constitute two independent crimes, irrespective of whether one party would accept the bribe, or vice versa. The rules apply to both the private and public sector.

The rules only apply if the recipient is an individual and not if the recipient is an organisation or a company. However, these entities may be subject to a corporate fine if the company directors have knowledge or should have knowledge that employees are engaging in unlawful activities without taking any action.

Lastly, both the Medicinal Products Act, LVFS 2009:6 and the Marketing Practices Act set out rules on good marketing practice. Giving a bribe to increase the sale of a medicinal product may violate such marketing practice and thus be unlawful under these rules.

8.2 Legislative or Self-Regulatory Provisions

The offering of benefits is generally not recognised in Sweden. Offering benefits to healthcare professionals should therefore take place with great restraint, towards recipients in both the private and public sectors. The Swedish Penal Code, which is described in **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals**, is interpreted against the code of conduct within the industry.

Furthermore, the LER Rules set out comprehensive provisions regarding the co-operation between pharmaceutical companies and healthcare professionals in relation to meetings arranged by pharmaceutical companies or

healthcare companies, consultation and assignments, collaborative projects, etc. These provisions also regulate the offering of meals, alcohol, recreational activities, donations and grants, etc. All employees, as well as senior management, in the healthcare sector and pharmaceutical companies are subject to these rules. According to the LER Rules, the basis for all co-operation is documentation, transparency, reasonability and that it must benefit all parties.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

It is not permitted to offer gifts to healthcare professionals. However, information and educational material may be provided only if the material is of a value not exceeding SEK450, is of a direct professional relevance to the recipient and of a direct benefit to patient care.

Items of medical utility may be provided with the purpose of educating employees and for the care of patients provided that they are of a value not exceeding SEK450 and are not routinely used in the recipient's business.

Furthermore, there are comprehensive restrictions in relation to offering of goods, meals and travel to healthcare professionals.

In any event, the above material may not be offered or distributed as an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to LVFS 2009:6 and the LER Rules, free samples of authorised medicinal products in Sweden may only be provided to:

- those with a pharmacy authorisation or persons responsible for medicinal products at a pharmacy;
- pharmacists at hospital pharmacies (the sample can however only be provided by a healthcare professional);
- other retailers who are authorised to sell the medicinal product; and
- to persons authorised to prescribe the medicinal product.

A pharmaceutical company may only provide a package of the smallest size and the number of samples per product to the same person is limited to one sample per year. In addition, medical samples may only pertain to new products (ie, a product that has been publicly available for less than two years). Each medical sample must be marked with the text "free medical sample, not for sale" or similar and must be accompanied by the SmPC.

Furthermore, a medical sample may only be provided following a written, dated and signed request by the recipient and a careful check must be made to ensure that the person sending the request is authorised to prescribe or dispense the medicinal product. A medical sample may not constitute an incentive to recommend, prescribe, purchase, sell or administer medicinal products.

9.3 Sponsorship of Scientific Meetings

A pharmaceutical company can organise or pay for meetings targeting healthcare professionals. This entails that a company may finance venues,

lectures, study materials and meals that are necessary to carry out the meeting.

A main and general condition for arranging or sponsoring a meeting is that the scientific and professional programme constitutes the dominant part and purpose of the meeting. The meeting may only concern the company's own business areas.

Meals and Travel

Meals should be moderate, and they may only be served in connection with the meetings. Alcoholic drinks must be limited and only be served in connection with meals (spirits may never be offered).

Travel and accommodation for participants may not be financed by the company or requested by the participants. Further, participants may not be offered fees from the pharmaceutical company and the participants are not allowed to request fees for their participation.

Sponsoring Events

Pharmaceutical companies may arrange or sponsor events taking place abroad if the majority of the participants come from another country besides Sweden or if relevant knowledge or experience cannot be obtained in Sweden. The choice of location and venue must be reasonable. For instance, seasonal leisure resorts and other luxurious or exclusive places should be avoided (eg, a ski resort during the winter season). The same applies to locations where major international events are being held in connection with the meeting (eg, sports events).

Events by Healthcare Institutions

For events jointly arranged by the healthcare institutions and the industry, such as meetings organised by the healthcare institutions, including its professions, and the industry where the parties share responsibilities and costs, there is no sponsorship situation as all parties are deemed organisers.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not allowed to finance social or recreational activities in connection with meetings (and these may not be requested by healthcare professionals). However, simple social activities (eg, background music or local performances) are allowed if they are not organised or requested by the pharmaceutical companies.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Donations to the healthcare sector are permitted provided that they are made to support research and development. The support in this regard must be intended to be used for real research and development and it may not be given on vague grounds, such as to a healthcare association which "works towards more research" within a certain area.

Donations may not be provided or requested with the purpose of financing healthcare professionals' or healthcare institutions' social activities or regular business operations. Furthermore, there cannot be any connection between the donation and past, present or future use, recommendation, sale or prescription of the donor's products or services. In addition, the donation may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The general limitations on gifts and other benefits as described earlier in **9. Gifts, Hospitality, Congresses and Related Payments** in principle ensure that rebates and discounts cannot be provided to healthcare professionals.

There is no explicit prohibition with regards to rebates and discounts to healthcare institutions. It has been the case that county councils ("Regions") which are handling the purchase of medicinal products have entered into agreements with pharmaceutical companies where the company has provided a discount on a medicinal product. These agreements have been subject to criticism, in particular concerning medicinal products that are included in the Swedish benefits system.

Consequently, the Swedish government and the Swedish Association of Local Authorities and Regions have concluded an agreement stating that no agreements regarding discounts on medicinal products included in the Swedish benefits system may be entered into between Regions and pharmaceutical companies. If agreements are concluded, the government's financial contribution to that Region will decrease, with an amount corresponding to the discount.

Furthermore, there may be instances where discount arrangements may give rise to unlawful inducements – eg, if a discount applies only after a healthcare provider has purchased a certain number of products.

9.7 Payment for Services Provided by Healthcare Professionals

The LER Rules contain provisions regarding employees and executives in the healthcare sector and their engagements with pharmaceutical companies, including in relation to research, education, conferences, product development and their participation on advisory boards. In order for a pharmaceutical company to engage the healthcare professional, there must be a legitimate need to carry out the assignment.

The assignment must be agreed upon in writing between the healthcare professional, its employer and the pharmaceutical company. The agreement should explicitly specify the services to be carried out and how remuneration is to be regulated. Any remuneration must be reasonable in relation to the nature of the assignment and the time spent. Any reimbursement of expenses must follow the employer's rules for travel and expenses. No other benefits, remuneration or gifts may be provided. If the healthcare professional carries out the assignment as part of normal work duties, the compensation must be paid to the employer.

In the agreement referred to above, there must be an obligation for the healthcare professional to declare that they are a consultant to, or a part-time employee of, the company when they express an opinion in public on a topic relating to the assignment. Also, a consultant should be urged to be transparent with their assignment in relation to other assignments mandated by public authorities or expert bodies.

The engagement with the healthcare professional may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

When engaging a healthcare professional for an assignment, consent must be obtained from the healthcare professional's employer through a written agreement; see **9.7 Payment for Services Provided by Healthcare Professionals**.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The LER Rules implement the 2013 EFPIA code of disclosure whereby value transfers in the form of sponsorships, donations and remunerations for consulting services will be made public. Pharmaceutical companies acting on the Swedish market must therefore publicly disclose the persons or organisations in Sweden that have received value transfers in a given year and the total value of these value transfers.

Value Transfers

A value transfer refers to direct or indirect transfers in cash or in kind, to or for the benefit of recipients, which are made in development or sale of a medicinal product for human use, irrespective of whether the purpose is promotional.

For value transfers to healthcare professionals, the pharmaceutical company must report the name and address where the person is mainly operating, consultancy fees and expenses for assignments, such as travel and accommodation.

For value transfers to healthcare organisations, the pharmaceutical company must report the name (eg, hospital, clinic, association) of the organisation, where the organisation mainly carries out its business, donations, contributions to expenses of certain activities (eg, sponsorship costs), consultancy fees, and expenses for assignments, such as travel and accommodation.

Meals, Travel and Accommodation

There is no obligation to report meals (eg, in relation to conferences), information and education material or items of medical utility. Conference fees as well as financing of travel and accommodation in connection with meetings/conferences are not relevant for Sweden since such arrangements are no longer allowed (since 1 January 2015); see **9.3 Sponsorship of Scientific Meetings**.

The disclosure should be made in accordance with the template in Appendix 1 to the LER Rules. It must be made in Swedish, but it is recommended that it is made in English as well. The disclosure can be made in either the LIF's co-operation database or on the pharmaceutical company's website. If disclosure is made on the website, a link to the report must be made in the LIF's co-operation database.

The GDPR

In light of the General Data Protection Regulation (EU) 2016/679 (GDPR), private companies as well as public authorities must comply with comprehensive new legal requirements on the processing of personal data. This has an impact on the publishing of value transfers. According to the LIF's opinion, written consent is required from the relevant healthcare professional (eg, a consultant) in order to disclose a value transfer. With regards to healthcare institutions, such as

hospitals, clinics, organisations or a limited liability company, consent is not required according to the LIF.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Disclosure must be made in accordance with rules of the national code that is applicable in the country where the recipient has its principal place of business or its seat. If any of these two are located in a country other than Sweden, and if the pharmaceutical company lacks the ability to disclose the value transfer through a group company in the country of destination, the pharmaceutical company must disclose the value transfer in accordance with the LER Rules.

The above rules are applicable to pharmaceutical companies that are members of the LIF, FGL, IML and EFPIA.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The MPA is responsible for the supervising and enforcement of compliance with the Medicinal Products Act and regulations issued under it (eg, LVFS 2009:6). In the case of unlawful advertising, the MPA has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance. Decisions by the MPA can be appealed to the Administrative Court in Uppsala.

The Swedish Consumer Agency is responsible for enforcing the general rules on advertising. The Swedish Consumer Agency is led by a Director General who is also the Consumer Ombudsman that represents consumer interests and has authority to issue prohibitive injunctions combined with a conditional fine for non-compliance with the Marketing Practices Act. Decisions by the Consumer Ombudsman can be appealed to the Patent and Market Court. The Consumer Ombudsman may also, under certain conditions, pursue legal action in court, where the Patent and Market Court and the Patent and Market Court of Appeal are the competent courts.

The IGN and the NBL are the self-regulatory bodies under the LIF. The IGN's competence comprises the review of medicinal product information and it determines, on its own initiative or after complaints, whether the pharmaceutical companies' marketing activities comply with good marketing practice. It may also refer a matter to the NBL. The NBL's competence includes handling appealed matters from the IGN or the LIF's compliance officer and being first and last instance in matters where a public authority has filed a complaint regarding advertising of medicinal products.

The rules relating to inducements in criminal cases are enforced by prosecutors under the Penal Code in civil courts (District Courts, Courts of Appeal and the Supreme Court).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

A company may file a complaint to the MPA, which may decide to initiate a supervisory matter. A company may also initiate legal actions for unfair advertising before the Patent and Market Court. Furthermore, it is possible to notify the IGN on advertising that is not compliant with the LER Rules.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The main sanction for violations of the advertising rules in the Medicinal Products Act is a prohibitive injunction combined with a conditional fine for non-compliance.

Furthermore, the Marketing Practices Act includes numerous sanctions depending on the nature of the violation. For instance, the provisions regarding misleading advertising may result in the following sanctions issued by the Patent and Market Court:

- prohibitive injunction – this is normally issued with a conditional fine, which according to the Court's practice generally amounts to approximately EUR100,000, though the conditional fine may be adjusted according to the circumstances on a case-by-case basis;
- special fine (fine for disruptive marketing practices) – if imposed, the amount of a market disruption charge is calculated on the basis of the trader's turnover, and the amount varies on a case-by-case basis from approximately EUR1,000 to EUR1 million, but cannot exceed 10% of the trader's yearly turnover; and
- third-party damages provided that the trader has intentionally or negligently violated the prohibition on, for instance, misleading marketing and that another trader or a consumer has suffered damages thereby.

An action before the Patent and Market Court may be pursued by the Consumer Ombudsman, a competitor, a consumer or a trade or consumer association. It should also be noted that both the MPA and the Consumer Ombudsman may issue an injunction combined with a conditional fine, which the trader may accept in order to avoid legal proceedings in court.

Many matters are handled by the IGN and the NBL. Both individuals and pharmaceutical companies may pursue an action before the IGN. The IGN's and the NBL's competence derives from contractual relationships with the members. Under this authority, the IGN and the NBL may fine members who violate the LER Rules. Fees determined by the IGN and the NBL may not exceed SEK500,000.

11.4 Relationship Between Regulatory Authorities and Courts

As stated in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**, the LER Rules are recognised by the pharmaceutical industry and the decisions from the IGN and the NBL may be considered by courts in relation to good marketing practice.

Proceedings initiated before the IGN or the NBL may be filed in parallel with a proceeding before a court or a public authority.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

No deviating enforcement trends relating to the rules governing advertising of medicinal products have been noted in Sweden. However, it should be noted that the increased use of social media has led to a number of enforcement actions in the past few years as well as recently updated social media and digital advertising guidelines by the LIF.

The social media guideline describes the most widely used digital channels in Sweden (eg, social media platforms, mobile applications and podcasts) and how they can be used to com-

municate to the public as well as to healthcare professionals.

The digital advertising guideline imposes a standard for the visual design of digital advertising, with the purpose of ensuring a balance between advertising messages and mandatory information, which satisfies user-friendliness and all regulatory and industry ethical requirements (despite the limited screen size and advertising space) that advertising in mobile devices entails. Since the development of digital channels is rapid, documents are continuously updated, and it is valuable for pharmaceutical companies to stay updated in relation to these guidelines.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

As of 1 January 2018, the LIF is no longer responsible for self-regulation and market surveillance of veterinary medicinal products. Instead, the Nordic association Veterinary Industry Nordic (ViNordic) is the self-regulatory enforcement body for veterinary medicinal products in Sweden.

In addition to the MPA and the Swedish Consumer Agency (the national enforcement bodies described in **11.1 Pharmaceutical Advertising: Enforcement Bodies**), ViNordic's marketing board handles, rules and administers fines on marketing matters among its member companies. According to the statutes of ViNordic's marketing board, the MPA, ViNordic's members and other parties who prescribe, deal as a wholesaler or retailer, use or dispense registered veterinary medicinal products in Sweden may pursue an action before ViNordic's marketing board. Consequently, in contrast to the IGN, as described in **11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe**, individuals (ie, consumers) may not pursue an action before ViNordic's marketing board.

Under this authority, ViNordic's marketing board may fine members who violate the applicable laws and rules. Fees determined by ViNordic's marketing board may not exceed SEK50,000.

In contrast to the LIF, ViNordic does not have its own ethical statutes for advertising veterinary medicines in Sweden. Instead, when handling and ruling on marketing matters, ViNordic's marketing board applies, inter alia, the following:

- national and EU law and case law;
- national authority regulations;
- older LER Rules editions containing rules for the veterinary industry;
- previous IGN and NBL decisions; and
- decisions of ViNordic's marketing board.

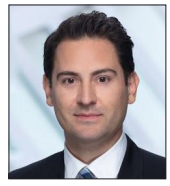
Against this background, the advertising rules for veterinary medicinal products are, in principle, fairly similar to those for human medicinal products, although less extensive as regards the self-regulatory framework and enforcement.

Contributed by: Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist,
Advokatfirman Vinge KB

Advokatfirman Vinge KB is a full-service business law firm with offices in Stockholm, Gothenburg, Malmö, Helsingborg and Brussels. The firm's intellectual property and life sciences groups, which consist of approximately 35 lawyers, have expertise in marketing-related consultancy in specialised sectors such as the biotechnology, pharmaceuticals and med-tech industries, and have extensive experience of legal market assessments, including advertising campaigns, product launches, product liability, compliance, marketing and advertising strategies. The team is continuously assisting both national and international pharmaceutical companies with negotiation and drafting a wide range of pharmaceutical-related agreements, as well as with advertising and compliance within the pharmaceutical sector.

Authors

Håkan Borgenhäll is a partner in the intellectual property group at Advokatfirman Vinge KB. His practice focuses on intellectual property and marketing law, particularly contentious matters. Håkan has served as an expert in the governmental committee in relation to the newly amended Swedish Patents Act. He was involved in the Swedish preparations for the coming Unitary Patent Court (UPC), and is involved in proposed amendments to Swedish intellectual property laws. Håkan has been the leading counsel in some of the most important patent disputes in recent decades, including litigation-related blockbuster pharmaceuticals and SPC disputes.



Stojan Arnerstål is a counsel and the head of the life sciences and health sector group at Advokatfirman Vinge KB. Stojan has special knowledge of and experience in advising clients within the life sciences sector, with a focus on transactional intellectual property and commercial agreements. He was previously an associate professor at the Institute of Intellectual Property, Marketing and Competition Law (IMC) at Uppsala University. He regularly teaches at the universities in Uppsala, Stockholm and Lund and is the author of several books.

Contributed by: Håkan Borgenhäll, Stojan Arnerstål, Åsa Hellstadius and Lisa Hörnqvist,
Advokatfirman Vinge KB

Åsa Hellstadius is a senior manager at Advokatfirman Vinge KB and a Doctor of Laws (LLD) in Intellectual Property Law with a specialisation in Patent Law. She advises clients on all matters related to intellectual property, and has extensive knowledge of legal issues related to life sciences. Åsa is regularly engaged in patent infringement and invalidity disputes, often in disputes of an international character. She is also the author of several books in the field of intellectual property.

Lisa Hörnqvist is a senior associate at Advokatfirman Vinge KB. She works in the corporate commercial practice group and advises on matters relating to life sciences, marketing, technology and data privacy.

Advokatfirman Vinge KB

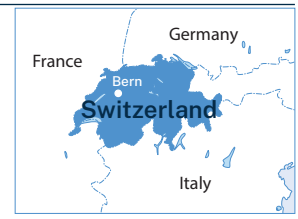
Smålandsgatan 20
Box 1703
SE-111 87
Stockholm
Sweden

Tel: +46 10 614 3000
Fax: +46 10 614 3190
Email: contact@vinge.se
Web: www.vinge.se

SWITZERLAND

Trends and Developments

Contributed by:
Oliver M Brupbacher and Claudia Götz Staehelin
Kellerhals Carrard see p.346



The Main Drivers in Swiss Pharmaceutical Advertising

Background

The pharmaceutical advertising landscape is undergoing significant changes, and the regulation of pharmaceutical advertising is being challenged by new and increasingly sophisticated demands. The "pen-and-notepad" days when promotional practice and regulation predominantly focused on direct advertising and gifts are definitely over. In their wake, pharmaceutical advertising is becoming ever more multifaceted and complex, as it develops towards fully integrated and often digital stakeholder relationship solutions. At the same time, it is becoming increasingly relevant to neighbouring legal fields such as compliance, litigation and investigations, as well as information governance and data protection.

Crucially, co-operation between the industry and various stakeholders along the entire therapeutic products development and value chain is gaining ever greater importance. Never was this more prominent than during the COVID-19 pandemic. Without manifold co-operation between the industry, research and healthcare professionals, as well as their organisations, research and development would have advanced far less quickly, and therapeutic products would have been less well targeted and would have entered the market much later.

Statistics of the regulatory disclosures of pecuniary benefits granted by pharmaceutical companies in Switzerland show that the amounts paid to healthcare organisations remain at a high level (CHF93 million in 2020), while the payments to HCPs significantly decreased (CHF6 million in 2020) and the transfers of value for research and development significantly increased (CHF83.5 million in 2020). While the latter fluctuations are probably largely due to the COVID-19 pandemic, the numbers are still high compared to other European countries, and it remains important that all parties involved in such collaborations act according to high ethical standards.

Patients as customers

Complementing the traditional focus on prescribers, patients and their organisations are increasingly being recognised as the true customers of healthcare. As patient-focused alliances become more widespread, integrity and transparency will become ever more crucial. This affects the entire therapeutic product life cycle, from the identification of unmet medical needs, to research and development, to the launch – where better informed regulatory approval discussions and patient-centred value stories come into focus – and the commercialisation, including generation of real-world product knowledge, improvement of the patient experience and treatment adherence, and support for access and reimbursement.

Digitalisation

The pharmaceutical advertising landscape is also shaped by the progress in digital technologies and by a shift to electronic advertising that

was fuelled in part by the COVID-19 pandemic. Meanwhile, the number of advertisements for professional promotion in the relevant Swiss trade media is estimated to have fallen by 20% in 2021. Digital engagement of patients and healthcare professionals can take many forms, such as:

- marketing and communication to raise disease and brand awareness;
- patient community-building on social media;
- patient education and training;
- support for treatment adherence and monitoring;
- patient-generated health data;
- wearables, apps and devices;
- pharma-as-a-service;
- big data; and
- personalised and precision medicine.

At the same time, a new style of patient advocacy is gaining traction, driven by the increasing focus of the pharmaceutical industry on rare diseases and orphan drugs.

The regulatory environment

In a regulatory environment shaped by a ban on pre-approval marketing and direct-to-consumer advertising of prescription drugs, such as in Switzerland, pharmaceutical companies seek to navigate this challenging landscape with multiple different strategies, including:

- disease awareness programmes;
- dissemination of scientific drug information; and
- indirect communication through healthcare professionals, healthcare organisations, patients, and patient organisations.

Meanwhile, the limits for permissible pharmaceutical advertising are narrow, and enforcement in this area is active, with competitors frequently bringing claims against each other and authorities issuing fines and other orders. Reputational considerations play an important role too, and put a spotlight on integrity and transparency in particular.

In Switzerland, a series of regulatory and self-regulatory measures and initiatives have recently been, and are still being, put into effect to reflect these changes in the pharmaceutical advertising landscape. They are spread over various different, and partially disparate, regulations, guidelines and best practice codes. This makes navigating the landscape dependent, in large part, on legal and regulatory expertise as well as extensive practical industry experience.

New Regime on Integrity and Transparency

As of 1 January 2020, a new integrity and transparency regime was introduced into the recently amended Therapeutic Products Act (TPA). The amended regulation shows obvious parallels with the criminal law on corruption in the Criminal Code (CC). The new Ordinance on Integrity and Transparency in the Therapeutic Products Sector (OIT) contains the implementing provisions. A parliamentary initiative that requires disclosure by hospitals and doctors of their vested interests is currently pending.

Factors influencing treatment

To enhance integrity, the granting and acceptance of pecuniary advantages in connection with prescription medicinal products are prohibited if they can influence the choice of treatment. Article 55 paragraph 2 TPA and Articles 3 et seq OIT explicitly describe the advantages that are considered permissible. These are, for example:

- advantages of modest value that are relevant for medicinal or pharmaceutical practice;

- support for research, education and training as long as certain criteria are met; and
- compensation for equivalent services in return.

Price discounts and refunds granted on the purchase of therapeutic products are also permitted if they do not influence the choice of treatment. Healthcare professionals are obliged to pass on these benefits to their patients or their insurers. As a result of a parallel amendment to the Health Insurance Act (HIA), healthcare professionals can agree with insurers to use a smaller portion of the obtained advantages for quality improvement measures (Article 56 paragraph 3 lit b, paragraph 3 bis HIA). As a second core element of the new regime, the granting and acceptance of price discounts and rebates for the purchase of therapeutic products (medicinal products and medical devices) must in principle be made transparent to the Federal Office of Public Health (FOPH) upon request (Article 56 TPA; Article 10 OIT). The distinction between discounts and equivalent compensation often proves difficult in practice.

Violations

Violations of Articles 55 et seq of the TPA may trigger administrative measures or criminal sanctions against the acting individuals (Articles 66 et seq, Article 86 paragraph 1 lit h, Article 87 paragraph 1 lit h TPA), or even against the companies or their management (Articles 6 et seq Administrative Criminal Law Act; Article 102 CC).

Clinical trials

Beyond the realm of therapeutic products marketing, integrity provisions apply in particular in connection with clinical trials of therapeutic products (Articles 53 et seq TPA; Human Research Act). Persons involved in clinical trials with medicinal products and medical devices, including the sponsor, must maintain scientific integrity and in particular must disclose conflicts of interest (Article 3 Clinical Trials Ordinance (ClinO), Article 3 paragraph 1 lit a Ordinance on Clinical Trials with Medical Devices, amended as per 26 May 2022 to also apply to in vitro diagnostics).

Increasingly Strict Self-Regulation for the Majority of Swiss Pharmaceutical Companies

Pharmaceutical self-regulation is dominated by the Pharma Code and the Pharma Cooperation Code of the Pharmaceutical Industry in Switzerland (the "Pharma Codes"). These codes cover the entire range of medicinal products – ie, both prescription and non-prescription, patented originals as well as generics and biosimilars (but not medical devices) and have been adopted by the respective industry associations:

- scienceindustries (*Wirtschaftsverband Chemie Pharma* Life Sciences);
- Interpharma (*Verband der forschenden pharmazeutischen Firmen der Schweiz*);
- vips (*Vereinigung Pharmafirmen in der Schweiz*);
- ASSGP (*Schweizerischer Fachverband für Selbstmedikation*); and
- Intergenerika (*Schweizer Verband der Generika und Biosimilar Firmen*).

Members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are required to sign the respective country codes. Accordingly, the majority of pharmaceutical companies in Switzerland are bound by the Pharma Code (127) and the Pharma Cooperation Code (60).

The Swiss Academy of Medical Sciences (SAMS) Guidelines on collaboration between the medical profession and industry were comprehensively

revised in August 2022 in accordance with the new integrity and transparency provisions of the TPA and the OIT, as well as international recommendations and industry codes. Among others, they now also cover virtual events, and they recommend the disclosure of vested interests and pecuniary benefits. Their scope of application is extended beyond physicians to now also cover other healthcare professionals.

Above and beyond legal requirements

While state law and regulations focus on protecting human health in connection with the use of therapeutic products, self-regulation is intended to prevent undue competition and unethical market behaviour. The Pharma Codes generally reflect the legal requirements, but often go beyond them. A Code Secretariat is entrusted with supervision of compliance with the Pharma Codes (Section 7 Pharma Code; Section 5 Pharma Cooperation Code).

In broad terms, the Pharma Code contains the general integrity rules both in the analogue and digital spheres, and the Pharma Cooperation Code contains the requirements for disclosure and transparency of pecuniary benefits to healthcare professionals, healthcare organisations and patient organisations. Unlike the Pharma Code, the Pharma Cooperation Code is limited to interactions in the context of prescription medicinal products (Section 11.2.1). This is because the purpose of disclosure is generally understood to create transparency with regard to any influences on prescribing behaviour.

Integrity and transparency

Following the above-mentioned revision of the TPA and the coming into force of the new integrity and transparency regime pursuant to the OIT, as well as the Code Consolidation of the EFPIA, the Pharma Codes have also been comprehensively revised. The revised codes came into force on 1 January 2021.

The Pharma Code has traditionally adopted a stricter approach to integrity than that adopted by state regulation. For example, it completely prohibits any offer or payment for entertainment and other leisure or hospitality activities (Section 32.5). The integrity provisions of the revised Pharma Code (Section 15) have now been updated and further tightened to align with Article 55 of the TPA and the OIT.

Accordingly, donations and grants (ie, money, assets or services not intended as compensation for a contribution that is delivered in support of healthcare, scientific research or medical training) may only be awarded to healthcare and patient organisations, but never to healthcare professionals (with the exception of support contributions for participation in continuing education and training, Article 6 OIT). Their range of permissible purposes has been restricted, and they have to be documented in writing in order to avoid a misuse of funds (Sections 15.5 et seq Pharma Code).

In order to clarify that allowances for meals are only permissible in consideration of an equivalent service (Article 7 OIT), such allowances are now only permissible in the context of expert discussions and events, whereby the limit per healthcare professional per meal has been reduced to CHF100 (Section 15.4 Pharma Code). This goes beyond statutory law, which allows this limit to be exceeded, subject to a written agreement. Furthermore, a new bid on multi-sponsoring has been introduced, whereby healthcare and patient organisations may not generally be required to exclusively support a pharmaceutical company (Section 15.7 Pharma Code).

As regards transparency, the self-regulatory obligation to disclose pecuniary benefits to healthcare professionals and healthcare organisations in the context of prescription medicinal products (Sections 24–29 Pharma Cooperation Code) has traditionally gone beyond Article 56 of the TPA and Article 10 of the OIT, which are limited to the disclosure of price discounts and rebates and do not apply to pecuniary benefits in their entirety. The revised Pharma Cooperation Code now aligns the disclosure requirements for pecuniary benefits to patient organisations with those for healthcare professionals and healthcare organisations (Section 36.1). To achieve as much transparency as possible, disclosure should, wherever possible, be made on an individual basis (Section 25.1). In fact, average consent rates to transparency disclosure by healthcare professionals and healthcare organisations are high in comparison with other European countries.

The Thin Line Between Information and Advertising

In Switzerland, advertising of prescription medicinal products to the general public is prohibited (Article 31 paragraph 1 TPA; Articles 3, 14 Ordinance on Advertising of Medicinal Products (OMPA); Sections 21 et seq Pharma Code). This is why the often thin line between information and advertising is particularly key to the co-operation and communication strategies of pharmaceutical companies.

Advertising of medicinal products is defined as all information, marketing and incentivising measures aimed at promoting the prescription, administration, sale, usage or application of specific medicinal products (Article 2 lit a OMPA). All advertising must be in accordance with the information about the medicinal product, and may only promote the indications and possible applications most recently approved by the Swiss Agency for Therapeutic Products (Swissmedic; Article 32 paragraph 1 lit c TPA; Article 5 paragraph 1, Article 16 paragraph 1 OMPA; Sections 23.1 et seq Pharma Code).

An activity qualifies as pharmaceutical advertising if a multitude of people are influenced by certain measures or if incentives are created that are intended to lead these people to change their consumption behaviour. Even the mere provision of information on the possible uses of medicinal products constitutes advertising if it is intended and able to influence consumer behaviour. That said, not every piece of information that creates a link to a specific medicinal product always qualifies as advertising. The boundary between information and advertising cannot be determined in an abstract manner, but depends on the entire circumstances of the individual case (Federal Administrative Court C-5490/2015, 28.3.2017, at 6.4.1; C-2798/2020, 27.8.2021, at 6.1.6 et seq).

Interactions between pharmaceutical companies and stakeholders in the healthcare sector

Against this background, the focus in modern industry practice is on the following direct and indirect interactions between pharmaceutical companies and the various stakeholders in the healthcare sector:

- patient engagement;
- pre-approval information to healthcare professionals;
- scientific engagement with healthcare professionals and healthcare organisations;
- continuing medical education and training;
- post-approval studies; and
- media releases, investor presentations and securities disclosures.

In recent practice, there has been a general tendency towards fully integrated digital customer relationship-solutions that span across channels and functions and include marketing, sales, medical, service, clinical and commercial. Current legislation and case law do not yet adequately reflect this trend.

Patient and pre-approval information

Patient engagement, such as disease awareness campaigns and similar patient communications that are limited to generic information about health, diseases, etc, is allowed in principle as long as it avoids any direct or indirect reference to individual medicinal products (Article 1 paragraph 2 lit c OMPA).

Pre-approval information to healthcare professionals (eg, at a medical conference or through medical science liaisons) and the media is allowed in principle if the aim is to provide or obtain scientific input on unauthorised medicinal products or indications, thereby avoiding any promotional activities, and as long as it is clearly stated that the medicinal product, indications, possible application, dosage, pharmaceutical form or packaging have not yet received marketing authorisation from Swissmedic. To that end, care must be taken to ensure that the information is provided directly to healthcare professionals or to the medical department of a healthcare organisation, and not to its marketing or sales department or even to patients. The same applies in principle to so-called managed access programmes, such as for compassionate use (Article 9b paragraph 1 TPA). In order to reflect this situation in a systematically correct way, the revised Pharma Code moved the rules on pre-approval information about medicinal products from the events section (Section 3), where they were traditionally placed, to the section on professional promotion of, and information about, medicinal products (Section 26).

Scientific engagement

In the field of scientific engagement – ie, scientific interactions between pharmaceutical companies and prescribers – the revised Pharma Code incorporates the previous recommendations in the context of distribution of advertising to healthcare professionals. Accordingly, professional promotion may only address those healthcare professionals and healthcare organisations that may reasonably be assumed to need, or be interested in, specific information in the performance of their activities. Digital communication, including through social media, must, whenever possible, be disseminated with the recipients' prior consent (Section 29).

The revised Pharma Code also implements the requirements for continuing medical education and training which have been developed in the context of the EFPIA Code of Practice. While the revised Pharma Code recognises the importance of, and the need for, participation and contributions by the pharmaceutical industry in medical training and education, it maintains that:

- such activities may not count as promotion;
- the pharmaceutical industry is responsible for making its activities known; and
- the content must be fair, balanced and objective and allow conclusions about different theories and accepted opinions (Section 31).

Furthermore, the revised Pharma Code introduces certain clarifications in the context of post-approval studies using authorised medicinal products, which are again based on the EFPIA Code of Practice. These clarifications are of particular interest in the context of real-world evidence studies that seek to obtain clinical evi-

dence regarding the usage and potential benefits or risks of a medicinal product, such as from product and disease registries, health records, patient-generated data – including in home-use settings and through apps – as well as insurance claims and billing activities. In order to ensure their integrity, such studies have to comply with recognised scientific standards and methods (Section 57). Equally, if professional promotion refers to investigations such as meta-analyses (combining the results of multiple scientific studies), pharmaco-economic studies (evaluating the cost and effects of therapeutic products) or field reports from practice, these must have been published in a recognised scientific medium (Section 25.7).

Challenging communication

Lastly, with growing competition among pharmaceutical companies in many areas, there has been a greater willingness to challenge hitherto unchallenged communication forms such as media releases and even investor presentations and securities disclosures, in particular in connection with marketing authorisations or reimbursement decisions. Such releases are allowed in principle, even if they relate to individual medicinal products, as long as they do not constitute advertising within the meaning of Article 2 lit a of the OMPA. Thereby, the precise limits where information ends and advertising starts can be difficult to establish. This delimitation can become even trickier where information obligations to investors under applicable stock exchange regulations have to be weighed against the prohibition under the therapeutic products law of advertising prescription drugs to the general public.

In this context, Swissmedic ruled that the information must be strictly limited to scientific, technical, organisational or financial aspects of a company's activities that are of interest to investors, and that they must under no circumstances be aimed at promoting a medicinal product. In the context of any presentation of new medicinal products or substances in development, as well as of the future prospects and focal points of research and development activities, only the product name, the active ingredient (Denominatio Communis Internationalis) as well as the therapeutic area or field of application may be given. Information addressed to investors and financial analysts may contain details and forecasts regarding turnover, market share and sales volume, but no further statements on the therapeutic benefit of medicinal products (Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09).

In addition to the restrictions on communication motivated by public health, conflicts between competitors under unfair competition law are also increasingly coming to the fore, as determined by the Pharma Code and the Federal Act against Unfair Competition.

Opportunities and Challenges of Digitalisation

There is no dedicated or comprehensive regulation for pharmaceutical advertising in the digital space in Switzerland. That said, the issues have been addressed in various regulatory and self-regulatory initiatives, most recently by the Pharma Codes Secretariat in its (non-binding) January 2021 Recommendations for using digital channels: professional promotion, continuing education and social media (the "Recommendations").

First and foremost, digital advertising raises complex questions of cross-border application of law. While the provisions on pharmaceutical advertising of the TPA and the OMPA are generally considered to be enforced only for websites

with Swiss domain names, the Recommendations recognise the particular nature of digital media that makes it difficult to limit its geographic sphere of influence. Accordingly, they adopt the general recommendation to structure such information or promotional measures to comply with the national regulations for the geographic area that is their primary target. They recognise the established practice that websites of country organisations focus on a national audience, while the websites of corporate group entities address a wider, more international audience and should at least comply with the national laws that apply at the corporations' headquarters. At the same time, the recommendations stress that information disseminated digitally should be structured so as to ensure that it meets other implicit conditions, which could mean that such information must meet the requirements of several legal systems at the same time (Chapter A.1).

The Recommendations adopt the general principles of responsibility and transparency. With respect to the former, companies are responsible for all medicinal product information and advertising initiated by them, regardless of the channel that is used. This applies to links to other websites as well as to interactive communication platforms (such as blogs and social media) and electronic media activities of their employees (Chapter A.2; see also Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09). The latter means that, when using digital channels, the owner or sponsor of the channel must always be identified by way of its physical and electronic address (Chapter A.3; see also Section 23.7 Pharma Code).

Electronic advertising

According to conventional understanding, electronic advertising, such as on the internet or via social media, without any access restriction, qualifies as advertising to the general public (Article 15 lit c OMPA). In 2019, the OMPA was amended to specify that, in order for professional advertising via electronic means to be compliant, its access must be restricted, by appropriate technical and password protections, to professionals authorised to dispense or apply medicinal products (Article 5a OMPA; Chapters A.4, B.2 Recommendations). The same applies to media releases and press kits in which direct or indirect reference is made to specific prescription medicinal products. These may only be accessible to media professionals and must be password-protected (Swissmedic Guidelines for the advertising of medicinal products on the internet, 2007/09).

Swiss legal literature discusses the question of whether, in the age of electronic advertising, the distinction as to whether an advertisement is to be understood as public or professional should be based more on the content of the advertisement and its presentation than on access, including the distinction between push- and pull-information (dissenting: Federal Supreme Court 2A_20/2007, 9.5.2007, at 8). The new Recommendations address various digital communication channels in particular, such as email, websites, webinars, podcasts, blogs, apps and social media, and they propose solutions to specific problems that may arise with regard to their use (Chapter B).

Harmonisation of the Rules for Medical Devices

Medical devices have traditionally been regarded as less hazardous than medicinal products. This has led to inconsistencies in the regulation of advertising between these two categories of therapeutic products. However, the issue has been recognised, and attempts at greater harmonisation are underway.

While Article 56 of the TPA on transparency applies to therapeutic products in general, only prescription drugs, and not medical devices, are currently subject to Article 55 of the TPA and the respective provisions of the OIT, despite the commonality of the underlying concern – ie, to ensure that treatment decisions are not influenced by economic incentives. Parliament decided to amend Article 55 of the TPA and the OIT to subject persons, and their employer organisations, that prescribe, dispense, use and purchase for this purpose medical devices to the same integrity requirements that apply to medicinal products. The entry into force of the revised provisions is not expected before 2025. Until such time, potential sanctions are regulated in particular by the general bribery provisions of the CC (see Articles 322 ter et seq, 322 octies et seq), which in the meantime leads to different legal standards, especially in the area of benefits and advantages granted to healthcare organisations.

Advertising for medical devices

In the context of the new Medical Devices Ordinance (Article 69) and the new Ordinance on In Vitro Diagnostics (Article 62), provisions on advertising for medicinal products have been introduced.

Advertising for medical devices may also be subject to self-regulation, namely the Swiss Medtech Code of Ethical Business Practice of the industry association Swiss Medtech, which has been established in line with the Code of Ethical Business Practice of MedTech Europe. The purpose of the Ethics Code is to increase transparency and protect integrity in all interactions between members of Swiss Medtech and healthcare professionals, as well as healthcare organisations, in compliance with national and local laws, regulations, or other professional codes of conduct. The comprehensively revised SAMS Guidelines on collaboration between the medical profession and industry now also address medical technology in greater depth.

Conclusion

In principle, as set out above, the trends and developments in pharmaceutical advertising in Switzerland are shaped by three basic factors:

- the recognition that co-operation with the various stakeholders – from patients to healthcare professionals and their respective organisations – is a key factor for innovation, effectiveness and efficiency, but also for potential abuse, in the healthcare sector;
- an increasing demand for integrity and transparency, and respective regulatory intervention; and
- data-driven approaches that are facilitated by new digital solutions and that, at the same time, require adequate regulatory responses.

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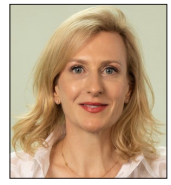
Authors

Oliver M Brupbacher is a partner at Kellerhals Carrard. He advises and represents national and multinational clients, in particular from the healthcare and life sciences sectors, in the areas of dispute resolution, regulatory, data and digital. He specialises in corporate investigations, litigation and arbitration, large-scale cross-border proceedings and mutual legal assistance, as well as high-profile regulatory matters, data protection and information governance. He also assists his clients in crisis management and cybersecurity. As a former senior litigation counsel, global product lawyer and head of global discovery at Novartis, Oliver combines deep expertise in his areas of practice with an intimate understanding of the industry and of clients' needs at all organisational levels, in both a domestic and international context.



Claudia Götz Staehelin is a partner at Kellerhals Carrard and specialises in litigation and arbitration, as well as in conducting internal investigations. She advises her clients in the areas of compliance, white-collar crime, cross-border proceedings, international mutual legal assistance and data protection. She also supports clients in crisis management. As former head of litigation at Novartis, Claudia combines dispute resolution expertise with many years of significant industry experience. She is recognised for her expertise in the field of healthcare and life sciences and advises and represents pharmaceutical and medical device companies in all areas of healthcare and pharmaceutical law.

Kellerhals Carrard

Henric Petri-Strasse 35
PO Box 257
4010 Basle
Switzerland

Tel: +41 58 200 30 00
Fax: +41 58 200 30 11
Email: info@kellerhals-carrard.ch
Web: www.kellerhals-carrard.ch

TAIWAN

Law and Practice

Contributed by:
Yulan Kuo, Jane Wang and Li-Ying Lin
Formosa Transnational Attorneys At Law see p.370

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TAIWAN

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

In Taiwan, advertising of medicines is mainly regulated by the Pharmaceutical Affairs Act (the "Act"), the Enforcement Rules of Pharmaceutical Affairs Act (the "Enforcement Rules of the Act"), the Consumer Protection Act, the Fair Trade Act, and the Principles for Dealing with Online Pharmaceutical Advertising. In addition, advertising of medicines is also regulated by the IRPMA Code of Practice (the "Code"), a self-regulatory code published by International Research-Based Pharmaceutical Manufacturers Association (IRPMA), which establishes general principles regarding marketing and promotion of medicines.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The IRPMA is a non-profit, non-governmental organisation comprising European, American, Japanese and Taiwanese research-based pharmaceutical companies. The Code is drafted based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, and establishes ethical standards for promoting pharmaceutical products to healthcare professionals. In addition to member companies of the IRPMA, the distributors, commissioned agents or representatives acting on behalf of all IRPMA member companies should also comply with the Code.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

"Advertising" refers to disseminating promotional messages or content by communication means, including television and radio, films, slides, newspapers, magazines, flyers, posters, signboards, computers, facsimiles, electronic videos, electronic voicemails or other methods to unspecific persons or the general public. Under the Act, the term "pharmaceutical advertisement" refers to advertising the medical efficacy of medicaments to unspecific persons (general public) by communication means aiming to solicit and promote the sale thereof. Also, any interviews, news reports or propaganda containing any information implying or suggesting medical efficacy are regarded as pharmaceutical advertisements. If the information is sufficient to establish a link to a specific medicament and promote consumer use, such information will be considered as pharmaceutical advertising. Only pharmaceutical businesses are allowed to advertise pharmaceuticals.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The relevant authority has clarified the difference between information and pharmaceutical advertising via administrative orders: if the information meets the following requirements, such information shall not be considered pharmaceutical advertising:

- the information is for the purposes of health promotion or disease prevention with a health education function;
- the information does not involve specific names of the medicaments; and

- the information has an obvious separation from the pharmaceutical advertising content.

The aforementioned "obvious separation" should be determined with respect to the effects as shown on a case-by-case basis and with the following requirements also being met:

- the pharmaceutical advertisement and the information shall not be published on the same page or on consecutive pages;
- the pharmaceutical advertisement and the information shall not be broadcast consecutively (there shall be other advertisements broadcast between the pharmaceutical advertisement and the information) nor have the same person to perform or endorse them, which would mislead the consumers to think that the "two" advertisements are the same "one"; and
- shall avoid any measures misleading the consumers to believe that the pharmaceutical advertisement and the information are the same.

In addition, if the advertisements of the same medicament are shown on different media and their overall effect meets the definition of "pharmaceutical advertisement" as stated above, then these advertisements should comply with the related laws and regulations on pharmaceutical advertising. For example, if a TV advertisement does not contain the name and the efficacy of a medicament, but such information is provided via consulting a hotline or health education manuals, then the TV advertisement shall be still regulated by related laws and regulations on pharmaceutical advertising.

Disease Awareness Campaigns and Other Patient-Facing Information

Based on the above, whether the disease awareness campaigns and other patient-facing information qualify as advertising depends on the circumstances. Generally speaking, no differences apply depending on the target audience. If the purpose of the campaign/information is health education (health promotion or disease prevention), the campaign/information does not involve specific medicaments, and there is obvious separation with no misleading information, then such campaign/information would not be considered "pharmaceutical advertising".

2.3 Restrictions on Press Releases Regarding Medicines

Press releases regarding medicines are permitted in Taiwan. Once the press release regarding medicines via media is deemed as "pharmaceutical advertising" as defined at **2.1 Definition of Advertising**, it shall subject to restrictions on pharmaceutical advertising. The details of restrictions on pharmaceutical advertising are illustrated at **4.2 Information Contained in Pharmaceutical Advertising to the General Public** and **6.1 Requirements for Prior Notification/ Authorisation**.

As to the issue of the target audience, pharmaceutical advertising of prescription medicines is only allowed in medical academic journals. For details on advertising prescription medicines, please see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**.

2.4 Comparative Advertising for Medicines

Comparative advertising for medicines is allowed in Taiwan if it is inspected by the relevant authority in advance. Additionally, such advertising must comply with the Principles

of Comparative Advertising as set forth by the Fair Trade Commission. For example, a pharmaceutical business shall not make any untrue or misleading statements to promote products in an advertisement, and the business cannot compare its products with products of other pharmaceutical businesses based on different standards or grades. A pharmaceutical business must take care when claiming its product is "the best", as such description constitutes comparative advertising.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

According to the Enforcement Rules of the Act, text and images used in a pharmaceutical advertisement are limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines and packaging, and the name and address of the manufacturer, as initially approved by the central relevant health authority; the name of the firm and the number of its drug permit licence and the advertisement approval document shall be published simultaneously or disseminated together with the pharmaceutical advertisement. According to the Code, no pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country. As such, in Taiwan, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications.

However, it is still possible to provide information about unauthorised medicines or unauthorised indications in a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings, in scientific or lay communications media and at scientific conferences, or during a public disclosure of information to stockholders and others. An unauthorised medicine and unauthorised indication can be introduced if such introduction will not be deemed as pharmaceutical advertising.

3.2 Provision of Information During a Scientific Conference

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals as long as such information will not constitute pharmaceutical advertising. Also, according to the "Ethics Code of Medical News or Research Published by Medical Institutions and Health Professionals", medical institutions and health professionals are allowed to quote such information and the source during a scientific conference as long as it is recognised by credible academic journals or institutions.

The Code explicitly allows the exception for the promotional information sharing during international scientific conferences. The Code states that promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- host country regulations should permit such an arrangement;
- the meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place;
- promotional material for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

3.3 Provision of Information to Healthcare Professionals

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications, regardless of whether the target is healthcare professionals or not. However, it is allowed to provide such information to healthcare professionals as long as it will not constitute pharmaceutical advertising (see **3.2 Provision of Information during a Scientific Conference**). According to the Code, continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. When providing content to CME activities and programmes, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

3.4 Provision of Information to Healthcare Institutions

As indicated in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is forbidden to have pharmaceutical advertisements for unauthorised medicines or unauthorised indications, regardless of whether the target is healthcare institutions or not. It is possible to provide information to healthcare institutions as long as it will not constitute pharmaceutical advertising. See details at **3.2 Provision of Information during a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

3.5 Information About Early Access or Compassionate Use Programmes

It is not expressly prohibited to publish the availability of compassionate use programmes. However, considering: (i) the compassionate use programme is applied under the circumstance that there is no domestic appropriate drug or alternative treatment; and (ii) the compassionate use programme must be applied by the medical care institutions to the central competent health authority for its special approval to manufacture and import the specific drug for the prevention of a chronic or seriously debilitating disease or a life-threatening disease, the publication of the availability of compassionate use programmes or other forms of early access must not consti-

tute pharmaceutical advertising or such publication must meet the related laws and regulations of pharmaceutical advertising.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

In Taiwan, any pharmaceutical business that wishes to advertise medicines, whether they are over-the-counter medicines or prescription medicines, must first apply for approval from the relevant healthcare authority. After obtaining approval, the pharmaceutical business can advertise and promote such medicines. The governmental approval process is illustrated at **6.1 Requirements for Prior Notification/Authorisation**. The Code provides standards for promotional information, namely:

- promotions must be consistent with locally approved product information;
- promotions must be clear, legible, accurate, balanced, fair and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the pharmaceutical product; and
- the advertiser must be able to substantiate the claimed efficacy.

Moreover, prescription medicines are only allowed to advertise in medical academic journals, not to the general public. For online advertising of prescription medicines in medical academic platforms, according to the administrative order, the platform must have installed an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements.

Advertisements shall not make any misleading or untrue statements to the audience. Any violation is subject to penalties under the Fair Trade Act, the Consumer Protection Act and the Civil Code.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Obligatory Information

Before publishing or broadcasting a pharmaceutical advertisement, a pharmaceutical business must submit all text, drawings or images constituting an advertisement to the relevant health authority for approval, and no modifications or alterations to the approved contents are allowed during the term being permitted to publish or to broadcast. The name of the firm, the number of its drug permit licence and the advertisement approval document shall be published simultaneously or disseminated together with the advertisement. The text and images used in a pharmaceutical advertisement are limited to:

- the name of the drug;
- its dosage form;
- prescription content;
- usage quantity;
- usage method;
- efficacy, guidelines and packaging; and
- the name and address of the manufacturer, as initially approved by the central relevant health authority.

The efficacy claimed in the text of an advertisement for Chinese medicine materials must be limited to the efficacy stated in the Compendium of Materia Medica.

Prohibited Information

Pharmaceutical advertising shall not do any of the following:

- publicise the medicament by making use of the name of anther person(s);
- warrant the efficacy or functions of the medicament by making use of materials or information contained in a book or publications;
- publicise the medicament by means of releasing an interview or news report; or
- publicise the medicament by any other improper means.

Additionally, pharmaceutical advertisements cannot contain any of the following:

- content involving efficacy related to sexual intercourse;
- content involving exchanging the drugs for prizes or any incentives whatsoever that are likely to encourage drug abuse;
- content involving any representation that the use of a particular drug will cure a particular disease or will improve a person's health or physiology in a particular area, or untrue or misleading statements; and
- exaggeration of a drug's efficacy or safety.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is no law or regulation expressly imposing restrictions on interactions between patients or patient organisations and industry. However, salespersons employed by a pharmaceutical business are permitted to promote sales only after their employment has been registered with the relevant health authority of the municipality or county (city). The salespersons may only promote sales to pharmacies, pharmaceutical firms, health and medical care institutions, medical research institutions, and institutions whose registrations have been approved by the relevant health authorities. Salespersons can only sell drugs manufactured or resold by the pharmaceutical business in which they are employed, and cannot conduct any act of peddling, street vending, tearing seals of medicaments, repackaging medicaments without authorisation, or illegally advertising medicaments.

As the law does not establish the definition of "promoting sales", there is still room for direct interaction between patients or patient organisations and industry, so long as the interactions do not involve "promoting sales". The Code also allows interactions between patients or patient organisations and the industry, as long as all interactions with patient organisations are ethical, and the independence of patient organisations must be respected; being the sole funder of the patient organisation or any of its programmes is not allowed.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

The same rules apply to both advertising to the general public and to the health professionals. Contents or information that must be included or that is prohibited are indicated at **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. In addition, prescription medicines are only allowed to advertise in medical academic journals, not to the general public. For online advertising of prescription medicines in medical academic platforms, the platform must have installed an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**).

5.2 Reference to Data Not Included in the Summary of Product Characteristics

In Taiwan, the content of pharmaceutical advertising of a specific medicine must be exactly the same as the content that has been inspected and reviewed by the relevant authority. The text and images used in pharmaceutical advertising are limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, packaging, and the name and address of the manufacturer, as approved by the central relevant health authority. Therefore, if the data or other clinical studies are not approved by the relevant authority, they cannot be referred to in the pharmaceutical advertisement. However, there is still room for the use of such information, as long as it complies with related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information During a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

5.3 Advertising of Combination Products

As indicated at **5.2 Reference to Data Not Included in the Summary of Product Characteristics**, the content of pharmaceutical advertising must be exactly the same as the content that has been inspected and reviewed by the relevant authority. If such information is not approved by the central relevant health authority, it cannot be referred to in the pharmaceutical advertisement. However, there is still room for the use of such information, as long as it complies with related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information During a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

According to the Code, medical journals or textbooks for academic use can only be offered to individual hospital departments (Benchmarks of Code of Practice). In addition, if the content involves any "pharmaceutical advertising", the company must comply with the relevant rules governing pharmaceutical advertising.

5.5 Medical Science Liaisons

Unlike the promotion of sale by pharmaceutical business salespersons, which needs to be registered according to the Act, there are no specific laws or regulations regulating the conduct of medical science liaisons (MSLs). There are no laws or regulations prohibiting MSLs from proactively discussing scientific information on unauthorised medicines or indications with healthcare professionals, as long as the conduct of the MSLs does not constitute pharmaceutical advertising and such conduct complies with the related laws and regulations as indicated at **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, **3.2 Provision of Information During a Scientific Conference** and **3.3 Provision of Information to Healthcare Professionals**. However, if MSLs are "promoting sales", the MSLs shall also be registered regardless of whether the company refers to them as salespersons or not.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertisements for medicines are subject to prior authorisation from the relevant health authorities; however, there are no specific laws or regulations regulating the conduct of medi-

cal science liaisons (MSLs). See **4.2 Information Contained in Pharmaceutical Advertising to the General Public** for information that needs to be submitted for approval. No publication or dissemination of pharmaceutical advertising may take place until a pharmaceutical business with a drug permit has completed an application form and submitted the same with photocopies of the drug permit and the approved labelling, usage instructions, packaging, the content of the advertisement and a review fee to the relevant health authority and has obtained approval from that health authority. Also, the term of validity of pharmaceutical advertisements approved by the relevant health authority is one year, which shall commence from the date of issuance of the approval document. An extension may be applied for by the business and approved by the issuing relevant health authority. Each period of extension shall not exceed one year. The central or direct municipal relevant health authority is in charge of approval (and rejection) of pharmaceutical advertisements.

6.2 Compliance With Rules on Medicinal Advertising

There is no requirement to adopt SOPs or to employ specific personnel to complete the process of applying for pharmaceutical advertisement approval from the relevant health authority. However, an applicant applying for such approval must be the pharmaceutical business which holds the drug permit for the drug that is to be advertised.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

In addition to the general rules specified in the Act and the Enforcement Rules of the Act, advertising on the internet for medicinal products is specifically regulated by the "Principles for Dealing with Online Pharmaceutical Advertising" (the "Principles").

The Principles provide as follows.

- A pharmaceutical business is allowed to advertise drugs or medicines on its official website without first applying for an approval, but the content of the advertisements must be identical to the drug permits, and the business must post photos of the drug's packaging.
- As well as advertising on its official website, a pharmaceutical business is allowed to advertise non-prescription medicines on websites targeting the general public by first applying for the approval set forth at **6.1 Requirements for Prior Notification/Authorisation**. For prescription medicines, in addition to having the approval, prescription medicines can only advertise in medical academic platforms which have an administrative measure to ensure that only registered healthcare professionals are allowed to view such advertisements. For example, the online platform must require member IDs or professional licence numbers to permit access to the webpage showing the advert for the prescription medicines.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

If a pharmaceutical advertisement contains prescription medicines, the website must have installed an administrative measure, such as a requirement to enter a member ID or professional licence number, to ensure that only healthcare professionals have access to such advertising content.

7.3 Provision of Disease Awareness Information to Patients Online

As indicated in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**, pharmaceutical companies are allowed to provide disease awareness information and/or materials to patients online as long as the information:

- is not pharmaceutical advertising;
- is for the purposes of health promotion or disease prevention with a health education function;
- does not include specific names of the medicaments; and
- has obvious separation from the pharmaceutical advertising content.

On the other hand, if the disease awareness information and/or materials to patients would be considered as "pharmaceutical advertising", the laws and regulations governing pharmaceutical advertising must be complied with.

7.4 Online Scientific Meetings

According to the Code, the purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organised or sponsored by a pharmaceutical business should be to provide scientific or educational information, and/or to inform healthcare professionals about products, as do online scientific meetings. Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- the host country regulations should permit such an arrangement;
- the meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.5 Use of Social Media

Pharmaceutical advertising on social media is allowed, so long as the advertisements comply with the rules indicated above such as **4.1 Main**

Restrictions on Advertising Pharmaceuticals to the General Public and **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The interaction between healthcare professionals/healthcare organisations and and pharmaceutical companies is mainly regulated by the Medical Care Act, the Physicians Act, and the Guidance for Interaction between Physicians and Vendors, all three of which only provide high-level principles. Corruption under the Criminal Code was previously applied to healthcare professionals at public hospitals, but such application ceased in 2008. The offence of breach of trust under the Criminal Code might still be applied in some particular circumstances. The Code also provides some self-regulatory details regarding such interactions.

Medical Care Act

The Medical Care Act aims to advance the comprehensive development of the medical care industry, the reasonable distribution of medical care resources, the improvement of the quality of medical care, the protection of the rights of patients and the promotion of the national health. It requires "[m]edical care institutions and their staff to refrain from taking advantage of opportunities resulting from medical practice to gain improper benefits". This applies to both individuals and organisations, but only provides general principles regarding the prohibition against "gaining improper benefits". Medical care institutions and the staff thereof who violate the aforementioned shall be subject to a fine of no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333).

Physicians Act

The Physicians Act establishes the standards for qualifications, management, practice and duty of physicians. It applies only to physicians and not healthcare institutions. A physician guilty of violating medical ethics in their professional practice shall be disciplined by the Medical Association or the relevant authority. This Act also provides a high-level limitation on the interactions between healthcare professionals and pharmaceutical companies.

Administrative Guidance

In 2006, Taiwan's Department of Health (DoH, which is now the Ministry of Health and Welfare) announced the Guidance for Interactions between Physicians and Vendors. The Guidance states the rules to be followed with respect to the attendance of physicians at medical seminars held by vendors, the receiving of gifts from vendors, the rules for doctors who are invited to provide consultation to pharmaceutical companies, and the principles for physicians and healthcare organisations to follow while conducting research sponsored by vendors. A physician who violates the Code will be disciplined by the Medical Association.

Corruption According to the Criminal Code

If the individual accepting bribes is a government employee, corruption, according to the Criminal Code, might apply. There was a time when healthcare professionals working in public hospitals were considered government employees. However, as confirmed by the Supreme Court in 2008, healthcare professionals at public hospitals are not considered civil servants as defined in the Criminal Code. Nevertheless, if the

healthcare professional has duties in an administrative or management position at the public hospital, such as with respect to procurement, the individuals can be charged with corruption if they accept bribes.

Breach of Trust of the Criminal Code

If the healthcare professional accepting gifts or money from pharmaceutical companies acts against their professional practice, which then causes damage to the hospital, the healthcare professional may be deemed to have committed a breach of trust. This applies only to individuals and not to organisations, regardless of whether the healthcare professional works for a public or private hospital.

IRPMA Code of Practice

The Code provides standards for the ethical promotion of pharmaceutical products to healthcare professionals helping to ensure that member companies' interactions with healthcare professionals and other stakeholders are appropriate and perceived as such, as well as considerable details regarding acts that pharmaceutical companies must do and must refrain from doing while interacting with healthcare professionals, and the principles for interactions with healthcare professionals. Specific sections include events and meetings, sponsorships, guests, fees for services, gifts, samples provided to healthcare professionals and the monitoring duty of the pharmaceutical companies with respect to the samples they provide, rules covering clinical research and transparency, among others.

8.2 Legislative or Self-Regulatory Provisions

Legislative provisions regarding the matter of benefits provided to healthcare professionals or healthcare organisations are mainly contained in the Medical Care Act and the Physicians Act, which only provide general and high-level limitations. The Medical Care Act could apply to both individuals and organisations, while the Physicians Act applies only to physicians. Corruption or breach of trust under the Criminal Code might apply in some particular circumstances, but only to individuals.

The Guidance for Interactions between Physicians and Vendors provides more details on this matter. It restricts physicians' and healthcare organisations' behaviours regarding benefits, but not those of pharmaceutical companies. In terms of self-regulatory provisions, the Code provides the most details regarding the offering of benefits by pharmaceutical companies. The Code restricts the behaviours of pharmaceutical companies in this regard.

Both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or cash equivalents such as gift certificates. The Code also prohibits offering personal benefits, such as sporting or entertainment tickets, electronic items and cultural courtesy gifts, such as gifts given on traditional festivals or flowers and funeral scrolls for funerals.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The Taiwan legal framework only has general provisions that limit interactions between healthcare professionals and pharmaceutical companies. The Guidance for Interactions between Physicians and Vendors and the Code provide more specific information, as addressed below.

The Medical Care Act and the Physicians Act provide a high-level requirement that medical

care institutions and their staff shall not take advantage of opportunities resulting from medical practice to gain improper benefits. Also, healthcare professionals must not violate medical ethics in their professional practice.

According to the Guidance for Interactions between Physicians and Vendors, physicians are allowed to accept gifts on the basis that such gifts:

- shall not violate the laws and the policies of the Medical Association or Guild;
- shall be reasonable in consistency with local practice, and shall not be expensive;
- shall not be cash or cash equivalents; and
- shall not involve an agreement or implication that a particular medical product will be used or that patients will be referred to a particular premises.

Briefly, the core concept is reasonableness and avoiding situations of quid pro quo. Although there is no specific monetary limit set, gifts of cash or cash equivalents are clearly forbidden.

The Code also provides that "[p]ayments in cash, cash equivalents (such as gift certificates) or personal services (any service unrelated to the healthcare professional's profession and that confer a personal benefit to the healthcare professional) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, or electronic items) must not be provided or offered." In addition, as from 16 May 2018, the Code forbids promotional aids (as defined in Benchmarks of Code of Practice, Article 6.(2), promotional aids are inexpensive small items bearing the name of the pharmaceutical companies or pharmaceutical products) from being provided to healthcare professionals, requiring that medical supplies cannot be provided to healthcare professionals for their personal use.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to the Regulations on Management of Medicament Samples and Gifts, a medicament that meets one of the following requirements can be declared as a medicament sample:

- the pharmaceutical firm is applying for registration or improvement of manufacturing technology purposes;
- due to business needs, the pharmaceutical firm, academic research or trial institute, contract research organisation, medical academic group or teaching hospital is applying for solely research or trial purposes;
- a specialised teaching hospital or teaching hospital at or above the regional level is applying for purposes of diagnosis and treatment of patients with critical or catastrophic illness;
- a patient is applying for personal uses, certified by a medical institution (medical devices that should be operated by a physician or professional are excluded);
- a medical device company is applying for specific exhibitions or demonstration purposes;
- a pharmaceutical firm is applying for educational promotion purposes, given that the medicament has been issued a licence in accordance with the stipulations of the Act; or
- an application is being made for purposes of public safety or public health or due to major disasters.

To be imported or manufactured, medicament samples must have obtained approval from the Taiwan Food and Drug Administration (TFDA) in

advance. In addition, the Regulations provide as follows.

- Medicament samples or gifts that have been approved may not be sold, transferred or used for other purposes.
- Medicament samples for technical improvement purposes may not be used for clinical purposes.
- For approved medicament gifts and medicament samples for educational promotion purposes, their package inserts, labels and packaging styles shall be consistent with those registered in the original permit licence. The package volume for medicament samples for educational promotion purposes may not exceed the minimum registered packaging volume.
- For medicaments approved as samples or gifts, the outer packaging shall be clearly marked with text stating "Sample" or "Gift". On samples for clinical trial purposes, text stating "For clinical trial" shall be marked.

The Code also provides principles regarding the offering of samples, as set out below.

- Subject: the healthcare professionals receiving samples of the medicine at issue shall have the power to prescribe the medicine.
- Labelling: the samples offered shall be clearly labelled as "samples".
- Monitoring and other responsibilities: the pharmaceutical company is required to maintain a monitoring system for tracking which healthcare professional possesses the samples.

Pharmaceutical companies offering samples are not allowed to collect clinical information from samples offered and may not provide any reward to healthcare professionals receiving such samples.

9.3 Sponsorship of Scientific Meetings

The Guidance for Interaction between Physicians and Vendors allows doctors to attend medical meetings held or sponsored by pharmaceutical companies, so long as the following principles are met.

- The main purpose of the meeting is regarding the improvement of medical quality, promoting the interests of patients and professional information exchange. In addition, at least two-thirds of the meeting time shall be spent on discussion of the topics as set forth/advertised.
- Sponsorship accepted by a healthcare professional is limited to registration, travel expenses and meals. If a healthcare professional is invited as a speaker or host, a speaker's fee or hosting fee is acceptable.
- The organiser of the meeting is required to disclose the name of the sponsors and inform attendees of the relationship with/between the organiser, speaker, host and sponsor.
- Any material published by healthcare professionals at the meeting must be based on scientific positivism and cannot be affected by the sponsor. Statements regarding alternative diagnosis/treatment must be made fairly.
- The organiser of the meeting or attending doctors must reject any improper intervention by the pharmaceutical companies related to the content of the meeting, the way the meeting proceeds and the selection of speakers.

The Code allows pharmaceutical companies to hold or sponsor events or meetings under certain limitations, as set out below.

- The purpose of the event must be related to science and education.
- Meetings abroad are not allowed except for international scientific congresses and symposia that derive participants from many countries. All events must be held in an appropriate venue conducive to the stated scientific or educational objectives and the purpose of the event or meeting. Renowned or extravagant venues must be avoided.
- Promotional information that appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products that are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:
  (a) host country regulations should permit such an arrangement;
  (b) the meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
  (c) promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
  (d) promotional material which refers to the prescribing information (indications, warnings, etc) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
  (e) an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.
- Pharmaceutical companies are also allowed to sponsor healthcare professionals to attend events, provided:
  (a) the event complies with the requirements in this Code as described at **7.1 Regulation of Advertising of Medicinal Products on the Internet**;
  (b) sponsorship of healthcare professionals is limited to payments for travel, meals, accommodation and registration fees, and after 1 January 2023, such sponsorship is limited to payments with reasonable and necessary connection with the hosting format, place and time of the event;
  (c) no payments are made to compensate healthcare professionals for time spent attending the Event; and
  (d) any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

As set out at **9.3 Sponsorship of Scientific Meetings**, the Guidance for Interactions between Physicians and Vendors allows healthcare professionals to attend events held or sponsored by pharmaceutical companies, provided that the purposes of such events are related to improvements of medical quality, promoting the interests of patients and professional information exchanges. The Code also requires that the purposes of events held or sponsored by pharmaceutical companies be related to science and education. No entertainment or other leisure

or social activities should be provided or paid for by member companies. Thus, pharmaceutical companies are not allowed to organise or sponsor cultural, sports or other non-scientific events, and healthcare professionals are also not allowed to attend such non-scientific events if their attendance is sponsored by pharmaceutical companies.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The Guidance for Interactions between Physicians and Vendors allows healthcare professionals or healthcare institutions to conduct research sponsored by pharmaceutical companies, provided that:

- the research and publication of the results thereof complies with the law, ethics and the requirements of the Helsinki Declaration and strictly adheres to clinical judgement;
- the reward for conducting the research shall be evaluated based on the time and effort expended, but not based on the results of the research;
- the name(s) of both the direct or indirect sponsor(s) shall be announced together with the publication of the results of the research;
- the healthcare professionals or healthcare institutions and the pharmaceutical company shall fully communicate before the research; and
- the pharmaceutical company shall not restrict the publication of the research results.

The Code states that pharmaceutical companies are allowed to offer items of medical utility to healthcare professionals if such items are of modest value, do not offset routine business practices, and are beneficial to enhancing the provision of medical services and patient care, such medical utility must not bear the name of product (both of branded and generic name) but may bear the company logo.

Both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or cash equivalents (such as gift certificates) to healthcare professionals. Neither the Code nor the Guidance has relevant content regarding donations of equipment or service from pharmaceutical companies.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Though there is no specific restriction with respect to rebates or discounts, both the Guidance for Interactions between Physicians and Vendors and the Code prohibit offering cash or cash equivalents to healthcare professionals. Thus, giving rebates is not allowed.

In addition, the requirements under the Medical Care Act and the Physicians Act indicated in sections **8. Pharmaceutical Advertising: Inducement/Anti-bribery** and **9. Gifts, Hospitality, Congresses and Related Payments** would apply. If a healthcare professional receives a rebate or discount which is considered to be an "improper benefit" or as "violating medical ethics", they could be subjected to the imposition of a fine in an amount no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333) and may be disciplined by the Medical Association or the relevant authority.

Furthermore, healthcare professionals at public hospitals who are in charge of administrative or management affairs may be found guilty of corruption if they accept rebates. Also, healthcare professionals at public or private hospitals may be found to be in breach of trust for their receipt

of rebates if the legal requirements for a breach of trust are met.

9.7 Payment for Services Provided by Healthcare Professionals

The Guidance for Interactions between Physicians and Vendors allows doctors to act as consultants to pharmaceutical companies or to provide advice, provided that:

- professional judgement shall not be affected due to acting as consultant or providing advice to the pharmaceutical company;
- obligations to patients shall not be neglected due to acting as consultant or providing advice to the pharmaceutical company; and
- subordination or any other relationship with the pharmaceutical company shall be laid open in any speech and/or publication of articles or reports.

The Code has relevant requirements, including:

- a written contract or agreement must be agreed upon in advance of the commencement of the services, which agreement or contract specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and must reflect the fair market value of the services provided.

The Q&A section of the Code also contains a services fee schedule for healthcare professionals, which provides as follows.

- For international congress held overseas, the international norms should be applied. For the symposia held in Taiwan, the international norms can only be applied when the international event is organised by an international society and it is not a satellite programme within the international event. Otherwise, the honorarium for local speakers should be limited to a maximum of NTD5,000/hour.
- The chairperson/moderator of the advisory board, who may concurrently serve as advisory board member, may be paid up to NTD20,000 (up to NTD10,000 per event as a member, and up to NTD10,000 as the chairperson).
- The chairperson/moderator, who may concurrently serve as a lecturer, may be paid up to NTD5,000/hour as a lecturer, and up to NTD10,000 as the chairman/moderator per event.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Except for the importation or manufacture of medicament samples, which must have obtained approval from the TFDA in advance, none of the activities referred to in this section are presently required by laws or regulations to have prior authorisation or notification.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

There is no particular law or regulation or self-regulatory code that requires pharmaceutical companies to disclose transfers of value to healthcare professionals or healthcare institutions. The Guidance for Interactions between Physicians and Vendors, however, requires the following.

- Regarding the event or meeting sponsored by a pharmaceutical company, the organiser of the event or meeting must disclose the name of the sponsors and inform attendees of the relationship/s between the organiser, speaker, host and sponsor (Article 2(3)).
- Where healthcare professionals are invited to be consultants or to provide advice to pharmaceutical companies, the subordination or any other relationship with the pharmaceutical company shall be laid open in any speech or publication of articles or reports (Article 5(3)).

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The above-mentioned Guidance for Interactions between Physicians and Vendors at **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value** does not distinguish between foreign companies or companies that do not yet have products on the market. Nevertheless, Article 2(3) applies only to the organiser of the event or meeting, and Article 5(3) applies only to healthcare professionals.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

For the rules on advertising, the central or direct municipal relevant health authority is in charge of enforcing the Act. The Fair Trade Commission will enforce any penalties for violations of the Fair Trade Act. Administrative disputes related to violations of pharmaceutical advertising rules are adjudicated by the Administrative Courts.

With regard to inducement, the Medical Care Act and the Guidance for Interactions Between Physicians and Vendors is enforced by the Ministry of Health and Welfare. The Physicians Act is enforced by the Ministry of Health and Welfare and the Taiwan Medical Association. The IRPMA Code of Practice is enforced by the IRPMA.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

If infringement by a competitor involves a fair trade/competition order, the company can bring a complaint to the Fair Trade Commission (FTC), and the FTC will collect evidence and make a decision as to whether to issue an administrative order to fine the competitor for its violation of the Fair Trade Act. If a competitor is not satisfied with the administrative order, it may sue the FTC, and such cases will be heard by the High Administrative Court. If infringement by a competitor constitutes the behaviour, as stated in the Fair Trade Act, that "for the purpose of competition, [shall] make or disseminate any false statement that is capable of damaging the business reputation of another", the company may even file a criminal complaint with the competent district prosecutor's office pursuant to the Fair Trade Act.

If the infringement by a competitor involves general civil issues, such as disparaging the company's goodwill or the making of untrue statements, the company may sue the competitor in the local civil courts.

If the infringement by a competitor involves intellectual property rights or trade secrets, the company may sue the competitor in the Intellectual Property and Commercial Court.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

General penalties for violating advertising rules under the Act are as follows.

- Anyone who is not a pharmaceutical business but makes a pharmaceutical advertisement is subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666); no pictorial or literal description or propaganda regarding the medical efficacy of any product other than the medicaments defined in this Act shall be made, otherwise, the violator shall be issued a fine ranging from NTD600,000 to NTD25 million and the violating products shall be confiscated and destroyed.
- Anyone who makes a pharmaceutical advertisement without first obtaining approval from the relevant authority, and anyone who violates the rules by advertising prescription medicines on any media other than in educational journals, and anyone who includes prohibited content in the advertisement will be subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666).
- Media businesses who help to post or play any pharmaceutical advertisement which has not been approved by the relevant authority will be subject to a fine in an amount ranging from NTD200,000 (approximately USD6,666) to NTD5 million (approximately USD1,666,666), and if the media business continues posting or playing said advertisement, it will be subject to a fine in an amount ranging from NTD600,000 (approximately USD20,000) to NTD25 million (approximately USD833,333); under the same Article, any media business that violates the rules by not keeping the record of the advertisement for six months will be subject to a fine in an amount ranging from NTD60,000 (approximately USD2,000) to NTD300,000 (approximately USD10,000).
- In addition to the above, the relevant authority may announce the name of the violator and the medicine, and may revoke the drug licence if the violation is serious; the medicine at issue will also be precluded from application for approval for pharmaceutical advertising for a period of two years.

Penalties under the Fair Trade Act are as follows.

- Anyone who makes untrue or misleading statements in an advertisement will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25,000,000 (approximately USD833,333), and if such person fails to correct its action after imposition of the fine, said person shall be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen with respect to endorsement or comparison advertisements. In addition to the above punishments, doctors or pharmacists are subject to disciplinary measures by their professional associations for violating their professional duties by making untrue or misleading state-

ments in connection with endorsements for medicines.

- Anyone making or disseminating any untrue statement for the purpose of damaging the business reputation of another business is subject to both criminal and administrative penalties. For criminal liability, the violator will be subject to detention or imprisonment for no more than two years and may be fined an amount of no more than NTD50 million. For administrative liability, the violator will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25 million (approximately USD833,333), and if it fails to correct its action after the fine, it will be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen in connection with comparison advertisements.
- Anyone engaging in any deceptive or obviously unfair conduct that is able to affect the trading order will be subject to a fine in an amount ranging from NTD50,000 (approximately USD1,666) to NTD25 million (approximately USD833,333), and if it fails to correct its action after the fine, it will be subject to another fine in an amount ranging from NTD100,000 to NTD50 million until its action is corrected. This is likely to happen in connection with comparison advertisements.

Regarding inducement, medical care institutions and the staff thereof who violate the Medical Care Act will be subject to a fine of no less than NTD50,000 (approximately USD1,666) and no more than NTD250,000 (approximately USD8,333). According to the Physicians Act, a physician found guilty of violating medical ethics in their professional practice will be disciplined by the Medical Association or the relevant authority. The Guidance for Interactions Between Physicians and Vendors was established according to the Physicians Act. Thus, the penalties or measures applicable for violations of the Guidance will also refer to the Physicians Act.

There is no statutory punishment for violating the requirements of the IRPMA Code of Practice, however, the IRPMA has its own Code of Practice Committee. If the Code of Practice Committee confirms the violation of the Code, each violation shall be punishable by a fine of NTD200,000.

11.4 Relationship Between Regulatory Authorities and Courts

The procedures or measures taken by the self-regulatory authority are not necessarily related to the procedures or measures taken by the courts. One can present the material of procedures or measures taken by the self-regulatory authority to the court, but any violation of the laws and regulations must be heard and decided by a court. The procedures before the court must follow the law and the court can take compulsory measures, while the procedures taken by the self-regulatory authority are self-imposed and, unlike the court, the self-regulatory authority cannot take compulsory measures.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

There have been no significant changes of enforcement in relation to pharmaceutical advertising in the past two years. However, the regulation of medical devices was shifted from the Pharmaceutical Affairs Act to the Medical Devices Act. The Medical Devices Act came into effect on 1 May 2021. According to the Medical Devices Act, its provisions shall apply to the management of medical devices, and the provisions of the Pharmaceutical Affairs Act governing medical devices shall no longer be applicable.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Advertising of veterinary medicines is separately regulated under the Veterinary Drugs Control Act. According to the Veterinary Drugs Control Act, the promotion or advertisement of veterinary medicines shall comply with the following:

- the presentation, promotion and advertisement of a veterinary drug is to be performed by veterinary drug manufacturers or dealers only;
- the presentation, promotion and advertisement of a veterinary drug must not claim, suggest or insinuate ingredients or efficacy that are false or exaggerated beyond the scope of the drug's product registration;
- non-veterinary drugs must not be presented, promoted or advertised as capable of preventing or treating animal diseases, or enhancing or regulating animal physiological functions; and
- interviews, news reports or promotions that suggest or insinuate the efficacy of preventing or treating animal diseases, or enhancing or regulating animal physiological functions are deemed as advertisements.

A person who is in violation of any the above may be subject to a fine of NTD200,000 to NTD1 million.

Unlike advertising of human medicines, the central enforcement body of the Veterinary Drugs Control Act is the Council of Agriculture, Executive Yuan. Compared to the comprehensive regulations on the advertising of human medicines under the Pharmaceutical Affairs Act, the Enforcement Rules of the Pharmaceutical Affairs Act and other relevant acts and rules, the regulations on the advertising of veterinary medicines are relatively simple.

Formosa Transnational Attorneys At Law is a full-service law firm in Taipei established in 1974. The firm provides legal assistance to high-profile clients from all over the world, including the USA, EU, UK, Japan, Korea, Singapore and China. With an elite team of 90 attorneys, the firm's practice includes all types of compliance checks, dispute resolution, fundraising, investments, M&A, employment, competition, franchising, data protection and privacy, and corporate social responsibility, among other fields of law. Its technology law department possesses a strong background in technology and extensive experience in IP laws with its IP attorneys and in-house engineers and scientists. The firm's professionals provide comprehensive services with respect to intellectual property matters, such as IP management, prosecution and litigation for patents, trade marks, copyrights, domain names and trade secrets, and advise businesses engaged in all sectors of the pharmaceutical industry and many other industries.

Authors

Yulan Kuo is a senior partner at Formosa Transnational Attorneys At Law whose practice focuses on patent litigation, IP, IT technology and biotechnology. Having been practising for 30 years, he counsels a broad range of hi-tech companies. His team handled the first patent litigation case adjudicated by the IP Court. His recent victory involved serving as the lead counsel for a leading company in the global market in a complicated case relating to IP disputes in the USA and Taiwan; he has also obtained favourable judgments from the IP Court. Yulan is a member of AIPPI, APAA, AIPLA, INTA and ACS.

Jane Wang is a partner at Formosa Transnational Attorneys At Law whose practice includes IP litigation, data protection, franchise and emerging technologies. She represents pharmaceutical companies in the IP Court and the Supreme Court before and after the enforcement of patent linkage in Taiwan. Jane co-chairs the IP/IT practice group of a top-tier global law firm network with 21,000 lawyers from 92 jurisdictions. In Taiwan, she co-chairs the IP and Innovative Technology Committee of the Taipei Bar Association. Jane is a founding member of the Taiwan Competition Law Institute and a member of INTA, APAA, AIPPI and LESI.

Li-Ying Lin is an experienced legal attorney whose practice focuses on intellectual property law, intellectual property litigations, and compliance and contracts in the IT industry and biopharmaceutical industry. She assists both international and domestic clients in contract negotiations, forming detailed strategies for litigation, dispute resolution and providing an overview of Taiwan's legal structure for doing business in Taiwan.

Formosa Transnational Attorneys at Law

13F, No136
Sec.3 Jen Ai Road
Taipei City 106
Taiwan

Tel: +886 2 2755 7366
Fax: +886 2 2708 8435
Email: ftlaw@taiwanlaw.com
Web: www.taiwanlaw.com/en/

萬國法律事務所
Formosa Transnational
Attorneys at Law

UK

Law and Practice

Contributed by:
Alison Dennis
Taylor Wessing see p.395

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UK

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Laws

Part 14 of The Human Medicines Regulations 2012/1916 (HMR) sets out the main UK laws on the advertising of medicines: The Medicines (Advertising of Medicinal Products (No 2)) Regulations 1975/1326 and The Medicines (Labelling and Advertising to the Public) Regulations 1978.

The Medicines and Healthcare Products Regulatory Agency (MHRA) Blue Guide (the "Blue Guide") explains the legal provisions and helps with interpretation and application of the laws that relate to the advertising of medicinal products.

The Cancer Act 1939 includes prohibiting certain advertisements relating to cancer treatments.

General consumer advertising laws equally apply to advertising of pharmaceuticals to the public. In relation to non-broadcast advertising, these include the Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008. In relation to broadcast advertising, the Broadcasting Acts 1990 and 1996 and the Communications Act 2003 apply.

However, the rules and their enforcement in relation to pharmaceutical advertising in the UK have been largely developed through self-regulatory schemes.

Self-Regulation

The Advertising Standards Authority (ASA)

The ASA is responsible for administering the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the "CAP Code") which is written and maintained by the Committee of Advertising Practice. The Broadcast Committee of Advertising Practice (BCAP) similarly writes and maintains the Code of Broadcast Advertising (the "BCAP Code"). These codes relate to all advertising to the general public, but also include specific provisions relating to the advertising of medicinal products.

Industry codes

The Association of the British Pharmaceutical Industry (ABPI) Code applies to prescription medicines and is enforced by the Prescription Medicines Code of Practice Authority (PMCPA), which operates independently of the ABPI.

The Proprietary Association of Great Britain (PAGB) is the largest UK trade association for over-the-counter (OTC) medicines. The PAGB has two codes applicable to pharmaceutical advertising:

- the PAGB Consumer Code for Medicines (for advertising directed to consumers); and
- the PAGB Professional Code for Medicines (for advertising directed to professionals).

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Industry Codes

The ABPI Code applies to members of the ABPI, and the ABPI represents suppliers of more than 80% of all branded medicines used by the NHS. Membership and affiliate membership of the ABPI are conditional upon an agreement to adhere to the spirit and letter of the ABPI Code. Non-members can also formally agree to abide by the Code and the jurisdiction of the PMCPA, and in doing so to fall under the judgement and sanction of the PMCPA rather than of the UK regulator, the MHRA. Around 60 non-member

companies have made such an agreement. Any person can make a complaint under the ABPI code, although most are made by competitors and by healthcare professionals.

The PAGB Code similarly applies to members of the association, and both they and authorised associate members of PAGB working with them can submit advertising copy for review and clearance to PAGB.

General Advertising Codes

The CAP and BCAP codes apply to public non-broadcast and broadcast advertising, respectively. The ASA is funded by the advertising industry and has an arrangement with the communications regulator, Ofcom, pursuant to which the ASA is given responsibility to regulate TV and radio advertising. Any individual or business can complain to the ASA, and the ASA also monitors advertising.

Clearcast approves television advertising pursuant to the UK Code of Broadcast Advertising.

Radiocentre is the industry body for UK commercial radio and is responsible for ensuring that medicine advertising on the radio is compliant with the UK Code of Broadcast Advertising.

Relationship with Legislation/the MHRA

The MHRA works closely with the self-regulatory bodies in the Medicines and Devices Advertising Liaison Group (MDALG) which meets once or twice a year to develop guidance and a common understanding of the applicable law, and publishes its minutes online.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

"Advertising" is defined in Regulation 7 of the HMR as "anything designed to promote the prescription, supply, sale or use of a product". Regulation 7(2) of the HMR includes a list of activities that are considered to be advertising, such as:

- door-to-door canvassing;
- visits by sales reps;
- supply of samples;
- inducements to prescribe or supply medicinal products;
- sponsorship of promotional meetings attended by those qualified to prescribe or supply medicinal products; and
- sponsorship of scientific congresses, including payment of travelling and accommodation expenses of persons qualified to prescribe or supply medicinal products.

Regulation 7(3) clarifies that the following are not considered an "advertisement":

- a medicinal product's package or package leaflet;
- reference material and announcements of a factual and informative nature; or
- correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question about a medicinal product.

Furthermore "publication" in relation to an advertisement is defined in Regulation 277(1) of the HMR as follows: "in relation to an advertisement means the dissemination or issue of that advertisement (a) orally; (b) in writing; (c) by means of an electronic communications network within the meaning of the Communications Act 2003;

or (d) in any other way, and includes causing or procuring such publication by or on behalf of another person". Advertising offences all relate to "publishing" an advertisement that breaches the HMR.

The Blue Guide adds that labelling and package leaflets are not considered advertising if they meet the requirements of Part 13 of the HMR. The Blue Guide also clarifies that any person, not just the manufacturer or distributor, may breach the HMR if they promote a medicine, and this includes individuals, journalists, publishers and public relations agencies.

The ABPI Code does not define "advertising" but defines promotion, in paragraph 1.17, as: "any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines".

This includes:

- journal and direct mail advertising;
- the activities of representatives, including any electronic or printed material used by them;
- the supply of samples;
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- the provision of hospitality for promotional purposes;
- the sponsorship of promotional events/meetings;
- the sponsorship of scientific events/meetings, including payment of travelling and accommodation expenses in connection therewith; and
- all other promotion.

The PAGB Consumer Code also does not define "advertising" but includes a list of items and activities considered as materials that are covered by the Code, including social media, text messages, websites, advertorials, and materials written by third parties but in relation to which members have had the opportunity to comment and to request amendments.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Labelling and package leaflets meeting the requirements of Part 14 of the HMR are not considered to be advertising.

Disease awareness and health education campaigns that do not make product claims are not considered to be "advertising". Appendix 7 of the Blue Guide provides detailed guidance which states that these campaigns must avoid the use of brand names and must not relate just to a limited range of treatments as this is likely to lead to the prescription of a specific prescription-only medicine or medicines. While a disease awareness campaign may refer to available treatment options, this should not encourage individuals to request a particular medicine, but rather should focus on raising awareness of symptoms or risk factors so that early diagnosis may be sought.

2.3 Restrictions on Press Releases Regarding Medicines

Laws

Press releases for prescription medicines are not specifically prohibited, but the MHRA requires that they should be made about a prescription medicinal product only where the press release is genuinely newsworthy. They must not be used to promote prescription-only medicines, but rather should promote balanced media coverage.

Section 7.7 of the Blue Guide requires that press releases provide the context for use of the medicine and the population for which it has been licensed, setting the product and results in the context of alternative treatments and current medical practice. Brand name use should be minimised, and the content should be factual and not sensationalised. Healthcare professional (HCP) statements should be balanced and informative, and perspectives from any patient should focus on the impact the disease has on them, and not on the specific medicine.

Appendix 5 of the Blue Guide is addressed to journalists and patient organisations writing about medicines, as even though neither will usually have commercial links with the product, they can still breach the HMR. The guidance is to inform rather than to promote, to provide balanced factual and accurate reporting without encouraging readers to seek a particular product and without exaggerating the potential benefits of a medicine.

The Blue Guide accepts the need for business press releases intended to keep shareholders informed and states that these should identify the commercial importance of the information and should be factual and balanced.

Self-Regulatory Industry Codes

The ABPI Code states that it is good practice to reference the summary of product characteristics (SmPC) with a press release, and manufacturers should consider including references "to other credible sources of information about a condition or a medicine". This is again to provide a balanced perspective.

The PAGB Code distinguishes between PR on the consumer-facing part of a website and that in a dedicated press section. Only the former requires PAGB pre-approval. However, the PAGB considers that an HCP's recommendation is not acceptable in consumer-facing PR, and nor is any celebrity endorsement.

2.4 Comparative Advertising for Medicines

Comparisons in Advertising to the Public

Section 5.6 of the Blue Guide states that comparative claims against another named product are prohibited in advertising to the public. This means that only claims that relate to a category of products may be made in advertisements of medicines to the public.

The PAGB Codes do not permit comparisons that denigrate another ingredient, product, or product category. The PAGB Consumer Code also requires that comparisons be made only where the point of difference is sufficiently significant to be meaningful to consumers. If the comparative claim is made in a context that allows a competitor to be identified, then the advertiser must provide information to the consumer which allows the consumer to verify the claim. The PAGB Professional Code requires that hanging comparisons are not made: the product category being compared should be made clear.

Comparisons in Advertising to Professionals

The Blue Guide (Section 4.3) states that comparative claims may only be made where they:

- relate to the licensed use;
- can be substantiated; and
- are either included in the SmPC or are not inconsistent with the SmPC.

Where new data shows a comparison that is contrary to what is stated in the SmPC, the SmPC must be updated before the comparison can be made.

The ABPI Code requires that comparisons are:

- not misleading;
- accurate, fair and can be substantiated; and
- do not create confusion between products or trade marks, and no unfair advantage over the reputation, brand or marks of a competitor is gained.

General Laws and Codes on Comparative Advertising

As a general legal principle applicable to all products, comparative advertising is permitted subject to compliance with the Business Protection from Misleading Marketing Regulations 2008 (SI 2008/126) and the Consumer Protection form Unfair Trading Regulations 2008 (SI 2008/1277). However, comparisons of one medicine against even a category of medicines must be approached with care. The principles under these general advertising laws include that:

- the comparison must not be misleading (ie, must not deceive or be likely to deceive);
- the comparison must not mislead by omission;
- the comparison must be fair – the products must meet the same needs or be intended for the same purpose (in this case, the same indication and intended patient population);
- there must be an objective comparison of one or more material, relevant, verifiable and representative feature of the products;
- the comparison must not discredit or denigrate the marks, names or features of the other product; and
- the comparison must not take unfair advantage of a trade mark, trade name or other distinguishing marks.

A breach of the general laws on comparative advertising can lead to one or more of the following actions by the competitor, although these are less likely to succeed where the comparison is with a category of medicines:

- passing off;
- trade mark infringement;
- trade libel;
- malicious falsehood; and
- copyright infringement.

The CAP Code states that even comparisons with an unidentifiable competitor must not mislead or be likely to mislead the consumer, and the selected elements for comparison must not give the advertiser an unrepresentative advantage.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is not permitted to provide information to patients or consumers on unauthorised medicines or unauthorised indications. All advertising must comply with the SmPC (Regulation 280 HMR).

Clause 3.1 of the ABPI Code states that a medicine must not be promoted prior to grant of a marketing authorisation. Clause 11.2 of the ABPI Code states that the promotion of indications not covered by the marketing authorisation for a medicine is prohibited. Section 4.1.1 of the PAGB Consumer Code includes similar provisions.

Under the ABPI Code Clause 1.17, information on unauthorised medicines or indications may

only be given to HCPs in response to an unsolicited written question from that HCP, but only if the response relates solely to the subject matter of the enquiry, is accurate, does not mislead and is not promotional in nature. Such responses are not considered to constitute "promotion".

3.2 Provision of Information During a Scientific Conference

Regulation 278 of the HMR does not permit the advertising of medicines without a marketing authorisation.

Clause 3.1 of the ABPI Code permits the "legitimate exchange of medical and scientific information during the development of a medicine". This is on the basis that the activity does not constitute promotion. A conference consisting of a passive audience of HCPs to which a presentation on a medicine in development is given is likely to be seen as promotional and therefore not permitted. Conversely, a small advisory board of HCPs with the relevant specialism who provide their clinical views on the indication and products in development in relation to specific requests for advice is more likely to be considered a permitted legitimate exchange on the basis that this is not a promotional activity.

Section 6.11 of the Blue Guide and Clause 11 of the ABPI Code permit the use of advertising material relating to products or indications not licensed in the UK at international symposia, conferences and meetings addressed to UK residents, including those held in the UK, where:

- the event is truly international and of high scientific standing;
- the medicine or indication is relevant and proportional to the purpose of the event/meeting;
- a significant proportion of the attendees are from countries outside the UK, and where the product and indication are licensed, on the condition that this includes at least one major developed country and the list of countries in which it is authorised are provided, with the statement that registration conditions differ by country;
- the ABPI rules on certifying are complied with;
- the material clearly and prominently indicates that the product or indication is unlicensed in the UK; and
- for an unlicensed indication, the UK prescribing information is readily available for a medicine authorised in the UK.

The ABPI Code applies to events for UK residents that are held outside the UK. The materials for these events are required to be compliant with the ABPI Code as well as any local requirements.

3.3 Provision of Information to Healthcare Professionals

See **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**.

Clause 3.1 of the ABPI Code permits the provision of advance information to NHS organisations where that information is solely directed to the budget decision-makers (not prescribers):

- involved in the purchase of medicines;
- who need to estimate their likely budgets in advance; and
- where those changes may significantly affect their level of expenditure such as through changes in the patient pathway and/or service delivery.

The information that may be provided must relate to a product:

- containing a new active substance, or containing a new active substance prepared in a new way;
- that is to have a significant addition to the existing range of authorised indications; or
- that is to have a novel and innovative means of administration.

The communication should:

- state whether or not the medicine has a UK marketing authorisation;
- state the likely cost or savings and budgetary implications (which must represent a significant change on likely expenditure);
- be factual and limited to an adequate but succinct account of the product's properties, with mentions of other products only being made to put the new product or indication into its therapeutic context;
- not be promotional in style; and
- not include mock-up drafts of the SmPC or package leaflets.

3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

3.5 Information About Early Access or Compassionate Use Programmes

Unlicensed medicines which are provided under a compassionate use or other early access programme cannot be promoted (Regulation 280(4) and Clause 11.1 of the ABPI Code). The programme itself cannot be promoted where this would amount to promotion of an unlicensed medicine, which will be likely in most cases except for public health campaigns, such as for COVID-19 vaccines.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is prohibited to publish an advertisement for a medicinal product unless there is an applicable marketing authorisation in place (Regulation 279 of the HMR). Under Regulation 280 of the HMR, any advertisement for a medicinal product must:

- comply with the SmPC;
- encourage rational use of the product by presenting it objectively and without exaggerating its properties; and
- not be misleading.

Regulations 283 to 292 of the HMR relate to the advertisement of medicines to the public. Restrictions on such advertising include on advertisements:

- likely to lead to use for the purpose of inducing an abortion (Regulation 283 of the HMR);
- likely to lead to use of a prescription-only medicine (Regulation 284 of the HMR);
- for narcotic or psychotropic substances (Regulation 285 of the HMR);
- that state or imply the necessity of a medical consultation or surgical operation;
- that offer to provide a diagnosis or suggest a treatment by post or electronic communication;
- that could lead to erroneous self-diagnosis;
- that suggest the effects of the medicinal product are guaranteed, are better than or equivalent to those of another identifiable treatment or medicinal product, or are not accompanied by any adverse reaction;
- that use, in terms that are misleading or likely to cause alarm, pictorial representations of changes in the human body of the disease or

injury or the action of the medicinal product on the human body;
- that suggest the health of a person who is not suffering from any disease or injury could be enhanced by taking the product, or that their health could be affected by not taking the product;
- that suggest the medicinal product is a food, cosmetic or other consumer product or that its safety or efficacy is due to it being natural;
- that include recommendations by scientists, HCPs or celebrities; and
- that are directed principally at children.

Consumer advertising is required to clearly identify that it is an advertisement, and the product is a medicinal product (Regulation 291 of the HMR).

Under the Cancer Act 1939, Section 4 specifically prohibits the publication of any advertisement offering to:

- treat any person for cancer;
- prescribe any remedy for cancer; or
- give any advice in connection with the treatment of cancer.

Licensed vaccine products approved by health ministers as part of a government-controlled vaccination campaign are exempt from the prohibition on advertising prescription-only medicines.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Laws

Regulation 291(2) of the HMR requires any advertisement of a medicinal product to include the following (see also Annex 3 of the MHRA Blue Guide):

- the name of the product;
- if there is only one active ingredient, the common name of the active ingredient;
- information necessary for the correct use of the medicinal product;
- an express and clear invitation to carefully read the instructions on the package or the package leaflet, as applicable; and
- for products with a Great Britain licence that are not also licensed in Northern Ireland or are prescription-only in Northern Ireland, a statement that the product is not available or not available without a prescription in Northern Ireland, as applicable.

The advertisement should be clear that the material or message is an advertisement and the product advertised is a medicine.

The MHRA Blue Guide (Appendix 3) provides detailed guidance on advertising medicines which may be promoted for use during pregnancy. The appendix applies both to consumer and to professional advertising.

Self-Regulation

The PAGB Consumer Code (Section 1.5.15) includes the following additional requirements for inclusion in advertisements for non-prescription-only products:

- therapeutic indication in line with the SmPC;
- products for conditions that are difficult to self-diagnose should state that people should obtain a doctor's diagnosis before using the product for the first time, particularly where this is stated in the SmPC;
- smoking cessation products should refer to the need for willpower to quit smoking successfully;
- promotion of medicines during pregnancy are only acceptable where a positive statement

in Sections 4.1 or 4.6 of the SmPC supports such use, and advertisements must encourage a cautious approach; and
- any other wording required as a condition of the marketing authorisation.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Guidance on the Law

The MHRA Blue Guide includes guidance for patient organisations in Appendix 5. This sets out the expectation that they will have robust procedures to ensure that they retain their independence from pharmaceutical companies, even if those companies provide them with support.

This means that any information provided by patient organisations should be under their editorial control to avoid it becoming promotional in nature and therefore subject to the medicinal product advertising laws. Patient organisations should also not actively encourage patients to seek a particular product from their doctor.

Patient organisations are also likely to be subject to Charity Commission rules.

The ABPI Code

Pharmaceutical companies are required to respect the independence of patient organisations and are not permitted to promote or request the promotion of a particular prescription-only medicine (Clause 27.1). They must not influence the text of patient organisation materials to favour their own interests (Clause 27.4), but may contribute to the drafting of patient organisation materials from a fair and balanced scientific perspective.

There must be a written agreement for all sponsorships, donations and grants to patient organisations (Clause 23.2).

The ABPI Code includes disclosure requirements imposed on manufacturers for interactions with patient organisations (Clause 4.4, 24.6 and 29). Manufacturers are required to document and annually publish on the company website at a national or European level:

- summary details of the monetary value of support to patient organisations, including in relation to sponsorship of events/meetings (Clause 10.11); and
- fees and expenses for the provision of contracted services by individuals representing patient organisations and the total amount paid per patient organisation per calendar year.

It is prohibited to provide gifts to individuals associated with patient organisations (Clause 3.5). Under Clause 24.3, donations and grants are only permitted to patient organisations if they:

- are made for the purpose of supporting healthcare, scientific research or education;
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines;
- are prospective in nature;
- do not bear the name of any medicine (the company name is acceptable); and
- are the subject of a written agreement detailing all the main elements of the arrangement (Clause 27.2), and which is certified.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Information Required by Law

Schedule 30 of the HMR details the information to be included in advertisements to HCPs. This includes the following.

- The number of the marketing authorisation.
- The name and address of the marketing authorisation holder.
- For an advertisement in Great Britain, a statement that the product is authorised under a UKMA(GB).
- The classification of the product:
  (a) general sale (G);
  (b) prescription-only (POM); and
  (c) pharmacy-only (P).
- The name of the medicine.
- The list of active ingredients, using their common names and placed immediately adjacent to the most prominent display of the name of the product.
- One or more indications consistent with the marketing authorisation.
- A succinct statement of the SmPC (which must be printed in a clear and legible manner and placed so that their relationship to the claims and indications can be readily appreciated by the reader) on:
  (a) adverse reactions, precautions and relevant contra-indications;
  (b) dosage and method of use relevant to the indications in the advertisement; and
  (c) if not obvious, the method of administration.
- The cost of either a specified package, quantity or recommended daily dose (except if more than 15% of the publication circulates outside the UK).

Schedule 30 of the HMR is clarified by Annex 4 of the MHRA Blue Guide.

The ABPI Code

Clause 12 of the ABPI Code restates the above list and adds the following items to be included in promotional materials.

- Any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the MHRA and that is required to be included in advertisements.
- The date the prescribing information was drawn up or last revised.
- The INN must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower-case x is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.
- In digital material the prescribing information may either be included directly or via a clear and prominent, direct, single-click link.
- Promotional material on the internet must include a clear prominent statement as to where the prescribing information can be found.
- Prescribing information must appear on at least one of the pages in a printed journal advertisement, and for those pages where it is not visible there should be a reference on the outer edge of the page for where to find the prescribing information, with a lower-case x no less than 2mm in height.
- The prominent statement “Adverse events should be reported. Reporting forms and

information can be found at Yellow Card | Making medicines and medical devices safer (mhra.gov.uk). Adverse events should also be reported to [relevant pharmaceutical company]".
- Where required, the inverted black equilateral triangle for products requiring additional monitoring.

Note that for an abbreviated advertisement to HCPs, meaning one that does not exceed 420 square centimetres, truncated information may be included rather than the full lists above (Regulation 295 of the HMR). These are referred to as "short form" advertisements in the Blue Guide, for which all information in Annex 5 must be given. These advertisements may only appear as an integral part of a publication and cannot be a loose insert or placed on the internet. Some innovative products which are new to the market in the previous two years may be subject to an agreement with the MHRA that a short form advertising form will not be used.

Information Prohibited by Law

The Blue Guide prohibits advertising which states or implies that a product is "safe" (paragraph 6.6).

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Promotional material to HCPs may refer to published studies if clear references are given. The materials may also refer to "data on file" if this data is not contrary to the SmPC, and this must be provided within ten working days of a response to a request from an HCP (Clause 14.3 ABPI Code).

5.3 Advertising of Combination Products

The European Union SmPC Guideline Section 4.1, Therapeutic Indications, states: "If the product's indication depends on a particular genotype or the expression of a gene or a particular phenotype, this should be stated in the indication."

European Union SmPC Guideline Section 5.1, Clinical Particulars, provides a summary of clinical trial information. Sometimes the predictive biomarker which was used and its brand name and or manufacturer are included, but the practice is not consistent and is not an absolute requirement. Once the In Vitro Diagnostics Regulations 2017/746 (IVDR) are in force and companion diagnostics are regulated under it, those diagnostics will recognise in their instructions for use (IFU) the specific medicines for which they are authorised companions, which is relevant in Northern Ireland.

Advertisements referring to medicinal products used in combination products must not include claims for the medicinal product that are not in the SmPC.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints may not be provided proactively unless the articles have been peer reviewed (Clause 16.5 ABPI Code). Reprints should be accompanied by prescribing information listed in Clause 12.2 of the ABPI Code.

5.5 Medical Science Liaisons

Medical science liaisons (MSLs) are subject to the same rules as any other employee of a manufacturer and are therefore not permitted to proactively discuss scientific information on unauthorised medicines or indications with healthcare professionals. Only discussions which are unsolicited individual written enquiries may be responded to.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Prior Authorisation/Vetting by the MHRA

Medicine advertising is not generally subject to prior authorisation by the MHRA. Prior vetting of advertisements can be requested by the MHRA and is sometimes undertaken in the following circumstances:

- a newly authorised product, subject to additional monitoring, is placed on the market (this is always applied for new active substances);
- upon reclassification; and
- where there have been previous advertising breaches.

Industry Bodies

The ABPI or the PMCPA do not as a rule authorise or vet advertisements, although the PMCPA monitors published advertising and meetings.

PAGB membership is conditional upon all over-the-counter medicine advertising aimed at consumers being approved by the PAGB prior to release (PAGB Consumer Code 1.4).

Other Self-Regulatory Bodies

Clearcast clears finished television advertisements against the UK Code of Broadcast Advertising. Radiocentre clears all advertisements featuring health claims and for medicines, medical devices and treatments before they are broadcast on the radio. The ASA offers a free but non-compulsory advice service against the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing.

6.2 Compliance With Rules on Medicinal Advertising

Regulation 281(2) of the HMR requires that authorisation holders establish a scientific service to compile and collate all information relating to the product. Regulation 281(3) of the HMR requires medical sales representatives to be given sufficient training and to have sufficient scientific knowledge to ensure the information they provide is as precise and complete as possible.

The ABPI Code requires members to establish a scientific service with a registered medical practitioner or a pharmacist registered in the UK, who will collate information received about the product (Clause 4.1).

Clause 8 of the ABPI Code requires all promotional materials to be certified by a registered medical practitioner or pharmacist registered in the UK, or a dentist for dental products. The certifier must be independent of the creation of the advertising and their details and qualifications must be notified in advance to the Advertising Standards and Outreach Unit, Vigilance and Risk Management of Medicines Division of the MHRA, and to the PMCPA. Changes in the names of nominated certifiers must be promptly notified.

The following promotions/materials must be certified to say that the final form of the material has been examined and that they believe it complies with the ABPI Code, is not inconsistent with the marketing authorisation and SmPC, and is a fair and truthful presentation of the facts about the medicine:

- all events or meetings involving travel outside the UK;
- educational material for the public or patients which relates to diseases or medicines but is

not intended as promotion for those medicines;
- material relating to working with patient organisations;
- material relating to collaborative working;
- material and items for patient support and associated supplementary information; and
- the written agreement for donations and grants.

Material in continuous use must be recertified at least every two years.

Training

The ABPI Code Clause 9 requires all employees and contractors engaging in the preparation or approval of the Code to be fully conversant with the Code and with pharmacovigilance requirements. All sales representatives must be given adequate training and have adequate scientific knowledge, and must take an exam within their first year of employment and pass it within two years to at least Level 3. Details of the number of representatives who have passed an examination and the exam status of the others must be provided to the PMCPA on request.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The Legal Position

The MHRA considers that material posted on UK websites and/or aimed at a UK audience is subject to UK medicines advertising legislation (paragraph 5.10 of the Blue Guide).

Prescription-only medicines may only be advertised on websites directed at HCPs (as determined by the nature of the content). It is not a requirement for such material to be access-restricted, but this is preferred (paragraph 6.3 of the Blue Guide). Websites with content for both consumers and including HCP advertising should have separate sections and should be clearly marked for the target audience. Where HCP materials are openly available, adequate non-promotional information should be provided in public areas to avoid consumers needing to access the sections for HCPs. There should be no direction of the public to materials for prescription-only medicines that are intended for HCPs. Journals intended for HCPs and published online are considered as directed to HCPs, but each page should state that they are so directed.

Company Websites

The Blue Guide paragraph 7.5 provides guidance on company websites and permits the following to be included in the publicly available areas:

- disease-related information;
- patient information leaflets (PILs), SPCs and public assessment reports (PARs) for their POM products; and
- other non-promotional reference information about the product that fairly reflects current evidence about the product and its benefit risk profile.

The ABPI Code applies to websites of:

- a UK company or with a UK company's authority; or
- an affiliate of a UK company, or with the authority of such a company, and where it makes specific reference to the availability or use of the medicine in the UK (Clause 1.2 of the ABPI Code).

Clause 12.6 ABPI Code requires that internet material includes a clear prominent statement of the location of the prescribing information.

Consumer Internet Advertising
The PAGB (1.5.12, rule 53) considers that the following fall within the remit of its Consumer Code and an offline version needs to be provided for review:

- brand websites and social media, including brand home pages (but not if the product is not mentioned);
- banner advertising;
- press releases intended for internet publication which are under the editorial control of the company; and
- pay-per-click advertising, such as that used on internet search engines.

Note that user reviews are not considered "advertising" unless adopted by the company, where they will be considered as such if the company curates the content, even if simply deleting certain reviews.

All internet content must include the essential information outlined in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**, but where there are significant space restrictions it may be acceptable to include the essential information one click away (PAGB 1.5.15).

Space-limited advertising is not considered appropriate for making:

- comparative claims other than sales claims;
- claims which require additional qualification;
- direct invitations to use a product; or
- encouragements to the user to read further information such as "Find out more about Brand X".

Where mobile advertisements consist of a series of swipeable or scrollable tiles, it may be acceptable to place the essential information on the tile at the end of the series.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

See **7.1 Regulation of Advertising Medicinal Products on the Internet**.

7.3 Provision of Disease Awareness Information to Patients Online

There are no specific permissions or prohibitions on posting disease awareness information and/or materials online, so the general rules apply. See **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

7.4 Online Scientific Meetings

There are no specific rules for online meetings in relation to pharmaceutical products.

7.5 Use of Social Media

See **7.1 Regulation of Advertising Medicinal Products on the Internet**.

Note that all paid-for posts (even without full creative control by the company) must be identified as advertising by using #ad. Care must be taken with retweets and "likes" to avoid celebrity endorsement of products, meaning companies should only do so if there is no implication that they used the product (PAGB Code 1.5.9).

Because of the complexity of rules around advertising medicinal products, it is wise for

pharmaceutical companies to have social media policies which limit the use of social media by employees to specifically authorised individuals. All other employees should be warned not to mention their company or its products in their personal social media activities: companies have been found to be in breach of the ABPI Code when employees have discussed their employer's products in their personal activities on social media.

While there is no specific provision in the UK about managing social media, the EFPIA guidance on discussion forums requires that a member company "facilitating or hosting" such a discussion "must be confident that they can moderate the site such that the content complies with relevant regulations, laws and codes including the EFPIA Code of Practice."

There is also EFPIA guidance on pharmacovigilance in digital channels which suggests that member companies consider developing specific guidance for digital channels and contact their pharmacovigilance experts for specific projects to meet their pharmacovigilance responsibilities.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The UK Bribery Act 2012 (Bribery Act) is the general law prohibiting the making of offers, promises or financial or other advantage to another person where the advantage is intended to induce improper performance of a function or activity and/or where it is known or believed that acceptance of the advantage would itself constitute the improper performance of a relevant function or activity (Section 1). It is equally an offence to request, agree to receive, or accept that advantage (Section 2). The provisions apply both to people in public service and to private businesses, and both individuals and entities can be subject to sanctions of the Bribery Act.

The Bribery Act has extraterritorial effect so that acts engaged in abroad by individuals or companies with sufficient proximity to the UK will also fall within the remit of its provisions.

There is a separate offence of "bribery of foreign public officials", which in the context of medicines can include regulators and those employed by public hospitals (Section 6).

Companies commit a criminal offence under the Bribery Act if they fail to prevent bribery (Section 7). It is a complete defence to that offence if the company can show that it had in place adequate procedures designed to prevent persons associated with the company (anyone performing services for or on behalf of the company, such as employees, agents or subsidiaries) from undertaking the questionable conduct. This underlines the need for good corporate governance, compliance policies and procedures.

The UK's NHS publishes provisions on conflicts of interest for compliance by entities within, and by individuals employed by, the NHS. These include Managing Conflicts of Interest: Revised Statutory Guidance For CCGs 2017 and Managing Conflicts Of Interest in the NHS Guidance For Staff and Organisations, which include notification requirements for those individuals.

8.2 Legislative or Self-Regulatory Provisions

Laws

Regulation 300(1) of the HMR provides that "a person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer or promise to such persons any give, pecuniary advantage or other benefit unless it is (a) inexpensive; and (b) relevant to the practice of medicine or pharmacy". HCPs are also not permitted to solicit or accept such gifts (Section 300(4)). There are similar restrictions on the provision of hospitality at meetings, which must be strictly limited to provision to HCPs and for the main purposes of the meeting, but is defined as including sponsorship of attendance and payment of travelling or accommodation expenses. Breach of these provisions is a criminal offence.

The ABPI Code

Clause 19 of the ABPI Code prohibits inducements, inappropriate payments and the provision of items to HCPs and other relevant decision-makers.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

The MHRA Blue Guide

Paragraph 6.15 discusses Section 300 of the HMR and defines "inexpensive" to mean items not costing the company more than GBP6 and representing a similar value to the recipient. Items relevant to the practice of medicine are those that have a clear business use, such as pens, notepads, calculators, diaries, calendars and coffee mugs.

The ABPI Code

Clause 19.2 permits patient support items to be provided to HCPs (not admin staff) if they are documented and certified in advance. The items must be inexpensive (no more than GBP10 excluding VAT) and directly benefit patient care, and may include the company name but not any product name unless essential for the item's correct use. The items must not be given out from exhibition stands.

Separately, patient access schemes are permitted if they meet the requirements of the ABPI Code.

Promotional aids may be given to HCPs and other decision-makers. Under the ABPI Code, in contrast to the MHRA Blue Guide, it is not permitted to provide mugs, stationery, computer accessories, diaries or other items for use in the home or car. Equally, items for use with patients such as surgical gloves are not permitted, nor must toys for waiting children be provided. Thus, only literature intended for patients may be provided in relation to prescription medicines. Memory sticks may be provided with saved promotional material if the volume of memory capacity is compatible with that material. It is also not permitted to provide HCPs with textbooks, unless part of a donation or grant for research and compliant with the relevant provisions. Equally, the provision of items to practices for long-term or permanent loan should be avoided.

9.2 Limitations on Providing Samples to Healthcare Professionals

Laws

Regulation 298 of the HMR permits the giving of samples solely to those qualified to prescribe medicinal products and for the purpose of acquiring experience in dealing with the product

in question. The following additional conditions apply to the giving of samples:

- it must be on an exceptional basis only;
- it must be in response to a written request from, signed and dated by the recipient;
- only a limited number of samples of the product in question may be supplied to the recipient in that year;
- the sample must be no larger than the smallest presentation of the product that is available for sale in the relevant region (Great Britain or Northern Ireland);
- it must be marked "free medical sample – not for resale" or bear a similar description;
- it must be accompanied by a copy of the SmPC; and
- the product must not be a narcotic or psychotropic substance.

The ABPI Code

Clause 17.2 reiterates the legal provisions, but adds further conditions:

- no more than four samples of a particular medicine may be provided to an individual health professional during a single year;
- samples of a particular medicine may be provided for no longer than two years after the HCP first requested it, except if it is an extension of an existing product, where that may be "new" (eg, in additional strengths and/or dosage forms), but not simply additional pack sizes;
- samples sent by post must be secured against opening by young children; and
- samples must not be provided simply as an inducement, but for the sole purpose of treating patients.

Companies are required to have adequate systems of control and accountability for the samples they distribute. These must show the number of samples supplied to each HCP.

9.3 Sponsorship of Scientific Meetings

See **8.2 Legislative or Self-Regulatory Provisions** for the relevant legal provisions, which are restated in the Blue Guide at paragraph 6.16. Note that the Blue Guide defines "advertising" as including sponsorship of meetings.

See **3.3 Provision of Information to Healthcare Professionals** for the content of international meetings.

The ABPI Code

The ABPI Code permits companies to hold, sponsor or support delegates to attend events and meetings that meet the Code's requirements. There are several conditions applicable to these meetings and events:

- the event/meeting must have a clear educational content;
- the programme, not the associated hospitality or venue, should attract delegates;
- the content must be appropriate and relevant;
- the venue must be appropriate and conducive to the main purpose of the event/meeting and not lavish or extravagant;
- any associated subsistence (food and drink), accommodation and travel costs must be strictly limited to the main purpose of the event/meeting, of secondary consideration, appropriate and not out of proportion to the occasion (see Clause 10.7);
- companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc); and
- any hospitality provided must not extend to an accompanying person unless that person qualifies as a proper delegate or participant at the meeting in their own right.

The cost of any subsistence (food and drink) provided must not exceed GBP75 per person, excluding VAT and gratuities.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are not permitted to sponsor cultural, sports or other non-scientific events in relation to or which are concurrent with scientific conferences (ABPI Code, Clause 10.1) as this would be considered an improper inducement (see **9.1 Gifts to Healthcare Professionals**).

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

The ABPI Code

The ABPI Code permits donations and grants to institutions, but not to individuals. These are permitted for supporting healthcare, scientific research or education and must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines. They must be prospective in nature and each subject to a specific and certified written agreement. The company must keep a record of the donation or grant, and these must be disclosed annually (see **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**).

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

The MHRA Blue Guide

Paragraph 6.14 of the Blue Guide provides guidance on examples to which Regulation 300 of the HMR will apply. Thus, cash returns to individuals and other personal benefits "in lieu" of discounts such as preferential loans, share options, shopping vouchers, gifts or special prices for travel, insurance, office equipment or computer software would constitute an offence under the HMR. Equally, a points scheme based on the volume of purchases is likely to constitute a breach.

The Blue Guide also clarifies that the offence may be committed by corporate and unincorporated bodies as well as individuals, and includes manufacturers and distributors of medicines, including wholesale dealers.

The ABPI Code

The ABPI Code adds that schemes which enable health professionals to obtain benefits in relation to the purchase of medicines are not acceptable, even if they are presented as alternatives to financial discounts. This would include the provision of gift vouchers, but also personal rebates.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible for companies to pay for bona fide services provided by HCPs. The requirement not to bribe an HCP to inappropriately prescribe is subject to the provisions of The Bribery Act (see **8. Pharmaceutical Advertising: Inducement/Anti-bribery**). Furthermore, the ABPI Code, Clause 24 imposes the following conditions:

- there must be a prior written agreement specifying the legitimate need, the services and the payment to be made;
- the criteria for selection of the particular HCP (and the number if several) must relate to the services and their expertise and be necessary to achieve the defined need of the company;
- the company must maintain records of the services and payments;
- remuneration for the services must be reasonable and reflect the fair market value of the services provided; and

- the agreement must also require the HCP to declare that they are contracted by the company when they write or speak in public about the company, including if they are an employee of the company while continuing to practise medicine.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The NHS conflicts of interest codes (see **8.2 Legislative or Self-Regulatory Provisions**) require that their employees and contractors notify hospitality and fees for services received from manufacturers.

The manufacturers are not under any obligation under the laws or codes to provide prior notifications of their activities with HCPs and HCOs.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Transparency is not currently a legal requirement in the UK, but is one that is imposed under the ABPI Code. The Code requires public annual disclosure of sums paid and benefits given to health professionals, other relevant decision-makers and healthcare organisations, such as:

- UK individuals, organisations, etc, for contracted services, such as HCPs and individuals contracted to patient organisations (Clause 24.4);
- patient organisations (Clause 4.4);
- individual members of the public, including patients and journalists (Clause 4.5);
- support of UK health professionals and other relevant decision-makers in relation to attendance at events/meetings (Clause 10.10);
- contributions to costs related to events/meetings (sponsorship) paid to healthcare organisations, patient organisations or organisations managing an event/meeting on their behalf (even if the identity of a support HCP is unknown to the company) (Clause 10.11), and individuals representing patient organisations (including donations, grants and collaborative working (Clause 20.5)); and
- payments made to contracted individuals in relation to market research (Clause 25.4).

Individuals must be identified, and fees and expenses reported separately.

Disclosures must be made annually on a publicly available website within six months of the end of the calendar year to which they relate and must remain in the public domain for at least three years. Records of disclosures must be retained for at least five years after the end of the calendar year to which they relate.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The ABPI Code is intended to apply to companies promoting medicines in the UK. Therefore, companies that do not yet have products on the market will not be members of the ABPI and will not be subject to the transparency requirements.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The MHRA enforces the HMR and can choose to do so through the courts. Regulation 303 of the HMR provides for criminal penalties of unlimited amount or imprisonment for up to two years for breaches of the laws regarding samples, medical sales representatives and inducements or hospitality. The MHRA can also require that a corrective statement be issued.

The MHRA generally only takes matters to court in the most egregious cases as it prefers to work with companies to ensure that they promote correctly, and will therefore more likely impose a vetting requirement on repeat offenders.

The Bribery Act is also applicable to inducements and hospitality, and may be enforced by the Serious Fraud Office.

The ABPI Code is operated by the independent PMCPA, which handles complaints about breaches through its own processes. Sanctions imposed include one or more of the following:

- the audit of a company's procedures for compliance with the Code;
- a requirement for the pre-vetting of future material;
- recovery of material from those to whom it has been given;
- the issue of a corrective statement;
- a public reprimand;
- advertising in the medical, pharmaceutical and nursing press of brief details of a public reprimand; and
- suspension or expulsion from the ABPI.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The UK does not have a regime for unfair competition actions. However, complaints can be made by competitors to any of the MHRA, the PMCPA or PAGB, or in the case of consumer advertising, the ASA, depending on which is appropriate given the product and/or the nature of the complaint.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

See **11.1 Pharmaceutical Advertising: Enforcement Bodies**.

11.4 Relationship Between Regulatory Authorities and Courts

See **11.1 Pharmaceutical Advertising: Enforcement Bodies**.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

The MHRA is particularly interested in websites offering medicinal treatment that extend to advertising pharmaceutical products. They are also concerned with the advertising of unlicensed medicines.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

There are four categories of veterinary medicines:

- Prescription-Only Medicine – Veterinarian (POM-V);
- Prescription-Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS);

- Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS); and
- Authorised Veterinary Medicine – General Sales List (AVM-GSL).

Regulation 10 of the Veterinary Medicines Regulations 2013 (VMR) prohibits the advertisement of human medicines for administration to animals, save that the holder of a wholesale dealer's authorisation may supply a list of authorised human medicinal products together with prices to a vet who has requested it if the list clearly states that the product is not authorised as a veterinary medicinal product and may only be prescribed and administered under the cascade. The cascade is a list of products that vets may administer to animals in a descending order if the higher-level product is not available and is set out in paragraph 1 of Schedule 4 of the VMR.

Regulation 11 VMR requires that:

- the advertising of veterinary medicinal products not be misleading or contain claims not in the SmPC; and
- products requiring a veterinary prescription or containing psychotropic drugs or narcotics are not advertised to the public.

Advertising of:

- POM-V is permitted to vets, veterinary nurses, pharmacists and professional animal keepers;
- POM-VPS is permitted to vets, pharmacists, suitably qualified persons and professional animal keepers; and
- NFA-VPS and AVM-GSL is permitted if the advertising is not misleading, and the claims are accurately taken from the SmPC, and in each case if this is within the SmPC.

It is not permitted in such advertising to give company or product-specific recommendations or endorsements, and any presentations must be unbiased and factual. It is considered by the MHRA to be good practice for vets to declare affiliations when presenting treatment options at conferences or training events.

Anti-microbials must not be advertised to professional animal keepers.

It is prohibited to advertise anything containing a veterinary medicinal product as suitable for top dressing (sprinkling on feed) unless the SmPC specifically permits this.

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Author

Alison Dennis co-heads Taylor Wessing's international life sciences and healthcare group. She works with international life sciences companies to cut through the complexity of EU regulation of medical devices and pharmaceuticals, and get their products to market. In a career of over 25 years, Alison has helped hundreds of life sciences companies manage the range of legal challenges involved in commercialising medical devices and medicinal products. She combines an encyclopaedic knowledge of the EU and UK life sciences regulatory environment with an analytical understanding of strategy and business in the life sciences sector.

Taylor Wessing

DX 41 London
5 New Street Square
London
EC4A 3TW
UK

Tel: +44 20 7300 4725
Email: a.dennis@taylorwessing.com
Web: www.taylorwessing.com

USA

Law and Practice

Contributed by:
Seth H Lundy, Nikki Reeves, Heather Bañuelos and Gillian Russell
King & Spalding LLP see p.418

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USA

1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The FDA's Authority Over Prescription Drug Advertising and Promotion

The Federal Food, Drug, and Cosmetic Act (FDCA) grants the United States (US) Food and Drug Administration (FDA) broad authority over the advertising and promotion of prescription drugs. FDA regulations, found in Title 21 of the Code of Federal Regulations (CFR), outline the requirements for prescription drug advertising and promotion. FDA guidance documents, found on the FDA's website and published in the Federal Register, describe specific FDA policies related to prescription drug marketing.

The FDA's Office of Prescription Drug Promotion (OPDP) is charged with ensuring that prescription drug advertising and promotion is truthful, balanced and not misleading. The FDA's Advertising and Promotional Labeling Branch (APLB) is responsible for the same for licensed biological products. Among other things, the OPDP and APLB provide written advisory comments on proposed promotional materials, review complaints about alleged violations, and issue untitled or warning letters citing false or misleading promotional materials.

The FTC's Authority Over Promotion of OTC Drugs

The Federal Trade Commission (FTC) Act (FTCA) prohibits "unfair or deceptive acts or practices in or affecting commerce", including the dissemination of false advertising for drugs. Under a joint FDA/FTC Memorandum of Understanding, the FDA holds primary jurisdiction over the labelling of all drugs and the advertising of prescription drugs, while the FTC maintains primary authority over the advertising of non-prescription drugs (also known as over-the-counter (OTC) drugs); see **2.1 Definition of Advertising**.

Other Sources of Oversight of Drug Promotion

State consumer protection laws, both civil and criminal, also prohibit false or misleading advertising.

The Lanham Act (15 USC 1125(a)) allows competitors and other entities that have suffered commercial harm to sue for false or misleading advertising.

Promotional activities may implicate the criminal Anti-Kickback Statute (AKS) (42 USC 1320a-7b) and the Civil Money Penalties Statute (42 USC 1320a-7a); see **8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals**. Violations of the AKS may also result in violations of the civil False Claims Act (31 USC 3729); see **11.1 Pharmaceutical Advertising: Enforcement Bodies**.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Some trade or medical associations issue voluntary guidelines on pharmaceutical advertising and promotion. These guidelines address a variety of issues, ranging from funding continuing medical education, engaging physicians as speakers or consultants, and giving gifts or items of value to physicians.

While the FDA's and FTC's rules are enforced through law, voluntary self-regulatory codes and professional guidelines establish standards of acceptable behaviour but hold no legal authority. The Pharmaceutical Research and Manufactur-

ers of America (PhRMA) has a Code on Interactions with Healthcare Professionals (PhRMA Code) which provides guidelines for pharmaceutical companies when interacting with healthcare professionals (HCPs). Though the code is voluntary, the US Department of Health and Human Services' Office of Inspector General (OIG) endorsed its use in a 2003 guidance document. Thus, many pharmaceutical companies adopt the PhRMA Code as company policy and some states have made it mandatory for pharmaceutical companies operating within their borders.

Other third-party guidelines relevant to communications about pharmaceuticals include:

- PhRMA's Direct to Consumer Advertising Principles;
- PhRMA's Principles on Responsible Sharing of Truthful and Non-Misleading Information;
- the Accreditation Council for Continuing Medical Education (ACCME) Standards; and
- the American Medical Association (AMA) policies.

In addition, the National Advertising Division (NAD), a non-judicial, advertising industry self-regulatory body, adjudicates advertising disputes brought by consumers, competitors or the NAD itself.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The FDA's authority under the FDCA includes oversight of promotional labelling for all drugs and advertising for prescription drugs. Section 201(m) of the FDCA defines drug labelling as "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article". Courts have defined "accompanying" broadly to include most types of promotional materials (eg, brochures, literature reprints, mailers, printed or digital sales aids, emails, slide decks, videos, websites and social media posts).

The FDCA does not define advertising; however, FDA regulations provide examples such as "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The FDA recognises certain limited categories of "non-promotional" communications that constitute neither labelling nor advertising and are, therefore, not subject to the requirements for prescription drug promotion under the FDCA.

One example of "non-promotional" information is disease awareness communications, which are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention or imply any specific drug. The FDA's long-standing policy is that disease awareness communications should be perceptually different (eg, different colour schemes, graphics, etc) and should appear physically separate from any branded advertising and promotion to avoid converting the disease awareness communication into implied promotion and advertising.

For additional examples of "non-promotional" communications, see **3.3 Provision of Information to Healthcare Professionals**, **3.4 Provision of Information to Healthcare Institutions** and

3.5 Information About Early Access or Compassionate Use Programmes.

2.3 Restrictions on Press Releases Regarding Medicines

In general, the FDA expects press releases discussing an approved drug to comply with FDA regulatory requirements for promotional labelling, including being truthful and not misleading, maintaining fair balance between risks and benefits, and disclosing appropriate risk information.

Press releases about investigational drugs (eg, announcing significant clinical study results or the filing of a new drug application with the FDA) should be non-promotional in intent, tone and context, and avoid promotional claims and commercial objectives. The press release should truthfully and accurately present all material information. Press releases that make conclusory statements regarding the safety or efficacy of the investigational drug, mischaracterise study data, or fail to adequately disclose the investigational status of the drug could be viewed as pre-approval promotion, and thus as misbranding an investigational drug under the FDCA.

2.4 Comparative Advertising for Medicines

Generally, the FDA requires that any comparative efficacy or safety claim be supported by scientifically appropriate and statistically sound data. The FDA does not typically permit a claim of superior efficacy or safety based solely on the differences in the FDA-approved labelling of drugs or a comparison of results from two different studies. Comparative claims should be clinically relevant to the approved use of the drug and must not be false or misleading.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The FDCA prohibits the introduction of a drug into interstate commerce that is intended for a use that has not been approved by the FDA. FDA regulations prohibit the promotion of an investigational (unapproved) drug as safe or effective for the purposes for which it is under investigation. This includes drugs that have never been approved, as well as unapproved indications for drugs that are approved for a different use.

Despite a broad prohibition on the promotion of unapproved drugs and indications, the FDA's current approach permits non-promotional communications about unapproved drugs and indications under the principles of scientific exchange. Importantly, a range of permissible communications qualify as scientific exchange, including:

- scientific publications and presentations;
- support for independent scientific and medical education;
- responding to unsolicited requests for information;
- distributing scientific or medical publications on unapproved uses and/or risks;
- listing information on ClinicalTrials.gov; and
- communications with payors in advance of approval.

3.2 Provision of Information During a Scientific Conference

Factual and non-promotional presentations, posters and abstracts about unapproved drugs or indications that are submitted to a scientific

conference are typically regarded as legitimate scientific exchange.

In addition, it is common practice for pharmaceutical companies to host booths or exhibits at scientific conferences, which may include a medical information booth. A medical information booth should be non-promotional and staffed by scientific or medical personnel. While companies should carefully consider promotional communications at both domestic and international conferences, there are no specific rules for medical information booths.

3.3 Provision of Information to Healthcare Professionals

As noted in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, although the FDA strictly prohibits the promotion of unapproved drugs and uses, it allows non-promotional scientific exchange, including the following limited "safe harbours" through which manufacturers can distribute or support information to HCPs about unapproved (off-label) uses of approved drugs.

FDA Off-Label Reprints Guidance – Proactive Distribution of Off-Label Reprints to HCPs

The FDA permits the proactive distribution of off-label reprints under recommendations stated in three guidance documents:

- "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (2009);
- "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices" (draft guidance, 2014) (hereafter "Off-Label Reprints Guidance"); and
- "Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products – Recommended Practices" (draft guidance, 2014) (hereafter "Risk Information Reprints Guidance").

The Off-Label Reprints Guidance

The Off-Label Reprints Guidance provides recommendations for the distribution of off-label scientific or medical journal articles, scientific or medical reference texts, and clinical practice guidelines. Each type of publication is subject to specific recommendations to ensure that distribution is appropriate.

Generally, off-label reprints should not be false or misleading and should not pose a significant risk to public health. The source of the publication should be considered, and should not be letters to the editor, special supplements funded by the manufacturer, or abstracts. Additionally, reprints should be provided in a complete and unabridged format, without alteration. Off-label reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's FDA-approved labelling – also known as the "prescribing information" or "package insert" (PI) – and a range of disclosures, including that the reprint discusses off-label uses of the company's product.

The Risk Information Reprints Guidance

The Risk Information Reprints Guidance permits the distribution of reprints about new risk information that may refute, mitigate or refine risk information in the FDA-approved labelling. The reprint should meet the range of standards presented in the FDA's Risk Information Reprints Guidance, including that it is published in an

independent, peer-reviewed journal and based on appropriate study design and methodology.

Risk information reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's PI and a range of disclosures, including that the information is not consistent with risk information in the FDA-approved labelling and the FDA has not reviewed the data.

FDA Unsolicited Requests Guidance – Reactive Distribution of Off-Label Information

Under the FDA's 2011 draft guidance, "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices", the FDA permits companies to respond to unsolicited requests for information on unapproved uses of approved prescription drug products. The guidance outlines the FDA's position and recommendations on:

- distinguishing between solicited versus unsolicited requests;
- distinguishing between public versus non-public requests; and
- responding to unsolicited requests.

Independent Scientific Education

The FDA's 1997 guidance, "Industry-Supported Scientific and Educational Activities", makes clear that the FDA will not regulate industry-supported scientific activities that are independent of the influence and control of the supporting company. The guidance outlines a number of factors that the FDA will consider in evaluating the independence of industry-sponsored scientific activities, including those that may discuss unapproved drugs or off-label uses of approved drugs.

3.4 Provision of Information to Healthcare Institutions

The FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Other Similar Entities – Questions and Answers" (Communications with Payors Guidance), established a safe harbour that expressly permits manufacturers to disseminate certain information about investigational drugs and unapproved uses of approved drugs to payor audiences prior to approval.

Communications disseminated in compliance with the guidance will not be considered violations of the prohibition on promotion of an investigational drug. The types of information about investigational drugs and unapproved uses of approved drugs that may be disseminated to payors before approval include:

- proposed indication;
- anticipated timeline for FDA approval;
- pricing;
- patient support programmes;
- patient utilisation projections; and
- results of clinical studies.

All information provided must be non-promotional, "unbiased, factual, accurate and non-misleading" and accompanied by a clear statement of the drug's investigational status and stage of development.

3.5 Information About Early Access or Compassionate Use Programmes

Compassionate use or "expanded access" programmes establish a pathway for a patient with an imminently life-threatening or serious disease or condition to access an investigational drug when the treatment is unavailable in clinical trials and there are no other similar or sufficient therapy alternatives.

Under the 21st Century Cures Act, companies developing investigational drugs are required to publicly publish an expanded access policy on the company website and/or the Reagan-Udall Foundation's Expanded Access Navigator website for the investigational drug.

The published policy must include:

- contact information for the manufacturer or distributor;
- the procedure for submitting requests;
- the general criteria that the manufacturer or distributor uses to evaluate the requests;
- the length of time anticipated to respond to the request; and
- a hyperlink or other reference to the clinical trial record containing all the required information that must be submitted to ClinicalTrials.gov about expanded access availability for the drug.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising to the general public, also commonly referred to as direct-to-consumer (DTC) advertising, is permitted in the US. Companies may promote prescription drugs to the general public provided that the communication meets the following fundamental requirements.

- On-label or consistent with label: advertising and promotion of prescription drugs must be consistent with the intended use for which the product is approved by the FDA, as established in the drug's FDA-approved labelling (ie, the PI). The labelling provides information on how to use the product safely and effectively for the approved indication, including but not limited to the patient population, dosage and administration. Advertising and promotion that discuss uses of the product that are not contained in or consistent with the FDA-approved labelling are regarded as unlawful "off-label" promotion. Refer to the FDA's 2018 guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers" (CFL Guidance), for details. See **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.
- Fair balance: the FDA regulations require prescription drug promotion and advertising to present a "fair balance" between product benefits and risks, ensuring that such information appears comparable in depth, detail and context. Promotional materials are misleading if they fail to present information about risks associated with a drug with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug. Refer to the FDA's 2009 draft guidance, "Presenting Risk Information in Prescription Drug and Medical Device Promotion", for details.
- Adequately substantiated: traditionally, all advertising and promotional claims about the safety or efficacy of a prescription drug have been required to be supported by substantial evidence or substantial clinical experience, which is the FDA's approval standard for prescription drug products. Under the CFL Guidance, claims should be supported by at least scientifically appropriate and statistically sound evidence.
- Otherwise truthful and not misleading: if prescription drug advertising and promotion is false or misleading in any particular, it will be considered misbranded under the FDCA and subject to enforcement.

Although not a requirement, the FDA strongly recommends the use of consumer-friendly language, and avoidance of technical language, scientific terms and medical jargon, in consumer-directed advertising and promotion.

The promotion of OTC drugs must also adhere to the product's approved labelling or monograph, as applicable. In addition, such promotion must be truthful and not misleading, including that all advertising claims are substantiated by competent and reliable scientific evidence. The FTC maintains regulations and guidelines governing consumer advertising to ensure that communications are not deceptive or misleading.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Consumer-directed prescription drug advertising and promotion must contain the following core elements, as required by the FDCA and FDA regulations.

Core Elements

Proprietary and established names

The placement, size, prominence and frequency of the proprietary (brand or trade) and established (generic) names for prescription drugs are specified in FDA regulations, with additional recommendations in the FDA's 2017 guidance, "Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements".

Quantitative composition

Advertising and promotion must include the quantitative amount of each ingredient of the advertised drug. Companies commonly include this information as part of the product logo.

Brief summary

Printed DTC advertisements must include information in "brief summary" that discloses each side effect, warning, precaution and contraindication. To fulfil this requirement, DTC print advertisements traditionally included the complete risk-related sections from the product's PI. To fulfil the adequate directions for use requirement, a copy of the PI has traditionally been provided.

Contrary to these traditional approaches, the FDA's 2015 revised draft guidance, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs", recommends that DTC printed promotional labelling and advertising utilise a "consumer brief summary" focused on the most important risk information, rather than an exhaustive list of product-related risks, presented in a way most likely to be understood by consumers. In addition, a copy of the PI is no longer recommended.

Major statement

Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in a clear, conspicuous and neutral manner in either audio or audio and visual. This is referred to as the "major statement". In addition, the advertisement must present a brief summary or, alternatively, make "adequate provision" for consumers to obtain the PI. The FDA's 1999 guidance documents, "Consumer-Directed Broadcast Advertisements" and "Consumer-Directed Broadcast Advertisements – Questions and Answers", provide recommendations for satisfying the adequate provision requirement through a toll-free telephone number, concurrent with a print advertisement in a widely distributed

publication, on a website, and/or in consultation with an HCP.

Adverse event reporting disclosure statement
DTC print advertisements must include the following MedWatch statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088."

Reminder Labelling and Advertising
Under FDA regulations, reminder labelling and advertising is exempt from the general requirements above if it is limited to the proprietary and established names of the drug, and does not include any indications, disease state information, dosage, or other product representations. Additional optional information includes quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, and price information.

Importantly, reminder labelling and advertising is not permitted for a prescription drug with a boxed warning in its FDA-approved labelling.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interactions between pharmaceutical companies and patients and/or patient organisations are permitted in the US, subject to the variety of limitations discussed in this chapter. For product-related advertising and promotion, communications must be on-label/CFL, fair and balanced, adequately substantiated and not otherwise false or misleading; see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

In addition, interactions must not implicate the AKS by inducing patient organisations or patients to recommend or use the advertised product; see **8. Pharmaceutical Advertising: Inducement/Anti-bribery** and **9. Gifts, Hospitality, Congresses and Related Payments**.

Companies may also communicate with patients and patient organisations, such as patient advocacy groups, in a non-promotional manner to respond to unsolicited requests for information (see **3.3 Provision of Information to Healthcare Professionals**) or to provide information about clinical studies for recruitment purposes.

In addition, companies interacting with patients must abide by applicable federal and state privacy laws and avoid providing advice for the diagnosis, treatment, care or prognosis of an individual, which would be regarded as unlawfully engaging in the practice of medicine.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Rules for the advertising and promotion of prescription drugs to HCPs are generally the same as those that apply to advertising and promotion to consumers, including the fundamental requirements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**), as follows:

- on-label or consistent with label;
- fair balance;
- adequately substantiated; and
- otherwise truthful and not misleading.

Prescription drug promotion and advertising to HCPs must also provide adequate directions for use, a requirement that is met by providing a copy of the FDA-approved labelling (ie, the PI).

Advertising and promotion targeting HCPs must also contain some of the same core elements as DTC advertising and promotion, including proprietary and established names and quantitative composition; see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. Unlike DTC advertising, a "brief summary" for HCP-directed print advertisements should follow the FDA's traditional approach, which means including the risk-related sections of the PI with the advertisement, but there is no requirement to include the MedWatch statement.

Promotion and Advertising to Payors

Under the FDCA, a company may provide healthcare economic information (HCEI) related to a product's indication to payor audiences, provided that it is supported by competent and reliable scientific evidence. The pathway to promote HCEI to payors grants some flexibility, but is still subject to other rules of prescription drug promotion. Refer to the Communications with Payors Guidance for details.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The US equivalent to the Summary of Product Characteristics (SmPC) is the FDA-approved label (ie, PI). As previously mentioned, promotional communications for prescription drugs must include only information about the drug that is either within the drug's FDA-approved label (on-label) or consistent with the label (CFL). The CFL Guidance explains a three-factor test to determine whether product-related information is CFL. If a product communication fails any of the three factors below, it is not considered CFL and risks being off-label.

- How does the information in the communication compare to the information in the FDA-approved label – does it suggest a different indication, patient population, limitations and directions for use/handling, and/or dosing or usage regimen?
- Does the information suggest use of the drug in a manner that could increase the potential for harm to health relative to the information reflected in the drug's FDA-approved label?
- Do the directions for use in the FDA-approved label enable the product to be safely and effectively used under the conditions suggested in the communication?

In order to be distributed as CFL, the information must be:

- substantiated by "scientifically appropriate and statistically sound" (SASS) evidence;
- factually accurate;
- presented with appropriate context, including disclosure of any limitations of the data, analyses and conclusions; and
- otherwise truthful and not misleading.

Examples of information that may be considered CFL include:

- comparisons;
- adverse reactions;
- onset of action;
- long-term safety or efficacy;
- patient subgroups;
- patient compliance or adherence; and
- patient perceptions, convenience and mechanism of action.

Refer to the CFL Guidance for details.

5.3 Advertising of Combination Products

The FDA does not have specific rules for the advertising of drugs with companion products. As noted in **5.2 Reference to Data Not Included in the Summary of Product Characteristics**, all promotional communications should be on-label or CFL. If the FDA-approved labelling of a combination product does not include details of each of the individual products in the combination, the company should evaluate the information under the CFL Guidance and consider potential off-label risks.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

If a reprint is on-label or CFL, it may be used in a promotional manner, subject to the basic requirements for advertising and promotion directed at HCPs. If a reprint discusses an unapproved use of the product (ie, off-label), then it might be distributed under the FDA's established safe harbour for off-label reprints; see **3.3 Provision of Information to Healthcare Professionals**.

5.5 Medical Science Liaisons

The primary responsibility of a Medical Science Liaison (MSL) is scientific engagement and education with HCPs, focusing on specific therapeutic areas, disease states and/or products in support of their company's product pipeline and portfolio. MSLs are also used to help support scientific initiatives, such as identifying and recruiting potential sites and investigators for company-sponsored studies, scientific and medical advisory boards, and internal training and education, among others.

In general, an MSL may engage HCPs proactively or reactively consistent with the FDA's policy on off-label communications, but their interactions should not be promotional; see **3.3 Provision of Information to Healthcare Professionals** and **3.4 Provision of Information to Healthcare Institutions**. Specifically, MSLs may proactively discuss with HCPs therapeutic areas and disease states generally, as well as approved uses of approved products. Proactive discussions of investigational drugs or unapproved uses of approved drugs are generally not regarded as permissible activities for MSLs, as these proactive communications could be perceived as pre-approval or off-label promotion.

A significant role of MSLs is reactive interactions with HCPs, in which an MSL responds to unsolicited requests for scientific or medical information; see **3.3 Provision of Information to Healthcare Professionals**.

Importantly, the role and responsibilities of an MSL are scientific and medical in nature, and not commercial or promotional. Because the separation of functions is critical to preserving the legitimacy of MSL scientific exchange activities, MSLs and Medical Affairs should remain independent of commercial influence, including reporting/supervisory structures.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

In general, there is no requirement for prior notification or authorisation for prescription drug advertising and promotion; however, there are limited exceptions:

- companies whose advertisements have violated FDA or FTC standards in the past may be asked to pre-clear their advertisements in the future;

- prescription drugs approved under the accelerated approval process are subject to a "presubmission" requirement (ie, promotional materials must be submitted to the FDA prior to the intended date of dissemination or publication); and
- DTC television advertisements must be submitted for pre-dissemination review (Refer to the FDA's 2012 draft guidance, "Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program", for details).

Companies always have the option to voluntarily submit proposed promotional labelling or advertising to the FDA for advisory review.

2253 Submission

The FDA's post-marketing reporting regulations require pharmaceutical companies to submit prescription drug promotional labelling and advertising materials to OPDP at the time of first use. This submission must be made using a completed Form FDA 2253 and must include a copy of the promotional material and the product's current PI.

6.2 Compliance With Rules on Medicinal Advertising

FDA regulations governing current Good Manufacturing Practices (CGMPs) require strict controls over labelling issued for use in drug product labelling operations. Although this regulation is typically applied to FDA-approved labelling (ie, PI), it should also be used for the development of promotional labelling.

It is best practice to adopt internal policies and standard operating procedures for managing the review, approval and use of promotional labelling and advertising. Typically, this is a cross-functional activity that includes company representatives from legal, regulatory, medical and compliance departments.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

In general, the FDA's standard advertising and promotion rules apply to advertising and promotion on the internet. The FDA expects prescription drug websites to:

- include risk information on the same screen as efficacy information;
- provide a prominent link to the PI;
- distinguish sites intended for US audiences and international audiences;
- ensure that all claims, images and graphics are CFL; and
- avoid links to off-label information.

Separately, the FTC has published several guides governing disclosures on the internet and social media, including ".com Disclosures: How to Make Effective Disclosures in Digital Advertising" (2013) and "Disclosures 101 for Social Media Influencers" (2019).

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

There is no requirement to limit access on pharmaceutical promotional websites intended for HCPs. However, it is common industry practice to include an interstitial page (eg, pop-up notice) for users to confirm they are a US HCP before accessing the page.

7.3 Provision of Disease Awareness Information to Patients Online

It is common practice in the US for pharmaceutical companies to develop disease awareness websites, social media pages, or online advertising directed to consumers. In general, the same rules that apply to traditional forms of disease awareness communications apply to online disease awareness content; see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

7.4 Online Scientific Meetings

The same rules apply to promotion and advertising in online scientific meetings or congresses as in in-person settings. For virtual events, promotional materials should be reviewed according to traditional FDA advertising and promotion rules, but with the digital format and functionality in mind. In addition, given that geographic limitations are inherently more fluid in a virtual setting, companies should consider including clear disclosures regarding the intended audience, particularly if the product approval status or indication differs outside the US.

As with traditional in-person conferences, the AKS (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**) and PhRMA Code apply to the provision of items of value (eg, items for attendees) or other hospitality associated with a virtual scientific meeting or congress; see **9. Gifts, Hospitality, Congresses and Related Payments**.

7.5 Use of Social Media

The FDA permits advertising and promotion of prescription drugs on social media. Generally, the FDA's standard advertising and promotion rules apply, regardless of the social media platform being used.

The FDA has also issued guidance documents relevant to the use of social media for prescription drug promotion.

- "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media" (2014) describes when companies will be held responsible for social media content, including user-generated content (UGC), and how to submit interactive social media content via Form FDA 2253.
- "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (2014) explains that the FDA's long-standing rules regarding disclosure of risk information apply even in the context of character-limited communications (eg, Twitter, sponsored links).
- "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices" (2014) describes how companies can address incorrect information posted about their products on social media or the internet by third parties unaffiliated with the company.

Various FDA guidance documents explain that a company is responsible for promotional content and communications that are:

- on sites that are owned, controlled, created, influenced or operated by, or on behalf of, the company;
- on a third-party site if the company has any control or influence over the third-party site; and/or
- generated by an employee or agent who is acting on behalf of the company to promote the company's product.

Notably, a 2014 warning letter to Zarbee's illustrates the potential for companies to be held responsible for independent UGC (eg, social media comments) if they endorse those statements by "liking", "sharing", or positively commenting on them.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

The Anti-Kickback Statute

The Anti-Kickback Statute (AKS) (42 USC 1320a-7b) prohibits individuals and entities from knowingly and wilfully soliciting, receiving, offering or paying any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in order to induce the provision of a good or service that is reimbursable under a federal healthcare programme, including Medicare and Medicaid.

The scope of the AKS is broad and applies to any individual or entity (including manufacturers, healthcare providers and organisations, and lay persons) that provides, offers, solicits or receives remuneration with improper intent. The courts have broadly interpreted the AKS to cover any arrangement where even one purpose of remuneration, though not its sole or primary purpose, is to provide value for the referral, purchase, use or recommendation of goods or services reimbursed by Medicare or Medicaid.

"Remuneration" includes anything of value and there is no de minimis exception. Remuneration includes gifts, payments and other things typically thought of as benefits, but also broadly includes price reductions (such as discounts or rebates) and free or below-cost products and services.

Safe Harbour Regulations

The OIG has promulgated final "safe harbour" regulations specifying certain types of arrangements/remuneration that will not be considered to contravene the AKS. The safe harbours include, among others, protection for certain discounts/rebates, warranties, employment and services arrangements. If an arrangement satisfies all the criteria of a safe harbour, it will be immune from criminal prosecution and civil exclusion under the AKS. Failure to satisfy any safe harbour does not necessarily mean that the arrangement violates the AKS; however, arrangements falling outside a safe harbour present a legal risk and may be more likely to be scrutinised as violations of the kickback prohibition. There are both criminal and civil penalties for violating the AKS.

State Statutes

Various states have also enacted similar anti-kickback statutes that apply to inducements related to healthcare items and services (including drugs) reimbursed by private insurance, not just those reimbursed by a federal or state healthcare programme. Requirements under state law must be reviewed on a state-by-state basis.

Civil Monetary Penalties

Similar to the AKS, the Civil Monetary Penalties (CMP) provisions of the Social Security Act (42 USC 1320a-7a) prohibit the offering or provision of inducements to federal healthcare programme beneficiaries and impose monetary penalties on entities that offer or transfer remuneration to such a beneficiary, when they know or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or

supplier of items or services paid for by certain government programmes.

Distinctions Between the AKS and CMP

A few distinctions between the AKS and the CMP are notable. Firstly, the CMP law prohibits inducements only to Medicare and state healthcare programme beneficiaries (Medicaid), not to all federal healthcare programme beneficiaries. Secondly, the CMP law may have indirect application (ie, the law is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner or supplier). Thus, a pharmaceutical manufacturer, which is not a provider, practitioner or supplier, could implicate the statute if it offered or gave remuneration to a beneficiary that it believed would be likely to induce the beneficiary to order an item or service from a particular provider, practitioner or supplier (eg, to choose a particular physician or pharmacy).

8.2 Legislative or Self-Regulatory Provisions

Because the penalties for violating the AKS and related civil statutes can be severe (including potentially leading to incarceration and/or exclusion from participation in federal healthcare programmes), there is a strong benefit to self-regulation.

Firstly, the OIG issued compliance guidance for pharmaceutical manufacturers – in part, to provide notice about activities that are likely to violate the AKS or CMP law. Companies self-regulate by developing internal policies and procedures that establish compliant practices and require auditing and monitoring of activities to ensure compliance.

Secondly, the PhRMA Code sets forth voluntary guidelines for companies to stake out industry positions on common activities that should not be deemed to violate the AKS or CMP law.

Finally, companies can adopt self-reporting protocols, consistent with guidelines from the OIG and the US Department of Justice, to self-report internally identified wrongdoing. Addressing potential fraud and corruption via internal policy and procedure, or by self-reporting to US authorities, can significantly help to mitigate potential allegations and/or penalties in the event of wrongdoing.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Under the PhRMA Code

The PhRMA Code expressly prohibits gifts that are intended for the personal benefit of HCPs, including practice-related items of de minimis value (eg, pens, pads, mugs, etc). Under the PhRMA Code, only items that "advance disease or treatment education" for patients may be furnished without charge to HCPs.

However, the PhRMA Code allows manufacturers to pay for or reimburse meals or travel expenses for HCPs in limited situations. Modest meals are generally permissible under the PhRMA Code only when they are provided in conjunction with:

- an "informational presentation or discussion conducted by company representatives or their immediate managers working in field sales" in the HCP's office;
- an HCP's travel or meetings for consulting, training or speaking services on behalf of the

manufacturer pursuant to a written agreement; or
- an HCP's attendance at a speaking or training event of the manufacturer.

In these situations, meals should be:

- modest;
- occasional;
- without attendance of spouses or guests;
- in a location that is conducive to educational or business content;
- subordinate in time and focus to the presentation, service or training at issue; and
- eaten on the premises (ie, no takeaway or two-hour meals for a 30-minute presentation).

The PhRMA Code also prohibits companies from providing or paying for alcohol at meetings or presentations with HCPs.

Similarly, covering or paying for "reasonable" travel expenses is generally permissible under the PhRMA Code when made for an HCP's travel for meetings or services involving consulting, training or speaking services on behalf of the manufacturer pursuant to a written agreement. Travel expenses should not be covered for personal expenses or for individuals travelling with the HCP.

Under the AKS and Similar State Laws

Under the AKS and similar state laws, there are no express protections for remuneration in the form of gifts, free samples, grants or donations to support scientific meetings, research, or cultural, sporting or other non-scientific events, or free or below-cost products or services, even when the value may be de minimis. Because many of these are common forms of business within the pharmaceutical industry, the PhRMA Code provides some level of protection for certain common arrangements in addition to specific regulatory safe harbour protections. Although it has been generally accepted by federal enforcement agencies, the PhRMA Code is not law or regulation. Thus, activities expressly condoned by the PhRMA Code, while not immune from prosecution, are less likely to be pursued by federal authorities, while activities prohibited by the PhRMA Code pose significant risks under the AKS.

9.2 Limitations on Providing Samples to Healthcare Professionals

The Prescription Drug Marketing Act (PDMA) permits a manufacturer to provide drug samples directly to a licensed healthcare practitioner or institution that:

- requests the samples;
- signs for or formally acknowledges receipt of the samples;
- agrees to legally prescribe and dispense the samples; and
- does not resell the samples or bill patients or health insurance for them.

The purpose of facilitating samples should generally be to ensure that patients and HCPs can reasonably evaluate whether a particular drug is appropriate for a particular patient. Samples should not be used as gifts or improper inducements for HCPs to prescribe a particular product, as such uses could violate the AKS.

9.3 Sponsorship of Scientific Meetings

Pursuant to the PhRMA Code, a manufacturer may provide financial support to third parties hosting scientific or educational conferences or meetings, including those for continuing medical education (CME). The PhRMA Code specifically provides that "a company should develop objective criteria for making CME grant (or support)

decisions to ensure that the programme funded by the company is a bona fide educational programme and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment", such as by covering the cost of attendance for specific HCPs.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The PhRMA Code expressly prohibits the support of HCP participation in cultural, sports or other non-scientific events.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Grants or donations to HCPs or institutions, whether monetary or in-kind, generally fall within the broad definition of "remuneration" under the AKS. While it is not the policy of federal or state agencies to prosecute bona fide charitable donations and altruistic grants, these arrangements can raise serious issues under the AKS if any purpose of the funding is related to generating business from the recipient or individuals involved with the recipient. Because there are no protections for grants or donations under the statutory exceptions or regulatory safe harbours of the AKS, manufacturers should be mindful of the following.

- A grant or donation should be made only to charitable or non-profit organisations that would use the funding in accordance with their charitable/non-profit mission.
- No purpose of the grant or donation should be to influence clinical or purchasing decision-making or to otherwise generate business for the manufacturer – some manufacturers demonstrate this by, inter alia:
  (a) funding grants and donations from non-sales and marketing budgets;
  (b) establishing and using a grants committee comprised of only non-commercial personnel;
  (c) carefully documenting each grant and donation, including its intended purpose; and
  (d) ensuring that there is no "return on investment" analysis with respect to grants or donations.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts and rebates to HCPs and institutions are protected from violating the AKS if they meet all the requirements of a statutory exception (42 USC 1320a-7b(b)(3)(A)) or regulatory safe harbour (42 CFR 1001.952(h)). In general, to be protected, a discount or rebate must:

- be a reduction in the amount a purchaser is charged for an item or service based on an arm's-length transaction;
- be disclosed to the purchaser in advance of any purchase being made and not paid prior to the purchase being made (ie, no upfront rebates or "pre-bates");
- not be paid in cash or cash equivalents (except for rebates paid by cheque);
- not be for the purpose of inducing the purchase of a different good or service, unless both items/services are reimbursed by the same federal healthcare programme using the same payment methodology, and the discount is fully disclosed to federal programmes;
- not be in exchange or payment for services;
- not result in the sale being made at a (net) price that is below the manufacturer's cost for manufacturing, marketing and distributing the product(s); and

- be structured to provide the price reduction to the buyer within a year of the purchase of the product to which it relates.

In addition, the manufacturer must clearly inform the buyer of its obligations under the safe harbour to report the discount to federal agencies, as required, and must refrain from doing anything to impede the buyer from meeting its reporting obligations.

9.7 Payment for Services Provided by Healthcare Professionals

In order to receive AKS protection under the personal services and management contracts safe harbour (42 CFR 1001.952(d)), compensation for a services arrangement must meet all of the specific regulatory requirements, including:

- having a written agreement that expressly defines the services to be provided for a term of at least one year;
- that the contracted services are commercially reasonable in the absence of other business or referrals generated between the parties;
- that the methodology for determining the compensation to be paid over the term of the agreement is set in advance, consistent with fair market value and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; and
- that the services must not involve any other violation of law.

The PhRMA Code provides additional guidance to help protect arrangements that cannot meet safe harbour protections, including factors that support the "existence of a bona fide consulting arrangement".

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The provision of products or services without charge by a manufacturer to an HCP may result in in-kind "remuneration" that implicates the broad scope of the AKS. In analysing whether or not services may constitute remuneration, a manufacturer should consider whether the services intended purely for the reasonable and expected support of the manufacturer's product for a patient might instead be intended to take the place of internal services or efforts that the HCP would ordinarily be expected to provide at their own cost and expense. The former types of arrangements arguably would not result in remuneration under the AKS, while the latter may implicate the broad scope of the statute.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The federal Physician Payments Sunshine Act (the "Sunshine Act") and its implementing regulations require certain pharmaceutical and biologic manufacturers to annually report to the Centers for Medicare and Medicaid Services (CMS) certain information about payments or transfers of value provided directly or indirectly to covered recipients during the previous calendar year. "Covered recipients" under the Sunshine Act and its implementing regulations include US physicians and teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anaesthetists and certified nurse midwives.

In addition to the federal reporting requirements, several states, including Connecticut, the District of Columbia, Massachusetts, Minnesota and Vermont, also require manufacturers to track and annually report certain information about payments or transfers of value provided to HCPs and healthcare organisations in the respective state. The specific transparency requirements vary from state to state. There are also several jurisdictions that require pharmaceutical representatives to be licensed/listed with local agencies, including Chicago, the District of Columbia, Nevada and Oregon. Many of these local requirements include transparency obligations for licensed/listed representatives, who are required to track and annually report certain information about their communications and interactions with HCPs.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The Sunshine Act requirements apply to foreign companies if the entity "operates in the United States" and meets the definition of an "applicable manufacturer". Determination of how transparency laws apply to entities based outside the US should be conducted on a case-by-case basis considering the entity and any subsidiaries. Some state laws mirror the Sunshine Act requirements, while other state laws are less clear but generally apply to manufacturers providing transfers of value to HCPs licensed by the state.

As a general matter, the Sunshine Act and state transparency laws do not apply to companies that do not yet have marketed products.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

See **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines** for information on regulatory and enforcement bodies for pharmaceutical advertising and promotion.

Both the Department of Justice (DOJ) and the OIG have authority to enforce the AKS, the CMP law, and the False Claims Act. The DOJ has jurisdiction over both criminal and civil enforcement actions, while the OIG has authority with respect to civil actions. The False Claims Act includes a whistle-blower provision allowing private citizens to bring claims on behalf of the US and to share in the government's recoveries resulting from such claims.

State attorneys general may take enforcement actions under similar state laws.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In most instances, FDA enforcement against unlawful promotion and advertising begins with an enforcement letter issued by the OPDP of the FDA. Repeat or egregious violations may prompt the FDA and FTC to initiate enforcement proceedings in federal court to enjoin the behaviour and seek penalties.

Competitors and consumers may also challenge unlawful promotion and advertising. The FDCA and FTCA do not provide a right of action to competitors or consumers; however, the submission of trade complaints to the FDA and/or FTC may prompt the agencies to act. HCPs, consumers and competitors can also notify

the FDA of unlawful pharmaceutical marketing through the FDA's "Bad Ad Program". In addition, competitors and/or consumers may seek to challenge advertising directly through state and/or other federal laws.

Companies may also challenge competitors' "false and misleading" advertising in court under the Lanham Act and before the self-regulatory body of the NAD of the Better Business Bureau (BBB), which is a voluntary process and not enforceable under law.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

FDA and FTC Enforcement

Penalties for unlawful pharmaceutical marketing and advertising vary depending on the statute used to challenge the activity. If the FDA or FTC pursue enforcement in federal courts, injunctions are common penalties; the FDA may also seize products. In more extreme cases, the FDA may co-ordinate with the DOJ to bring criminal charges. Misdemeanour convictions of "misbranding" a drug can result in a fine of USD1,000 and a year in prison. A felony conviction could result in a USD10,000 fine and three years in prison.

In a typical challenge under the Lanham Act, the court may award injunctive and/or monetary remedies, based on lost profits or loss of goodwill due to false advertising, or to reimburse the costs of corrective advertising. In extraordinary cases and in some jurisdictions, courts may also consider granting a preliminary injunction, disgorgement of profits, treble damages, and/or an award of attorney's fees.

AKS

Under the AKS, criminal sanctions include a fine not exceeding USD250,000 or imprisonment for up to five years, or both, for each offence. In addition, monetary penalties for each offence may be increased to USD500,000 for organisations. Civil penalties include fines of up to USD50,000 for each violation, and monetary damages of up to three times the amount paid for referrals and/or exclusion from the Medicare programme. Furthermore, any claims submitted to Medicare or Medicaid as a result of an illegal kickback now automatically constitute false or fraudulent claims under the federal False Claims Act.

The False Claims Act

Penalties for violating the False Claims Act can be civil and/or criminal, with statutory civil penalties between USD5,000 and USD10,000 (which can be increased to up to USD23,607) per false claim and triple the amount of the damage to the government. For criminal violations, the False Claims Act can be enforced with imprisonment and/or criminal fines.

11.4 Relationship Between Regulatory Authorities and Courts

Regulatory authorities such as the FDA and FTC may pursue enforcement against unlawful advertising and promotion in federal court, while state enforcement occurs in a state court. Self-regulation through the NAD is a voluntary process. Although NAD decisions are not binding in court, some cases may be referred to the FTC for potential enforcement.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Based on OPDP enforcement letters issued over the past few years, the FDA is focused on a range of digital and broadcast advertising and promotional activities, including DTC television advertisements, consumer videos, websites, emails, sponsored links and social media. Con-

sistent with past enforcement letters, the most cited violation continues to be false or misleading presentation of risk information; however, there is also a strong focus on false or misleading efficacy claims. Products with boxed warnings in their labelling are a frequent target of OPDP letters.

For both the FDA and FTC, marketing by physicians, celebrity spokespeople and influencers is a key focus area for both prescription and OTC drugs. Recent enforcement related to influencer and spokesperson marketing has cited omission or minimisation of risk information, overstatement of efficacy, and lack of adequate disclosure of the relationship between the influencer and the sponsoring company.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The FDA's Center for Veterinary Medicine (CVM) is responsible for regulating the promotion and advertising of approved prescription animal drug products under the FDCA and related regulations. Like human drugs, the advertising and promotion of prescription animal drugs must be:

- on-label or consistent with label;
- adequately substantiated;
- present a fair balance between product benefits and risks; and
- otherwise truthful and not misleading.

Many of the FDA's guidance documents for advertising and promotion, as well as scientific exchange, also apply to prescription animal drugs. The FDA's post-marketing reporting regulations require animal drug companies to submit prescription drug promotional labelling and advertising materials at the time of first use, which is made using Form FDA 2301. The CVM provides written advisory comments as part of optional pre-dissemination reviews for proposed promotional materials, reviews complaints about alleged violations, and issues untitled or warning letters citing false or misleading promotional materials. The most common violation for prescription animal drugs is omission or minimisation of risk information, followed by misleading efficacy claims.

King & Spalding LLP has more than 1,200 lawyers in its 22 global offices and helps companies advance business interests in more than 160 countries. The firm's FDA and life sciences practice plays a critical role within this context. With over 40 lawyers and professionals in the US and Europe, the group counsels more than 250 large, mid-cap and start-up drug, biotech and medical device companies, food manufacturers, distributors, healthcare providers and technology ventures. The EU team focuses on EU and national (French, Belgian and German) issues associated with the legal requirements for pharmaceuticals/biologics, medical devices, cosmetics and foods. The firm's clients receive tremendous synergy from the interaction of the FDA/regulatory and healthcare teams with the product liability, government investigations, discovery, appellate, intellectual property, corporate and litigation teams. More than 400 lawyers and professionals in 17 areas devote all or a substantial portion of their practices to the life sciences industry.

Authors

Seth H Lundy serves as deputy chair and a partner in King & Spalding LLP's FDA and life sciences practice. Seth is widely recognised as a leading national authority on compliance with federal and state fraud and abuse laws, and represents prominent pharmaceutical and medical device manufacturers in complex legal and regulatory matters and investigations. A frequent author and speaker on compliance within the biopharma industry, Seth works to help clients identify and predict burgeoning areas of enforcement and compliance. He also develops business and marketing strategies that respond to ever-changing federal regulatory schemes.

Nikki Reeves is an FDA and healthcare compliance lawyer with over 20 years of experience. Nikki co-chairs King & Spalding LLP's life sciences and healthcare industry group and is a partner in the FDA and life sciences practice group. She advises pharmaceutical and medical device companies on pre- and post-market FDA regulatory compliance and enforcement matters, ranging from clinical trials to labelling, advertising and promotion of FDA-regulated products. She is a thought leader on federal Sunshine, state and international transparency/disclosure laws and leads two industry compliance coalitions. Nikki currently serves on the advisory board for FDAnews.

Heather Bañuelos is counsel in King & Spalding LLP's FDA and life sciences practice group. Heather's practice focuses on regulatory strategies for the labelling, advertising and promotion of FDA-regulated products. She regularly serves on promotional, medical and scientific review committees for pharmaceutical companies. She is a frequent author and speaker on advertising and promotion topics. Heather's experience in FDA law spans over 20 years, including positions as associate chief counsel in the FDA's Office of the Chief Counsel and as senior in-house regulatory counsel for pharmaceutical companies.

Gillian Russell is counsel in King & Spalding LLP's FDA and life sciences practice and advises pharmaceutical, biotechnology and medical device companies on a variety of FDA regulatory, compliance and enforcement matters. Gillian has significant experience counselling clients on new product launches, physician and direct-to-consumer advertising, and social media. She regularly acts as primary legal counsel on companies' promotional review committees, advising on promotional and non-promotional communications and activities. Gillian is a frequent author and speaker on advertising and promotion topics, and is a member of the planning committee for the 2022 FDLI Advertising and Promotion Conference.

King & Spalding LLP

1700 Pennsylvania Avenue – NW
Suite 900
Washington
DC 20006
USA

Tel: +1 202 737 0500
Fax: +1 202 626 3737
Email: kslaw@kslaw.com
Web: www.kslaw.com

Trends and Developments

Contributed by:
Bryant Godfrey and August Horvath
Foley Hoag LLP **see p.425**

Relevant Laws or Codes Governing Pharmaceutical Advertising in the USA

In the US, prescription drug advertising is primarily regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations, as well as through FDA guidance documents (see 21 USC Section 352(n); 21 CFR Section 202.1). Other federal and state government entities that enforce various false and/or deceptive advertising claims (pertaining to prescription drugs) include the US Federal Trade Commission (FTC) and individual state attorneys general. Pharmaceutical company product-related statements have also drawn enforcement scrutiny from the US Securities and Exchange Commission (SEC) where investors have somehow been misled.

Over-the-counter (OTC) and non-prescription drug advertising is primarily regulated by the FTC under 15 USC Sections 52–57, where false or deceptive OTC drug advertising (likely to induce the product's purchase) is unlawful and enforceable by the FTC. The National Advertising Division (NAD) of the Better Business Bureau (BBB), the advertising industry's self-regulatory body, independently reviews and monitors national advertising for accuracy and truthfulness, and offers a voluntary dispute resolution process for advertisers. Many challenges to OTC drug advertising are brought before the NAD for review and adjudication.

Pre-approval Product Communications

As a general matter, promotion of a prescription drug prior to FDA approval of that drug is not allowed (see 21 CFR Section 312.7(a)). Over the last several years, the FDA has taken increased interest in pharmaceutical company prescription drug product communications that cross over into promotional territory (as opposed to pure scientific discourse), issuing enforcement letters to a number of companies. The letters consistently highlight communications that tend to make conclusive statements or representations regarding the safety and efficacy of an investigational new drug (a drug being studied in clinical trials) where the safety and efficacy have not yet been established and the product lacks FDA approval. The FDA's focus on these types of communications has shown no signs of waning. Although typically issued as Untitled Letters, during 2022 the FDA's Office of Prescription Drug Promotion (OPDP) issued a one-of-a kind Warning Letter for the pre-approval promotion of an investigational drug product being studied for the treatment of COVID-19.

Product Safety

One area of pharmaceutical company advertising that consistently garners FDA scrutiny is communications involving product safety. Tracing back through decades of enforcement letters from the OPDP and its predecessor, the Division of Drug Marketing, Advertising and Communications (DDMAC), the agency routinely objected to various promotional statements and tactics viewed as minimising or omitting important risk information. Embedded in the OPDP's mission is the aim to protect public health by helping to ensure that prescription drug promotion is truthful, balanced and accurately communicated. Downplaying or completely omitting risk infor-

mation from product advertising and promotion will continue to capture the OPDP's enforcement interest, as these misrepresentations work to throw off balanced promotional presentations.

Over the years, prescription drug product safety communications have also caught the attention of the US Department of Justice (DOJ), particularly when false statements relating to product safety were made in order to increase the sales of prescription drugs.

The Federal Trade Commission

The Federal Trade Commission (FTC) is the primary federal government agency enforcing on unfair and deceptive trade practices, including false advertising. The FTC's primary authority stems from the FTC Act, 15 USC Sections 41–58, under which it has exclusive enforcement authority.

The FTC shares primary responsibility with the FDA in the agencies' concurrent jurisdiction over pharmaceutical advertising, marketing and promotion, according to a memorandum of understanding pursuant to which the FDA regulates all aspects of prescription drugs and the mandated labelling of all other FDA-regulated products, while the FTC has primary responsibility over "the truth or falsity of all advertising (other than labelling) of foods, (non-prescription) drugs, devices and cosmetics". The two agencies advise each other on matters within the other's turf; the FTC defers to the FDA's judgement where the subject matter of OTC drug advertising mirrors FDA-regulated labelling, for example, whereas the FTC has advised the FDA on potential deception in direct-to-consumer advertising of prescription drugs.

The FTC actively enforces on what it deems unfair or deceptive practices in the advertising of OTC drugs, devices and cosmetics, including such things as the efficacy of analgesics. The FTC, sometimes jointly with the FDA, also enforces on disease prevention or treatment claims by foods, dietary supplements and other products that the agencies contend render these products unapproved or misbranded drugs or medical devices.

Social Media Marketing and Influencers

Given that we are predominantly living in a digital age, it is no surprise that pharmaceutical company advertising and promotion has increasingly explored digital delivery methods. Through the use of various social media platforms, companies are finding new and innovative ways to deliver tailored messaging to consumers as well as healthcare professionals. Although these platforms may present new ways of delivering content, the rubric of FDA rules and policies governing prescription drug advertising has not really changed that much – as evidenced from OPDP enforcement letters implicating various social media platforms. At the end of the day, prescription drug advertising must be truthful, non-misleading and balanced, no matter the medium.

The FDA has also continued taking interest in influencer advertising – where pharmaceutical companies use various celebrities and/or influencers to market to their large social media following. Influencer marketing for prescription drugs is overseen by the FDA, while that for non-prescription drugs and other products is overseen by the FTC. Sometimes the agencies act jointly, as they did in a late 2021 series of letters to companies and influencers promoting the nicotine-containing liquids used in vaping devices. These letters and other actions by the FDA and FTC stress the dual requirements associated with influencer marketing:

- the advertising must be truthful, non-misleading and contain all disclosures that would be required in any other advertising; and
- any material connection between the influencer and the advertiser must be disclosed, as the FTC considers the failure to disclose such connections to be a distinct deceptive practice.

Competitor Activities

Over the last several years, the FDA had taken a pretty inactive stance on competitor superiority claims. Remarks made in 2018 by the FDA's former director of the Center for Drug Evaluation and Research (CDER), Dr Janet Woodcock, at a discussion hosted by the Alliance for a Stronger FDA, signalled that the agency was more inclined to let competitors "duke it out" when it came to disputes not involving threats to human health or safety.

However, recent enforcement letters issued by the OPDP during 2022 (where the OPDP specifically objected to unsubstantiated product superiority claims) seem to have signalled an end to this look-away era and a resurgence of interest in competitor claims generally. On top of this, when questioned about the OPDP's stance on product superiority claims, the head of the OPDP, during the Food and Drug Law Institute's 2022 Advertising and Promotion Conference for Medical Products Conference in Washington DC (13 October 2022), stated that the OPDP is still interested in pursuing unsubstantiated comparative/superiority claims and referenced an enforcement letter as an illustrative example.

Given this shift, pharmaceutical companies wishing to stop competitors from making inaccurate or misleading product comparative claims may want to consider:

- submitting competitor complaint letters to the OPDP;
- seeking redress under the false/misleading advertising provisions of the Lanham Act; and/or
- submitting complaints to the FTC and individual state attorneys general.

Competitors may also lodge a self-regulatory challenge before the National Advertising Division (NAD), although participation in this forum is voluntary, and compliance with the NAD's decision is not legally enforceable.

Since the FTC and state attorneys general are not always responsive to competitor complaints that primarily affect the commercial positions of the parties rather than consumer welfare, the federal Lanham Act litigation may be the only effective option to shut down a competitor's offending marketing claims. However, such litigation has drawbacks, as follows:

- the complaining plaintiff carries the burden to prove the advertiser's claims false, whereas a regulator could require the advertiser to substantiate them;
- Lanham Act litigation permits counterclaims against the original plaintiff for any of its own allegedly false advertising that the sued party can dig up; and
- like any federal litigation, the process can be lengthy, invasive and expensive.

Off-Label Promotion

Although not at a level seen in the early to mid-2000s, the OPDP has not stopped issuing enforcement letters for off-label promotion. The wording and the charges, however, do differ as they are carefully crafted to focus more on misbranding, as opposed to vilifying speech. For example, recent letters cite off-label communi-

cations as providing evidence of a new, intended use for which the products' labelling did not provide adequate information for use, rendering the products misbranded. The last couple of letters focused on sales representatives' oral statements and email communications. Given its efforts to continue asserting its presence in this space, continued but measured FDA enforcement against off-label promotion should be expected going forward.

Investor Lawsuits/SEC Scrutiny

Investor lawsuits against pharmaceutical companies for misleading statements made in public-required and investor-related disclosures are becoming more and more commonplace. Often, these statements also appear in company-issued press releases, which have the potential to be viewed as promotional – depending on what is stated and how it is stated. When crafting press releases concerning product performance, potential, or a candidate product's likelihood of FDA filing success, not only should pharmaceutical companies be aware of the various FDA promotional requirements that apply, but they should also think about SEC implications. Many investor lawsuits allege that the company at issue made misleading statements about its product's safety or efficacy that turned out to be not as rosy as depicted, or that somehow actually resulted in a negative FDA action, usually causing injury to investors due to a decrease in stock prices.

Consistency with Labelling Communications

As the FDA has expressed an increased interest in real-world evidence (ie, clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data – which is data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources), many pharmaceutical companies have started incorporating, or at least considering how and whether to include, information in advertising and promotional materials that is supported by real-world evidence.

Often, the information supported by the real-world evidence is not included in FDA-approved labelling for the product at issue. As companies continue to navigate this new area of information, the FDA's guidance for the industry, "Medical Product Communications That Are Consistent With the FDA-Required Labelling – Questions and Answers", in combination with lessons learned from various enforcement letters citing the use of real-world evidence, will continue to be of interest to companies. From an enforcement standpoint, several letters issued by the OPDP in 2022 focused on the quality and strength of the supportive evidence.

Healthcare Fraud and Abuse Considerations

In recent years, pharmaceutical company speakers' programmes (a practice where pharmaceutical companies pay healthcare practitioners (HCPs), who often prescribe the companies' products, to promote these products to other HCPs) and speaker training meetings have faced intense government scrutiny where the allegations have been that these events induced HCPs to prescribe prescription drug products in violation of the Anti-Kickback Statute (AKS) and False Claims Act (FCA). These programmes tend to be the highest-risk marketing practice in the pharmaceutical industry and most likely will retain that designation for some time going forward.

Conclusion

Navigating US rules and policies governing pharmaceutical advertising requires focused attention on several sources of oversight – both official and unofficial – each with unique require-

ments. Violations of official government-imposed requirements can land companies into significant trouble. However, industry self-regulatory activities are unlikely to yield the same level of enforcement consequences. Nonetheless, one thing is certain – care should be taken to avoid false, misleading and/or deceptive promotional claims and practices, as these tend to be at the heart of many challenges to pharmaceutical product advertising.

Foley Hoag LLP is a nationally recognised, full-service life sciences practice that draws on the talents of a wide variety of professionals – many of whom have had previous careers as scientists, medical doctors and high-ranking government officials – to advise clients across the industry ranging from start-ups to Fortune Future 50 companies. The firm's advertising and marketing legal team provides a broad range of regulatory, advisory and disputes-oriented representation around the promotion of goods and services, and brings considerable experience to all the legal issues affecting a business's ability to promote its offerings. From offices in Boston, New York, Paris and Washington, DC, the team helps clients achieve their business goals while minimising risk, as they navigate the complex waters associated with the development, approval, commercialisation, reimbursement and coverage of innovative medical products and services.

Authors

Bryant Godfrey is a partner at Foley Hoag LLP and is co-chair of the firm's healthcare and life sciences and FDA practice groups. He provides strategic regulatory advice to pharmaceutical, medical device and biotech companies, helping them to navigate challenges relating to the development, manufacturing, approval and promotion of drugs, biologics, medical devices and combination products. Having spent nearly a decade at the US Food and Drug Administration in senior regulatory and policy roles, including as the head lawyer of the FDA's Office of Prescription Drug Promotion, his experience encompasses a wide range of issues relating to advertising and promotion, scientific exchange, investigations of off-label marketing, product jurisdiction, medical product development and approval/clearance, labelling, and post-marketing commitments and requirements, among others.

August Horvath is a partner at Foley Hoag LLP who counsels clients on how to substantiate and defend marketing claims they wish to make for their products and services, helps them challenge false and disparaging advertising by competitors, and assists in managing relationships with competitors, customers and suppliers without running afoul of antitrust laws. He represents clients in federal and state enforcement actions and in litigation against competitors and consumer classes. August's hands-on experience in survey research and statistical analysis gives him exceptional insight into developing substantiation protocols, and designing and assessing research into the implied meaning of advertising claims.

Foley Hoag LLP

1717 K Street NW
Washington, DC
20006
USA

Tel: +1 202 223 1200
Fax: +1 202 785 6887
Email: contact@foleyhoag.com
Web: www.foleyhoag.com

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