Study on Best Practices in the Public Procurement of Medicines

Final Report

Gesundheit Österreich Beratung GmbH
Tetra Tech International Development
September 2022

EUROPEAN COMMISSION

Directorate-General for Health and Food
Directorate B Health systems, medical products and innovation Unit D.2 Medical products: quality, safety, innovation
Contact: Laure GESLIN

E-mail: SANTE-ATF@ec.europa.eu

HADEA-HP-TENDER@ec.europa.eu

European Commission
B-1049 Brussels

Study on Best Practices in the Public Procurement of Medicines

Final Report

Authors:

Sabine Vogler (Gesundheit Österreich Beratungs GmbH)
Maximilian Salcher-Konrad (Gesundheit Österreich Beratungs GmbH)
Katharina Habimana (Gesundheit Österreich Beratungs GmbH)

Supported by:

Gonzalo Dominguez (Tetra Tech)
Margit Gombocz (Gesundheit Österreich Beratungs GmbH)
Valentin Kandler (Gesundheit Österreich Beratungs GmbH)
Peter Schneider (Gesundheit Österreich Beratungs GmbH)
Nina Zimmermann (Gesundheit Österreich Beratungs GmbH)

Procurement expertise and input:

Eveli Bauer (Estonian Health Insurance Fund)
Nina Uldal, Trine Ann Behnk (Amgros)
Jean-Michel Descoutures (Réseau des Acheteurs Hospitaliers, RESAH)
Helena Panayiotopoulou (Ministry of Health Cyprus)

Quality assurance:

Mariana Dates (Tetra Tech)
Jaime Espin (Andalusian School of Public Health – EASP)

Project assistant:

Monika Schintlmeister (Gesundheit Österreich Beratungs GmbH)

October 2022

Directorate-General for Health and Food
Third Health Programme

2022

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*)**:**

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

PDF	ISBN 978-92-95224-29-2	doi : 10.2925/044781	HW-04-22-229-EN-N

Luxembourg: Publications Office of the European Union, 2022

ACKNOWLEDGEMENTS

The study team would like to express their thanks to the large number of experts in procurement and pharmaceutical pricing and reimbursement who have volunteered their time to provide their insights on procurement practices in Europe. Their contributions were essential in developing this report.

In particular, the study team would like to thank the experts at the following institutions who reviewed and validated country fiches:

- Austria: Tirol Kliniken
- Belgium: Az Glorieux Ronse
- Bulgaria: Ministry of Health and Public Procurement Agency
- Croatia: Ministry of Health, Agency for medicinal products and medical devices of Croatia (HALMED), and UHC Rijeka
- Cyprus: Ministry of Health
- Denmark: Amgros and Danish Medicines Council
- Estonia: Estonian Health Insurance Fund
- Finland: Ministry of Health and Social Affairs
- France: Réseau des Acheteurs Hospitaliers (Resah)
- Germany: Ministry of Health
- Hungary: National Health Insurance Fund Management (NEAK)
- Iceland: Landspitali
- Ireland: Health Service Executive (HSE)
- Italy: Consip
- Latvia: Procurement Division of the National Health Service
- Lithuania: Ministry of Health, National Health Insurance Fund under the Ministry of Health, and Central Procurement Organisation CPO LT
- Luxembourg: Health Directorate at Ministry of Health
- Malta: Directorate of Pharmaceutical Affairs (DPA) at MFH & Central Procurement & Supplies Unit (CPSU) at Ministry for Health (MFH)
- Norway: Norwegian Medicines Agency (NoMA) and a senior procurement expert at Sykehusinnkjøp (LIS)
- Portugal: Shared Services for Ministry of Health (SPMS)
- Romania: Ministry of Health
- Slovenia: University Medical Center (UMC) Ljubljana
- Slovakia: Ministry of Health
- Sweden: Stockholm Region
- Switzerland: Federal Office of Public Health (FOPH)

The study team further expresses their gratefulness to the following:

- interview partners and others who agreed to formal and informal discussions providing important background information for the study;
- everyone participating in the online survey and coordinating responses across different institutions in their countries;
- participants in a series of four online workshops;
- everyone providing us with contacts and connecting us to the right people in the study countries to learn more about procurement practices.

The study team gratefully acknowledges the support of the European Commission that commissioned this study. Several Services and Agencies (DG SANTE, DG GROW, HaDEA, DG HERA) provided valuable comments to a draft version of this study.

ABSTRACT

English

Public procurement of medicines (PPM) is a strategic policy option to foster competition and improve access to medicines, as well as addressing important further policy objectives, including ensuring security of supply, protecting the environment, and improving crisis preparedness. In this study, PPM practices across 32 European countries (EU-27 plus EEA/EFTA countries and the UK) were mapped and analysed. The report presents findings regarding the organisational form of procurement for different types of medicines (ranging from facility-based procurement and group procurements to centralised procurement at regional or national levels) in the study countries, application of different forms of procedures and techniques (including the use of different award criteria, such as the Most Economically Advantageous Tender), and specific forms of procurement in the hospital sector. Possible impacts of PPM practices on a set of policy objectives (access to medicines, affordability and availability of medicines, security of supply, competitive market, protecting the environment, and supporting crisis preparedness) were assessed. The study also reports on the use of supporting policies, such as horizon scanning and health technology assessment, and the experience with cross-country joint procurements. The study includes a set of best practices for optimising PPM in Europe.

French

Les marchés publics de médicaments (MPM, en anglais: PPM, *public procurement of medicines*) sont une option politique stratégique pour favoriser la concurrence et améliorer l'accès aux médicaments. Ils répondent aussi à d'autres objectifs politiques importants, notamment le besoin d'assurer la sécurité de l'approvisionnement, protéger l'environnement et améliorer la préparation aux crises. Dans cette étude, les pratiques MPM de 32 pays européens (UE-27 plus les pays de l'EEE/AELE et le Royaume-Uni) ont été cartographiées et analysées. Le rapport présente des conclusions concernant l'organisation de l'approvisionnement pour différents types de médicaments (allant de l'approvisionnement en établissement et des achats groupés à l'approvisionnement centralisé au niveau régional ou national) dans les pays de l'étude, l'application de différents types de procédures et de techniques (y compris l'utilisation de différents critères d'attribution, tel que celui de l'offre économiquement la plus avantageuse) et des formes spécifiques de passation des marchés dans le secteur hospitalier. Les impacts possibles des pratiques MPM sur un ensemble d'objectifs politiques (accès aux médicaments, accessibilité financière et disponibilité des médicaments, sécurité d'approvisionnement, marché concurrentiel, protection de l'environnement et soutien à la préparation aux crises) ont été évalués. L'étude rend également compte de l'utilisation de politiques de soutien, telles que l'analyse prospective et l'évaluation des technologies de la santé, et de l'expérience des achats conjoints entre pays. L'étude comprend un ensemble de bonnes pratiques pour optimiser les MPM en Europe.

KEY FINDINGS

English

Public procurement of medicines (PPM) is defined as all aspects surrounding the process of purchasing medicines by a contracting authority from economic operators chosen by the contracting authority. PPM can be applied strategically to improve access to (affordable) medicines as well as addressing further policy objectives such as fostering competition in the market, encouraging greener pharmaceutical manufacturing, supporting security of supply, and ensuring crisis preparedness and handling.

A **mapping of PPM policy and practices** in outpatient and inpatient pharmaceutical sectors in the 32 study countries (all European Union (EU) member states, Iceland, Liechtenstein, Norway, Switzerland, and the UK) showed the following key findings:

- **Organisation of PPM:** The organisation of PPM varies depending on the medicines purchased and the health care sector. Within countries, most common organisational forms are facility-based PPM (mainly in the inpatient sector, i.e. procurements conducted by hospitals) and national centralised PPM (usually done for selected medicines, such as vaccines or products included in national health programmes). A few study countries have also been collaborating with other countries to jointly procure medicines (e.g. the Baltic countries jointly procure vaccines, and some of the Nordic countries had joint Nordic tenders to purchase old hospital medicines).
- **PPM procedures:** Open procedures are predominantly used across the study countries. Two-stage procedures and negotiated procedures are less commonly applied.
- **PPM techniques:** Around one quarter of PPM procedures (documented in the European Commission TED database) are conducted as framework agreements that define the terms for contracts to be awarded for a certain period of time for recurring purchasing to one or more suppliers.
- **Award criteria:** Most contracts are awarded based on the price as sole award criterion. The EU Procurement Directive encourages a more strategic approach through consideration of a well-chosen set of award criteria (Most Economically Advantageous Tender (MEAT) criteria), and there is potential for more frequent use of MEAT criteria.
- **Hospital procurement:** In the inpatient sector, PPM is mainly organised at facility level (either by individual hospitals or a group of hospitals) but more centralised forms (mainly through a national centralised purchasing body (CPB), such as in Denmark, Norway or Portugal) have also been established.
- **Biosimilar procurement:** Biological medicines with high price tags are frequently used in the hospital setting, suggesting scope for leveraging competition from biosimilar medicines into substantial savings. However, barriers for more widespread use of biosimilars have been identified, including practices of biological originator suppliers to disincentivise or impede procurement of biosimilars and policy frameworks that do not encourage biosimilar uptake (e.g. prescribers not permitted to switch patients to a biosimilar or pharmacists not allowed to substitute products).
- **Interface management:** Overall, there is limited coordination across inpatient and outpatient sectors, even though the initiation of a therapy in the hospital setting is known to impact on further prescribing in the community. Some best practice examples of so-called interface management measures that aim to bridge the gap between inpatient and outpatient care include cross-sectorial formularies, cross-sectorial (reimbursement) committees and funding mechanisms at the interface as well as capacity-building and collaboration projects.

Analysis of different PPM policies and practices across the study countries led to the following conclusions:

- **Variety of PPM practices**: Procurement practices vary across European countries, often reflecting the heterogeneity in health care systems. As a result, in terms of optimising public procurement of medicines, no one size fits all, and procurement policies need to be integrated into the national set-up of the healthcare system.
- **PPM system:** The set-up of a PPM system consists of a variety of procedures and procurement techniques, as well as accompanying non-procurement related policies and tools. Thus, optimising PPM can be achieved through several of these features.
- **Different levels of maturity of PPM across countries:** Countries that use a range of PPM policies and practices as well as supporting policies were observed to generally also have a well-developed pharmaceutical pricing and reimbursement policy framework, higher spending on pharmaceutical expenditure and, in some but not all cases, higher availability of medicines.
- **Impact on prices:** According to data analysed in this study, countries with more advanced PPM systems (using more centralised procurement, applying a variety of PPM procedures and techniques, and using supporting policies) were found to have lower unit prices. This finding is consistent with previous studies on savings from PPM.
- **Joint procurement:** Joint procurement, including within country and cross-country, can help achieve lower prices and make small markets attractive for suppliers, as well as providing other benefits, such as information sharing and capacity building; however, implementation is resource intensive.
- **Security of supply:** Security of supply may be addressed through use of relevant award criteria, awarding multiple winners, and joint procurement.
- **Environment:** Environmental criteria are starting to be used, but evidence on their impact is still developing. Experience suggests that thorough consultation with suppliers ahead of introduction of environmental criteria leads to suppliers being able to comply with criteria without negatively impacting prices or the number of competitors submitting bids.
- **Balancing trade-offs:** Trade-offs between policy objectives (e.g. lower price, security of supply, green pharmaceutical design) need to be made. Applying a strategic approach to PPM can support negotiating these trade-offs, such as consideration of further award criteria in addition to the price (through MEAT) and awarding multi-winner contracts to balance competition and security of supply.
- **Barriers:** Major barriers to optimisation of PPM include the limited attractiveness of (small) markets for suppliers, limited capacity of procurers and lack of funding, as well as, particularly related to off-patent medicines, shortages and PPM practices of originator companies to impede uptake of off-patent medicines.
- **Good practice examples:** A toolbox of best practices in PPM includes collaboration (across countries and across sectors) and communication (e.g. dialogue with users and suppliers), e-procurement, strategic use of PPM procedures and techniques aligned with the stage of the medicine in the product life cycle, and application of supporting policies and tools (e.g. horizon scanning, health technology assessment).
- **Policy recommendations:** Policy-makers are encouraged to develop and communicate a PPM vision and strategy, to support their implementation through investments such as into capacity-building and to adapt the strategy, if necessary, based on findings from evaluations. Intra-country and cross-country collaboration shall be a major principle in implementation.

French

Les marchés publics de médicaments (MPM, en anglais: PPM, *public procurement of medicines*) sont définis comme l'ensemble des aspects entourant le processus d'achat de médicaments par un pouvoir adjudicateur auprès d'opérateurs économiques choisis par le pouvoir adjudicateur. Les MPM peuvent être appliqués de manière stratégique pour améliorer l'accès à des médicaments (abordables) ainsi que pour répondre à d'autres objectifs politiques tels que le renforcement de la concurrence sur le marché, l'encouragement d'une fabrication pharmaceutique plus verte, le soutien à la sécurité de l'approvisionnement et la préparation et la gestion des crises.

Une cartographie de la politique et des pratiques des MPM dans les secteurs pharmaceutiques ambulatoires et hospitaliers dans les 32 pays de l'étude (tous les États membres de l'Union européenne (UE), l'Islande, le Liechtenstein, la Norvège, la Suisse et le Royaume-Uni) a montré les principales conclusions suivantes:

- **Organisation des MPM :** L'organisation des MPM varie selon les médicaments achetés et le secteur de la santé. Au sein des pays, les formes organisationnelles les plus courantes sont les MPM en établissement (principalement dans le secteur des patients hospitalisés, c'est-à-dire les achats effectués par les hôpitaux) et les MPM centralisés au niveau national (un système généralement utilisé pour certains médicaments, tels que les vaccins ou les produits inclus dans les programmes de santé nationaux). Quelques pays de l'étude ont également collaboré avec d'autres pays pour acheter conjointement des médicaments (par exemple, les pays baltes achètent conjointement des vaccins et certains pays nordiques ont lancé des appels d'offres conjoints pour acheter d'anciens médicaments hospitaliers).
- **Procédures des MPM :** Les procédures ouvertes sont principalement utilisées dans les pays de l'étude. Les procédures en deux étapes et les procédures négociées sont moins couramment appliquées.
- **Techniques des MPM :** Environ un quart des procédures MPM (documentées dans la base de données TED de la Commission européenne) sont conduites sous la forme d'accords-cadres qui définissent les termes des contrats à attribuer pendant une certaine période pour des achats récurrents à un ou plusieurs fournisseurs.
- **Critères d'attribution :** La plupart des marchés sont attribués sur la base du prix comme seul critère d'attribution. La directive européenne sur les marchés publics encourage une approche plus stratégique en tenant compte d'un ensemble bien choisi de critères d'attribution (critères de l'offre économiquement la plus avantageuse (MEAT, en anglais: *Most Economically Advantageous Tender*)), et il est possible d'utiliser plus fréquemment les critères MEAT.
- **Approvisionnement des hôpitaux :** dans le secteur des patients hospitalisés, les MPM sont principalement organisés au niveau de l'établissement (soit par des hôpitaux individuels, soit par un groupe d'hôpitaux), mais des formes plus centralisées (principalement par le biais d'une centrale d'achat (CPB, en anglais: *centralised purchasing body*), comme au Danemark, en Norvège ou Portugal) ont également été créées.
- **Approvisionnement en médicaments biosimilaires :** les médicaments biologiques dont le prix est élevé sont fréquemment utilisés en milieu hospitalier, ce qui suggère qu'il est possible de tirer parti de la concurrence des médicaments biosimilaires pour réaliser des économies substantielles. Cependant, des obstacles à une utilisation plus répandue des biosimilaires ont été identifiés, notamment les pratiques des fournisseurs des médicaments biologiques pour dissuader ou entraver l'achat de biosimilaires et les cadres politiques qui n'encouragent pas l'adoption des biosimilaires (par exemple, les prescripteurs ne sont pas autorisés à faire passer les patients à un biosimilaire ou les pharmaciens ne sont pas autorisés à délivrer des produits de substitution).

- **Gestion de l'interface :** Dans l'ensemble, la coordination entre les secteurs des patients hospitalisés et des patients externes est limitée, même si l'on sait que l'initiation d'un traitement en milieu hospitalier a un impact sur la prescription ultérieure dans la communauté. Parmi les exemples de meilleures pratiques de mesures dites de gestion d'interface qui visent à combler le fossé entre les soins hospitaliers et ambulatoires, citons les formulaires intersectoriels, les comités intersectoriels (de remboursement) et les mécanismes de financement à l'interface ainsi que les projets de renforcement des capacités et de collaboration.

L'analyse des différentes politiques et pratiques des MPM dans les pays de l'étude a conduit aux conclusions suivantes:

- **Variété des pratiques des MPM :** Les pratiques d'approvisionnement varient d'un pays européen à l'autre, reflétant souvent l'hétérogénéité des systèmes de soins de santé. Par conséquent, en termes d'optimisation des marchés publics de médicaments, il n'y a pas de solution unique et les politiques d'achat doivent être intégrées dans la configuration nationale du système de santé.
- **Système des MPM :** La mise en place d'un système de MPM comprend une variété de procédures et de techniques d'achat, ainsi que des politiques et des outils d'accompagnement non liés à l'achat. Ainsi, l'optimisation des MPM peut être obtenue grâce à plusieurs de ces caractéristiques.
- **Différents niveaux de maturité des MPM selon les pays :** Les pays qui utilisent une gamme de politiques et de pratiques des MPM ainsi que des politiques de soutien ont généralement aussi un cadre de politique de tarification et de remboursement des produits pharmaceutiques bien développé, des dépenses plus élevées pour les dépenses pharmaceutiques et, dans certains cas, mais pas tous, une plus grande disponibilité des médicaments.
- **Impact sur les prix :** Selon les données analysées dans cette étude, les pays disposant de systèmes de MPM plus avancés (utilisant des achats plus centralisés, appliquant une variété de procédures et de techniques des MPM et utilisant des politiques de soutien) se sont avérés avoir des prix unitaires plus bas. Ce résultat est cohérent avec les études précédentes sur les économies réalisées grâce aux MPM.
- **Achats conjoints :** Les achats conjoints, y compris à l'intérieur d'un pays et entre pays, peuvent aider à obtenir des prix plus bas et rendre les petits marchés attractifs pour les fournisseurs, tout en offrant d'autres avantages, tels que le partage d'informations et le renforcement des capacités; cependant, la mise en œuvre nécessite beaucoup de ressources.
- **Sécurité d'approvisionnement :** La sécurité d'approvisionnement peut être assurée par l'utilisation de critères d'attribution pertinents, la sélection de plusieurs lauréats et l'approvisionnement conjoint.
- **Environnement :** Les critères environnementaux commencent à être utilisés, mais les preuves de leur impact sont encore en cours d'élaboration. L'expérience montre qu'une consultation approfondie des fournisseurs avant l'introduction de critères environnementaux permet aux fournisseurs de se conformer aux critères sans impact négatif sur les prix ou sur le nombre de concurrents soumettant des offres.
- **Équilibrer les compromis :** des compromis entre les objectifs politiques (par exemple, prix plus bas, sécurité d'approvisionnement, conception pharmaceutique verte) doivent être consentis. L'application d'une approche stratégique aux MPM peut soutenir la négociation de ces compromis comme, par exemple, la prise en compte de critères d'attribution supplémentaires en plus du prix (par le biais de l'offre économiquement la plus avantageuse ou MEAT) et l'attribution de contrats à plusieurs gagnants pour équilibrer la concurrence et la sécurité d'approvisionnement.

- **Obstacles :** les principaux obstacles à l'optimisation des MPM comprennent l'attractivité limitée des (petits) marchés pour les fournisseurs, la capacité limitée des acheteurs et le manque de financement, ainsi que, en particulier en ce qui concerne les médicaments hors brevet, les pénuries et les pratiques MPM des entreprises qui entravent l'adoption de médicaments non brevetés.
- **Exemples de bonnes pratiques :** une boîte à outils des meilleures pratiques en matière de MPM comprend la collaboration (entre les pays et entre les secteurs) et la communication (par exemple, le dialogue avec les utilisateurs et les fournisseurs), l'approvisionnement en ligne, l'utilisation stratégique des procédures et des techniques des MPM alignées sur le stade du médicament dans le cycle de vie du produit et l'application de politiques et d'outils de soutien (par exemple, l'analyse prospective et l'évaluation des technologies de la santé).
- **Recommandations politiques :** les décideurs politiques sont encouragés à développer et à communiquer une vision et une stratégie MPM, à soutenir leur mise en œuvre par des investissements tels que le renforcement des capacités et à adapter la stratégie, si nécessaire, sur la base des conclusions des évaluations. La collaboration intra-pays et transnationale sera un principe majeur de la mise en œuvre.

EXECUTIVE SUMMARY

Background and study objectives

Public procurement of medicines (PPM) is a strategic policy option to foster competition and improve access to medicines, as well as to address important further policy objectives, as highlighted in the 2020 "Pharmaceutical Strategy for Europe".[1] Against this backdrop, the European Health and Digital Executive Agency (HaDEA) as contracting authority under the mandate of the European Commission (EC) commissioned a **study on best practices** in PPM.[2]

The general study **objective** was **to collect and analyse evidence to optimise PPM** as a tool that can contribute to accessibility, affordability, and availability of medicines, and to encourage greener pharmaceutical design and manufacturing in both outpatient and hospital sectors, as well as supporting security of supply, and crisis preparedness and handling in these sectors. For the purpose of the study, PPM is defined as all aspects surrounding the process of purchasing medicines by a contracting authority, such as a body of public law (e.g. governments, local health authorities, and social health insurance institutions) or an institution affiliated to the public sector, from economic operators (suppliers) chosen by the contracting authority. The general objective is operationalised through six specific objectives: a **mapping of** all relevant **stakeholders** related to PPM in the study countries, a **mapping of PPM policy and practices** in the study countries with a view for optimisation, an investigation of **possible impacts of optimised PPM** in the study countries, an identification of **barriers** to optimised PPM, a development of **best practices** in PPM and an update and extension of the **2010 PHIS Hospital Pharma report** on medicines management in the inpatient sector.

The **32 study countries** include all 27 European Union (EU) member states, the European Free Trade Association (EFTA) countries Iceland, Liechtenstein, Norway, Switzerland, as well as the UK. Both outpatient and inpatient sectors are investigated.

Methods

The study applies a **mix of qualitative and quantitative methods** to address research questions in six areas of interest, none of which are dealt with through one methodological approach alone. Instead, **triangulation of methods and data sources** is used across the study. Research methods used included a literature review (covering both academic and grey literature), which was partly used to populate country fiches (fact sheets) for each of the 32 study countries. The country fiches were reviewed by country experts. Several stakeholder consultation activities were performed, including a series of four online workshops, exploratory interviews, and an online survey, allowing stakeholders (including national authorities for pricing and reimbursement of medicines, public procurers, payers, pharmacists, patient representatives, and representation of the pharmaceutical industry and wholesalers) to provide input and assess the potential of PPM practices to impact on various policy objectives. Finally, quantitative analysis of procurement data (sourced from the Tenders Electronics Daily (TED) database of the EC) and pharmaceutical sales data (provided by the healthcare data provider IQVIA) was performed to assess the relationship between different PPM practices and outcomes, including access to medicines, affordability, availability, security of supply, competition in the market, environment, and crisis preparedness.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0761&from=EN

[2] The study was commissioned through the Framework contract SANTE/2016/a1/039 concerning the provision of services in the area of evaluation, impact assessment, monitoring and implementation and of other relevant services, in relation to the health and food policies (LOT 1) with reopening of competition.

Public procurement of medicines across the study countries

Mapping of PPM policies and practices

The study found important variation in how PPM is conducted and integrated into the heterogenous health systems in the study countries (Table I). **Four core organisational forms of PPM** within countries were identified: centralised procurement at national or at regional levels, group procurement (voluntary joint procurement) and facility-based procurement (done by individual health care facilities). Most study countries **use more than one PPM organisational form**, depending on the type of medicines and the sector. Overall, the two most common forms are **facility-based procurement** (particularly for the hospital setting) and **a national centralised procurement system** (however, in many cases only done for few selected products).

Table I: Organisation of PPM in the study countries

	Organisational form	Medicines and sectors	CAs
National	**National centralised PPM:** Medicines are purchased by the CA for the whole country (at least for one sector, e.g. inpatient sector)	Frequently used for vaccines and medicines under a national health programme In some countries: All or nearly all medicines (both sectors or the inpatient sector only)	National CPBs (in some countries only operating in the inpatient sector)
	Regional centralised PPM: Medicines are purchased by the CA for a region or for a group of users (at least for one sector, e.g. inpatient)	In some countries: All or nearly all medicines (usually both or the inpatient sector only)	Regional CPBs
	Group PPM: Voluntary collaboration of purchasers to jointly procure medicines	Defined medicines (selected on a case-by-case basis) Mainly done in the inpatient sector (collaboration of hospitals)	Individual CAs (definition of a lead procurer)
	Facility-based PPM: Procurement done at the level of the individual healthcare facility (e.g. hospital, local health unit)	All or selected medicines Mainly done in the inpatient sector (predominant organisational form for hospital procurement in many countries)	Individual CAs
Cross-national	**Cross-country collaboration in PPM**: Voluntary collaboration of countries to jointly procurement	Selected medicines (e.g. medicines with high price tags, off-patent medicines)	Usually individual CAs (definition of a lead procurer)
	International pooled PPM: Medicines are purchased by a CA for several countries that are the users	E.g. joint procurement of COVID-19 vaccines	A supra-national CA

CA = contracting authority, CPB = central purchasing body, PPM = public procurement of medicines

Source: Authors

Additionally, some countries operate **tendering-like systems for off-patent medicines** in the outpatient setting, where public payers launch tenders per off-patent active substance and the winning bid (or bids) is assigned preferential reimbursement status for a defined period of time.

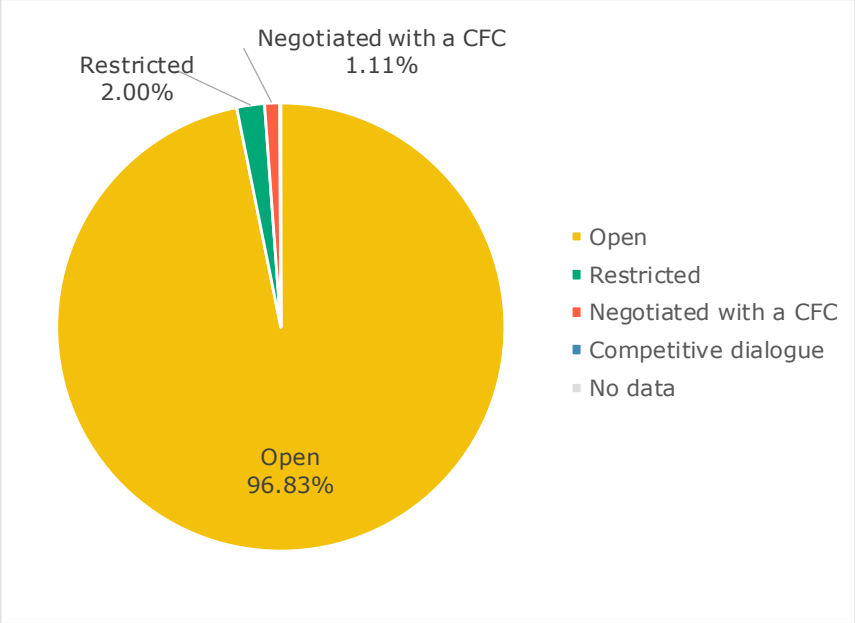
Table I also presents cross-national PPM, which can, in principle, take two forms:

- **Voluntary cross-country PPM collaboration** of (usually national) contracting authorities of different countries; examples of procurement collaborations include the **Baltic Procurement Initiative** (joint procurement of vaccines included in the national immunisation schedules of at least two of the three member countries Estonia, Latvia, and Lithuania) or the **joint Nordic tenders** conducted by some of the members **of the Nordic Pharmaceutical Forum** (Denmark, Iceland, Norway, Sweden) to jointly purchase mainly "old" (well-established) hospital medicines; and

- **Pooled PPM with the involvement of a supranational institution**, such as the joint procurement of COVID-19 vaccines by EU member states (organised by the EC) and of COVID-19 therapeutics (through the Joint Procurement Agreement).

According to EC TED data, **open procedure tenders** were by far the most frequently used procurement procedure from 2008-2021 (Figure I).

Figure I: Key PPM procedures for medicines in the study countries, 2008-2021



Procurement procedures describe award processes to conduct a procurement. They include according to EU Directive 2014/24[3]: **Open procedure**: a formal procurement method where any interested economic operator may submit a tender in response to a call for competition; **restricted procedure**: a formal, two-stage procurement method where any economic operator may submit a request to participate in response to a call in the first stage but only pre-qualified suppliers may submit tender in the second stage; **competitive procedure with negotiations (negotiated with a call for competition / CFC)**: a two-stage procurement method that involves pre-selection of suitable potential suppliers by the contracting authority and negotiations of submitted tenders; **competitive dialogue**: a two-stage procurement method where the contracting authority pre-selects potential suppliers based on their initial submissions and initiates a dialogue with them to identify the best possible method to address a need specified.

Source: European Commission TED data, analysis by authors

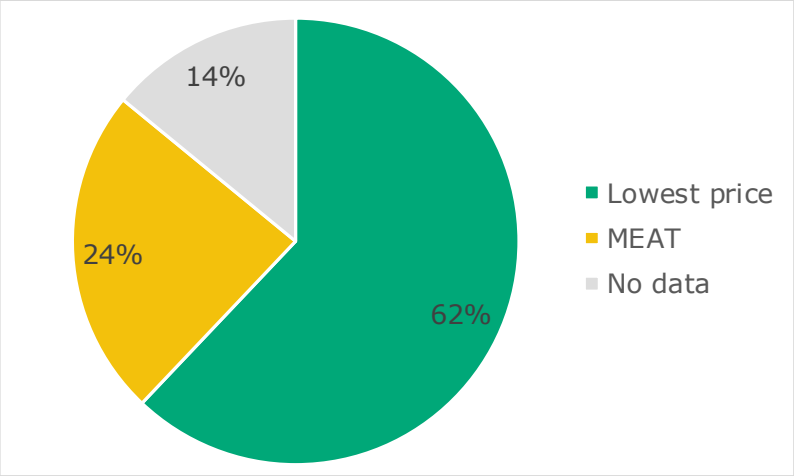
Procurement techniques relate to different methods for managing a procurement procedure, e.g. by making use of e-procurement or repetitive calls for recurring purchases. A commonly applied procurement technique is a **framework agreement**, which describes an arrangement between one or more contracting authorities and one or more suppliers that provides the terms which govern contracts to be awarded for a certain period of time for recurring purchasing. More than one quarter of all procurements of pharmaceutical products in the study countries were conducted under framework agreements (aggregated data for all study countries from 2008-2021, according to the EC TED database). Framework agreements were reported to be used for different types of medicines, including generics and biosimilars, medicines with high price tags as well as vaccines.

According to the EU Directive, contracts should be awarded to the **Most Economically Advantageous Tender (MEAT)**, which allows several (including non-price) criteria to be used together. While this approach comes into increasing use in the study countries, it currently still accounts for a minority of PPM procedures, and most are awarded based

[3] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0024

on price only (Figure II). Overall, use of award criteria may vary between contracting authorities. Further relevant award criteria include (added) **therapeutic value** and – increasingly – **security of supply**. **Environmental criteria** are not yet widely used but there is experience in some countries (e.g. the Nordic countries in both national and joint tenders). Local production does not play a role as award criterion in the study countries.

Figure II: Award criteria in PPM in the study countries, 2008-2021



MEAT = Most Economically Advantageous Tender

Source: European Commission TED data, analysis by authors

In most study countries, contracts are usually **awarded to a single winner**, at least for some medicines.

PHIS Hospital Procurement Update

To account for the developments during the last decade (e.g. high-priced medicines, frequently biologicals, that enter the hospital markets, increase of pharmaceutical spending on medicines in absolute terms and as a share of total pharmaceutical expenditure, the launch of biosimilar medicines and implementation of policies to encourage their uptake), the 2010 PHIS Hospital Pharma Report[4] was updated for all countries covered in this study, with a focus on **procurement practices**:

- In the majority of study countries, the main route for procurement of hospital medicines is **facility-based**. CPBs exist and are responsible for most PPM activities in hospitals in some countries (e.g. Amgros in Denmark, LIS in Norway), and they are set for an expanding role in other countries (e.g. Estonia). There appears to be a **trend towards more centralised PPM** in the hospital sector.
- Most hospitals in the study countries have their own **hospital pharmaceutical formulary** (HPF) even when some (or all) medicines used in hospitals are subject to centralised procurement (at national or regional levels within a country). In facility-based PPM, medicines need to be included in the HPF (based on a **decision by the Pharmaceuticals and Therapeutics Committee**, which is usually established at hospital level).
- Medicines used in hospitals are usually **funded through** a **diagnosis-related groups (DRG)** system, but some countries have specific funding schemes for defined medicines (e.g. dedicated funds to support purchasing and uptake of medicines with high price tags).

[4] Vogler S, Habl C, Leopold C, Morak S, Mazag J, Zimmermann N. PHIS Hospital Pharma Report. Pharmaceutical Health Information System. Gesundheit Österreich: Vienna, 2010. https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Hospital%20Pharma_Report_2.pdf

- To afford high-priced medicines and to manage uncertainty, **managed-entry agreements** (MEAs) are in place for some inpatient medicines in almost all study countries. MEAs may be concluded at national (or regional) levels, or, rather frequently, by the procuring hospitals.
- In several study countries, hospital systems are **decentralised** which contributes to limited data availability on procurement practices in individual hospitals as well as the prices paid.
- In most countries, there is **limited coordination between** the hospital and the outpatient **sectors**, despite the fact that medicines selected for the start of a therapy (often in inpatient care) can have a major impact on the follow-up prescribing (often in outpatient settings). In some countries, there are **good practice** examples **of interface management** measures to bridge the gap between inpatient and outpatient care, such as cross-sectoral formularies, cross-sectoral committees, specific funding mechanisms, IT projects, and capacity-building initiatives across the sectors.

Key findings related to **biosimilar procurement** include the following:

- **Uptake of biosimilar medicines varies** greatly, both between European countries and within individual countries. Similarly, and potentially related to uptake, **procurement practices for biosimilar medicines vary**. The vast majority of study countries includes biosimilars in public procurement activities. In most countries, the same organisational framework applies as for the procurement of other medicines. **Framework agreements** and dynamic purchasing systems (**DPS**) are commonly applied PPM techniques for purchasing biosimilar medicines.
- Specific aspects of biosimilar procurement include the **monitoring of patent expiry** to optimise timing of tenders and **working with prescribers** to ensure procured products are being used (e.g. through use of treatment guidelines).
- **Supplier practices in relation to procurement may impede competition** and thus reduce savings potentials. For instance, manufacturers of biologicals have been offering large discounts to hospitals to disincentivise them to switch to a biosimilar after patent expiry. In the Netherlands, such a discounting scheme for the originator of an anti-rheumatic biological (etanercept) has led to an intervention by the competition authority.
- **Policies to encourage uptake of biosimilars in hospital settings** are yet to be implemented in several countries (e.g. prescribing of biological medicines by the international non-proprietary name (INN), or substitution of a biological originator by a biosimilar). Adoption of an appropriate biosimilar-supporting regulatory and policy framework has been urged by several hospital pharmacists.

Evaluation of the impact of PPM policies and practices

PPM can be implemented using a variety of procedures and techniques as well as supporting policies and tools. Design choices for PPM depend on the policy objectives to be targeted, existing policy frameworks and institutional set-ups, and the type of medicine to be procured. Analysing the impact of PPM therefore requires disentangling the different PPM components. Table II summarises the findings of the impact evaluation per core objective based on a mix of data sources, including stakeholder assessment.

Table II: Analysis of impact of PPM design on achieving policy objectives

PPM design	Afford	Avail	Secur	Comp	Green	Crisis	Comments
Centralisation/ pooling (joint PPM)	+*	++*	+	+	+	++	PPM approaches which exploit the potential of **larger volumes** as well as **improved capacity** through collaboration have been successful in making (small) markets attractive and optimising PPM processes. Lower prices are not necessarily the major objective (availability of medicines and security of supply can be key drivers for joint procurement). Suppliers only consider pooling beneficial in crisis situations, but not for achieving other objectives, including maintaining a competitive market with good availability of medicines and security of supply in the long-term.
Strategic use of PPM procedures and techniques, based on a life cycle approach	++*	++*	++*	++*	0	+	Different procedures are appropriate for different types of medicines; **framework agreements and DPS** were found to be suitable tools for off-patent medicines, as they help to encourage competition, resulting in lower prices while keeping several suppliers in the market.
Award criteria: use of MEAT criteria	+	++*	++*	++*	++*	+	Use of MEAT criteria, in which the price criterion is **strategically accompanied by a mix of other award criteria**, can help achieve defined policy objectives (including, but not limited to, affordability).
Selection of winner(s): multiple bids	+	++	++	++	0	++	Multiple winner approaches are in particular supportive for the security of supply and **sustainable PPM**.
Supporting tools (e.g. HTA, comm.)	++*	++	+	+/-	++	+	Selection of appropriate supporting policies and tools (not necessarily PPM features) was found to be beneficial for **achieving several different objectives**.

Abbreviations for objectives: afford = affordability for procurers (e.g. expressed in lower prices), avail = availability (i.e. medicines in the formulary), secur = security of supply (e.g. no or low number of shortages and disruptions), comp = competition (e.g. number of bids received, participation rate in a call), green = greener design and manufacturing (e.g. reduced ecological footprint), crisis = preparedness and ability to handle (public health) crisis such as a pandemic

Further abbreviations: comm. = communication, HTA = Health Technology Assessment, MEAT = Most Economically Advantageous Tender, PPM = public procurement of medicines

Classification: ++ = strongly contributing to achieving the policy objective, + = contributing to the policy objective,- = not supporting the policy objective, -- = strong barrier / disincentive to achieving the policy objective, +/- = supporting and hindering, depending on design and conditions or conflicting views of stakeholder group, 0 = neither supporting nor hindering. Data accompanied by an asterisk (*) are based on more robust evidence (literature and data analysis in this study), data not marked are largely based on stakeholder assessment.

Source: Authors based on a triangulation of methods

Data on the impact of PPM procedures and techniques is limited in some cases. In those cases, stakeholder perceptions served as guidance for the impact analysis. However, **perspectives of procurers and suppliers** may **differ**. For instance, purchasers have stressed the benefits of pooled procurement, whereas suppliers are hesitant and consider this only as an instrument for crises.

Analysis of quantitative data showed that **lower unit prices** were observed **in countries with more advanced PPM** (i.e. more centralised procurement, use of different PPM procedures and techniques, MEAT award criteria, and application of

supporting policies and tools). This is in line with evidence from previous studies which generally reported savings from PPM.

Overall, **countries with higher level of PPM maturity** were usually those with a well-developed pharmaceutical pricing and reimbursement policy framework, higher spending on pharmaceutical expenditure and, in some but not all cases, higher availability of medicines (earlier launch countries).

Joint procurement, including within country and cross-country, can help achieve lower prices and make small markets attractive for suppliers, thereby achieving better availability of medicines and mitigating the risk of shortages. Joint procurement also provides other benefits, such as information sharing and capacity building. However, implementation is resource intensive.

Some policy objectives (e.g. low prices, security of supply, green pharmaceutical design) may be conflicting and thus some **trade-offs** need to be made. Applying MEAT criteria allows appropriate consideration of further award criteria beyond the price. Award multi-winner contracts also support achieving potentially conflicting policy objectives such as competition and security of supply.

Policy implications and conclusions

Barriers to optimising PPM

The study identified **barriers to optimising PPM at several levels**: they can relate to limitations in PPM policy and practices which could be addressed through optimisation of procedures and challenges in the context of PPM in the broader sense, including potential impacts of PPM on policy objectives such as availability, affordability and similar. **Key barriers** encountered in several countries include issues with availability of medicines due to **limited attractiveness of the market to suppliers** (in particular for smaller countries, although this challenge was experienced by the majority of study countries), **limited capacity of procurers** (e.g. understaffing, low and inappropriate skills), and **lack of funding**.

Key barriers related to procurement of **off-patent products** include the following:

- **Supply issues**, which appear to be more common in smaller countries. Commercial reasons for non-supply may also apply to on-patent medicines when products are not registered in a particular market.
- Practices by suppliers to **impede market entry and uptake of competitor products**, in particular for biosimilar products (e.g. pricing structures that lock hospitals into continued use of higher-priced originators, "loss leader" practices to initiate treatment with a specific product in hospital at reduced price followed by higher prices for treatment continuation in the outpatient setting, subsidising out-of-pocket payments for patients to continue using the product, as well as practices to impede the chances of competitor products being selected as winners in tenders).
- Lack of uptake of biosimilars which may be due to **lack of interaction between procurers and prescribers**. Procurers therefore need to work with prescribers to ensure that procured products meet the needs of patients and are being prescribed.

Barriers specific to the **hospital sector** include a lack of (transparent) data to compare procurement practices and outcomes (including prices), and lack of collaboration between individual hospitals. The fragmented landscape for hospital procurement in most countries impedes a strategic approach to procurement.

Challenges which purchasers encountered in **cross-country joint procurement** include the differences between national legal, policy and administrative systems and

processes, the requirement for more resources compared to national procurement, limitations in the extent to which countries can participate due to fragmented health system, possible hesitancy on the supplier side to respond to cross-country tenders, and the need to address language issues.

Best practice examples for PPM

Some **best practices** to address the challenges mentioned above and providing wider optimisation potential in PPM were identified, including:

- **Cross-country collaboration**, with the intention to jointly procure medicines (to make smaller markets more attractive), as well as sharing knowledge and experiences across countries (not necessarily linked to solely PPM).
- **E-procurement**, which allowed (easier) implementation of valuable PPM techniques such as framework agreements and DPS,
- Use of a **range of PPM procedures and techniques, aligned** to the policy objective and the type of medicines (e.g. monopoly products with high price tags versus off-patent medicines) and linking PPM to supporting pricing and reimbursement policies and tools as well as necessary demand-side measures (e.g. to allow switching and substitution of biosimilar medicines, with a view to encourage biosimilar uptake)
    - In this context, awareness of a product's position in the life cycle helps identify suitable procurement processes (ranging from less competitive forms such as negotiations for newly marketed, on-patent products to more competitive procedures such as open tenders as more competitor products become available) and criteria (considering security of supply criteria as products approach the later stages of their life cycle). Such a **product life cycle approach** to procurement, was pioneered by AMGROS, the CPB for public hospitals in Denmark.
- **Dialogue with suppliers** and systematic **collaboration of public procurers** of medicines
- **Legal changes** (to allow for implementation of novel PPM procedures and techniques), and **transparent, clear operational rules and procedures** (administrative management)
- Specific policies to ensure **bridging the gap between outpatient and inpatient sector**, such as through measures related to formulary development or funding schemes

Policy recommendations

Policy-makers are encouraged

- to **develop and communicate a PPM vision and strategy**, based on a holistic perspective where PPM is one major component of the pharmaceutical policy framework,
- to **support the implementation of the PPM strategy through investments** such as into capacity-building as well as changes in the legal and institutional framework,
- to **monitor and adapt** the strategy, if necessary, based on findings from evaluations, and
- to consider intra-country and cross-country **collaboration** as a key principle in implementation.

In operational terms, **strategic selection of PPM policies and practices should be aligned with** the **objectives** defined at the strategic level **and** the product's place in the **life cycle.** Important practices to be considered include application of **MEAT** criteria and **multiple-winner approaches**, **data collection and analysis**. **Transparent and clear processes,** and improvement in **IT systems** are considered beneficial and supportive approaches.

The European Commission may support these policy recommendations by offering a **platform to facilitate exchange of experiences** between PPM practitioners as well between procurement experts and further experts, e.g. those working in public authorities for pharmaceutical pricing and reimbursement.

Conclusions

Procurement is a key **pharmaceutical policy that can help achieve better access to medicines**, including making more medicines available at lower prices. Procurement practices vary across European countries, often reflecting the heterogeneity in health care systems. In terms of optimising public procurement of medicines, **no one size fits all**, and procurement policies need to be integrated into the national set-up of the healthcare system. A **life cycle approach** to procurement which considers the place of a medicine along the pharmaceutical value chain can help determine which procurement procedure (less vs. more competitive) to use and what award criteria are most relevant. Understanding the market can be helped by thorough market research and engagement with suppliers ahead of the launch of procurement procedures.

Importantly, through its leverage as key area for procurement, PPM can help address further policy objectives, including security of supply and crisis preparedness for the health sector, a competitive market for pharmaceuticals, as well as environmental objectives. However, not all objectives may be simultaneously attainable. A strategic approach to pharmaceutical procurement is therefore needed.

Policy-makers are encouraged to put **attention to PPM** and to (further) develop a **PPM vision and strategy**, which can be then operationalised based on learnings on how to **optimise PPM in technical terms**.

RÉSUMÉ

Contexte et objectifs de l'étude

Les marché publics de médicaments (MPM, en anglais PPM: *public procurement of medicines*) sont une option politique stratégique pour favoriser la concurrence et améliorer l'accès aux médicaments, ainsi que pour atteindre d'autres objectifs politiques importants, comme le souligne la «Stratégie pharmaceutique pour l'Europe» de 2020.[5] Dans ce contexte, l'Agence exécutive européenne pour la santé et le numérique (HaDEA, en anglais: *European Health and Digital Executive Agency*), en tant que pouvoir adjudicateur sous mandat de la Commission européenne (CE), a commandé une **étude sur les meilleures pratiques** en matière de MPM.[6]

L'**objectif** général de l'étude était de **collecter et d'analyser des preuves pour optimiser les MPM** en tant qu'outil pouvant contribuer à l'accessibilité, y compris financière et à la disponibilité des médicaments. L'optimisation doit également encourager une conception et une fabrication pharmaceutiques plus écologiques dans les secteurs ambulatoire et hospitalier, et soutenir la sécurité de l'approvisionnement des médicaments, ainsi que la préparation et la gestion des crises dans ces secteurs. Dans le cadre de cette étude, les MPM sont définis comme tous les aspects entourant le processus d'achat de médicaments par un pouvoir adjudicateur, tel qu'un organisme de droit public (par exemple les gouvernements, les autorités sanitaires locales et les organismes sociaux et d'assurance maladie) ou une institution affiliée au secteur public, auprès d'opérateurs économiques (fournisseurs) choisis par le pouvoir adjudicateur. L'objectif général est opérationnalisé à travers six objectifs spécifiques: une **cartographie** de toutes les **parties prenantes** liées aux MPM dans les pays de l'étude, une **cartographie de la politique et des pratiques MPM** dans les pays de l'étude en vue de leur optimisation, une enquête sur les **impacts possibles de l'optimisation des MPM** dans les pays de l'étude, une identification des **obstacles** à l'optimisation des MPM, un développement des **meilleures pratiques** sur les MPM et une mise à jour et extension du rapport ***PHIS Hospital Pharma*** de 2010 sur la gestion des médicaments dans le secteur hospitalier.

Les **32 pays étudiés** comprennent les 27 États membres de l'Union européenne (UE), les pays de l'Association européenne de libre-échange (AELE), l'Islande, le Liechtenstein, la Norvège, la Suisse, ainsi que le Royaume-Uni. Les secteurs ambulatoire et hospitalier sont étudiés.

Méthodes

L'étude applique un **mélange de méthodes qualitatives et quantitatives** pour aborder les questions de recherche dans six domaines d'intérêt, dont aucun n'est traité par une seule approche méthodologique. La **triangulation des méthodes et des sources de données** est utilisée tout au long de l'étude. Les méthodes de recherche utilisées ont consisté en une revue de la littérature (couvrant à la fois la littérature académique et la littérature grise), qui a été en partie utilisée pour remplir les fiches pays (fiches d'information) pour chacun des 32 pays de l'étude. Les fiches pays ont été examinées par des experts nationaux. Plusieurs activités de consultation des parties prenantes ont été menées, notamment une série de quatre ateliers en ligne, des entretiens exploratoires et une enquête en ligne, permettant aux parties prenantes (y compris les autorités nationales de tarification et de remboursement des médicaments, les acheteurs publics, les payeurs, les pharmaciens, les représentants des patients et la représentation de l'industrie pharmaceutique et les grossistes) afin de fournir des informations et d'évaluer l'impact potentiel des pratiques MPM sur divers objectifs

[5] "Pharmaceutical Strategy for Europe", COM(2020) 761, available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0761&from=EN

[6] L'étude a été réalisée via le Contrat cadre SANTE/2016/a1/039 relatif à la provision de services dans les domaines de l'évaluation, des evaluations d'impact, du suivi et de la mise en oeuvre, et d'autres services pertinents, dans le secteur des politiques de santé et alimentaire (LOT 1) avec réouverture de la concurrence.

politiques. Enfin, une analyse quantitative des marchés (provenant de la base de données Tenders Electronics Daily (TED) de la CE) et des données de ventes pharmaceutiques (fournies par le fournisseur de données de santé IQVIA) a été réalisée pour évaluer la relation entre les différentes pratiques sur les MPM et leurs résultats, couvrant l'accès aux médicaments, l'accessibilité financière, la disponibilité, la sécurité d'approvisionnement, la concurrence sur le marché, l'environnement et la préparation aux crises.

Marchés publics de médicaments dans les pays de l'étude

Cartographie des politiques et pratiques MPM

L'étude a révélé d'importantes variations dans la manière dont les MPM sont dirigés et intégrés dans les systèmes de santé hétérogènes des pays étudiés (Tableau I). **Quatre types de base de MPM** au sein des pays ont été identifiés: l'approvisionnement centralisé au niveau national ou régional, l'approvisionnement groupé (approvisionnement conjoint volontaire) et l'approvisionnement par établissement (effectué par des établissements de santé individuels). La plupart des pays étudiés utilisent plus d'un type de MPM, selon le type de médicaments et le secteur. Dans l'ensemble, les deux formes les plus courantes sont l'approvisionnement par établissement (en particulier pour le milieu hospitalier) et le système national d'approvisionnement centralisé (cependant, dans de nombreux cas, uniquement pour quelques produits sélectionnés).

Tableau I: Organisation des MPM dans les pays de l'étude

	Type	Medicament et secteur	PA
National	**MPM centralisé au niveau national:** Les médicaments sont achetés par le CA pour l'ensemble du pays (au moins pour un secteur, par exemple le secteur des patients hospitalisés)	In some countries: All or nearly all medicines (both sectors or the inpatient sector only) Fréquemment utilisé pour les vaccins et les médicaments dans le cadre d'un programme national de santé Dans certains pays : (Presque) tous les médicaments (les deux secteurs ou le secteur hospitalier uniquement)	CA nationales (dans certains pays, seulement dans le secteur hospitalier)
	MPM centralisé au niveau régional: Les médicaments sont achetés par le CA pour une région ou pour un groupe d'utilisateurs (au moins pour un secteur, par exemple les patients hospitalisés)	Dans certains pays : (Presque) tous les médicaments (les deux secteurs ou le secteur hospitalier uniquement)	CA régionales
	MPM de groupe: Collaboration volontaire des acheteurs pour se procurer conjointement des médicaments	Médicaments définis (sélectionnés au cas par cas) Fait principalement dans le secteur hospitalier (collaboration des hôpitaux	PA individuels (définition d'acheteur principal)
	MPM par établissement: Approvisionnement effectué au niveau de l'établissement de santé individuel (par exemple hôpital, unité de santé locale)	Tous les médicaments ou certains médicaments Fait principalement dans le secteur hospitalier (forme organisationnelle prédominante pour l'approvisionnement hospitalier dans de nombreux pays)	PA individuels
Trans-national	**Collaboration transnationale dans les MPM**: Collaboration volontaire des pays pour des achats conjoints	Médicaments sélectionnés (par exemple, médicaments à prix élevé, médicaments hors brevet)	En général, PA individuels (définition d'acheteur principal)
	MPM international mutualisé: Les médicaments sont achetés par un CA pour plusieurs pays utilisateurs	Par exemple: achats conjoints de vaccins COVID-19	Un PA supra-national

PA = pouvoir adjudicateur (en anglais, CA: *contracting authority*), CA = centrale d'achat (en anglais, CPB: *central purchasing body*), MPM = marché public de médicaments (en anglais, PPM: *public procurement of medicines*)

Source : Auteurs

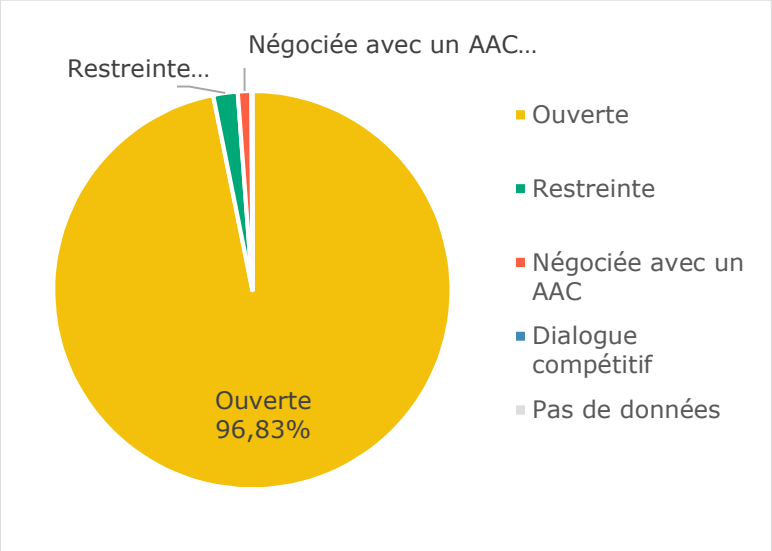
De plus, certains pays appliquent des **systèmes de type appels d'offres pour les médicaments hors brevet dans le secteur ambulatoire**, où les payeurs publics lancent des appels d'offres par substance active hors brevet et l'offre (ou les offres) gagnante se voit attribuer un statut de remboursement préférentiel pour une période de temps définie.

Le tableau I présente également les MPM transnationaux, qui peuvent, en principe, prendre deux formes :

- **Collaboration volontaire transnationale des MPM** entre les pouvoirs adjudicateurs (généralement nationaux) de différents pays ; des exemples de collaborations en matière d'approvisionnement incluent la ***Baltic Procurement Initiative*** (achat conjoint de vaccins inclus dans les calendriers nationaux de vaccination d'au moins deux des trois pays membres, l'Estonie, la Lettonie et la Lituanie) ou les **appels d'offres nordiques conjoints** menés par certains des membres du ***Nordic Pharmaceutical Forum*** (Danemark, Islande, Norvège, Suède) pour acheter conjointement des médicaments hospitaliers principalement « anciens » (bien établis); et
- **MPM mis en commun avec l'implication d'une institution supranationale**, comme l'achat conjoint de vaccins contre le COVID-19 par les États membres de l'UE (organisé par la CE) et de médicaments contre le COVID-19 (via l'accord d'achat conjoint).

Selon les données du portail TED de la CE, les appels d'offres ouverts ont été de loin la procédure de passation de marchés la plus fréquemment utilisée de 2008 à 2021 (Figure I).

Figure I : Principales procédures de MPM pour les médicaments dans les pays de l'étude, 2008-2021



Les procédures de marché décrivent les processus d'attribution d'un marché. Ils comprennent, conformément à la Directive UE 2014/24[7]: **Procédure ouverte**: une méthode formelle de passation de marché où tout opérateur économique intéressé peut soumettre une offre en réponse à un appel à la concurrence; **procédure restreinte**: une méthode formelle de passation de marché en deux étapes dans laquelle tout opérateur économique peut soumettre une demande de participation en réponse à un appel lors de la première étape, mais seuls les fournisseurs présélectionnés peuvent soumettre une offre lors de la deuxième étape; **procédure concurrentielle avec négociations (négociée avec appel à la concurrence, AAC, en anglais CFC: *call for competition*)**: méthode de passation des marchés en deux étapes, qui implique la présélection des fournisseurs potentiels appropriés par le pouvoir adjudicateur et la négociation des offres

[7] Directive 2014/24/UE du Parlement européen et du Conseil du 26 Février 2014 sur la passation des marches publics et abrogeant la directive 2004/18/CE (Texte présentant de l'intéret pour l'EEE) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0024

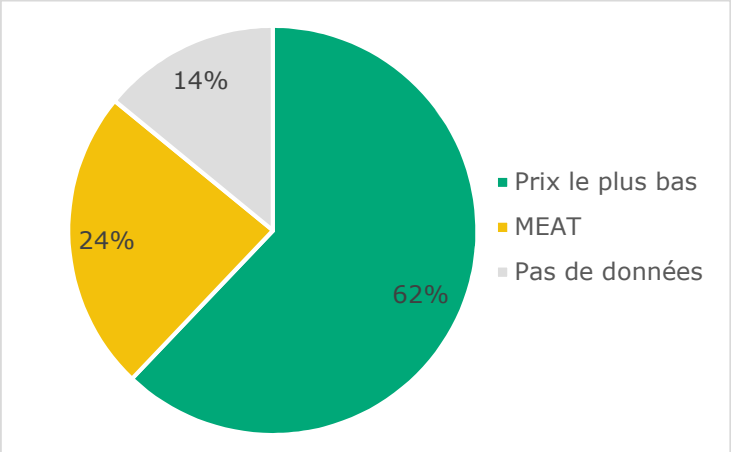
soumises ; **dialogue compétitif**: méthode de passation des marchés en deux étapes où le pouvoir adjudicateur présélectionne les fournisseurs potentiels sur la base de leurs offres initiales et engage un dialogue avec eux pour identifier la meilleure méthode possible pour répondre à un besoin spécifié.

Source: données TED de la Commission européenne, analyse des auteurs

Les techniques de passation de marchés concernent différentes méthodes de gestion d'une procédure de passation de marchés, par exemple le recours à l'e-procurement ou aux appels répétitifs pour des achats récurrents. Une technique de passation des marchés couramment appliquée est un **accord-cadre**, qui décrit un arrangement entre un ou plusieurs pouvoirs adjudicateurs et un ou plusieurs fournisseurs qui prévoit les conditions régissant les contrats à attribuer pour une certaine période de temps pour des achats récurrents. Plus d'un quart de tous les achats de produits pharmaceutiques dans les pays de l'étude ont été effectués dans le cadre d'accords-cadres (données agrégées pour tous les pays de l'étude de 2008 à 2021, selon la base de données TED de la CE). Des accords-cadres ont été signalés comme étant utilisés pour différents types de médicaments, notamment les génériques et les biosimilaires, les médicaments à prix élevé ainsi que les vaccins.

Selon la directive de l'UE, les contrats doivent être attribués à **l'offre économiquement la plus avantageuse (MEAT)**, ce qui permet d'utiliser plusieurs critères (y compris non tarifaires). Bien que cette approche soit de plus en plus utilisée dans les pays étudiés, elle ne représente encore actuellement qu'une minorité de procédures de MPM, et la plupart des marches sont attribués uniquement sur la base du prix (Figure II). Dans l'ensemble, l'utilisation des critères d'attribution peut varier d'un pouvoir adjudicateur à l'autre. D'autres critères d'attribution pertinents incluent la **valeur thérapeutique** (ajoutée) et – de plus en plus – la **sécurité d'approvisionnement**. Les **critères environnementaux** ne sont pas encore largement utilisés, mais il existe une expérience dans certains pays (par exemple, les pays nordiques dans les appels d'offres nationaux et conjoints). La production locale n'est pas un critère d'attribution dans les pays étudiés.

Figure II: Critères d'attribution dans les MMP dans les pays de l'étude, 2008-2021



MEAT = Offre économiquement la plus avantageuse

Source: données TED de la Commission européenne, analyse des auteurs

Dans la plupart des pays étudiés, les contrats sont généralement attribués à un seul lauréat, du moins pour certains médicaments.

Mise à jour de l'approvisionnement hospitalier du PHIS

Pour tenir compte des développements au cours de la dernière décennie (par exemple les médicaments à prix élevé, souvent biologiques, qui entrent sur les marchés hospitaliers, l'augmentation des dépenses pharmaceutiques en médicaments en termes absolus et en pourcentage des dépenses pharmaceutiques totales, le lancement de médicaments biosimilaires et la mise en œuvre des politiques visant à encourager leur

adoption), le rapport *PHIS Hospital Pharma* de 2010[8] a été mis à jour pour tous les pays couverts par cette étude, en mettant l'accent sur les **pratiques d'approvisionnement**:

- Dans la majorité des pays étudiés, la principale voie d'approvisionnement en médicaments hospitaliers est **basée sur les établissements**. Les centrales d'approvisionnement (CPB) existent et sont responsables de la plupart des activités de MPM dans les hôpitaux de certains pays (par exemple, Amgros au Danemark, LIS en Norvège), et elles sont appelées à jouer un rôle croissant dans d'autres pays (par exemple l'Estonie). Il semble y avoir une **tendance vers des MPM plus centralisés** dans le secteur hospitalier.
- La plupart des hôpitaux des pays de l'étude ont leur propre **formulaire pharmaceutique hospitalier** (HPF, en anglais: *hospital pharmaceutical formulary*) même lorsque certains (ou tous) les médicaments utilisés dans les hôpitaux font l'objet d'un approvisionnement centralisé (au niveau national ou régional dans un pays). Dans les MPM par établissement, les médicaments doivent être inclus dans le HPF (sur la base d'une **décision du comité pharmaceutique et thérapeutique**, qui est généralement établi au niveau de l'hôpital).
- Les médicaments utilisés dans les hôpitaux sont généralement **financés par le biais d'un système de groupes liés au diagnostic** (DRG, en anglais: *diagnosis-related groups*), mais certains pays ont des régimes de financement spécifiques pour des médicaments définis (par exemple des fonds dédiés pour soutenir l'achat et l'utilisation de médicaments à prix élevé).
- Afin d'acheter des médicaments à prix élevé et de gérer l'incertitude, des **accords d'accès contrôlé** (MEA, en anglais: *managed-entry agreements*) sont en place pour certains médicaments destinés aux patients hospitalisés dans presque tous les pays de l'étude. Les MEA peuvent être conclus au niveau national (ou régional) ou, assez fréquemment, par les hôpitaux acheteurs.
- Dans plusieurs pays étudiés, les systèmes hospitaliers sont **décentralisés**, ce qui contribue à la disponibilité limitée des données sur les pratiques d'approvisionnement dans les hôpitaux individuels ainsi que sur les prix payés.
- Dans la plupart des pays, il existe une **coordination limitée** entre les secteurs hospitalier et ambulatoire, malgré le fait que les médicaments sélectionnés pour le début d'une thérapie (souvent en soins hospitaliers) peuvent avoir un impact majeur sur la prescription de suivi (souvent en ambulatoire). Dans certains pays, il existe des exemples de **bonnes pratiques** de mesures de **gestion d'interface** pour combler le fossé entre les soins hospitaliers et ambulatoires, tels que les formulaires intersectoriels, les comités intersectoriels, les mécanismes de financement spécifiques, les projets informatiques et les initiatives de renforcement des capacités dans tous les secteurs.

Les principales conclusions liées à **l'approvisionnement en biosimilaires** sont les suivantes:

- **L'adoption des médicaments biosimilaires varie** considérablement, tant entre les pays européens qu'au sein de chaque pays. De même, et potentiellement liées à l'adoption de ces médicaments, **les pratiques d'approvisionnement en médicaments biosimilaires varient.** La grande majorité des pays étudiés inclut les biosimilaires dans les marchés publics. Dans la plupart des pays, le même cadre organisationnel s'applique que pour l'achat d'autres médicaments. **Les accords-cadres** et les systèmes d'achat dynamiques (**DPS**: en anglais: *dynamic purchasing systems*) sont des techniques de MPM couramment appliquées pour l'achat de médicaments biosimilaires.

[8] Vogler S, Habl C, Leopold C, Morak S, Mazag J, Zimmermann N. PHIS Hospital Pharma Report. Pharmaceutical Health Information System. Gesundheit Österreich: Vienna, 2010. https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Hospital%20Pharma_Report_2.pdf

- Les aspects spécifiques de l'approvisionnement en biosimilaires comprennent la **surveillance de l'expiration des brevets** pour optimiser le calendrier des appels d'offres et la **collaboration avec les prescripteurs** pour s'assurer que les produits achetés sont utilisés (par exemple grâce à l'utilisation de directives de traitement).
- **Les pratiques des fournisseurs en matière d'approvisionnement peuvent entraver la concurrence** et donc réduire les potentiels d'économies. Par exemple, les fabricants de produits biologiques ont offert d'importantes remises aux hôpitaux pour les dissuader de passer à un biosimilaire après l'expiration du brevet. Aux Pays-Bas, un tel système de rabais pour le princeps d'un antirhumatismal biologique (etanercept) a conduit à une intervention de l'autorité de la concurrence.
- **Les politiques visant à encourager l'adoption des biosimilaires en milieu hospitalier** doivent encore être mises en œuvre dans plusieurs pays (par exemple, la prescription de médicaments biologiques par la dénomination commune internationale (DCI) ou la substitution d'un princeps biologique par un biosimilaire). L'adoption d'un cadre réglementaire et politique approprié à l'appui des biosimilaires a été préconisée par plusieurs pharmaciens hospitaliers.

Evaluation of the impact of PPM policies and practices

Les MPM peuvent être mis en œuvre en utilisant une variété de procédures et de techniques ainsi que des politiques et des outils de soutien. Les choix de conception pour les MPM dépendent des objectifs politiques à cibler, des cadres politiques et des structures institutionnelles existants, et du type de médicament à acheter. Analyser l'impact des MPM nécessite donc de démêler les différentes composantes des MPM. Le tableau II résume les conclusions de l'évaluation d'impact par objectif principal sur la base d'un mélange de sources de données, y compris l'évaluation des parties prenantes.

Table II: Analyse d'impact du design des MPM sur la réalisation des objectifs politiques

Design des MPM	Access	Dispo	Secur	Conc	Vert	Crise	Commentaires
Centralisation/ pooling (MPM conjoint)	+*	++*	+	+	+	++	Les approches MPM qui exploitent le potentiel de **volumes plus importants** ainsi que **l'amélioration des capacités** grâce à la collaboration ont réussi à rendre les (petits) marchés attractifs et à optimiser les processus MPM. La baisse des prix n'est pas nécessairement l'objectif principal (la disponibilité des médicaments et la sécurité de l'approvisionnement peuvent être les principaux moteurs de l'approvisionnement conjoint). Les fournisseurs considèrent que la mise en commun n'est bénéfique que dans les situations de crise, mais pas pour atteindre d'autres objectifs, notamment le maintien d'un marché concurrentiel avec une bonne disponibilité des médicaments et la sécurité de l'approvisionnement à long terme.
Utilisation stratégique des procédures et techniques MPM basée sur l'approche du cycle de vie	++*	++*	++*	++*	0	+	Différentes procédures sont appropriées pour différents types de médicaments ; les **accords-cadres et les DPS** se sont avérés être des outils appropriés pour les médicaments hors brevet, car ils contribuent à encourager la concurrence, entraînant une baisse des prix tout en maintenant plusieurs fournisseurs sur le marché.
Critères d'attribution: utilisation du critère MEAT	+	++*	++*	++*	++*	+	L'utilisation des critères MEAT, dans lesquels le critère de prix est **stratégiquement accompagné d'un mélange d'autres critères d'attribution**, peut aider à atteindre des objectifs politiques définis (y compris, mais sans s'y limiter, l'abordabilité).
Sélection de gagnant(s): offres multiples	+	++	++	++	0	++	Les approches à gagnants multiples sont particulièrement favorables à la sécurité d'approvisionnement et à des **MPM durables**.
Outils de soutien (ex. ETS, comm)	++*	++	+	+/-	++	+	La sélection de politiques et d'outils de soutien appropriés (pas nécessairement des caractéristiques des MPM) s'est avérée bénéfique pour **atteindre plusieurs objectifs différents.**

Abréviations pour les objectifs : access = accessibilité financière pour les acheteurs (exprimée par exemple en prix plus bas), dispo = disponibilité (c'est-à-dire médicaments dans le formulaire), secur = sécurité d'approvisionnement (ex. absence ou faible nombre de pénuries et de perturbations), conc = concurrence (ex. nombre d'offres reçues, taux de participation à un appel), vert = conception et fabrication plus écologiques (par exemple, empreinte écologique réduite), crise = préparation et capacité à gérer une crise (de santé publique) telle qu'une pandémie

Autres abréviations : comm. = communication, ETS = évaluation des technologies de la santé (en anglais, HTA = *Health Technology Assessment*), MEAT = offre économiquement la plus avantageuse (*Most Economically Advantageous Tender)*, MPM = marché public de médicaments

Classification : ++ = contribue fortement à la réalisation de l'objectif politique, + = contribue à l'objectif politique,- = ne soutient pas l'objectif politique, -- = obstacle important/dissuasion à la réalisation de l'objectif politique, +/- = soutient et entrave, en fonction de la conception et des conditions ou des points de vue contradictoires du groupe de parties prenantes, 0 = ni soutien ni entrave. Les données accompagnées d'un astérisque (*) sont basées sur des preuves plus solides (littérature et analyse des données dans cette étude), les données non marquées sont largement basées sur l'évaluation des parties prenantes.

Source : Auteurs sur la base d'une triangulation des méthodes

Les données sur l'impact des procédures et techniques MPM sont limitées dans certains cas. Dans ces cas, les perceptions des parties prenantes ont servi de guide pour l'analyse d'impact. Cependant, les **points de vue des acheteurs et des fournisseurs** peuvent **différer**. Par exemple, les acheteurs ont souligné les avantages des achats groupés, alors que les fournisseurs sont hésitants et n'y voient qu'un instrument de crise.

L'analyse des données quantitatives a montré que des **prix unitaires inférieurs** ont été observés dans les **pays dotés d'un MPM plus avancé** (c'est-à-dire un approvisionnement plus centralisé, l'utilisation de différentes procédures et techniques de MPM, les critères d'attribution du MEAT et l'application de politiques et d'outils de soutien). Cela est conforme aux preuves d'études précédentes qui ont généralement fait état d'économies grâce aux MPM.

Dans l'ensemble, les **pays ayant un niveau de maturité des MPM plus élevé** étaient généralement ceux qui avaient un cadre politique de tarification et de remboursement des produits pharmaceutiques bien développé, des dépenses pharmaceutiques plus élevées et, dans certains cas mais pas tous, une plus grande disponibilité des médicaments (pays de lancement antérieur).

L'approvisionnement conjoint, y compris à l'intérieur d'un pays et entre pays, peut aider à obtenir des prix plus bas et à rendre les petits marchés attractifs pour les fournisseurs, améliorant ainsi la disponibilité des médicaments et atténuant le risque de pénurie. L'approvisionnement conjoint offre également d'autres avantages, tels que le partage d'informations et le renforcement des capacités. Cependant, la mise en œuvre demande beaucoup de ressources.

Certains objectifs politiques (par exemple, prix bas, sécurité d'approvisionnement, conception pharmaceutique verte) peuvent être contradictoires et certains **compromis** doivent donc être faits. L'application des critères MEAT permet une prise en compte appropriée d'autres critères d'attribution au-delà du prix. L'attribution de contrats à plusieurs lauréats contribue également à la réalisation d'objectifs politiques potentiellement contradictoires tels que la concurrence et la sécurité de l'approvisionnement.

Implications politiques et conclusions

Obstacles à l'optimisation des MPM

L'étude a identifié des **obstacles à l'optimisation des MPM à plusieurs niveaux**: ils peuvent être liés aux limites de la politique et des pratiques des MPM qui pourraient être résolues par l'optimisation des procédures et des défis dans le contexte des MPM au sens large, y compris les impacts potentiels des MPM sur les objectifs politiques tels que la disponibilité, y compris la disponibilité financière et d'autres objectifs similaires. Les **principaux obstacles** rencontrés dans plusieurs pays couvrent les problèmes de disponibilité des médicaments en raison de **l'attractivité limitée du marché pour les fournisseurs** (en particulier pour les petits pays, bien que ce défi ait été rencontré par la majorité des pays de l'étude), la **capacité limitée des acheteurs** (par exemple, le manque de personnel, l'insuffisance et le manque de compétences) et le **manque de financement**.

Les principaux obstacles liés à l'achat de **produits non brevetés** sont les suivants:

- **Les problèmes d'approvisionnement**, qui semblent être plus fréquents dans les petits pays. Des raisons commerciales de non-approvisionnement peuvent également s'appliquer aux médicaments brevetés lorsque les produits ne sont pas enregistrés sur un marché particulier.
- Pratiques des fournisseurs pour **empêcher l'entrée sur le marché de produits concurrents et leur adoption,** en particulier pour les produits biosimilaires (par exemple, les structures de prix qui enferment les hôpitaux dans l'utilisation continue de princeps plus chers, les pratiques de « produit d'appel » pour initier un traitement avec un produit spécifique à l'hôpital à prix réduit suivi de prix plus élevés pour la poursuite du traitement en ambulatoire, subvention des paiements

directs pour que les patients continuent à utiliser le produit, ainsi que des pratiques visant à empêcher les produits concurrents d'être sélectionnés comme gagnants dans les appels d'offres).

- Le manque d'adoption des biosimilaires qui peut être dû au **manque d'interaction entre les acheteurs et les prescripteurs.** Les acheteurs doivent donc travailler avec les prescripteurs pour s'assurer que les produits achetés répondent aux besoins des patients et sont prescrits.

Les obstacles spécifiques au **secteur hospitalier** comprennent un manque de données (transparentes) pour comparer les pratiques d'approvisionnement et les résultats (y compris les prix), et le manque de collaboration entre les hôpitaux individuels. Le paysage fragmenté de l'approvisionnement des hôpitaux dans la plupart des pays empêche une approche stratégique de l'approvisionnement.

Les défis rencontrés par les acheteurs dans le cadre des **achats conjoints entre pays** comprennent les différences entre les systèmes et processus juridiques, politiques et administratifs nationaux, la nécessité de disposer de plus de ressources par rapport aux achats nationaux, les limites dans la mesure dans laquelle les pays peuvent participer en raison d'un système de santé fragmenté, la possible hésitation du côté des fournisseurs à répondre aux appels d'offres internationaux et la nécessité de résoudre les problèmes linguistiques.

Exemples de bonnes pratiques pour les MPM

Certaines **bonnes pratiques** pour relever les défis mentionnés ci-dessus et fournir un potentiel d'optimisation plus large dans les MPM ont été identifiées, notamment:

- **Collaboration transnationale**, avec l'intention d'acheter conjointement des médicaments (pour rendre les marchés plus petits plus attractifs), ainsi que de partager les connaissances et les expériences entre les pays (pas nécessairement liées uniquement aux MPM).
- **E-procurement**, qui a permis la mise en œuvre (plus facile) de précieuses techniques de MPM tels que les accords-cadres et les systèmes d'achat dynamiques (DPS en anglais: *dynamic purchasing systems*).
- Utilisation d'une **gamme de procédures et de techniques de MPM, alignées** sur l'objectif politique et le type de médicaments (par exemple, produits monopolistiques à prix élevé par rapport aux médicaments hors brevet) et liant les MPM aux politiques et outils de tarification et de remboursement ainsi qu'aux mesures de demande nécessaires (par exemple, pour permettre le changement et la substitution de médicaments biosimilaires, en vue d'encourager l'adoption des biosimilaires).
    - Dans ce contexte, la connaissance de la position d'un produit dans le cycle de vie aide à identifier les processus d'approvisionnement appropriés (allant de formes moins compétitives telles que des négociations pour des produits nouvellement commercialisés et brevetés à des procédures plus compétitives tels que des appels d'offres ouverts à mesure que davantage de produits concurrents deviennent disponibles) et leurs critères (en tenant compte des critères de sécurité d'approvisionnement à mesure que les produits approchent des dernières étapes de leur cycle de vie). Une telle **approche du cycle de vie des produits** pour l'approvisionnement a été lancée par AMGROS, la centrale d'achat pour les hôpitaux publics au Danemark.
- **Dialogue avec les fournisseurs et collaboration systématique des acheteurs publics** de médicaments.
- **Modifications juridiques** (pour permettre la mise en œuvre de nouvelles procédures et techniques de MPM) et **règles et procédures opérationnelles transparentes et claires** (gestion administrative).

- Politiques spécifiques visant à **combler le fossé entre le secteur ambulatoire et le secteur hospitalier**, par exemple par le biais de mesures liées à l'élaboration de formulaires ou de programmes de financement.

Recommandations politiques

Les décideurs politiques sont encourages à:

- **développer et communiquer une vision et une stratégie MPM**, basées sur une perspective holistique où les MPM sont une composante majeure du cadre de la politique pharmaceutique,
- **soutenir la mise en œuvre de la stratégie MPM par des investissements** tels que le renforcement des capacités ainsi que des changements dans le cadre juridique et institutionnel,
- **suivre et adapter** la stratégie, si nécessaire, sur la base des résultats des évaluations, et
- considérer la **collaboration** intra-pays et transnationale comme un principe clé de la mise en œuvre.

En termes opérationnels, la **sélection stratégique des politiques et pratiques MPM doit être alignée sur** les **objectifs** définis au niveau stratégique **et** sur la place du produit dans le **cycle de vie**. Les pratiques importantes à prendre en considération comprennent l'application des critères **MEAT** et des **approches à gagnants multiples, la collecte et l'analyse des données. Des processus transparents et clairs** et l'amélioration des **systèmes informatiques** sont considérés comme des approches bénéfiques et favorables.

La Commission européenne peut soutenir ces recommandations politiques en offrant une **plate-forme pour faciliter l'échange d'expériences** entre les praticiens MPM ainsi qu'entre les experts en passation de marchés et d'autres experts, par exemple ceux qui travaillent dans les pouvoirs publics pour la tarification et le remboursement des médicaments.

Conclusion

Les marchés publics de médicaments sont une **politique pharmaceutique clé qui peut contribuer à un meilleur accès aux médicaments**, notamment en rendant plus de médicaments disponibles à des prix plus bas. Les pratiques d'approvisionnement varient d'un pays européen à l'autre, reflétant souvent l'hétérogénéité des systèmes de soins de santé. En termes d'optimisation des marchés publics de médicaments, il n'y a pas de solution unique et les politiques d'achat doivent être intégrées dans la configuration nationale du système de santé. Une approche du cycle de vie de l'approvisionnement qui tient compte de la place d'un médicament tout au long de la chaîne de valeur pharmaceutique peut aider à déterminer quelle procédure d'approvisionnement utiliser (plus ou moins compétitive) et quels critères d'attribution sont les plus pertinents. La compréhension du marché peut être facilitée par une étude de marché approfondie et un dialogue avec les fournisseurs avant le lancement des procédures d'approvisionnement.

Il est important de noter que grâce à leur effet de levier en tant que domaine clé pour les achats, les MPM peuvent aider à atteindre d'autres objectifs politiques, notamment la sécurité de l'approvisionnement et la préparation aux crises pour le secteur de la santé, un marché concurrentiel pour les produits pharmaceutiques, ainsi que des objectifs environnementaux. Cependant, tous les objectifs ne peuvent pas être atteints simultanément. Une approche stratégique de l'approvisionnement pharmaceutique est donc nécessaire.

Les décideurs politiques sont encouragés à prêter **attention aux MPM** et à développer (plus encore) une **vision et une stratégie des MPM**, qui peuvent ensuite être opérationnalisées sur la base des apprentissages sur la manière d'**optimiser les MPM en termes techniques**.

TABLE OF CONTENTS

Table of tables

Table of figures

Table of boxes

LIST OF ABBREVIATIONS

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
AIM	International association of mutual benefit societies
APC	Area Prescribing and Medicines Management Committees
ATC	Anatomical Therapeutic Chemical Classification system (of the WHO)
BBG	Bundesbeschaffung GmbH / Austrian Federal Procurement Agency (Austria)
BCG	Bacille Calmette-Guerin (vaccine)
CA	Contracting authority
CAN	Contract Award Notices
CDF	Cancer Drugs Fund (UK)
CEPI	Coalition for Epidemic Preparedness Innovations
CFC	Call for Competition
COVAX	COVID-19 Vaccine Global Access Facility
COVID-19	Coronavirus disease 2019
CPB	Central Purchasing / Procurement Body
CPM	Centralised Procurement of Medicines
CPSU	Central Procurement & Supplies Unit (Malta)
CPV	Common Procurement Vocabulary (of the EU)
DKMA	Danish Medicines Agency
DPS	Dynamic purchasing system
DRG	Diagnosis-related group
EAHP	European Association of Hospital Pharmacists
EC	European Commission
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
EHIF	Estonian Health Insurance Fund
EHPPA	European Health Public Procurement Alliance
EMA	European Medicines Agency
EPF	European Patients' Forum
EphMRA	European Pharmaceutical Market Research Association
ESIP	European Social Insurance Platform
EU	European Union
EXPH	Expert Panel on effective ways of investing in health
EXPP	EC Government Experts Group on Public Procurement
FAAP	Fair and Affordable Pricing initiative
FOPH	Federal Office of Public Health
G-CSF	Granulocyte colony-stimulating factor
GIRP	European Healthcare Distribution Association
GÖ B	Gesundheit Österreich Beratungs GmbH / Austrian National Public Health Institute
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
HERA	European Health Emergency preparedness and Response Authority
HIV / AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HIO	Health Insurance Organisation (Cyprus)
HMA	Heads of Medicines Agencies
HOM	Hospital-only medicine

HPF	Hospital pharmaceutical formulary / formularies
HPV	Human papillomavirus
HSE	Health Service Executive (Ireland)
HTA	Health Technology Assessment
IHSI	International Horizon Scanning Initiative
IMF	Innovative Medicines Fund (UK)
JPA	Joint Procurement Agreement
KEF	Közbeszerzési és Ellátási Főigazgatóság (KEF) / Directorate-General for Public Procurement and Supply (Hungary)
KPI	Key Performance Indicator
LMIC	Low- and middle-income country(ies)
LIS	Legemiddelinnkjøpssamarbeid / Norwegian Drug Procurement Cooperation (Norway)
MEA	Managed-entry agreement
MEAT	Most Economically Advantageous Tender
MEL	Medizinische Einzelleistungen / Single medical services (Austria)
MoH	Ministry of Health
MS	Member State (of the EU)
NCAPR	Network of competent authority / authorities for pricing and reimbursement of medicines
NEAK	Nemzeti Egészségbiztosítási Alapkezelő /National Health Insurance Fund (Hungary)
NHS	National Health Service
NICE	National Institute for Health and Care Excellence (United Kingdom)
NUB	Neue Untersuchungs- und Behandlungsmethoden / New Methods for Diagnostics and Treatment (Germany)
OECD	Organization for Economic Co-operation and Development
PAHO	Pan American Health Organization
PHIS	Pharmaceutical Health Information System (project)
PPM	Public procurement of medicines
PPRI	Pharmaceutical Pricing and Reimbursement (project and network)
PTC	Pharmaceuticals and Therapeutics Committee
Resah	Réseau des Acheteurs Hospitaliers (France)
SO	Specific objective
SPMS	Serviços Partilhados do Ministério da Saúde / Shared Services of the Ministry of Health (Portugal)
SUKL	Státní ústav pro kontrolu léčiv / State Institute for Drug Control (Slovakia)
TED	Tenders Electronic Daily
TLV	Tandvårds- och läkemedelsförmånsverket / National Dental and Pharmaceutical Benefits Agency
UNICEF	United Nations International Children's Emergency Fund
VEAT	Voluntary ex ante transparency
WHO	World Health Organization
ZSG	Zielsteuerung Gesundheit (health care sector reform process in Austria)

LIST OF COUNTRY NAME ABBREVIATIONS

BE	Belgium
BG	Bulgaria
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
DE	Germany
EL	Greece
HR	Croatia
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LI	Liechtenstein
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom

1. INTRODUCTION

Public procurement of medicines (PPM) is highlighted in the European Commission's (EC) "Pharmaceutical Strategy for Europe" as an area where actions can be taken to improve access to medicines for patients in the European Union (EU) [1]. Against this background, and with upcoming changes to the legislative environment for pharmaceuticals in the EU, the European Health and Digital Executive Agency (HaDEA) as contracting authority (CA), under the mandate of the EC, commissioned a "**Study on Best Practices in the Public Procurement of Medicines**". The study was conducted by Gesundheit Österreich Beratungs GmbH (Austrian National Public Health Institute / GÖ B) and Tetra Tech Sp. z o.o., as members of a consortium led by Economisti Associati, and under the Framework contract SANTE/2016/a1/039 concerning the provision of services in the area of evaluation, impact assessment, monitoring and implementation and of other relevant services, in relation to the health and food policies (LOT 1) with reopening of competition. The findings of this study are presented in this report. The background to the study and research questions to be addressed are described in the present **Chapter 1**, while research methods are presented in **Chapter 2**. The study provides an overview procurement and related policies in Europe (**Chapter 3**), and assesses their impact on different policy objectives (**Chapter 4**). The report includes dedicated sections on PPM in hospital settings, including procurement of biosimilar medicines (**Chapter 5**), and cross-country collaborations (**Chapter 6**). Finally, barriers and best practices are presented (**Chapter 7**), and the report closes with a set of conclusions (**Chapter 8**). Following the list of references (**Chapter 9**), additional documents and information are provided in the Annexes (**Chapter 10**). Note that the outline of this report is aligned with the study objectives and work packages of this study as described below.

1.1. Background

Public procurement is a commonly applied policy option to achieve and improve sustainable access to affordable medicines. The use of tendering has been recommended by the World Health Organization (WHO) in conjunction with other policies, contingent on applying additional evaluation criteria than price alone when awarding contracts [2].

Public procurement of medicines (PPM) is applied in many countries, in particular in low- and middle-income countries (LMIC). In Europe, PPM is most commonly used in the hospital setting and for public services (e.g. national immunisation programmes and pandemic plans); products frequently subject to PPM include vaccines and medicines with competition, such as generics and biosimilars [2-6].

Some forms of PPM have particularly attracted attention of policy makers. Specifically, there is interest in potential benefits of pooling purchase volumes through **joint procurement**, and procurers have already gained some experience with this form of PPM [7]. Pooling in PPM can take place in different ways, both intra-country (e.g. centralised procurement through a national or regional centralised procurement body (CPB) or group procurements of hospitals) and cross-country. Cross-country joint procurement may be organised through a designated, e.g. supra-national, institution which performs procurement on behalf of countries, (such as the Revolving and Strategic Funds of the Pan American health Organization (PAHO)), or as cooperation of different countries (e.g. the joint procurement of the Gulf Cooperation Council) [8]. Moves towards joint PPM have also been observed in Europe: some European countries introduced national centralised procurement for some or all medicines, especially in the hospital sector [9], and joint tenders were conducted by cross-country collaborations established during the last decade (e.g. the Nordic Pharmaceutical Forum) [10].

PPM is thus a well-established policy, which has been used for long in several countries, and there are principles for good practice on how to conduct PPM [11]. Nonetheless, there are **few (systematic) reviews** that assessed the impact of PPM on access to medicines or on individual components of access.

Most analyses focused on **lower prices and/or savings** for public budgets achieved by PPM, usually compared to other pricing policies or a situation of no policy action [5, 12-28]. Lower prices were attributed to competition and/or larger volumes as result of pooling.

Some studies also examined further impacts of PPM (or of specific organisational frameworks and designs of PPM, e.g. centralised procurement). Endpoints of these analyses included **competition** in the market (e.g. expressed by the number of bidders) [22, 23, 29-31], **timely delivery** (centralisation was found to slow down process and prolong delivery times) [25, 32], **accountability and anti-corruption** (lower risk of corruption in centralised processes) [33-35], **rational selection** [36], and **availability** [37]. A major concern in this respect is that PPM practices that aim for the lowest price may lead to **shortages and withdrawals** of suppliers from the market [5, 38]. However, there is yet a lack of robust evaluations on this topic.

The methodological approaches of existing studies evaluating PPM practices vary, including quantitative as well as some qualitative or even descriptive works. However, several publications (e.g. [32, 39-46]) highlighted the **importance of the design of PPM** (e.g. PPM organisational framework, practices and techniques), which should be aligned with the goals of PPM, **and of supporting measures**. The latter include information systems, e-procurement and strengthening the capacity of public procurers [3, 47]. Since medicines are special goods given their sensitive character and the particularities of the health system, further policies and supporting instruments such as horizon scanning to identify promising medicine candidates with potential high budget impact [48] and health technology assessment (HTA)[49], which are used to manage the entry of new medicines in the health system, and demand-side measures to encourage the uptake of off-patent medicines [50], also play a role as accompanying measures.

The body of evidence described above as well as learnings from anecdotal reports suggest a strategic approach to PPM may be most promising in achieving improved access to medicines. This includes, among other features, consideration of further award criteria than the price of the medicines (including the promotion of "green" and socially responsible public procurement), collaborative approaches, innovation in procurement, and aligning the choice of PPM practices and techniques to the policy objectives, the type of medicines to be procured and their position in the pharmaceutical value chain. The "**strategic procurement**" concept [51] (not solely related to medicines) has been promoted by supranational institutions such as the EC [52-57], the Organisation for Economic Co-operation and Development (OECD) [58] and the WHO [59, 60]. Furthermore, to address the challenges in public procurement in the health sector, the Expert Panel on effective ways of investing in health (EXPH, an independent group of expert established by the EC) issued recommendations about optimising PPM in a strategic way, including by ensuring those engaged in public procurement understand how the process can be used to promote wider social, economic and environmental objectives, and encouraging cooperative procurement in beneficial circumstances [3].

Stakeholders also addressed some of the elements subsumed under strategic public procurement in their position papers: industry associations (European Federation of Pharmaceutical Industries and Associations (EFPIA) and "Medicines for Europe") appreciate use of different award criteria than solely price and avoidance of a "winner-take-it-all" approach, but maintain a critical view on joint procurement beyond emergency situations [61-66], whereas the European Associations of Hospital

Pharmacists (EAHP) urged for the involvement of pharmacists in the procurement processes [67].

1.2. Motivation for this study and purpose

As described in the previous section, there are strong indications that PPM can contribute to improved access to medicines, in particular if used more strategically.

PPM as strategic policy option to foster competition and improve access, and to address important further policy objectives, is also highlighted in the **2020 "Pharmaceutical Strategy for Europe"** [1]. The strategy calls on public procurers to "design smart and innovative procurement procedures, e.g. by assessing the role of 'winner-takes it all' procedures and improving related aspects (such as price conditionality, timely delivery, 'green production' and security and continuity of supply)"[1].

Public procurers in the EU have been benefiting from the 2014 revision of the **EU public procurement legislation**, resulting in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC [68] (EU Public Procurement Directive) which provided the legal framework for the use of valuable tools. The Directive specifies different forms of procedures (open tenders and various forms of restricted procedures, including provisions for innovation procurement) and the conditions under which these can be used, as well as PPM techniques to implement these procedures. The Directive also specifies that contracts should be awarded to the Most Economically Advantageous Tender (MEAT), which allows for explicit consideration of a combination of criteria other than price. However, use of such optimised public procurement practice is only partially known for medicines, since knowledge on PPM implementation, including challenges and good practice examples, has not yet been systematically collated and studied for the EU Member States (MS).

Against this backdrop, this **study aims to collect and analyse evidence in the study countries to optimise public procurement of medicines** as a tool that is able to contribute to accessibility, affordability and availability of medicines, and to encourage greener pharmaceutical design and manufacturing as well as to support crisis preparedness and handling in both outpatient and hospital sectors. Study countries include **all EU countries, EEA/EFTA[9] countries, and the UK.** A legal investigation on compliance of MS with EU public procurement directives is not scope of this study.

1.3. Research questions addressed in this study and scope

The general study objective of a **collection and** an **analysis of evidence to optimise PPM** is operationalised through the following **six specific objectives** (SO) with defined research questions:

- SO1: To map all relevant stakeholders involved in PPM, impacting PPM or targeted by PPM in the study countries (***Stakeholder Mapping***);
- SO2: To map existing policies and practices in PPM in the study countries and to explore avenues for improvement (***Policy Analysis***);
- SO3: To assess the impact of PPM practices in the study countries on different policy objectives, including affordability and availability of medicines, security of supply, protecting the environment, maintaining a competitive market, and crisis preparedness and handling (***Impact Analysis***);

[9] EEA (European Economic Area) comprises EU MS and Iceland, Liechtenstein, and Norway. EFTA (European Free Trade Association) comprises all countries mentioned before as well as Switzerland.

- SO4: To identify barriers and constraints in PPM in the study countries and to develop approaches to address them (***Barriers Analysis***);
- SO5: To develop sets of best practices in PPM for the study countries, in particular with regard to the application of MEAT criteria other than price alone, fostering environmentally sustainable manufacturing, more resilient and secure supply system and to be prepared for handling health crises well and joint procurement (***Best Practices Toolbox***);
- SO6: To update and extend the analyses and recommendations of the 2010 PHIS Hospital Pharma report (***PHIS Hospital Update***).

Specific research questions for each SO are listed in Annex 1. This annex also provides an overview where relevant findings for each research question are described in this study report.

2. METHODS

The specific objectives of the study are being addressed through a **mix of methods**. This chapter provides an overview of all methods applied in the study, including limitations of the methodological approaches and/or underlying data.

2.1. Triangulation of methods

The study applies a **mix of qualitative and quantitative methods** to address research questions in six areas of interest (SOs). Importantly, none of the six overarching SOs are addressed through one methodological approach alone. Instead, triangulation of methods and data sources is used across the study. **Figure 1** presents an overview of the specific methodological approaches and data sources used to address research questions in the six SOs. The specific contributions are described in more detail in **Chapters 2.2-2.5** below. The figure also shows which information is presented in the study's **online dashboard**.[10] While not technically a research method itself, the dashboard (described in more detail in **Chapter 2.6**) contains data collected or prepared during this study and was used by the study team to analyse data presented in this report. Moreover, the dashboard contains more data than the findings that could be included in the report. The dashboard therefore presents an opportunity for users to conduct further analyses and explore data on their own.

Figure 1: Triangulation of methods

				Stakeholder consultation			Quantitative data			
Specific objective	General question	Literature review	Country fiches and expert review	Workshops	Interviews	Online survey	TED data	IQVIA data	Impact analysis	Presentation of findings in online dashboard
SO1	Which stakeholders are involved in PPM, and in which role?									No
SO2	What are current national PPM policies in the studied countries?									Yes
SO3	How can PPM contribute to savings?									Yes
SO4	Barriers to optimise PPM?									Partly
SO5	Which are best practices to optimising PPM?									Partly
SO6	Which are current hospital PPM practices?									Yes

Major data source
Supplementary data source / use in some cases
Method not used for this question

data collection and analysis
field research method

Source: Authors

2.2. Literature review

The study team conducted a **narrative review of peer-reviewed and grey literature** as the basis for identifying relevant stakeholders and their roles in PPM in the study countries (SO1: Stakeholder mapping), obtaining an overview of current PPM policies and practices in the study countries (SO2: Policy analysis), including in hospitals (SO6: PHIS Hospital Update), and for identifying barriers as well as best practices for optimising PPM (SO4: Barriers analysis and SO5: Best practices toolbox). In addition to addressing the study questions listed above, which reflect the planned contributions of the literature review according to the work plan at the outset of the study, the literature review was also found to be a source of valuable information for assessing the impact of PPM on various policy objectives (SO3: Impact Analysis). Overall, the aim of the literature review was therefore to survey descriptive information as well as analytical studies of the performance of PPM in the study countries. The literature review was

[10] The dashboard will be submitted as a deliverable to the CA / EC who will then decide on its future use.

conducted to support specific tasks within the study, rather than to develop a stand-alone, systematic literature review on the topic of PPM.

Literature was identified from several sources to ensure comprehensive coverage of all relevant reports. Source selection was informed by the specific purposes for which the literature review was conducted (i.e. the specific objectives mentioned above).

First, **general searches for PPM-related literature** were conducted. General search terms related to PPM, including "public procurement" and "pharmaceuticals" and variations of these terms, were used to search bibliographic databases Google Scholar and MEDLINE via PubMed. Similar terms were used (where applicable) to search the websites of relevant international and supranational organisations, including the EC, EUROSTAT, Organization for Economic Co-operation and Development (OECD), the Pharmaceutical Pricing and Reimbursement (PPRI) network, United Nations International Children's Emergency Fund (UNICEF), World Health Organization (WHO), and the World Bank. A structured search was also conducted in MEDLINE via PubMed for existing systematic reviews on PPM. This search retrieved eight existing systematic reviews [5, 12-15, 47, 69, 70], which were reviewed to identify any relevant original studies. In addition, studies and reports on pharmaceutical policies in general as well as PPM policies that the study team were already familiar with were reviewed. These included reports from the PPRI network of competent authorities on pharmaceutical pricing and reimbursement and the Pharmaceutical Health Information System (PHIS) [6, 71-114], studies authored by the study team [4, 9, 115-120], and other studies [3, 14, 16, 18, 19, 26, 44, 121-135].[11]

Second, **targeted country-specific database searches** were conducted to identify relevant literature relating to the PPM set-up and experiences in each of the 32 study countries. This information was used to populate country fiches for each of the study countries. The country fiche template is available in Annex 2 and further information on development and use of country fiches is presented in **Chapter 2.3**.

Targeted literature searches in **electronic databases** were conducted for each of the study countries, combining search terms for public procurement of medicines with the name of each country. Literature searches were primarily conducted in Google Scholar, with supplemental searches conducted in MEDLINE via PubMed in case of no or low yield of relevant records from the primary source. Google Scholar was selected as the primary literature database because it contains both academic (peer-reviewed) and grey literature such as reports by governmental institutions and international organisations. Procurement-specific database searches were supplemented by targeted searches for procurement-specific information in updated published country profiles or briefs from the PPRI network [136] and the European Observatory on Health Systems and Policies [137] and targeted searches for pharmaceutical-specific information in country reports on public procurement by the EC and the OECD [138, 139]. These included published reports of the PPRI network[12] dating back to 2009/2010, as well as information from eight further countries[13] which was available either as draft national PHIS Hospital Pharma Report or provided to a survey of the PHIS project management to the authors affiliated to GÖG who conducted the 2008-2010 PHIS project [140]. Further, key publications on public procurement of medicines, or in health care (such as the Opinion of the Expert Panel on effective ways of investing in health (EXPH)) on this matter [3], were reviewed to identify any PPM-related examples or details from the study countries. When central purchasing bodies were identified from prior research, the websites of these bodies were also searched for relevant information.

[11] Not an exhaustive list.
[12] Reports were available for Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Sweden and the UK.
[13] Germany, Estonia, Hungary, Ireland, Italy, Romania, Slovenia and Spain

One part of the literature and documentation review was the development of a **glossary** (see Annex 3, [141]) to present key concepts of PPM. This was an additional, unplanned deliverable, which, the study team considered important to ensure common understanding and clarity in communication with stakeholders (see **Chapters 2.3** and **2.4**). The development of this glossary was guided by legal texts, in particular the EU Procurement Directive 2014/24/EU [68], as well as existing glossaries on related topics [142, 143].

Third, **stakeholders and country experts** were consulted to identify any additional literature not retrieved through database searches or included in previously identified reports. Country experts were involved in the study to review country fact sheets and were also asked by the study team about additional nationally relevant reports. Stakeholder input for the study was obtained through interviews and workshops (see **Chapters 2.3** and **2.4**) and stakeholders had the opportunity to refer the study team to relevant literature.

Several sources were used for the literature review, including consultation with country experts, to avoid solely relying on reports indexed in academic databases and solely available in English.

All identified references and their full texts (where available) were compiled into a **single, searchable bibliographic reference management database** (EndNote X9). As of 27 September 2022, the database contained 858 unique entries. Due to this large number of entries and the variety of sources used to populate it, the database itself became a key complementary source of literature for the various work streams. Study team members used the search function of the reference management software (including searching full texts of included reports) to identify potentially relevant references, in addition to searching other repositories (see above).

2.3. Country fiches and expert review

Country fiches (fact sheets) were developed for each of the 32 study countries as a key resource for mapping PPM practices across Europe. These documents contain mostly **standardised information about PPM in the study countries** and were used to address questions related to all specific objectives. The country fiches provide, in a compact form, triangulated information on who the relevant actors are for PPM in each country (SO1: Stakeholder mapping), what PPM procedures and techniques are being applied (SO2: Policy analysis), what the (expected or actual) impact of different policies is (SO3: Impact analysis), what barriers exist for PPM (SO4: Barriers analysis), whether there are any best practices that can be shared (SO5: Best practices toolbox), and how procurement and medicines provision work in the inpatient care setting (SO6: PHIS Hospital update).

A country fiche template (available in Annex 2) was developed by the study team and reviewed and piloted by PPM experts (the study sub-contractors).

Information on public procurement processes to be included in the country fiches was collated from three main sources. **Information from all three main sources** was triangulated to populate the final versions of the country fiches.

Firstly, information was retrieved **from publicly available documents**, as described in the literature review, specifically reports identified from targeted country-specific searches (see **Chapter 2.2**), including published reports of the PPRI network and from the PHIS project [6, 71-114], as well as information available from CPBs (where applicable). PPM-specific examples or details from the study countries were also extracted from other publications [3, 14, 16, 18, 19, 26, 44, 121-135].

Secondly, information obtained from publicly available documents was **validated** through a **review conducted by public procurement experts in the study countries**. Country experts were primarily identified through existing networks (PPRI and PHIS networks), as well as the EC Government Experts Group on Public Procurement (EXPP), Subgroup on Health Public Procurement. Given the scope of the country fiche, ranging from specific procurement-related aspects to wider pharmaceutical policy areas such as pricing and reimbursement, country experts were only asked to review the sections of the country fiche that fell into their area of expertise. Country experts then either liaised with other experts in their country to review the remaining sections, or the study team identified experts for those sections. Country experts were also asked to provide additional information on procurement practices that was not covered in publicly available documents. Review of pre-populated country fiches was either done electronically or through phone interviews.

Finally, country-specific information on PPM was also obtained through a series **of three online workshops** on optimisation of public procurement of medicines. Each workshop focused on different aspects of public procurement (see **Chapter 2.4.1**) and featured presentations by procurement experts on procurement policies and practices, providing country-specific insights, as well as group discussions where participants were encouraged to draw on their country-specific experience.

While the study team have been able to rely on their own networks and those of the EC to identify public procurers and other public bodies involved in the pharmaceutical system in the study countries, **not all contacted experts have responded** to invitations to review country fiches, **or have not been able to validate all the contents** in the country fiches. As of 26 September 2022, country fiches have been fully validated for 19 countries (AT, BG, CH, CY, DE, DK, EE, FI, ES, FR, HR, IE, IT, LV, LT, MT, NO, PT, SK) and partly validated (i.e. information was reviewed in some sections only) for seven countries (BE, HU, IS, LU, RO, SI, SE). No validation was performed for six countries (CZ, EL, LI, NL, PL, UK).[14] Lack of validation for some countries is therefore acknowledged as **a limitation of this study**. Where no validation through country experts was possible, only information deemed robust (e.g. information from published studies and reports, or from official sources such as reports by procurement bodies and other public bodies) was used. The country fiches are available in Annexes 4.1 – 4.32 and are referred to as **"PPM country fiches"** as sources throughout the remainder of the report.

2.4. Stakeholder consultation: workshops, interviews, online survey

An important source of information for this study are stakeholder consultations which were conducted through four online workshops, interviews, and an online survey. These stakeholder engagement activities serve **multiple purposes**, including collating different perspectives and views from relevant stakeholder groups on aspects of PPM, learning about different country examples and experiences, and informing relevant stakeholder groups about the ongoing study, introducing some of the topics it analyses, and obtain feedback on specific aspects. Offering several stakeholder engagement activities ensured that all stakeholder perspectives could be considered, even if not all stakeholders participated in all activities.

Stakeholder consultation provides information to address all study questions, including questions relating to who conducts and is affected by PPM in the study countries (SO1: Stakeholder mapping), how PPM is organised and conducted in the study countries and what procedures are used to procure different types of medicines (SO2: Policy analysis), what impacts can be expected from optimising PPM (SO3: Impact analysis), what barriers and best practices exist (SO4: Barriers analysis and SO5: Best practices

[14] Even for countries, which were listed as "fully validated", country experts could not validate and provide missing information to some questions and topics beyond their scope of expertise.

toolbox), and what specific aspects need to be considered in procurement of hospital medicines (SO6: PHIS Hospital Procurement Update).

2.4.1. Workshops

A total of four **online workshops** were held **in February and March 2022**. The first three workshops addressed different aspects of PPM with a view to optimising procurement, whereas the fourth workshop focused on the online dashboard built by the study team:

- Workshop 1: Optimising PPM to increase competition, availability, security of supply and "green" manufacturing (16 February 2022);
- Workshop 2: Optimising PPM to ensure preparedness and handling of public health crises and emergencies and joint procurement practices (21 February 2022);
- Workshop 3: Optimising PPM in the hospital setting (24 February 2022);
- Workshop 4: An online dashboard on PPM in Europe (7 March 2022).

All workshops were held virtually. The invitation policy aimed to **balance representation of all relevant stakeholder groups** while providing all participants with a fair chance to interact and share their experience and perspective. Participation was possible upon invitation only, and the different stakeholders were contacted through their network or group, or their associations. Table 1 provides an overview of the participation rate per stakeholder group in the four workshops. The group of public procurement experts was underrepresented compared to competent authorities for pharmaceutical pricing and reimbursement. In a few cases there were more participants than originally addressed by the invitation policy, usually with prior notice and permission of the study team after consultation with the CA / EC.

Table 1: Participation in the workshops on PPM

Stakeholder group	Workshop 1	Workshop 2	Workshop 3	Workshop 4
MS: Public procurement	10	10	7	8
MS: Competent authorities for PR, payers	18	18	13	9
Social health insurance	4	5	1	- [3]
Patients a/o consumers	0	1	0	- [3]
Industry and wholesale	5	6	10	- [3]
Hospital / community pharmacy	6	3	25	- [3]
European Commission	10	13	5	6
Contractor[1]	6	8	8	7
Total	**59**	**64**	**70[2]**	**30**

Notes: PR = pricing and reimbursement (of medicines)
[1] Excluding procurement experts supporting the core study team (counted as part of the "MS: public procurement" group)
[2] One participant could not be identified to which group s/he belonged
[3] No participation from this stakeholder group planned for this workshop

Source: Authors

All four workshops followed a **similar structure**. After an introduction to the study and the aims of the workshop, two to three brief presentations in the plenary session were dedicated to the topic of the respective workshop. One presentation was given by the study team and further input and experience was provided by (procurement) experts (apart from the fourth workshop where only the study team gave presentations). Following the plenary presentations, three break-out sessions were held in parallel. Break-out sessions were moderated by procurement experts or core team members according to a pre-defined set of questions tailored to the specific topic of the workshop. Participants were encouraged to draw on the experience from their countries, allowing the study team to gain insights into country-specific procurement processes and issues.

All participants discussed the same questions, independent of the break-out session they had been assigned to. Key points discussed during the break-out sessions were reported back to the plenary where there was scope for additional discussions. During the plenary sessions, interactive polls and word clouds allowed additional input from workshop participants. Moderated break-out sessions and interactive elements in the plenary sessions allowed all participants to provide input.

Further details on the organisation of the workshops and their findings are available in a dedicated **summary report** (Annex 5).

2.4.2. Interviews

Between January and July 2022, **semi-structured exploratory interviews** were conducted with country experts, as well as with representatives from UNICEF, the European Commission (DG SANTE) Expert Panel on effective ways of investing in health (EXPH), the (DG GROW) Commission Government Experts Group on Public Procurement (EXPP), Subgroup on Health Public Procurement (HPP), and the European association of research-based pharmaceutical companies (EFPIA).[15] Interview partners were selected based on their hands-on experience with PPM or recent work related to the subject. Interview partners were sent an outline of questions and topics to be addressed during the interview in advance. These outlines served as a guide for the interview but there was scope for deviating from the guide when necessary (e.g. to follow up on specific points or to prioritise specific areas). Interviews were conducted online by one member of the study team while a second member of team took notes. The notes were shared subsequently with the interview partner for review and approval.

2.4.3. Stakeholder consultation: online survey

Stakeholder input was further provided through an online survey that aimed to **obtain the views of participants** (broken down by stakeholder group) on how specific PPM practices and procedures impact on different policy objectives, including overall access to medicines.

PPM practices and procedures assessed in the survey match those reviewed in the country fiches and include the form of organisation of PPM (e.g. centralised, facility-based, cross-country), specific procedures as described in EU legislation (open procedure, restricted procedure, competitive dialogue with or without negotiation), procurement techniques such as dynamic purchasing system (DPS) or framework agreements, award criteria and processes, and supporting policies and tools. The policy objectives being assessed include those immediately related to access to medicines (affordability and availability), as well as additional policy focus areas of the study, i.e. security of supply, crisis preparedness, competition, and the environment. The contribution of each PPM practice or procedure to a specific policy objective was assessed on a Likert scale or through a ranking exercise, allowing a quantification of its potential to affect positive outcomes, and relative ranking of different policy options. Responses were weighted by representation of different stakeholder groups in the sample (average ranks / average importance / average contribution to a policy objective).

The full survey is shown in Annex 6. The survey was conducted via **EUSurvey** and a draft **survey was piloted** with procurement experts (sub-contractors), the EC, and colleagues who were not involved in the study. Annex 7 provides further details on survey methodology, challenges encountered while conducting the survey, and results.

[15] Note that Medicines for Europe, the association of generic and biosimilar companies, participated in other stakeholder consultation activities (workshops and survey).

Invitations to participate in the survey were shared with public procurers, pharmaceutical pricing and reimbursement authorities, regulatory bodies, social insurances and payer organisations, pharmaceutical companies and wholesalers, hospital and community pharmacists, and patient and consumer organisations (see **Table 2**). At the closure date of the survey, **58 responses** had been submitted.

Table 2: List of stakeholder groups invited to participate in the online survey

Stakeholder group	How invited
Public procurers	• Personal invitations sent to participants of four project workshops (PPM 1, PPM 2, Hospital procurement, Dashboard) • Personal invitations sent to sub-contractors of the study • Invitations sent via DG GROW to the Subgroup on Health Public Procurement of the EXPP and the health group of the Big Buyers network • Invitations sent via the European Health Public Procurement Alliance (EHPPA)
National competent authorities for pricing and reimbursement	• Personal invitations sent to participants of four project workshops (PPM 1, PPM 2, Hospital procurement, Dashboard) • Invitations sent via the Network of competent authority / authorities for pricing and reimbursement of medicines (NCAPR)
National competition authorities	• Invitations sent via DG COMP to the European Competition Network
Regulatory bodies	• Invitations sent via the Heads of Medicines Agencies (HMA) network
Social insurance	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement) • Invitations sent via the International association of mutual benefit societies (AIM) and the European Social Insurance Platform (ESIP)
Patients and consumers	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement) • Invitations sent via European Patients' Forum (EPF)
Industry	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement) • Invitation sent to the European Federation of Pharmaceutical Industries and Associations (EFPIA) who declined to participate • Invitations sent via Medicines for Europe • Invitations sent via European Cluster Collaboration Platform
Wholesalers	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement) • Invitations sent via the European Healthcare Distribution Association (GIRP)
Hospital pharmacists	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement) • Invitations sent via the European Association of Hospital Pharmacists (EAHP)
Community pharmacists	• Personal invitations sent to participants of three project workshops (PPM 1, PPM 2, Hospital procurement)

Source: Authors

Analysis of the survey results was adapted according to the number of responses available for each question. The overall number of 58 responses was considered sufficient by the study team conduct quantitative analysis, including for obtaining valid results for subgroups (individual stakeholder groups). For some figures and tables stakeholder groups with fewer than 4 answers were not represented. Whenever respondents did not assess a specific question, the report highlights this.

The analyses were performed in a **descriptive and, to the extent possible, quantitative way** (counts of answers, counts of ranks, average ratings, average points, average importance / inversed rankings). Qualitative rankings performed by the respondents on Likert scales were transformed into figures (e.g. assessments of the contribution of a given policy ranging from "fully contributing" to "a barrier" were translated into numbers ranging from 2 to -2) to allow the calculation of an average point indicator (see Annex 7 for details).

2.5. Data analysis

Analysis of quantitative data is used to better understand what procurement practices are applied in the study countries (SO2: Policy analysis), including for biosimilar medicines and in hospital settings (SO6: PHIS Hospital update), what the potential impacts of PPM practices are on savings and other policy objectives (SO3: Impact analysis), and what best practices are for optimising PPM (SO5: Best practices toolbox).

Data sets analysed include **procurement-specific data** on contract notices and contract award notices for publicly procured medicines from EU MS, EEA countries, and Switzerland which are submitted to the Tenders Electronic Daily (TED) portal by participating countries [144], and **data on pharmaceutical sales**, as collected by IQVIA [145]. Methods for preparing these two data sets for analysis and challenges encountered are described in **Chapters 2.5.1** and **2.5.2**, while **Chapter 2.5.3** describes how the analysis of the impact of PPM on different policy objectives was conceptualised. For the latter, data from the survey were also used, adding a third data set to the list of sources contributing to address SO3 (Impact analysis).

2.5.1. TED data

TED is the online version of the "Supplement to the Official Journal" of the EU, dedicated to public procurement procedures that are subject to European public procurement rules [144]. An invitation to tender must be published in the Supplement – and is therefore included in the TED database – for contracts with values above EUR 144,000 (for central government authorities) or above EUR 221,000 (for sub-central contracting authorities) [68]. On its website, TED publishes up to 676,000 contract award notices per year, including 258,000 contract notices which are worth approximately EUR 670 billion. TED data sets are divided in three groups[16]:

- **Calls for Competition (CFC)**:[17] This data set contains contract notices (invitations to tender) from 2006 up to 2020 and has more than 6 million rows. It includes information about the contracting authority, the subject of the tender (see description of the vocabulary of products used below), what procedure is being used and details on the procurement process, such as the use of different award criteria. Procedures as per EU Directive 2014/24 include open procedures, restricted procedures, competitive procedures with negotiation, competitive dialogues, innovation partnerships, and negotiated procedure without prior publication. These procedures are described in the study glossary (Annex 3).

- **Contract Award Notices (CAN):** The data set of contract awards electronic notices contains data from 2006 up to 2020 and has approximately 8.5 million rows with information about awarded contracts.

- **Voluntary ex ante transparency (VEAT)**: This comparatively small data set (around 175,000 rows) contains notices about contracts with low value that can be awarded without publishing an open contract notice. Procurers can voluntarily publish these notices but are not obliged to do so. The data set is therefore unlikely to be representative of lower-value procurements and has been excluded from the analysis.

[16] TED data sets are available online to download in CSV (text) format at https://data.europa.eu/data/datasets/ted-csv?locale=en and the individual electronic notices in XML format are available via FTP at ted.europa.eu (user: guest, password: guest).

[17] The dataset is labelled "Contract Notices" (abbreviated CN) on the TED website. In this report, it is referred to as "Calls for Competition" (abbreviated CFC) to avoid confusion with the first dataset (Contact Award Notices, or CAN).

TED data set records are tagged with codes according to the Common Procurement Vocabulary (CPV) which establishes a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of procurement contracts.[18] Relevant CPV codes from the group of pharmaceutical products were identified and used to retrieve PPM procedures from two of the three data sets mentioned above: **Contract Award Notices (CAN) and Calls for Competition (CFC)**. The list of CPV procurement codes and further details on the process of cleaning and preparing TED data for analysis are provided in Annex 8.

2.5.1.1. Use of TED data in the study

Through **descriptive analysis**, TED data were used to gain insights on how procurement is done in the study countries. A list of **key performance indicators for procurement** were used to compare procurement practices across countries as well as across different types of medicines (see **Table 3**). Indicators were selected to obtain insights into different aspects of procurement, including obtaining an overview of the volume of public procurement of medicines, which procedures are used and by whom, what offers are submitted, and how contracts are awarded. Selected indicators from **Table 3** are presented in the results chapters of this report. All indicators are available in the online dashboard.

In addition to mapping procurement practices, **TED data were combined with IQVIA data** to allow assessments of the relationship between procurement practices used in a country (and for a given type of product) and policy-relevant outcomes, such as affordability and availability of medicines (see **Chapter 2.5.3**).

Table 3: List of indicators for TED data

Indicator group	Indicator		Source
Overall	Awards/calls	Number of contract awards	CFC
		% of contract notices resulting in contract awards (% of contracts awarded)	CFC
		% of contracts with general CPV code (33600000) without any specification	CAN/CFC
		Number of contract awards	CAN
Analysis of procedures/ calls	Shares per types of procedures	Share of procedure for contract notice (procedures: accelerated open procedure, accelerated restricted procedure, competitive dialogue, contest, design contest, innovation partnership, negotiated procedure with contract notice, competitive procedure with negotiations, open procedure, restricted)	CFC
		% of tender received electronically of all tenders received	CFC
		% of cancelled procedures	CFC
		% of corrected procedures	CFC
	Procedures by type of call(er)	% of main activity of procuring body	CFC
		% of procedures involving joint procurement	CFC
		Average number of awards per call planned	CFC
		% of procedures involving central procurement bodies	CFC
		% of type of contract in the call	CFC
		% of procedures under a framework agreement	CFC
		% of contracts divided into lots	CFC
	Procedures by type of criterion	% of procedures awarded by lowest price (i.e. price being the sole attribution criterion)	CFC
		% of procedures awarded through other criteria in addition to price	CFC
Analysis of offers	Offers	Number of offers received per call	CAN/CFC
		Sub-indicator: % of contracts for which there was a single bid (excluding frameworks)	CAN/CFC
		% of electronical offers	CAN

[18] CPV codes are listed in EC Regulation 213/2008: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0213

Indicator group	Indicator		Source
		% of calls with no offer	CFC
		Average number of offers per call	CFC
Analysis of contracts	Contracts per type of industry	% of contracts awarded to non-EU-based companies	CAN
		% of contracts awarded to EU-based companies	CAN
		% of contracts awarded to SMEs	CAN
	Contract value	Average value per contract/lot	CAN

Source: Authors.

2.5.1.2. Challenges in working with TED data

Through its mandate (publication of procedures subject to European public procurement rules), TED represent the most comprehensive publicly available data set on public procurement in Europe. Nevertheless, some **challenges** were encountered in working with TED data, resulting in possible limitations to the inferences drawn from the analyses conducted, as described below.

Firstly, **only procurements above the threshold value** are required to be reported in the TED database. Lower value procurements are therefore likely to be missing, an issue that might be more relevant for smaller countries compared to larger countries, and for countries where procurement is conducted decentralised for relatively small volumes. Due to lack of data on procedures below the threshold, the extent of this limitation is unclear. However, the study did not solely rely on TED data; the analysis was complemented by collecting qualitative information on procurement practices in the study countries.

Secondly, TED data entries do not always provide sufficient details on specific types of medicines to be procured: 35% of procedures were labelled with the generic code for pharmaceutical products (without further details on the types of medicines procured), while for the remaining procedures, most (73%) used codes equivalent to Anatomical Therapy Class (ATC)-1 level (representing 14 main anatomical or pharmacological groups). Less than 5% used codes equivalent to ATC-3 level or a more granular classification that allows inference about the chemical, pharmacological or therapeutic subgroup or even individual product to be procured. The **lack of granular information** presents a limitation, even if some procedures relating to a product of interest can be identified (other procedures with that same product are likely to be "hidden" in a procedure with the code for general pharmaceutical products). In addition, analyses of the relationship between PPM practices and outcomes are limited to an aggregate (i.e. non-product-specific) level, with scope for confounding.

Finally, exploratory analyses identified some **possible errors in the data**, including issues with the **reliability of contract values** (see Annex 8). To the extent possible, data were validated, and non-validated data were excluded from the analyses. Upon further exploration of the contract values (including consultation with experts at DG GROW who extensively use this data set), the study team decided **not to use contract values as proxies for prices** of publicly procured products due to two reasons: firstly, contract award values entered into TED may not be accurate, as revealed by data checks described in Annex 8; secondly, tenders often include different products (resulting in the use of a generic code for "pharmaceutical products" without further details, as described above) and contract values and product volumes are not available separately for the various products included. This precludes the use of TED data for analysis of unit prices for medicines.

2.5.2. IQVIA data

In addition to publicly available data on public procurement of medicines obtained from TED, the study analyses IQVIA MIDAS sales data that were provided by the EC to the study team through a project-specific arrangement.

The IQVIA MIDAS data set compiles **sales data in a standardised and comparable way**, including cross-country analysis of performance for most of the study countries (excludes Cyprus, Iceland, Liechtenstein, Malta, see **Table 4**). The metrics include:

- Geographic information and where a product is used: region, country, sector
- Manufacturer details: corporation, manufacturer
- Product categorisation: ATC level 2,3 and 4
- Product information on molecule(s), salt, route of administration (New Form Code (NFC) 123, an international classification developed by the European Pharmaceutical Market Research Association, EphRMA)
- Product information on international prescription status
- Product information on whether patent has expired (Generic Product Classification)

Data measures in IQVIA MIDAS include:

- Sales (USD, EUR, fixed and variable exchange rates)
- Volume (kilogram / international units / Standard Units)

It should be noted that prices included in the IQVIA data set correspond to **list prices and do not represent real (net) prices**. Lack of availability of real (net) price data is an issue commonly encountered in pharmaceutical policy research. However, there is uncertainty about the source of price data included in the IQVIA data set: prices may not reflect list price as published in the official price data sources but instead have been calculated based on sales and volume data, which may not be fully representative if not all distribution channels in a country are surveyed). IQVIA price data are therefore labelled **"price proxies" or "proxy unit prices"** in this study.

Table 4: IQVIA data - coverage of study countries

COUNTRY	Hospital sector covered	Retail sector covered
AUSTRIA	YES	YES
BELGIUM	YES	YES
BULGARIA	YES	YES
CROATIA	YES	YES
CYPRUS	NO	NO
CZECH	YES	YES
DENMARK	NO	YES
ESTONIA	NO	YES
FINLAND	YES	YES
FRANCE	YES	YES
GERMANY	YES	YES
GREECE	NO	YES
HUNGARY	YES	YES
ICELAND	NO	NO
IRELAND	YES	YES
ITALY	YES	YES
LATVIA	NO	YES
LIECHTENSTEIN	NO	NO
LITHUANIA	YES	YES
LUXEMBOURG	NO	YES
MALTA	NO	NO
NETHERLANDS	YES	YES
NORWAY	YES	YES
POLAND	YES	YES
PORTUGAL	YES	YES
ROMANIA	YES	YES
SLOVAKIA	YES	YES
SLOVENIA	NO	YES
SPAIN	YES	YES

COUNTRY	Hospital sector covered	Retail sector covered
SWEDEN	YES	YES
SWITZERLAND	YES	YES
UK	YES	YES

Source: Authors based on IQVIA meta data information

2.5.2.1. Use of IQVIA data in the study

IQVIA data were **analysed descriptively** to obtain information on pharmaceutical sales volumes in the study countries. This contributes to the policy analysis, as well as addressing specific questions related to procurement of different types of products, e.g. medicines used in hospitals or biosimilars. In addition to the descriptive analysis, IQVIA data are combined with TED data to answer questions about the relationship between PPM practices and availability and affordability of medicines (see **Chapter 2.5.3**).

Table 5 provides a **list of indicators** based on IQVIA data. Selected indicators are presented in the report. All indicators can be assessed for each country in the data set, and for each group of products, in the online dashboard.

Table 5: List of indicators for IQVIA data

Indicator group		Indicator
Pharmaceutical sales	Market	% of sales in the hospital vs. retail market
		% of sales that are prescription medicines vs. non-prescription products
	Type of product	% of sales that are originator products
		% of sales that are generic products
		% of sales that are biosimilar products
Prices	Average proxy unit prices	Average yearly proxy unit price in EUR across all products
		Average yearly proxy unit price in EUR for originator products
		Average yearly proxy unit price in EUR for generic products
		Average yearly proxy unit price in EUR for biosimilar products

Note: The data source used for all indicators in this table are IQVIA MIDAS sales data [145]

Source: Authors

2.5.3. Impact analysis

As stated in the EU Pharmaceutical Strategy for Europe [1], PPM is seen as a tool to improve access to medicines. Furthermore, PPM may also contribute to other national policy objectives. The study therefore aimed to **assess the potential impacts of PPM on different policy objectives** (SO3: Impact analysis).

Firstly, the relationship between PPM practices and **overall access to medicines** was assessed. Access to medicines is defined as the patient's ability to obtain medicines [142]. To operationalise this complex concept consisting of multiple domains, access to medicines is typically broken down into two core components that are rooted in the human right to health approach and reflected in the United Nations Sustainable Development Goals [146-148]: availability (i.e. whether a medicine is within reach of a patient; this is also linked to security of supply, as lack of and/or gaps in the availability of medicines may be due to problems in the supply chain) and affordability (i.e. the extent to which medicines are available to the people who need them at a price they / their health system can pay).

Secondly, the potential impact of different PPM practices (such as forms of organisation, use of different PPM procedures and techniques) on **six specific policy objectives** was assessed[19]:

- Availability of medicines

[19] Indicators for these policy objectives are described below in Table 7.

- Affordability of medicines
- Competition in the market
- Security of supply of medicines
- Environmental protection
- Crisis preparedness

Following the triangulation approach (see **Chapter 2.1**), a mix of methods was applied to assess potential impacts of PPM. This includes **quantitative analysis** of procurement (TED) and sales (IQVIA) data, which is described in detail below. In addition, **data collected through the stakeholder survey** (stakeholders assess whether in their opinion and experience policies contribute to the six policy objectives, for details on the methodology see **Chapter 2.4.3**), **evidence from published literature** (**Chapter 2.2**), and qualitative data from **stakeholder workshops and interviews** (**Chapters 2.4.1** and **2.4.2**) were analysed.

2.5.3.1. Outline of analytical approach

For each policy objective, the analysis compares how countries applying **specific PPM practices (PPM organisation, processes, and award criteria)** fare compared to countries that do not apply that practice. In addition, a composite indicator for the **maturity (degree) of PPM** in a country was constructed. The degree of PPM was calculated as the sum of sub-indicators for the use of PPM at centralised national level, centralised regional level, group level, or facility level, the application of a variety of procedures and techniques, the application of MEAT criteria, and the use of a range of PPM supporting policies (for details see **Table 6**).

PPM practices were divided into three main domains: **organisation of PPM** (i.e. what is the institutional set-up of PPM in a country?), **PPM processes** (i.e. what types of procedures and techniques are used in a country?), and **award criteria** (i.e. how are contracts awarded?). Indicators for the PPM domains are listed in **Table 6**. The indicators were drawn from different sources, including TED and IQVIA data sets and the PPM country fiches.

The **analysis was conducted at the aggregate level** rather than a country-specific level (i.e. countries were grouped according to the policies applied). This allowed identification of possible relationships between PPM practices and outcomes independent of the specific country context, providing an opportunity to draw out learnings that can be applied to other countries. For analyses using maturity (degree) of PPM, countries were grouped into high, moderate, and low degree of PPM based on the distribution of scores across the study countries. The list of study countries, their PPM degree ranking and assigned group are provided in Annex 9.

Table 6: List of indicators of PPM practices

PPM domain	Indicator	Source
Organisation of PPM	% of procedures awarded by central purchasing body	TED
	% of procedures involving joint procurement	TED
PPM processes	% of procedures as open tenders	TED
	% of procedures under framework agreements	TED
	% of procedures using electronic auctions	TED
	Frequent vs. no / low use of dynamic purchasing system (DPS)	PPM country fiches
Award criteria	% of procedures using MEAT	TED
	Frequent vs. no / low use of security of supply criteria	PPM country fiches
	Frequent vs. no / low use of environmental criteria	PPM country fiches
Degree of PPM	Composite indicator of degree of PPM in a country. Sum of the following sub-indicators: • Use of different organisational forms of PPM for inpatient and outpatient sector (1-4 points for use of facility-based, group procurement, centralised procurement at regional	PPM country fiches

PPM domain	Indicator	Source
	level, and at national level, respectively; weighted (multiplied) by the use of these organisational forms for one sector only or both sectors; standardised according to whether only one or several of the organisational forms were applied in the country) • Use of a variety of PPM practices, including the different procedures specified in the EU public procurement Directive, PPM techniques including framework agreements, DPS, and multi- and single-winner awards (1 point awarded for each applied practice; weighted by their use in one or both sectors; standardised according to the maximum number of points available) • Use of MEAT criteria (points awarded for use in one or both sectors; standardised with a factor of 1:7 based on the total the number of potentially applicable award criteria as assessed in the PPM country fiches) • Use of PPM supporting policies (points awarded for systematic or irregular use of each of a range of 22 different supporting policies, such as market research, horizon scanning, HTA, logistics management, MEA, engagement with suppliers, users of PPM, and patients; standardised by the maximum number of points available)	

Source: Authors

Outcomes for the six policy objectives and for overall access to medicines were assessed using selected outcome indicators (see **Table 7**). For access to medicines, indicators at the country level were selected which do not take therapeutic area into consideration. These are intended to be indicators at the meta-level, representing overall access to medicines in a country. **Overall affordability** is measured through the share of public health expenditure that is spent on pharmaceuticals. This measure focuses on affordability of medicines for the health system while taking into account varying levels of public spending on health (note that this measure does not include other aspects that may include affordability to individual patients, such as out-of-pocket payments). **Overall availability** is measured as the share of newly approved medicines that are included in a country's reimbursement list and are therefore in theory routinely available to patients (note that patients may still face hurdles in accessing reimbursed medicines, e.g. through co-payments). A separate aspect of availability – the time until newly approved medicines are available in a country – was not included as separate measure. A robustness check showed similar results when comparing the rankings of PPM characteristics of the study countries and their rankings by availability of medicines or time to availability.

For each of the six policy objectives, indicators were selected after review of existing indicators and availability of data in the TED and IQVIA data sets as well as other publicly available data sets (e.g. OCED, Eurostat). Differently from the analysis of overall access to medicines, these indicators were analysed for different **groups of medicines** (at WHO ATC-2 level) in order to account for possible differences in the impact of PPM practices according to therapeutic area and product type (see below for details on the groups of medicines). The **availability of medicines** within each group was assessed through the number of individual products (molecules, as indicated by WHO ATC-5 codes) used in a country. This indicator therefore measures whether countries are able to access all available medicines in a therapeutic area. **Affordability** is measured through the average approximated unit price for a product in the group of medicines. While this proxy is not meaningful for any specific product, the average across all products indicates price levels and therefore affordability across countries. **Competition in the market** was measured as the average number of offers for procurement procedures conducted for products in that group of medicines. This indicator assesses the extent to which suppliers compete for contracts in a given therapeutic area. For **security of supply**, the selected indicator (share of products within a group of medicines for which sales data have been recorded throughout the study period) aims

to identify any shortages during the study period. Medicines shortages are notoriously difficult to assess and compare across countries [149]. Therefore, an indicator that would approximate whether individual products are sold throughout a given period, without necessarily indicating a shortage (products may also be discontinued in a country) was used. No suitable indicators could be identified for the domains of **environment and crisis preparedness**. Potential impacts of PPM practices on these two policy objectives were therefore only assessed through the online survey.

Table 7: Outcomes indicators for six policy areas

Policy area	Indicator	Source
Access to medicines	• Affordability of medicines: Share of public health expenditure spent on pharmaceuticals • Availability of medicines: Share of new medicines approved by the EMA from 2017-2020 and included in a country's reimbursement list	• Eurostat [150] • EFPIA Patients W.A.I.T. Survey [151]
Availability of medicines	Number of different WHO ATC-5 codes per therapeutic area	IQVIA MIDAS [145]
Affordability of medicines	Average proxy unit price	IQVIA MIDAS [145]
Competition in the market	Average number of offers per procedure	TED [144]
Security of supply of medicines	Share of pharmaceuticals with sales data throughout study period (2008-2021)	IQVIA MIDAS [145]
Environment	No indicators for quantitative analysis; impact was assessed through stakeholder survey (see Chapter 2.4.3 and Annex 7)	-
Crisis preparedness	No indicators for quantitative analysis; impact was assessed through stakeholder survey (see Chapter 2.4.3 and Annex 7)	-

Source: Authors

2.5.3.2. Grouping of medicines for analysis

Due to discrepancies in the underlying classification systems used to categorise medicines in the TED and IQVIA data sets,[20] a new, common categorisation was developed that allows the two data sets to be matched. The new classification consists of **eleven main categories of medicines** (see **Table 8**). Some of these categories (or sub-categories) were selected for further analysis, as described below; all categories are available in the online dashboard.

Grouping of medicines was primarily based on "classes" used in the pharmaceutical products group of the CPV categorisation.[21] These classes (identified by the first four digits of the CPV code) largely correspond to WHO ATC-1 levels, i.e. they are grouped by the anatomical system which the medicines are used for. However, CPV classes merge some of the ATC-1 levels (e.g. ATC-1 levels B and C fall under the same CPV class). These mergers were reviewed and, where a **split of CPV classes into several smaller groupings** was deemed of value for assessing public procurement of medicines, new groupings were created.[22] An "unspecified" group was required to reflect the large number of notices in the TED database with a generic "pharmaceutical products" coding. Given the lack of information about what products these notices concerned, no further analysis was conducted for this group. Annex 10 provides details

[20] TED uses the Common Procurement Vocabulary (CPV) listed in EC Regulation 213/2008 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0213), while IQVIA uses an ATC categorisation developed by EphRMA.

[21] See EC Regulation 213/2008: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0213

[22] This was the case for CPV class 3365, which included general anti-infectives for systemic use, vaccines, antineoplastic and immunomodulating agents. For the purpose of assessing public procurement, having three separate groupings for anti-infectives, vaccines, and antineoplastic and immunomodulating agents was deemed more valuable, since procurement would typically be conducted for agents within each of these groupings individually (e.g. vaccine procurement is often done at a centralised level, whereas procurement of potentially high-cost antineoplastic immunomodulating agents may be of particular interest to hospitals).

on specific CPV and WHO ATC codes summarised under the main groups of medicines shown in **Table 8**.

As elaborated in the **product life cycle approach to procurement** employed by the Danish CPB for hospitals, Amgros, different PPM procedures and techniques may be best suited to different types of products [152]. For analysis of possible impacts of PPM practices, **groups of medicines representing different stages of the product life cycle**, as well as vaccines (which are often subject to different procurement routes than other products), were selected. For each of the stages, a **"tracer" group** or subgroup of medicines was selected and the analysis of the relationship between PPM practices and outcomes was assessed for each tracer group. Due to limited granularity of TED data (as described in **Chapter 2.5.1.2**), these tracer groups were restricted to the aggregate levels of WHO ATC-1 or ATC-2 level equivalents, rather than representing individual products. Types of medicines according to their product life cycle stage and their selected tracer groups are described below:

- **On-patent products:** Over the past 5 years (2017-2021), antineoplastic agents (WHO ATC code L01) represented more than 20% of all new marketing authorisations for new drugs granted by the European Medicines Agency (EMA) [153]. This constitutes by far the largest category of new medicines and antineoplastic agents were therefore selected as tracer group for on-patent medicines. Only non-generic products from this group were included in the analysis.
- **Products with analogue competition:** A therapeutic area with previously high unmet need and a number of new treatment options emerging over the past two decades is Hepatitis C. Procurers may build on the analogue competition between different antivirals for systemic use (WHO ATC code J05), as is done by Amgros in its procurement of hospital medicines for Danish hospitals [154].
- **Generic products:** Antithrombotic agents (WHO ATC code B01) constitute the group with the highest number of generics approved by the EMA behind antineoplastic agents [153]. Since the latter have already been selected as tracer group for on-patent products, antithrombotic agents were selected for generic products. Only generic products from this group were included in the analysis.
- **Biosimilar products:** Biological products with competitors (biosimilars) are most commonly found for antineoplastic and immunomodulating agents (accounting for more than two-thirds of all EMA-authorised biosimilars [153]). From that group, immunosuppressants (WHO ATC code L04) were selected as tracer group since the other group with a similarly high share of biosimilars (antineoplastic agents (L01)) was already selected to represent on-patent products. Only biosimilar products from this group were included in the analysis.
- **Vaccines:** All vaccines are grouped in the same main category. Analysis of vaccines was deemed relevant because these products are often procured separately from other medicines, e.g. through ministries of health or other CPBs for use in national immunisation programmes.

Table 8: Main categories of medicines for analysis

Group no.	Main group of medicines	Use for impact analysis
1	Unspecified	No
2	Alimentary tract and metabolism	No
3	Blood, blood-forming organs and cardiovascular system	Antithrombotic agents (a subgroup of group 3) were selected to represent generic products (only generic products were included in the analysis)
4	Dermatology and musculo-skeletal system	No
5	Genitourinary system and hormones	No
6	General anti-infectives	Antivirals for systemic use (subgroup of group 6) were selected to represent products with analogue competition
7	Vaccines	Used for analysis on vaccines
8	Antineoplastic and immunomodulating agents	• Antineoplastic agents (subgroup of group 8) were selected to represent on-patent products (only non-generic products were included in the analysis) • Immunosuppressive agents (subgroup of group 8) were selected to represent biosimilar medicines (only biosimilar medicines were included in the analysis)
9	Nervous system and sensory organs	No
10	Respiratory system	No
11	Various medicinal products	No

Source: Authors

Descriptive analyses of procurement and pharmaceutical sales data were performed. For access to medicines indicators, rankings of countries by degree of PPM on the one side and indicators for affordability and availability on the other were compared. For other domains, countries were grouped according to the PPM practices of interest or the overall degree of PPM and average values within each group were calculated for the outcome of interest. No tests for statistical significance were conducted. The analysis did not control for any other variables than the PPM practice being assessed. Due to these limitations, quantitative analysis was complemented by evidence obtained from the literature as well as from stakeholder consultations. Accordingly, no claims of causality can be made with respect to the impact of PPM practices.

The raw but cleaned IQVIA and TED data are also available in the study's online dashboard (see **Chapter 2.6**). Indicators on procurement procedures, sales volumes, and price proxies were defined by the study team to provide snapshots of PPM and the pharmaceutical market in the study countries for which data are available.

2.5.3.3. Limitations of the impact analysis

Some limitations in the analysis of potential impacts of PPM should be acknowledged.

Firstly, **challenges with measuring access to medicines** are well-known, and there are research projects dedicated solely to the purpose of defining adequate indicators[23]. Besides technical issues with identifying and consistently measuring specific indicators, a key challenge is the need to view access to medicines in the context of complex health systems, resulting in access being subject to barriers at the individual (household), regional, national, and international levels [155]. Similar considerations apply to the other policy objectives assessed in this study. The study team decided to **focus on a small number of indicators** for the core policy objectives of interest to allow a meaningful analysis (acknowledging the constraints of what was measured), rather than assessing a broad array of indicators that would be difficult to interpret. The selected

[23] E.g. the Access to Medicine Index created by the Access to Medicine Foundation: https://accesstomedicinefoundation.org/

indicators are readily available or constructible based on data already held by the study team.

Secondly, there is **no clear causal pathway** leading from PPM practices (i.e. exposures) to the different policy objectives (i.e. outcomes) that is free of potential confounders. For example, availability of medicines in a given country may be partially impacted by procurement practices as well as a multitude of other factors, including medical needs of the population, medical practices, marketing strategies of manufacturers, institutional set-up for reimbursement and pricing, and ability to pay for medicines, among others. Any analysis is therefore limited to establishing associations between PPM practices and outcomes. While such analysis can produce essential insights for policy making, it is important to acknowledge that **PPM practices need to be seen in the context of other policies** as well as structural factors in place in the study countries. A **health systems perspective** was therefore applied in this study [155], which was implemented by including information on the pharmaceutical pricing and reimbursement system in the assessment of PPM systems in the study countries. Nevertheless, the nuances of this information cannot be represented in the quantitative assessment of potential impacts of PPM.

Thirdly, and related to the confounding issue mentioned above, due to limited granularity in the information contained in TED files (see **Chapter 2.5.1.2**), the analysis is limited to the **aggregate level**, (i.e. main groups of medicines as shown in **Table 8**), rather than conducted at product level. The analysis at aggregate level itself is a mitigation measure to address the issue of limited ability to match IQVIA and TED data at the product level.

2.6. Development of an online dashboard

Data collected using the methods described in **Chapters 2.2-2.5** are visualised and prepared for analysis in the study's **online dashboard**.

The dashboard was used in the study as a **tool to visualise and analyse data**, in particular quantitative data on procurement and sales of medicines (TED and IQVIA data). Beyond its function as an analytical tool, the dashboard is also used to present findings from the study, including results from the policy analysis and analysis of possible impacts of PPM and thereby acts as a **dissemination tool**. Core components of the dashboard are listed in **Table 9.**

Table 9: Components of the online dashboard

Dashboard page	Contents
Policy mapping	• Mapping of PPM organisational set-up, practices, award criteria, and supporting policies in the study countries
Country information	• Brief written summaries of the PPM system in the study countries
Indicators	• Indicators on PPM practices (TED data) • Indicators on medicines sales and price proxies (IQVIA data) • Indicators on relationship of PPM practices with availability, affordability, competition, and security of supply • Key results from the online stakeholder survey on potential impacts of PPM
PPM glossary	• Online version of the study's glossary of procurement-related terms
Downloads	• List of files for download

Source: Authors

The dashboard was implemented in Power BI due to its primary use as a data analysis tool. Power BI allows handling of large data sets in an online environment. It includes an array of customisable presentation options for data, such as maps and various charts, with options for the user to further customise these using filters and drill-down menus.

Development of the dashboard was initially informed by the needs of the study team. However, stakeholders who may utilise the dashboard to inform procurement decisions and pharmaceutical policy making were invited to provide feedback on a draft version of the dashboard in March 2022 (see **Chapter 2.4.1** and Annex 7). In a dedicated online workshop, representatives from procurement bodies and authorities responsible for pharmaceutical pricing and reimbursement in the study countries, as well as representatives from the EC, were briefed on the development of the dashboard and its current and planned functions, and were invited to provide feedback to take into account for further development.

Note that access rules to the dashboard have not yet been defined. The dashboard will be submitted as a project deliverable to the CA / EC who will then decide on its future use.

3. POLICY ANALYSIS IN THE STUDY COUNTRIES

3.1. Stakeholder mapping

The first specific objective of the study was to map relevant stakeholders involved in PPM. Note that these findings may be influenced by the maturity of PPM systems in the study countries. While some countries have more advanced PPM systems, with established CPBs that can provide reliable information, other countries have highly decentralised and less developed systems where reliable information is more difficult to obtain.

While most countries have some form of dedicated **procurement body for medicines** (either as a stand-alone organisation or attached to another key player in the health care system, such as the ministry of health (MoH) or a payer organisation, see **Table 10**[24]), the mandate of these bodies varies in scope, ranging from a CPB function responsible for conducting all or almost all procurement for hospital medicines (e.g. Amgros in Denmark, LIS in Norway) or any medicine (MoH in Cyprus performing PPM for all inpatient medicines and an outpatient sector that is mainly private) to a more limited **role** responsible for procurement of specific medicines such as vaccines and other products for national health programmes (e.g. BBG in Austria, EHIF in Estonia), or a support function for facility-based procurement (e.g. HSE in Ireland). Variation exists with regard to the level of legal **obligation** of use of CPB: for instance, in Denmark, use of Amgros is mandatory for all hospitals, while in Norway hospitals could also conduct their own procurements. Obligations may also be limited to defined medicines (e.g. in Portugal certain medicines must be procured by the CPB SPMS based on a list, whereas hospital and health units can procure other medicines on their own or request SPMS to procure on their behalf).

Key players in PPM are **public hospitals** or **non-public hospitals that are qualified as bodies governed by public law** (see **Chapter 5**). While procurement is centralised for hospitals in some countries, the dominant form of PPM of hospital medicines is facility-based procurement. This is often complemented by voluntary occasional joint procurements with other hospitals (group procurement) and/or making use of non-for-profit, or sometimes private companies which offer procurement services.

As a result, **CPBs** have not only been identified at national level, but **regional CPBs** in line with the EU Procurement Law also exist in several countries (see **Table 10**). Some of the CPBs active at regional or local level offer services for public procurers in the region (or in the municipalities), whereas some CPBs target university or other hospitals in a country. Most regional CPBs identified only procure for the inpatient sector. Exceptions are CPBs in Italy and Spain. Regional CPBs may not operate strictly according to regional geographical or administrative boundaries. For example, CPBs in Belgium such as Mercur Hosp or HospiLim focus their services on hospitals in a specific region but are not necessarily bound to operating in these regions only.

In some countries, private companies offer procurement services, including for hospitals and community pharmacies. These were not included in the stakeholder mapping which focused on public procurement only.

A few countries apply tendering or tendering-like policies in the outpatient sector (e.g. Denmark, Germany, the Netherlands, Sweden). In these countries, the **public payers** for outpatient medicines (e.g. NHS, social health insurance) launch tender-like procedures for an active ingredient, and the winner (or multiple winners) will be awarded a place on the reimbursement list (for details see **Box 1** in **Chapter 3.3.1**).

[24] Note that the table only shows CPBs involved in PPM. In many countries, CPBs for the public sector exist but are not involved in PPM.

In the hospital setting, **prescribers** and **hospital pharmacists** can play important roles for PPM, as they collaborate with procurers in preparing tender specifications. Procurement committees consisting of the three professions (procurers, doctors, pharmacists; in some cases also other professions, such as nurses, health economists, legal experts, or representatives from the hospital senior management staff) are common in the study countries and can exist both at hospital level and at regional or national level. For example, in Belgium, the hospital pharmacy, procurement department, clinical department, and the legal department of a hospital are often involved in preparing tenders. In Iceland, the procurement department of the country's largest hospital (which conducts centralised procurement of hospital medicines as well as other high-cost medicines) works closely with the Pharmaceuticals and Therapeutics Committee (PTC), as well as specialist doctors and the hospital pharmacy when preparing tenders. Similar arrangements are in place in other countries that use procurement through CPBs or at facility level.

Prescribers and pharmacists thus provide essential input into procurement procedures. Involving these professions early in the procurement process is also seen as success factor to ensure uptake of procured medicines (e.g. when biosimilar medicines are procured, see **Chapters 3.6** and **5.4.2**).

Pharmaceutical pricing and reimbursement authorities, as well as HTA bodies, are typically not directly involved in PPM in the study countries. However, these bodies may work closely with procurers, as the decisions taken by authorities and HTA bodies can heavily influence procurement activities. For example, in the UK, any medicine that is recommended for routine use upon assessment by the national HTA body, the National Institute for Health and Care Excellence (NICE), has to be made available to patients in the National Health System (NHS) and therefore needs to be purchased by health care providers for their patients. In Norway, health economic advisers form part of committees preparing national tenders for hospital medicines. While not a procurement activity per se, pricing and reimbursement authorities play an important role in setting up and organising tender-like systems in the off-patent, outpatient market through selection of a product with preferred reimbursement status for a limited period of time (e.g. TLV in Sweden, DKMA in Denmark, NEAK in Hungary).

The **pharmaceutical industry and wholesalers** are involved in PPM as suppliers. However, the extent to which products are procured directly from manufacturers vs. wholesalers varies across countries. For example, in Estonia and Slovakia, bids for tenders are mostly submitted by wholesalers, with no presence of pharmaceutical manufacturers in the country. Associations of pharmaceutical companies can also play important roles in shaping the framework under which medicines are purchased. In Ireland and the UK, the associations of the research-based pharmaceutical industry negotiate agreements about price ceilings with the relevant authorities.

Patient and public involvement in procurement activities is not commonly practiced in the study countries. Patients may be involved in reviewing medicines for inclusion in national or regional reimbursement lists or hospital formularies through participation in Pharmaceuticals and Therapeutics Committees (PTCs) and other committees (e.g. Austria, Denmark, Estonia, Lithuania, Malta, UK). While this does not constitute a direct role in procurement, patients therefore contribute to determining which medicines to procure in some countries.

Successful **cross-country collaborations in PPM** in the study countries have so far either been driven by procurers in the participating countries (supported by political will to implement cross-country initiatives [117]), with one procurement body taking the lead for a given procedure, or it was organised centrally through the EC. The latter has only been used for joint procurement of medicines during the COVID-19 pandemic (with different instruments used for vaccines and therapeutics, respectively, see **Chapter 6.2.2**). Since 2021, a new Directorate-General for European Health Emergency

preparedness and Response Authority (DG HERA) is responsible for joint procurements at the EU level. **Chapter 6.2.1** provides for descriptions of how cross-country joint procurement was conducted in the Nordic and Baltic countries, respectively.

Table 10: List of procurement bodies involved in PPM at national level in the study countries

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
Austria	Bundesbeschaffung GmbH (BBG) / Bundesbeschaffung Austria GmbH	Yes	In some cases if requested by the federal state or hospitals	Not spec.
Belgium	Service public fédéral - Stratégie et Appui (SPF) / Federal Public Service - Policy and Support (FPS)	Yes	Can launch national tenders	Not spec.
Bulgaria	Central Purchasing Authority at the Ministry of Health (CPB-HS)	Yes	Responsible for establishing framework agreements between suppliers and health care providers	Not spec.
	Агенцията по обществени поръчки (АОП) / Public Procurement Agency (PPA)	No	Only providing support to contracting authorities; not conducting procurement on its own	Not spec.
Croatia	Ministarstvo zdravstva / Ministry of Health (MoH)	Yes	Acts as CPB for defined procedures (tendering and framework agreements)	Not spec.
Cyprus	Φαρμακευτικές Υπηρεσίες / Ministry of Health (MoH) -Purchasing and Supply Services Department	Yes	Performs central PPM procedures for all inpatient medicines, the outpatient sector is mainly private	Inpatient
Czech Republic	Not appl.	Not appl.	Not appl.	Not appl.
Denmark	Lægemiddelstyrelsen / Danish Medicines Agency (DKMA)	No	Involved in the tendering-like system for pricing outpatient medicines	Outpatient
	Amgros	Yes	Acts as CPB for all medicines used in public hospitals (note that hospitals – and Amgros – are owned by the Danish regions)	Inpatient
Estonia	Procurement Department in Eesti Haigekassa / Social Health Insurance	Yes	Acts as CPB for some medicines for national health programmes, vaccines, and selected medicines for hospital use	Not spec.
Finland	National Advisory Committee on Pharmaceuticals	No	Not an agency, but the Committee was established by hospital districts in early 2021 for the procurement of new medical products for hospital use. In practice, the HUS Pharmacy of the Hospital District of Helsinki and Uusimaa takes care of the negotiations phase for the whole of Finland for novel therapies.	Inpatient

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
France	Réseau des Acheteurs Hospitaliers (Resah)	Yes	Regional CPB for metropolitan region of Paris but designated by the direction générale de l'offre des soins (DGOS) as national procurer for hospital procurement	Inpatient
	UniHA (Union des Hôpitaux pour les Achats)	Yes	Regional CPB in the Lyon region but designated by the direction générale de l'offre des soins (DGOS) as national procurer for hospital procurement	Inpatient
Germany	Paul-Ehrlich-Institut, Bundesministerium für Gesundheit (BMG) / Ministry of Health (MoH)	Yes	Procurement of vaccines	Outpatient
	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) / Federal Institute for Medicines and Medical Devices (a business area of the MoH)	No	Operationally involved in the procurement of therapeutics, coordinates the needs assessment	Outpatient and inpatient
	Zentrum für Pandemie-Impfstoffe und –Therapeutika (ZEPAI) / Center for Pandemic Vaccines and Therapeutics (a business area of the MoH)	No	Operationally involved in the procurement of vaccines and therapeutics	Outpatient and inpatient
	Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr (BAAINBw) / Federal Office of Bundeswehr Equipment, Information, Technology and In-Service Support	Yea	One of the four federal CPBs, framework agreements for medicines and medical devices	Outpatient
	Sickness funds	No	Involved in the tendering-like system for pricing outpatient medicines	Outpatient
Greece	Ενιαία Ανεξάρτητη Αρχή Δημοσίων Συμβάσεων (ΕΑΑΔΗΣΥ) / Hellenic Single Public Procurement Authority (HSPPA)	No	Involved in public procurement strategy, no procurement of medicines	Not spec.
	Εθνική Κεντρική Αρχή Προμηθειών Υγείας (ΕΚΑΡΥ) / National Central Authority of Health Procurements	Yes	CPB mainly for the inpatient sector; established in in 2018 as successor of the Health Procurement Committee (EPY)	Mainly inpatient
Hungary	Közbeszerzési és Ellátási Főigazgatóság (KEF) / Directorate-General for Public Procurement and Supply	Yes	CPB responsible for centralised procurement procedures for the public sector, including for health care. Conducts procurement of some medicines used by hospitals (use of centralised procurement by hospitals is voluntary).	Inpatient
	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Health Insurance Fund	Yes	Organises centralised tenders for some inpatient medicines. Involved in the tendering-like system for pricing outpatient medicines.	Not spec.
	Állami Népegészségügyi és Tisztiorvosi Szolgálat (ÁNTSZ) / National Public Health and Medical Officer Service (NPHMOS)	Yes	Conducts procurement of some vaccines	Outpatient

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
Iceland	Landspitali	Yes	National hospital conducting centralised procurement for hospital medicines (voluntary centralised procurement) as well as for all high-cost medicines funded from a separate budget (including those used in hospitals and outpatient settings; mandatory use of centralised procurement)	Not spec.
Ireland	Health Service Executive (HSE)	Yes	Acts as CPB for a few selected medicines (e.g. Hepatitis C medication, direct acting anti-retroviral drugs, orphan drugs, and vaccines). Also runs a DPS for hospitals and supports hospital procurers.	Not spec.
Italy	Consip	Yes	Federal CPB for public administration, including health care (for inpatient and outpatient medicines, mainly off-patent)	Not spec.
Latvia	Iepirkumu nodaļa / Procurement Division of the National Health Service	Yes	Acts as CPB for defined medicines (inpatient and outpatient)	Not spec.
Liechtenstein	n.a.	n.a.	n.a.	n.a.
Lithuania	Centrinė perkančioji organizacija (CPO LT) / Central Procurement Organization (CPO LT)	Yes	Responsible for centralised procurement (not only medicines) upon contract with authorities. Runs e-catalogue platform.	Not spec.
Luxembourg	Not appl.	Not appl.	Not appl.	Not appl.
Malta	Central Procurement & Supplies Unit (CPSU) at Ministry for Health (MFH) with support and guidance from other MFH units and several committees	Yes	CPSU manages sourcing and supply of materials, works and/or services across the National Healthcare Services.	Outpatient and Inpatient, all medicines centrally procured
	Emergency Response Unit at the CPSU at MFH (ERU)		ERU may launch emergency calls for medicines in case of shortages or inavailability of medicines from stock lists.	
Netherlands	Sickness funds	No	Involved in the tendering-like system for pricing outpatient medicines	Outpatient

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
Norway	Sykehusinnkjøp HF (LIS) / Norwegian Drug Procurement Co-operation	Yes	LIS negotiates prices and conducts tender competitions with manufacturers for all medicines used in specialist care (inpatient) as well as medicines that are covered by the National Insurance Scheme (including some medicines used in the outpatient setting). Note that LIS is owned by the regional health authorities.	Not spec.
	Helsedirektoratet / Norwegian Directorate of Health	Yes	Acts as contracting authority, as well as overseeing contracts and supplier management, for a pilot project for centralised procurement of medicines in the outpatient setting (PCSK9 inhibitors).	Outpatient
	Folkehelseinstituttet (FHI) / Norwegian Institute of Public Health (NIPH)	Yes	Responsible for procuring vaccines	Outpatient
Poland	Zakład Zamówień Publicznych przy Ministrze Zdrowia (ZZP) / Public Procurement Department at the Ministry of Health	Yes	Procurement of vaccines for national immunisation programmes, medicines for the national reserve (e.g. typhoid vaccines), treatment of bleeding disorders and HIV/AIDS, and some other medicines	Not spec.
	Narodowy Fundusz Zdrowia (NFZ) / National Health Fund	Yes	According to legislation, responsible for the organisation of joint procedures for the purchase of medicines	Not spec.
	National Institute of Public Health – National Institute of Hygiene (Narodowy Instytut Zdrowia Publicznego – Państwowy Zakład Higieny, NIZP-PZH)	Yes	Conducts public procurement for some medicines	Outpatient
Portugal	Serviços Partilhados do Ministério da Saúde (SPMS) / Shared Services of Ministry of Health	Yes	Mainly responsible for PPM in Portugal for SNS institutions (not limited to medicines) and provides services to the users of PPM (hospitals and ARS) and serves as key contact to suppliers	Not spec.

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
Romania	Agenția Națională pentru Achiziții Publice (ANAP) / National Agency for Public Procurement	Yes	Contract/tender design, promotion and implementation of public procurement policies, establishment and implementation of the system of verification and control of unitary application of legal provisions, procedures in the field of public procurement, monitoring the efficient functioning of the public procurement system	Not spec.
	Ministerul Sanatatii / Ministry of Health	Yes	Yes, for few medicines (vaccines and medicines in national health programmes (such as antituberculosis medication and antiretrovirals (HIV)))	Not spec.
Slovakia	Ministry of Health of the Slovak Republic	No	Prepares several centralised procurement procedures in health field, including the establishment of DPS for medicines	Not spec.
	Vseobecná Zdravotná Poistovňa (VsZP) / General Health Insurance	Yes	Procurement of some high-cost medicines	Not spec.
Slovenia	Not appl.	Not appl.	Not appl.	Not appl.
Spain	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad (INGESA) / National Institute for Health Management under the Ministry of Health	Yes	National CPB for some defined medicines	Not spec.
Sweden	Adda	Yes	Company operated by the association of local authorities, conducting procurement for some medicines e.g. vaccines	Outpatient
	Tandvårds- och läkemedelsförmånsverket (TLV) / Dental and Pharmaceutical Benefits Agency	No	Involved in the tendering-like system for off-patent outpatient medicines. TLV indicates the "product-of-the-month" based on the lowest price submitted by manufacturers.	Outpatient
Switzerland	Bundesamt für Gesundheit (BAG) / Federal Office of Public Health (FOPH)	Yes	Overall responsibility is for positive lists of medicines containing the prices and tariffs that are reimbursed by public health insurance, but acts as CPB for pandemic supplies and vaccines	Not spec.
United Kingdom	NHS England Commercial Medicines Unit (CMU)	Yes	Responsible for procurement and supply of medicines for public hospitals in England	Inpatient
	NHS National Services Scotland National Procurement and Logistics	Yes	National procurement service for high-spend items used in hospitals and the health service in Scotland	Not spec.

Country	Name of the institution (national language and English)	CPB	Involvement in PPM	Sector
	Procurement and Logistics Service (PaLS)	Yes	Provides procurement and logistics services to all public Health and Social Care (HSC) organisations in Northern Ireland, including procurement of medicines	Not spec.
	NHS Wales Shared Services Partnership (NWSSP)	Yes	Services include a procurement and logistics services for medicines Wales	Not spec.

Note: appl. = applicable, n.a = not available, spec. = specified
Not all abbreviations of institutions only mentioned in this table were included in the list of abbreviations

Source: PPM country fiches

Table 11: List of regional CPBs involved in PPM in the study countries

Country	Name of the institution (national language and English)	Involvement in PPM	Sector
Austria	Provincial hospital funds which own hospitals, e.g. Landeskrankenanstalten-Betriebsgesellschaft des Landes Kärnten (KABEG), Steiermärkische Krankenanstaltengesellschaft m.b.H. (KAGES), Burgenländische Krankenanstalten-Ges.m.b.H. (KRAGES), Niederösterreichische Landesgesundheitsagentur (LGA), Oberösterreichische Gesundheitsholding GmbH (OÖG), Salzburger Landeskliniken Betriebsgesellschaft mbH (SALK), Tirol Kliniken, Wiener Gesundheitsverbund (WGV)	For the hospitals in their group	Inpatient
	Procurement units of religious order's hospitals	For the hospitals in their group	Inpatient
Belgium	Regional CPBs such as Mercur Hosp or HospiLim; regional health authorities	Hospital CPBs purchase for hospitals in their group; regional authorities conduct regional tenders for vaccines	Outpatient and inpatient
Bulgaria	Not appl.	Not appl.	Not appl.
Croatia	Not appl.	Not appl.	Not appl.
Cyprus	Not appl.	Not appl.	Not appl.
Czech Republic	Not appl.	Not appl.	Not appl.
Denmark	Not appl.	Not appl.	Not appl.
Estonia	Not appl.	Not appl.	Not appl.
Finland	University hospitals (representing five expert responsibility areas (ERAs) for specialised care)	Conducting procurement in their expert areas for hospitals. For novel medicines HUS Pharmacy of the Hospital District of Helsinki and Uusimaa takes care of the negotiations for the whole of Finland.	Inpatient
France	Several group purchasing organisations such as Groupement de Coopération Sanitaire Achats du Centre, Agence Générale des Equipements et Produits de Santé (AGEPS) l'Assistance Publique – Hôpitaux de Paris, UNICANCER Achats	For the hospitals in their group. Hospitals or hospital groups not linked to a CPB may join a regional and a central procurement body depending on the type of medicines required. Note that Resah and UniHA have been assigned as national CPBs in 2019.	Inpatient
Germany	AGKAMED (not a regional CPB, but a group procurement organisation)	For member hospitals and rehabilitation clinics	Inpatient
	Dienstleistungs- und Einkaufsgemeinschaft Kommunaler Krankenhäuser eG im Deutschen Städtetag (GDEKK, not a regional CPB, but a group procurement organisation)	For district hospitals	Inpatient
Greece	Regional CPBs	For hospitals in their region	Inpatient
Hungary	Not appl.	Not appl.	Not appl.
Iceland	Not appl.	Not appl.	Not appl.
Ireland	Not appl.	Not appl.	Not appl.
Italy	Centrali di Committenza Regionali / Regional central procurement bodies	Procurement of medicines in their region	Outpatient and inpatient
Latvia	Not appl.	Not appl.	Not appl.
Liechtenstein	Not appl.	Not appl.	Not appl.

Country	Name of the institution (national language and English)	Involvement in PPM	Sector
Lithuania	Not appl.	Not appl.	Not appl.
Luxembourg	Not appl.	Not appl.	Not appl.
Malta	Not appl.	Not appl.	Not appl.
Netherlands	Inkoopcombinatie Ziekenhuis Apothek-en Academische Ziekenhuizen (IZAAZ) / Group purchasing hospital pharmacy of university hospitals	For university hospitals which part of Nederlandse Federatie van Universitair Medische Centra (NFU) / Netherlands Federation of University Medical Centers (eight medical centers)	Inpatient
Norway	Not appl.	Not appl.	Not appl.
Poland	Not appl.	Not appl.	Not appl.
Portugal	Not appl.	Not appl.	Not appl.
Romania	N.a.	N.a.	N.a.
Slovakia	Not appl.	Not appl.	Not appl.
Slovenia	Not appl.	Not appl.	Not appl.
Spain	Regional CPBs, such as Consorci de Salut i Social de Catalunya / Catalan Health and Social Care Consortium	Regional CPBs are commonly used for inpatient medicines	Outpatient and inpatient
	Andalusian regional health service	Operates a regional tendering system for outpatient off-patent medicines	Outpatient
Sweden	Regioner / Regions	Procurement body in each region is responsible for administering the process of procuring medicines for inpatient settings	Inpatient
Switzerland	Grouping of hospitals, e.g. Centrale d'achats et d'ingénierie biomédicale (CAIB) des Hôpitaux Universitaires Genéve (HUG) et des Centre hospitalier universitaire vaudois (CHUV)	For hospitals in their region	Inpatient
United Kingdom	Regional procurement hubs (in England) include NHS Commercial Solutions (CS), NHS North of England Commercial Procurement Collaborative (NOE CPC), East of England NHS Collaborative Procurement Hub (EOE), NHS London Procurement Partnership (LPP)	The purchasing groups conduct joint procurement of hospital medicines on the basis of framework agreements concluded by the CMU	Inpatient

Note: appl. = applicable, n.a = not available, spec. = specified

Not all abbreviations of institutions only mentioned in this table were included in the list of abbreviations.
Note that no reliable information on use of regional CPBs could be found for Romania.

Source: PPM country fiches

3.2. Organisation of PPM

The second specific objective of this study was to map existing policy and practices in PPM in the study countries. This addresses the following study question: what are current national PPM policies and practices in the study countries?

It should be noted that the findings presented may be subject to information bias: while some countries (with more advanced PPM systems) are able to provide more and reliable information, other countries (with less developed systems) may be less well represented.

Figure 2 through **Figure 5** below show how different forms of procurement are used in the study countries. Overall, the two most common forms of organisation for PPM are **facility-based procurement** and **a national centralised procurement system**.

While **facility-based procurement** is common for hospital medicines (see also **Chapter 5**), it is more rarely used for outpatient medicines (**Figure 2**). Similarly, voluntary **group procurement**, i.e. joint procurement by groups of contracting authorities such as hospitals, is mostly only used for procurement of hospital medicines, although Italy is a special case with regional centralised procurement for outpatient medicines in primary care units (see **Figure 3**). Other countries with facility-based procurement in both sectors include Luxembourg and Switzerland. Group procurement and facility-based procurement also typically go hand in hand: in almost all countries where group procurement is used, individual facilities also conduct their own

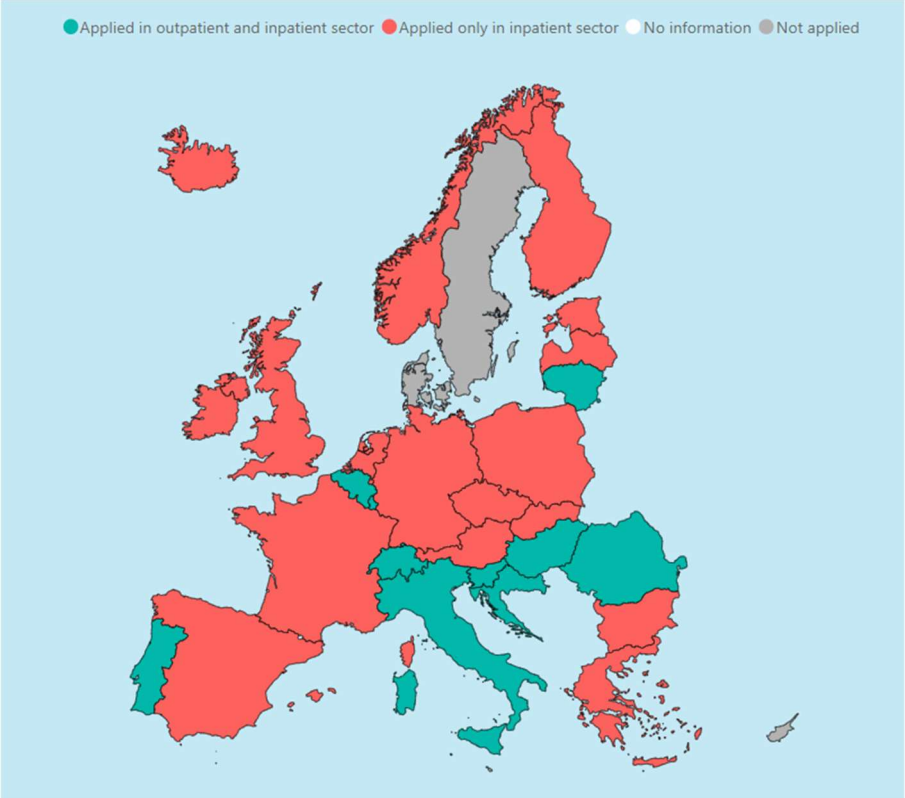
procurement. Group (joint) procurement and facility-based procurement may be used by the same institutions but for different products. An exception is Sweden, where medicines used in the hospital setting are primarily procured at regional level, with group procurement between individual hospitals as supplementary route (and de facto no facility-based procurement).

Centralised procurement at the regional level (i.e. regional procurement conducted through a CPB) is conducted for medicines in both inpatient and outpatient settings (see **Figure 4**). Regional CPBs were identified in 12 countries where they mostly serve hospitals, but sometimes also additionally the outpatient sector (see also **Table 11**). Regional CPBs include regional or municipal health authorities, but also not-for-profit associations organised at the regional level and regionally operating health insurances (in Germany and Spain).

Centralised procurement at the national level through a CPB is common throughout Europe, both for inpatient and outpatient medicines (**Figure 5**). The only two study countries where no centralised procurement at national level is conducted are Czechia and Finland (in Finland there is no CPB, but for novel therapies, the HUS Pharmacy of the Hospital District of Helsinki and Uusimaa takes care of the negotiations phase for the whole of Finland at once). However, the scope of medicines for which centralised procurement is done varies across countries, with some countries using this form of organisation for effectively all medicines (e.g. Malta) while others use it for effectively all medicines in the inpatient setting (e.g. Denmark, Norway), and yet several others only use it for specific types of medicines (e.g. vaccines for national health programmes). Note that the figure does not distinguish between these different forms of national centralised procurement of medicines (CPM).

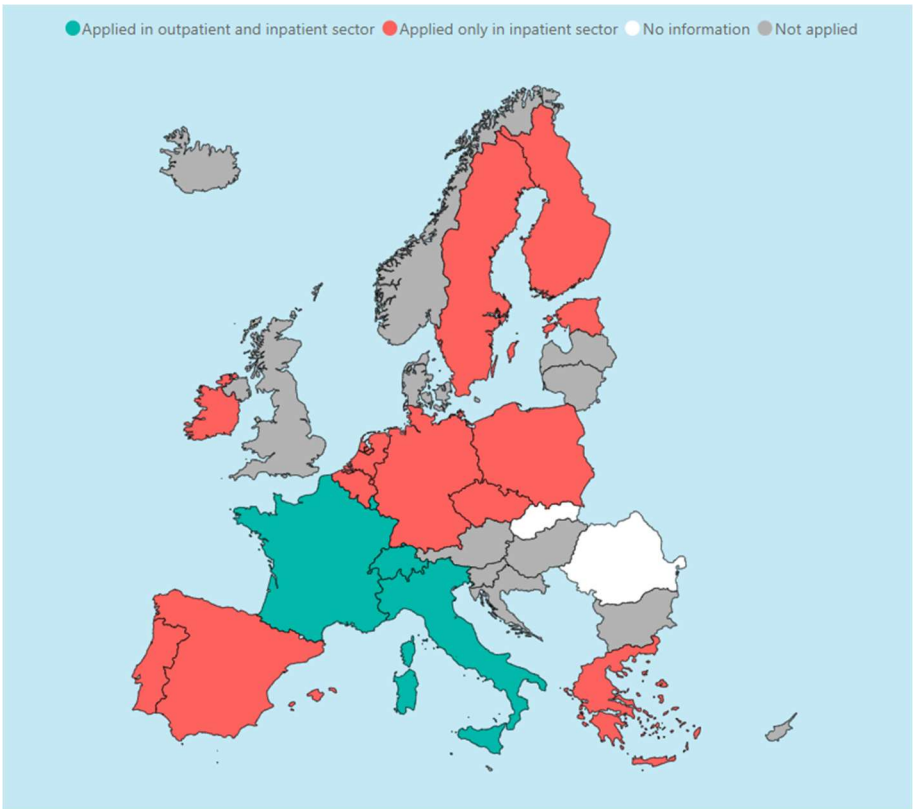
In most countries that use **some form of centralised procurement**, this is complemented by facility-based procurement for inpatient medicines (although in these countries one form of procurement may dominate, and the other is only used for specific products). Exceptions are Cyprus, Denmark, and Malta where effectively all medicines that can be centrally procured are indeed purchased through that route (in Denmark and Cyprus, this only applies to hospital medicines; in the case of the latter, centralised PPM at national level is de facto only used for hospital medicines).

Figure 2: Use of facility-based procurement in the study countries



Source: PPM country fiches

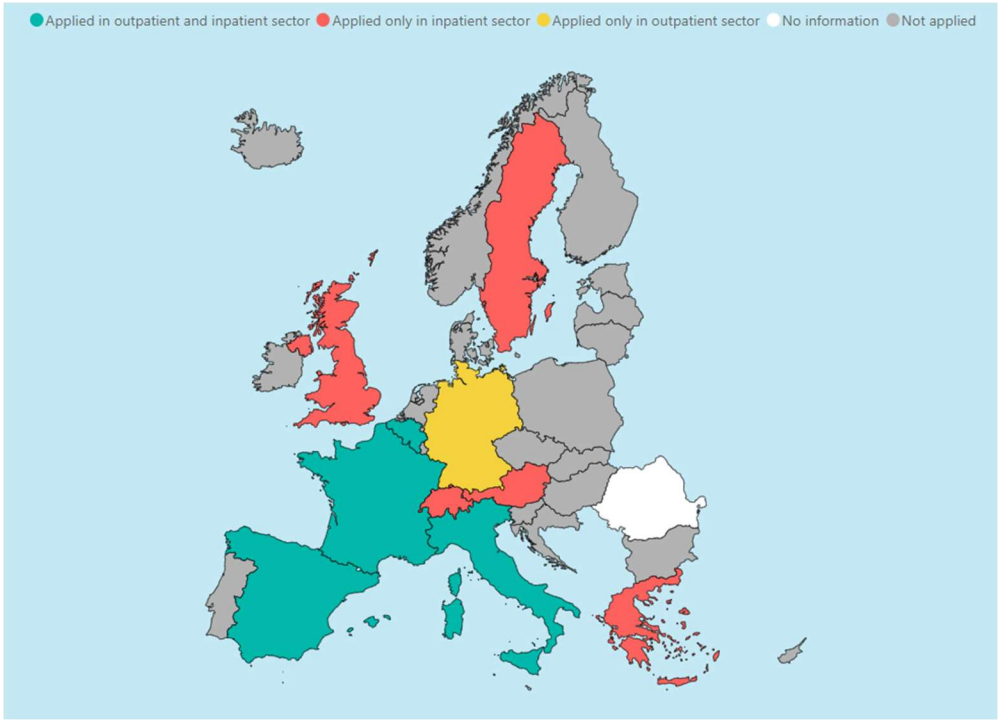
Figure 3: Use of group (joint) procurement in the study countries



Note: Group procurement refers to joint (pooled) procurement by two or more public procurers, but without involvement of a formal, institutionalised CPB.

Source: PPM country fiches

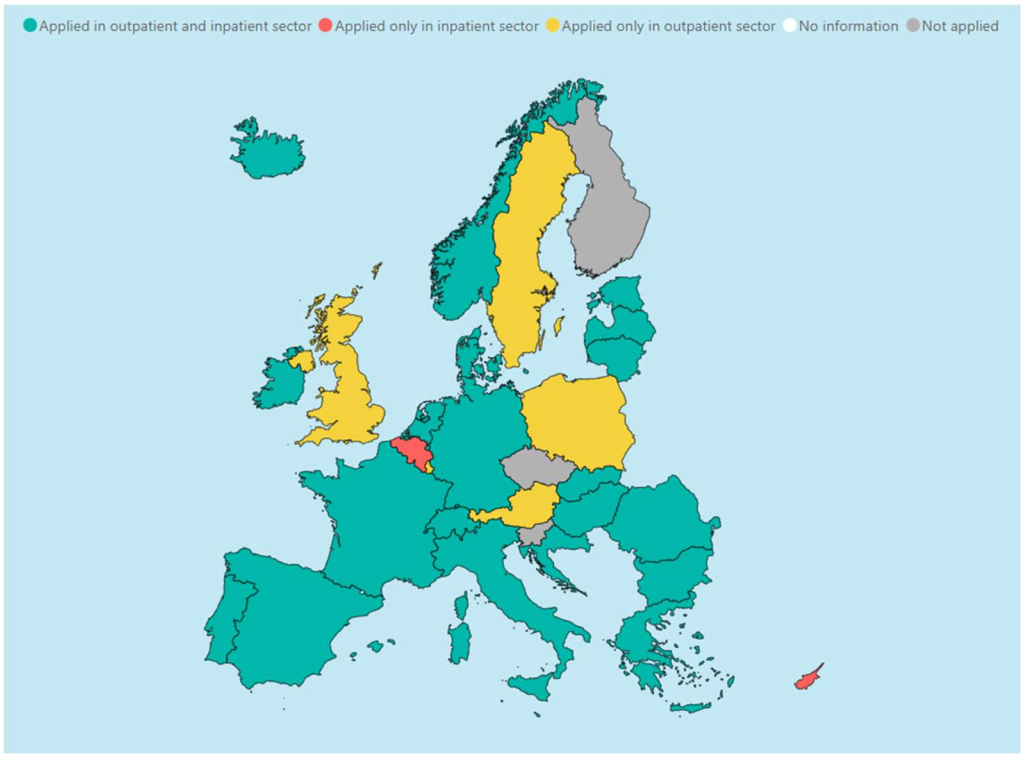
Figure 4: Use of centralised procurement at the regional level in the study countries



Note: Centralised procurement at regional level refers to procurement that is conducted jointly by a centralised procurement body for several buyers in a region.

Source: PPM country fiches

Figure 5: Use of centralised procurement at the national level in the study countries



Note: In some countries, centralised procurement may only be done for very few, selected products (e.g. vaccines or therapeutics used in national health programmes, such as for treatment of HIV/AIDS or Hepatitis C). These countries are shown as applying CPM at national level in the figure but should not be confused with countries that systematically apply CPM at national level for all products (e.g. Malta).

Source: PPM country fiches

3.3. PPM practices

In this chapter, the use of various procurement practices in the study countries is described. This includes forms of formal procedures (generally those specified by EU Directive 2014/24, although national legislation may include other procedures; **Chapter 3.3.1**), as well as procurement techniques (**Chapter 3.3.2**). The latter refer to methods of implementing and facilitating procurement procedures, including through framework agreements, platforms for efficiently processing procurements (to allow for dynamic purchasing system / DPS), and the number of suppliers being awarded a contract. Note that additional procedures techniques are described in EU Directive 2014/24.

3.3.1. PPM procedures

EU Directive 2014/24 specifies the following types of procedures [68]:

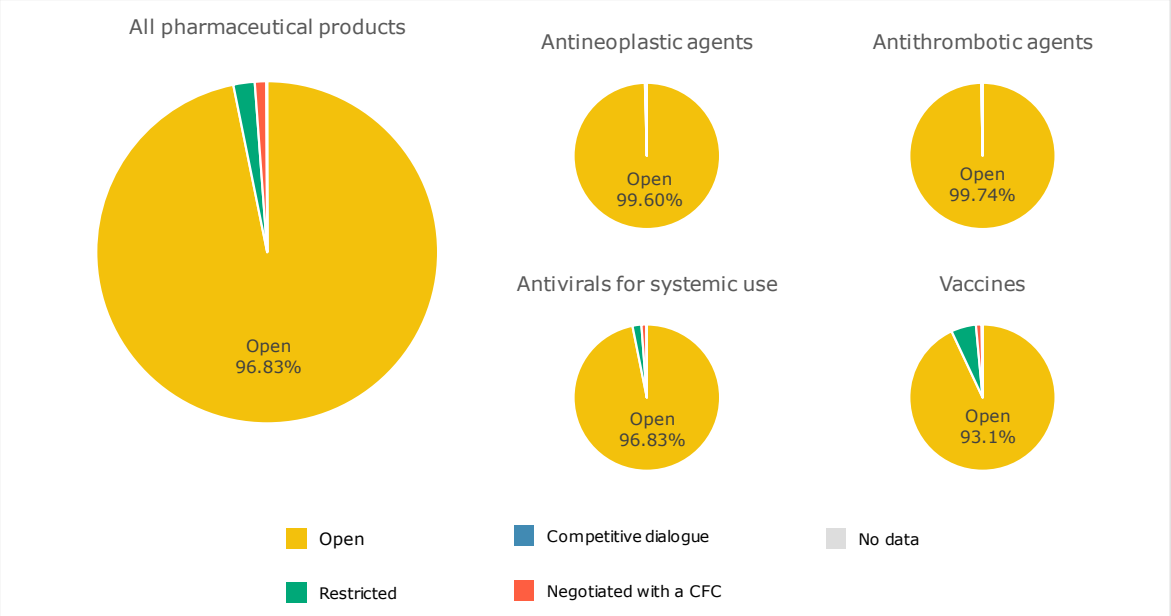
- **Open procedure:** a formal procurement method where any interested potential supplier may submit a tender. In this one-stage procedure, suppliers respond to an open call for competition set up by the purchaser (contracting authority) which details the criteria used for awarding the contract.
- **Restricted procedure:** a formal, two-stage procurement method where any interested potential supplier can submit a request to participate in the first stage, but only suppliers who fulfil pre-qualification criteria set out by the purchaser (contracting authority) may submit tenders in the second stage.
- **Competitive procedure with negotiation:** a two-stage procurement method that involves pre-selection of suitable potential suppliers by the purchaser (contracting authority) and negotiations of submitted tenders.
- **Competitive dialogue:** a two-stage procurement method that involves the purchaser (contracting authority) pre-selecting potential suppliers based on their initial submissions and initiating a dialogue with them to identify the best possible method to address the need specified by the purchaser. Competitive dialogue leaves more space for the best way to address a need compared to the competitive procedure with negotiation, where the purchaser uses pre-specified criteria to assess bids.
- **Negotiated procedure without prior publication:** a variant of the negotiated procedure for exceptional cases where it is known that only a specific supplier can fulfil the procurement needs. In PPM, this may be the case for on-patent medicines without therapeutic alternatives where there is a single supplier, or for addressing needs arising from emergency situations, e.g. a pandemic.
- **Innovation partnership:** a procurement method intended for situations where innovative solutions are required because the needs of the purchaser cannot be addressed by existing products, services, or works. Innovation partnership includes selection of one or more partners based on their proposed research and development projects.

Innovation partnership and negotiated procedure without prior publication are intended for exceptional circumstances. In the case of the latter, a voluntary ex ante transparency notice can be published, but there is no obligation to do so. Comparatively few notices were included in the specific TED database reporting on these cases and the database was therefore excluded from the analysis (see **Chapter 2.5.1**).

Among the key procurement procedures listed in EU Directive 2014/24 [68], **open procedure tenders** are most frequently used across study countries. Open procedures were used in 97% of all contract notices included in the TED database from 2008-2021 (see **Figure 6**). Other procedures, including restricted procedure, negotiated procedure, and competitive dialogue, jointly accounted for just over 3% of procurements conducted

in this period. Comparatively more non-open procedures were conducted for antivirals for systemic use (4.6% restricted procedures) and vaccines (5.5% procedures) while antineoplastic and antithrombotic agents were both almost exclusively procured through open procedures.

Figure 6: Procedures used for procurement of medicines included in TED database in the study countries, 2008-2021



Note: Figure shows the proportion of different types of publicly listed procedures aggregated for all study countries, and for all medicines (classified as "pharmaceutical products" in the TED database) and selected groups of products.

Source: European Commission (TED) data [144], analysis by authors

Open procedures also emerged as the most common form from a review of country practices in the PPM country fiches. 26 of the study countries use this open form of tenders in some capacity, 20 of which use it in both inpatient and outpatient settings. In some countries, open procedure tenders are used for products with no or limited competition (e.g. Portugal, Slovakia, UK), although others also use this procedure for off-patent (but possibly still high-cost) medicines (e.g. Belgium and Hungary for selected medicines, and more widely used in Croatia, Cyprus, Estonia, Ireland, and Iceland). At the national centralised level, open procedures are commonly used to procure vaccines (e.g. Austria, Estonia, Hungary, Ireland, Luxembourg, Norway, Poland, UK). CPBs for hospitals also commonly use open procedures (e.g. Cyprus, Denmark, Norway, Sweden, UK). In some countries, these are restricted to specific types of medicines, e.g. high-cost medicines or biosimilars (e.g. Estonia, Hungary, Latvia, Lithuania, Poland). At the facility-level, open procedures are commonly used because they represent the simplest procedure form.

Some countries use open procedures to identify suitable suppliers with whom to conclude framework agreements (Austria, Bulgaria, Latvia).

Competitive procurement with negotiations and **competitive dialogue** were less frequently used and typically only for specific products or in specific situations. These procedures are used for facility-level procurement as well as centralised procurement at the regional or national levels. In Belgium, Ireland, and Poland, competitive dialogue has been used to procure medicines used to treat haemophilia (extended half-life recombinant factor VIII). Competitive procurement with negotiations is being used for new (patented) medicines in Cyprus, Finland, and Ireland, and for other situations where there is only one supplier in Estonia. In Portugal, competitive procurement with negotiations is a fall-back option when other procedures are not possible, e.g. because

of time constraints. In Slovakia, competitive procurement with negotiations is used for active substances with annual expenditure between 15,000 and 30,000 per hospital. Austria also uses negotiated procedures to find suppliers for framework agreements.

Restricted procedures were not commonly applied, although some countries use them in the context of dynamic purchasing systems (DPS, see **Chapter 3.3.2.2**).

As described, procurement is mainly used in the inpatient sector. However, **tendering or tendering-like procedures** are also applied **in the outpatient sector** by some countries. These systems are targeted at off-patent medicines; the winner (or sometimes the winners) will gain access to the positive list (i.e. reimbursement list for publicly funded medicines) for a defined period of time, and usually doctors will be obliged, or at least encouraged, to prescribe the selected medicines and/or, in case of generic substitution, pharmacists have to dispense the medicines which won the bids. **Box 1** provides some country examples; further countries with tendering or tendering-like systems in the outpatient sector include Malta, Hungary, Romania and some regions in Spain (e.g. Andalusia, however meanwhile no longer in place). Belgium applied this policy, informally known as the "Kiwi light model", for only two substances (amlodipine and simvastatin) in 2007 and 2008 and then stopped the practice as the winner of the second tender could not supply [116].

Evidence on the **impact** of tendering-like systems for off-patent products in the outpatient sector is mostly restricted to savings gained (see **Chapter 4.2.1**). As for competitive tendering in general, concerns about shortages and supply issues exist. While the number of shortages has increased in the last decade [156], the contribution of tendering practices for outpatient medicines to shortages could not be assessed (for details of a few studies, e.g. on the Dutch preference price policy and the Swedish "product of the months", that analysed the impact see **Chapter 4.3**).

Box 1: Tendering or tendering-like procedures for off-patent, outpatient medicines – country examples

Tendering-like system with bi-weekly changes **in Denmark**: Manufacturers submit price bids for reimbursable outpatient medicines to the Medicines Agency on a bi-weekly basis. The winner is awarded (almost) the entire reimbursement market of the respective active ingredient for a period of two weeks, and the price of the lowest-priced medicine is calculated as the reimbursement price. However, in case of only small price differences between prescribed and preferred product, pharmacists are allowed to dispense the prescribed medicine. If the winner fails to supply the market, the medicine will be removed from the price list for the two-week contract period, and the supplier who offered the second-lowest price is asked to supply at the price it bid. Denmark has been operating this system since the mid-1990s, and has optimised it, e.g. by strong IT system which conducts the price recalculations automatically (e.g. in case of supply issues). Concerning the logistical challenge due to bi-weekly changes, there is option for pharmacies to return the stock to suppliers and wholesalers who provide a credit note [116].

"Rabattverträge" in Germany: The sickness funds (competing health insurers) conclude so-called "discount contracts" with the suppliers of off-patent outpatient medicines. While the payers receive confidential discounts, they ensure exclusivity in prescribing and dispensing of the medicines included in the contracts. One commonly used type is the so-called "open house contracts" in which a sickness fund defines the requested discount, and all manufacturers of the respective active ingredient can join, without any further negotiations, if they agree to grant the determined discount [157].

"Preference price policy" in the Netherlands: In 2005, Dutch health insurers started to launch tenders for a few off-patent active ingredients, but after a court ruling in 2008 which forbid joint tenders, as health insurers are obliged to compete, the insurers have been launching individual tenders of generics and some of them also biosimilars medicines. Over the years, the system was adapted, for instance most insurers decided to extend contract duration of initially six months to one year and longer, as frequent changes could possibly irritate patients. Furthermore, some health insurers have adapted the policy by moving away from the "winner-takes-it-all" principle [116].

"Product of the month" in Sweden: For defined active ingredients, the generic which has offered the lowest price is considered as the preferred product for the respective month, and it will be dispensed in the pharmacies due to the mandatory generic substitution. Biologicals are not included in the "Product of the Month" system [113, 119].

3.3.2. PPM techniques

3.3.2.1. Framework agreements

An important **PPM technique** for contracting authorities are **framework agreements**. These are typically concluded by a CA, frequently a CPB, with one or more suppliers to set the conditions for procurement of medicines over a defined time period, including in some cases the price of the product. Details of the procurement process (e.g. volumes purchased or which supplier to purchase from) can still be decided by individual health care providers (e.g. individual hospitals). Framework agreements may also address security of supply concerns and some countries use them to contract multiple suppliers to reduce the risk of shortages due to one supplier failing to deliver.

Framework agreements are **commonly used** in European countries and are particularly often used in the **off-patent market**. In fact, in some countries, framework agreements are the most commonly used form of procurement. For example, the Danish CPB for hospitals, Amgros, uses framework agreements as default option for medicines that face any competition (including medicines with analogue competition, generics, and biosimilars).

Examples of where framework agreements are used by CPBs include:

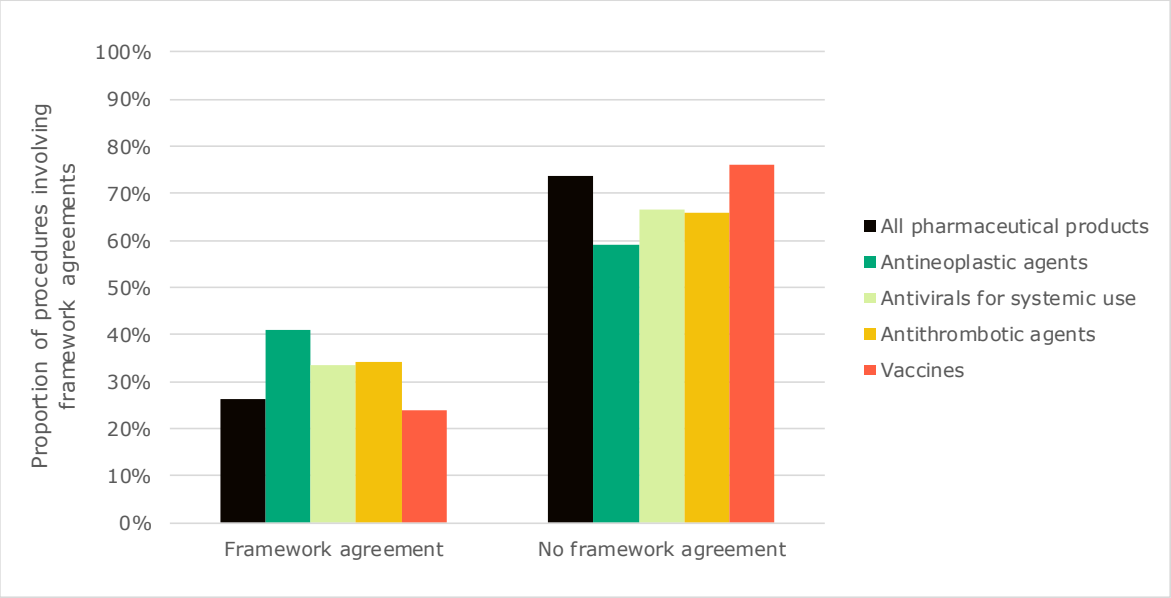
- Austria (vaccines and medicines used in the inpatient setting, including high-cost medicines),
- Belgium (medicines used in the inpatient setting),
- Bulgaria (medicines used in the inpatient setting),
- Croatia (not limited to specific products),

- Denmark (used for medicines with analogue competition, generic and biosimilar medicines),
- Estonia (used for medicines used in national health programmes (HIV/AIDS and tuberculosis medicines; vaccines), high-priced hospital medicines and biosimilar medicines),
- France (for off-patent medicines or medicines attributed to therapeutic classes),
- Hungary (used for centrally tendered inpatient medicines and vaccines),
- Italy (mainly used for off-patent medicines),
- Latvia (used for vaccines, standard tuberculin, peritoneal dialysis products, products for phenylketonuria and other genetic disorders, immunobiological preparations, and parenterally administered oncological medicines),
- Norway (medicines used in the inpatient setting),
- Portugal (mainly used for off-patent medicines),
- Sweden (used for vaccines),
- Slovakia (used for off-patent medicines),
- the UK (used for generic medicines; branded medicines, biosimilar medicines, and IV fluids; blood products, dose banded chemotherapy, and flu vaccines for hospitals).

Framework agreements are also used by individual hospitals, including in Estonia, France, Ireland, Slovakia, and Slovenia.

Across all study countries, routine procurement data entered in the TED database show that framework agreements were used for **26% of all procedures** (see **Figure 7**). Framework agreements were particularly commonly used for antineoplastic agents (41% of procedures).

Figure 7: Use of framework agreements for procurement of medicines in the study countries, 2008-2021



Note: Figure shows the proportion of publicly listed procedures that involved establishment of a framework agreement. Data were aggregated for all study countries and are shown for all pharmaceutical products (as a defined category in the TED database) and selected groups of products.

Source: European Commission (TED) data [144], analysis by authors

3.3.2.2. Dynamic purchasing systems (DPS)

Dynamic purchasing systems (DPS) are not yet well established in Europe. DPS is a procurement technique for making recurring purchases while allowing economic operators to join the system on an ongoing basis. Currently, eight countries (France, Ireland, Italy, Lithuania, Romania, Slovakia, Spain, Sweden) are using DPS for procurement of medicines in some capacity. However, DPS use is limited in some countries and only some contracting authorities may use it (including in Spain and Sweden).

Other countries report favourable experiences with their DPS, including Italy where this procurement technique is used systematically and for a wide range of off-patent medicines, and France, where the DPS allows quicker launching of procedures for off-patent medicines compared to standard procedures. However, DPS in Italy was only possible after transformation of the EU Procurement Directive [68] into national law. The Italian Budget Law 2020 allowed application of the DPS for the call of single and multi-contractor open procedures; this added to an amendment in the Budget Law 2019 which regulated the purchase of biological and biosimilar medicines through the mandatory use of framework agreements, which enhanced their uptake.

DPS may gain in importance for PPM in Europe. For example, Ireland only recently introduced a DPS system to procure off-patent medicines, following recommendation for implementing this in a strategy paper by the HSE Drugs Management Programme [158]. Since introduction of the DPS in January 2020, this has been used by some groups of hospitals. The stage 1 supplier qualification is done at a national level, while each individual hospital agrees criteria for inclusion in the mini-competition that meets their individual requirements.

3.3.2.3. Single vs. multiple winner awards

Study countries showed some variation with respect to the application of single- vs-multi-winner contracts. In most countries, awarding a **single winner** remains the default for at least some medicines. This may be due to the **characteristics of the product** in question: for on-patent products, this may be the only possible award mechanism. In the UK, single-winner contracts are also used for products that just came off-patent. However, single-winner contracts may also be selected based on **market characteristics**: in smaller countries, a limited number of suppliers are typically operating (e.g. in Estonia and Latvia). Splitting contracts may not be feasible when there is a single possible supplier (for on-patent medicines). Finally, single-winner contracts remain widely used due to their **ease of implementation**.

Single-winner contracts are also common for **tendering-like systems for off-patent medicines in the outpatient sector**. In these systems, a single product within a group is typically selected on the basis of bids and designated as the preferred product for dispensing and reimbursement (see also **Box 1**). The incentive for suppliers is that a winning bid contracts the entire market, or a large sub-market (for a limited period of time).

However, single-winner contracts raise the issue of **possible shortages** should the winning supplier fail to deliver. Some countries have legal and contractual measures in place to mitigate this risk (e.g. a ban on exporting medicines when there is a shortage in the country; substituting the product for an available alternative; penalty payments in case of failure to supply) or use security of supply criteria in the tender specifications (see **Chapter 3.4**).

Alternatively, when multiple suppliers are in the market, contracts for products with competition (either off-patent or through therapeutic competition) may be split. **Awarding multiple winners** with contracts can therefore address security of supply

concerns, however, depending on the respective market shares attributed to the winner and also their capacity to supply in case of deliveries of competitors. As shown in the survey conducted for this study (see also the country fiche in Annexes 4.1-4.32), multi-award procedures have been reported for medicines used in the inpatient and outpatient settings. In some countries, multi-award procedures are the default for some types of medicines, e.g. for biosimilars (Italy), supply-critical products (Austria, Belgium, France), high-cost medicines used in the inpatient setting with more than one supplier (Estonia, Latvia), or medicines used for national health programmes (e.g. hepatitis C treatment and vaccines in Ireland). Other countries award multiple winners as default when possible (e.g. Bulgaria, Portugal).

As with all procurement procedures and techniques, there may be variation within countries when procurement is de-centralised. For example, in Sweden, some regions use multi-winner awards for inpatient medicines, but each region has its own processes, including whether to use single- or multiple-winner awards.

3.4. Award criteria

According to EU Directive 2014/24, contracts should be awarded to the **most economically advantageous tender** (**MEAT**) which allows use of several (price and non-price) criteria. The MEAT is to be defined by each CA according to its needs and may be based on price or cost alone, or on the best price-quality ratio. This allows for the inclusion of other criteria that may be relevant for the procurement of medicines, including technical and functional aspects, environmental and social criteria, delivery conditions, and value-added services such as training and assistance. While MEAT may also be defined on the basis of price alone, the concept is intended to explicitly state which criteria are used to identify what constitutes the most economically advantageous offer.

Despite the intention of promoting the use of different criteria, MEAT is only **used in a minority of PPM procedures**. **Figure 8** shows that only 24% of procedures for all pharmaceutical products were awarded according to MEAT criteria across the study countries from 2008-2021. However, use of MEAT criteria varies across therapeutic areas, with substantially heavier use among procedures for vaccines, while price dominates as award criterion for other categories (e.g. used for 84% of procedures for antineoplastic agents).

MEAT requires transparency about the **method for assessing which tender is the most advantageous**, i.e. how criteria are weighted. These criteria may include price, which remains to be most commonly used, but in some countries (Denmark, France, Ireland) some tenders were conducted where price was weighted at less than 50%. In the UK, where MEAT criteria are used to award most contracts for inpatient medicines, there is currently still a strong emphasis on costs, although other criteria also feature (including product training). However, there is an expectation in the UK that award criteria will increasingly focus on outcomes for patients.

Including award criteria other than price may result in higher unit prices. The use of MEAT therefore requires an assessment about the willingness to pay for the added value generated by these additional criteria, which can be challenging and create a barrier to using MEAT. Accordingly, some countries are more hesitant in using MEAT and **price still dominates as award criterion** for PPM (see **Figure 8**). In Estonia and Portugal, while legislation provides for use of MEAT, it is rarely applied. Malta has abandoned use of MEAT criteria and instead awards contracts to the tender with the best price-quality ratio.[25] Price is used in some form in essentially all procedures in Europe. However, most

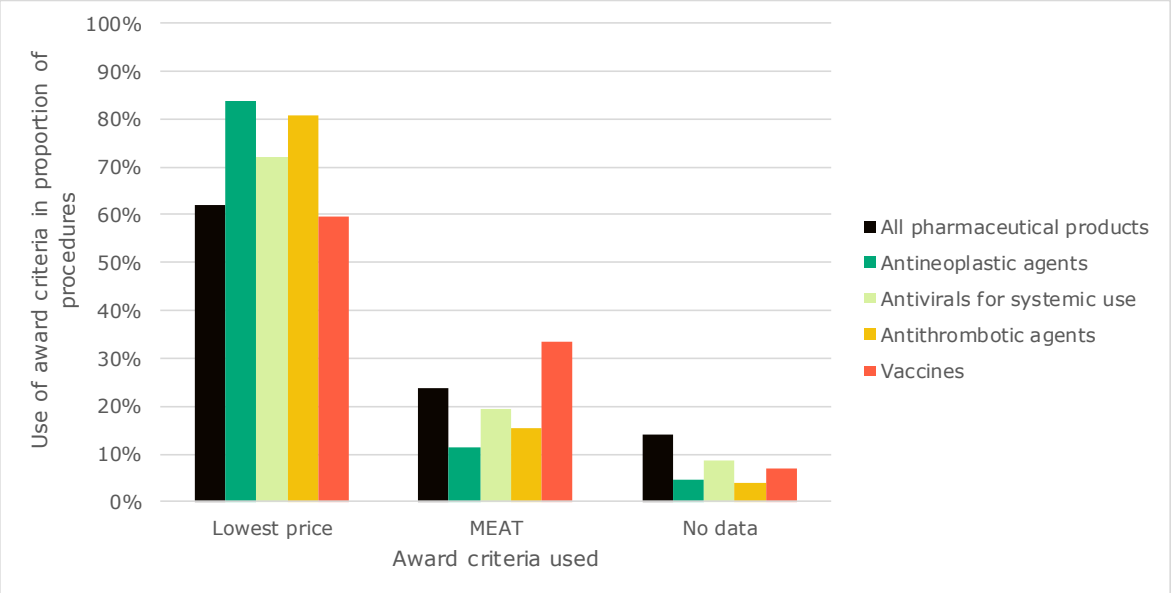
[25] The best price-quality ratio can be the basis for awarding the MEAT, but other approaches, including price only or a cost-effectiveness approach, can also be used. Malta only applies the best price-quality ratio.

countries report that price is used in combination with other criteria for at least some procedures.

Reasons for using price alone were provided by procurement experts participating in stakeholder engagement activities (see Annex 5) and reviewing the PPM country fiches (see Annexes 4.1-4.32). These include the notion that price is the **easiest criterion to assess**, requiring the least resource input from procurers. This may be particularly relevant for facility-based procurement where no dedicated resources are available to develop and assess other criteria than price. In small markets with little competition, price may be the **only criterion to differentiate suppliers**, as not all suppliers would be able to fulfil additional criteria. This may also be true for larger markets when procuring **products that are not expected to vary** with respect to any other criteria than price. For example, in Norway, so-called "H-prescriptions" (medicines initiated in specialist care, but continued in the outpatient setting) are procured based on price alone because the products are considered equal. Quality criteria about the product characteristics may also be included as **minimum criteria**, e.g. when only pre-filled syringes (rather than vials) are to be purchased. In that case, quality criteria are fulfilled by all potential suppliers and price remains as the only award criterion. Procurers also mentioned the potential for **legal appeals when contracts are awarded based on other criteria**; price – the most commonly used criterion – may therefore be the safest bet to avoid litigation after a procedure.

It should be noted that the **use of award criteria may vary between individual procurers within a country**. For example, different regional health authorities in Hungary used different award criteria to procure HPV vaccines. These ranged from price only for some procedures to considering effectiveness in combination with price in others, while others used product characteristics [159].

Figure 8: Award criteria used in procurement procedures in the study countries, 2008-2021



Note: Figure shows the proportion of publicly listed procedures awarded according to lowest price or most economically advantageous tender criteria for all pharmaceutical products and for selected categories of medicines.

Source: European Commission (TED) data [144], analysis by authors

The literature review and workshops highlighted **supply issues as key considerations for PPM**. Security of supply can feature in the award criteria and this can be reflected in combining it with other criteria to award the contract to the MEAT. **Security of supply** is used as an award criterion together with other criteria in some countries

(Belgium, Bulgaria, Denmark, France, Iceland, Ireland, Latvia, Netherlands, Norway, Spain, Sweden). The criterion can take different forms. For example, there may be a requirement for holding stock for a minimum number of months' supply (two months in Iceland), or a requirement for a bank guarantee (Latvia). In other countries, security of supply is not used as criterion but the concept is acknowledged as important by procurers. For example, in Austria, security of supply may be addressed by splitting contracts. In Malta, supply is partly managed through the use of delivery time in the tender specifications. In Bulgaria, security of supply used to be addressed through the requirement for a certificate from the bidders to acknowledge awareness of the quantities to be supplied. However, this was found to violate the principles of non-discrimination and equal treatment in public procurement by a court.

Non-compliance of suppliers with contractual obligations (e.g. non-delivery, delays) is perceived as a major issue for procurers. Penalties in case of non-compliance can be built into contracts, and reporting of shortages by the supplier can be enforced through penalties. Monitoring of shortages may also require cooperation between public institutions to allow procurers to react in a timely fashion: in Italy, notifications of upcoming shortages submitted to the regulatory body, AIFA, are shared with the CPB, Consip.

Local production does not play an important role for PPM in Europe. The criterion is not used in 18 of the 32 study countries, and information was missing for 13. Local production criteria may run against legal provisions about fair competition. In Belgium, no local criteria are used, but production in a "low risk" region is applied as criterion. France is planning on using it to address security of supply issues in upcoming tenders but has not yet implemented it.

Environmental criteria are not yet widely used in PPM. Pilot projects are underway in some countries and using public procurement to achieve environmental goals is clearly a topic of interest to procurers and policy makers. For example, the Austrian government has published a guide for sustainable procurement [160]. However, due to the mostly decentralised nature of PPM, uptake of the recommendations for pharmaceutical procurement remains to be seen. Activities in other countries also show increased awareness about incorporating the environment into public procurement (e.g. the EC has issued a handbook on green public procurement [161], the public procurement office in Slovakia created a working group on this topic [162], in Czech Republic, a research project investigated uptake of green procurement (following 2020 adaptions in the Waste Act and the End-of-Life Products Act)[163]), and in Cyprus tendering documents and contracts may include environmental aspects.

Scandinavian countries have gained more experience with environmental criteria for procurement of pharmaceuticals. In Norway, the CPB for hospitals (LIS) has included environmental criteria about the manufacturing of antibiotics, which contribute 30% to the award criteria [164]. LIS acknowledge that the environmental standards it desires may not be attainable by all suppliers and that performance on these indicators would need to be assessed comparatively, i.e. selecting the supplier that performs best among its peers. In Denmark, the CPB for hospitals (Amgros) reported overall positive experience with the inclusion of environmental criteria in its tenders, including for joint Nordic tenders with Norway and Iceland (see Annex 5 and [165]). Criteria used so far have focused on packaging and transport (documentation on what the suppliers have done to prevent pollution and wastewater) and were developed after intensive consultations with suppliers. Suppliers were able to fulfil the criteria, and the number of bids did not change after these additional criteria were added. However, assessing additional criteria requires more resources on behalf of the procurers. For further information on environmental and further award criteria in hospital procurement see also **Chapter 5.2.9**).

Overall, the use of environmental criteria is still continuing to evolve. Stakeholders from both the procurer and supplier side have mentioned issues with identifying suitable criteria that are meaningful and operational at the same time (see Annex 5).

Added therapeutic value is used as an award criterion in some countries. In most cases, this only relates to medicines used in the hospital setting and is not used systematically (Belgium, Germany, Denmark, Ireland, Netherlands, Norway, Sweden, Slovakia), although Spain also applies it in the outpatient setting. In Estonia, added therapeutic value has been used for procurement of the HPV vaccine. Added value may be assessed by external bodies, e.g. HTA bodies or other institutions collaborating with procurers (e.g. in Denmark, the Danish Medicines Council provides an assessment of the therapeutic value of new hospital medicines, and this information is used by the procurement body, Amgros, when conducting price negotiations with manufacturers). Added therapeutic value was not reported to be used in most other countries (Austria, Bulgaria, Cyprus, Finland, France, Hungary, Iceland, Italy, Lithuania, Luxembourg, Latvia, Malta, Poland, Portugal).

Additional details on the use of different award criteria for procurement of medicines in the hospital setting are provided in **Chapter 5.2.9.**

3.5. Supporting tools and impacting policies

PPM policy and practices are to be seen in the larger context of **pricing and reimbursement policies, and their supporting tools**.

3.5.1. Horizon scanning and HTA

Horizon scanning is considered a valuable but resource-intensive tool both generally and in the context of PPM (i.e. as a preparatory measure for strategic procurement decisions and preparation of procedures). The current leading horizon scanning system is the International Horizon Scanning Initiative (IHSI), a spin-off of the Beneluxa Initiative (a cross-country collaboration that, among others, aims to jointly negotiate prices but does not aim to conduct joint procurement).

Some countries involved in the Nordic Pharmaceutical Forum (Denmark, Norway, Sweden) are also members of IHSI [48]. These countries also have their own horizon scanning systems as part of systematic approaches to introducing new medicines. In the case of Denmark, horizon scanning is done by the CPB for the hospital sector, and in Sweden, the regions (who are responsible for procurement of specialist medicines) are collaborating on horizon scanning. In Norway, this is conducted by the Norwegian Medicines Agency (NoMA) which does not conduct procurement itself. In the UK, the PharmaScan database is used to systematically identify emerging medicines. In its framework for commercial agreements about market introduction of new medicines, NHS England includes, as the first step towards market access, manufacturers submitting information about new products to the database [166]. Other countries with horizon scanning systems in place (although not always used systematically) include Austria, Cyprus, Ireland, Italy, Lithuania, Malta, and the Netherlands. The recently adopted EU Regulation on health technology assessment (HTA) also foresees a "horizon scanning" activity aimed at facilitating joint HTA (Art 22) [167].

HTA is conducted in all study countries, however, there is variation in how much HTA is embedded in the pricing and reimbursement process and how sophisticated the methodology is [6]. With regard to procurement, HTA seems not to be applied in procurement processes with the exception of procurement bodies who purchase centrally for the whole country or a region (e.g. Amgros in Denmark, individual regions in Sweden). HTA – typically performed by a dedicated body or unit, or outsourced to third parties – may be used by procurers in the preparation of negotiations when introducing new medicines.

3.5.2. Managed-entry agreements

For monopoly medicines with high price tags (e.g. cancer medicines, orphan medicinal products) and sometimes also low-price, high-volume products with high budget impact, the study countries frequently negotiate so-called **managed-entry agreements (MEAs)**, either financial or performance-based [168-171]. Procurement bodies are usually not involved in these negotiations which are led by payers or pricing authorities. However, a few CPBs (e.g. the Ministries of Health in Malta, Amgros in Denmark) reported negotiating MEAs, and hospitals may also conclude MEAs on their own in some countries (see **Chapter 5.2.6**). In some countries, pricing and reimbursement authorities also act as CPBs for some medicines. In these cases, MEAs are also concluded by the procuring body (e.g. NEAK in Hungary). If procurers are not involved in MEAs, they may not know the negotiated discounted price (e.g. reported from Portugal [32]); their reported savings from PPM are thus overestimated as based on the official list prices.

3.5.3. PPM-supporting elements

Several but not all countries have **national procurement strategies** in place. In some cases, these are regularly or semi-regularly updated. Procurement strategies may be used to map out **major reforms** in the procurement set-up, as has happened in Bulgaria where reforms including the establishment of a CPB for the health sector were laid out in a national procurement strategy; in Ireland, where plans for the (now implemented) establishment of a DPS and leveraging of joint purchasing power for hospital medicines were described; and in Greece, where major reforms including a centralisation of procurement was planned. In other countries, procurement strategies relate to the **operational principles** of conducting efficient procurement (e.g. Amgros in Denmark follows a strategic approach to procurement along the pharmaceutical product life cycle; the NHS in England has issued frameworks for commissioning of new medicines and biologicals; and LIS in Norway has published a strategy for how to further develop the organisation).

Procurement strategies also exist for non-centralised procurement. For example, NHS hospital trusts in the UK regularly publish their procurement strategies which may include considerations about the general vision for procurement, approaches to procurement (category management and value-based procurement), involvement of stakeholders, and supply chain transformation, as well as operational considerations, such as use of contract management and stock management.[26]

Another important supporting tool for optimising PPM is **capacity-building for procurement staff**. For example, national procurement agencies in Bulgaria and Sweden, which are not involved in procurement themselves, provide basic and advanced training to public procurers. These agencies may also offer guidance and support to procurers on specific topics, e.g. on green procurement in Sweden. In other countries, training is mostly hands-on, which may include dedicated training sessions on specific procurement procedures (e.g. Denmark, Estonia, Italy, Malta). In the UK, a general framework (not specific to health) exists to guide capacity building among public procurers (Commercial Skills and Competency Framework).

Other important supporting policies that are widely used across the study countries and conducted by procurers include **market research** in preparation of tenders and **needs assessment** of the users of medicines.

[26] See for example the published procurement strategies of Frimley, Oxford University Hospitals, and Salisbury NHS foundation trusts [172-174].

3.6. PPM procedures and practices for biosimilar medicines

In most countries, **no unique PPM processes** are used to procure biosimilar medicines (i.e. there are no specific procedures or techniques that are only used for biosimilars and not for other medicines). For example, in Denmark, England, and Spain, framework agreements are generally used by national or regional CPBs for off-patent medicines in the inpatient setting, including for generic (non-biological) and biosimilar products, Cyprus generally uses open procedures for off-patent products, including for biosimilars, Lithuania includes biosimilars in its regular centralised procurement processes for hospital medicines, and in Italy and France, DPS are also mostly used for these products. Some countries **exclude biosimilars from tendering** (e.g. Latvia).

Procurers are **aware of the specificities of biosimilars** – in particular, the complex nature of these products and the patents protecting intellectual property rights, large potential for cost savings compared to biological originator products, and potential actual or perceived limitations regarding their interchangeability – and use existing practices accordingly [42]. This relates in particular to the **frequency of procedures**, which are longer for biological medicines compared to others in a number of countries (e.g. every two years in Ireland, and for centralised tenders in Hungary, Sweden, and the UK, every four years in Malta), although not in all (e.g. annual tenders in Poland). In addition, preparation of tenders for biological medicines may require additional **input from clinical specialists** and hospital pharmacists. Involving specialists may also help ensuring that the winning product is used, as – despite existing evidence demonstrating interchangeability of reference products and biosimilars with respect to efficacy and safety [175] - there is still some scepticism among prescribers and patients (see **Chapter 5.4.3**).

Due to their cost-saving potential, biosimilars are often targeted in **pilot schemes to optimise PPM**, e.g. through centralised or other joint procurement forms. In Estonia, the CPB at the health insurance fund is expanding its mandate to procure more medicines used in the inpatient setting, including those with the highest cost containment potential (previously conducted at hospital level). This expansion follows successful pilot projects for centralised procurement of biosimilars. Another example of novel procurement practices being used for biosimilars is Ireland. These cases are described in a **dedicated chapter in the PHIS hospital procurement update** included in this report, which provides more details on biosimilar use and procurement in the inpatient setting (see **Chapter 5.4**).

A key supporting policy for procurement of biosimilars is the **monitoring of patent expiry dates**. This provides procurers with the market knowledge required to design efficient procedures, including when to issue new tenders. Patent expiries are used to inform the timing of tenders in Belgium, Croatia, Cyprus, Denmark, Estonia, France, Hungary, Lithuania, Norway, and the UK, although other countries may also apply this practice. In England, guidance was developed by the NHS for procurement of biological medicines. This guidance highlights the importance of timing of procedures being in line with market entry of biosimilars, but also includes considerations about supporting mechanisms to ensure uptake of biosimilars, e.g. by implementing a switch programme through a local project management approach that involves all stakeholders [176].

An instrument to ensure optimal use of potential cost savings through biosimilar use is to have **flexibility in contracts** to allow issuing new tenders when biosimilars become available. An example is England, where shorter contract durations are used for products that just came off-patent. The regular two-year cycle of tenders may also be interrupted by so-called transition tenders which are used to place new products on the market [176]. In Romania, contracts may also be opened when new competitors become available, but this has not been used in practice yet.

Monitoring of patent expiries is not necessarily done by the procurers themselves. In Lithuania, public institutions including the State Patent Bureau and the State Medicines Control Agency collaborate to monitor patent expiries and possible market entry of competitor products.

In the **outpatient setting**, countries that have **tendering-like systems** in place may have specific provisions for biological medicines within them. In Hungary, price bids for biosimilars are submitted every year, rather than every six months (as is the case for other generic products), to identify the preferred product that is reimbursed at 100%. The longer time frame is intended to avoid frequent switching of patients [177]. In Germany, some sickness funds specify a target discount rate for specific active substances and then contract with any supplier willing to provide that rate (so-called "Open House" contracts) [119]. Biosimilar substitution is not allowed in countries using tendering-like systems, including Germany, Denmark, Hungary, and the Netherlands (see **Chapter 5.4.3.3**), although this was planned to be introduced in Germany in 2022.

Another specificity of biosimilar procurement is the scope for **supplier actions to effectively extend the period of market exclusivity** for originator products. Such actions include contractual agreements and pricing structures, patient schemes, as well as legal rulings on multiple patents protecting intellectual property rights (known as "patent thickets" in the US [178]) that impede market entry or significant uptake of competitor products. Recent examples of such cases in the Netherlands and Romania are described in **Box 2**.

Box 2: Examples of supplier practices impeding biosimilar competition

Netherlands: discount scheme to tie hospitals to originator etanercept

In the Netherlands, the manufacturer of originator etanercept, Pfizer, recently had to abandon a pricing strategy that effectively locked hospitals into purchasing their product rather than switching to cheaper biosimilars. Supply contracts for the purchase of originator etanercept included clauses that disincentivised switching to competitor products, as discounts agreed with Pfizer would decrease in line with reduced future purchase volumes. Hospitals attempting to switch to biosimilars would therefore lose access to the originator product at the negotiated price. The Netherlands Authority for Consumers and Markets investigated these contracts and found that they were likely to breach competition rules, leading to the manufacturer agreeing voluntarily to stop using the discount clauses in its contracts.

Romania: delaying market entry of biosimilars for rituximab, trastuzumab, and erlotinib

In Romania, the manufacturer of originators rituximab and trastuzumab, Roche, was found guilty for two different sets of practices impeding market entry and uptake of biosimilar products in the national centralised procurement system. In the first case, the manufacturer offered its products to wholesalers participating in a national tender for rituximab and trastuzumab at a higher price than its own bid. This practice ensured that the wholesalers, who – if successful in winning the tender – could also supply competitor products, would not win a national contract, thereby effectively cementing the monopoly position of the originator products.

In the second case, the manufacturer was found guilty for delaying market access for biosimilar erlotinib by steering patients towards its own product using a patient card, call centre, and by subsidising the price difference between the originator and biosimilar products in order for patients to continue using the originator.

Belgium: including free-of-charge additional services in bids to hospitals

In Belgium, it is not allowed to request (by a hospital) or provide (by a supplier) a medicine with free of charge additional services including patient support programmes or training on the correct use of the product and educational material or software for patient monitoring. In addition, services (such as software) that are not related to the supply of medicines cannot be integrated in any way (even at cost) to a request or offer.

The Belgian medicines agency FAMHP reminded both hospitals and suppliers in 2019 that it is illegal to do so and that the law on medicinal products allows a range of penalties for a violation of the specifications. FAMHP also insisted that the hospital, as a contracting authority, must respect equal access and fair competition.

Source: [179-181]

4. EVALUATION OF THE IMPACT OF PPM

The third specific objective of this study was to measure the impact of PPM in the study countries due to optimised practice in PPM, aiming to answer the following study question: how can PPM contribute to different policy objectives?

Actual and potential impacts were assessed through a mix of methods. Firstly, quantitative data on procurements conducted in Europe from 2008-2021 as well as data on pharmaceutical sales in that period were used to assess the relationship between PPM practices and a set of six policy objectives (availability and affordability of medicines, competition in the market, security of supply, protecting the environment, and crisis preparedness, see **Chapter 2.5.3**). Secondly, stakeholders were asked to assess the potential contribution of different PPM practices on each of these policy objectives (see **Chapter 2.4.3** and Annex 7). Stakeholder views on the impact of PPM on different policy objectives were also voiced during stakeholder workshops and interviews (see **Chapters 2.4.1** and **2.4.2** and Annex 5). Finally, evidence on PPM impacts from published studies was also taken into consideration.

4.1. Impact of PPM procedures and practices on access to medicines

Access to medicines is conceptualised as consisting of two core components: affordability and availability of medicines. Key findings regarding the relationship of PPM and access to medicines based on the triangulation of quantitative analysis of procurement and sales data, online survey of stakeholders, and qualitative research with stakeholders are summarised in **Box 3**. Detailed results are described below.

Box 3: Key findings: PPM processes and access to medicines

- Countries with **more mature PPM systems** (using more centralised PPM, using a variety of practices, applying MEAT, and using supporting policies) are those with **higher public spending** on medicines.
- The relationship between maturity of PPM systems and **availability of newly marketed medicines** (i.e. number of medicines included in the reimbursement list) is heterogeneous, as countries with high, moderate, and low degrees of PPM are generally all able to have most products available at some point (not taking into consideration differences in time to availability). However, accounting for data inconsistencies, countries with high degree of PPM appear to have more new medicines included in their reimbursement lists compared to other countries.
- Stakeholders generally view PPM as an important tool to improve access to medicines, although there were discrepancies in how specific forms of procurement were assessed: while authorities considered **centralised PPM at national level** to be the most likely to positively impact on access to medicines, procurers themselves assessed centralised PPM at **regional level** as most beneficial, and suppliers considered **less centralised forms** of procurement to be contributing most.

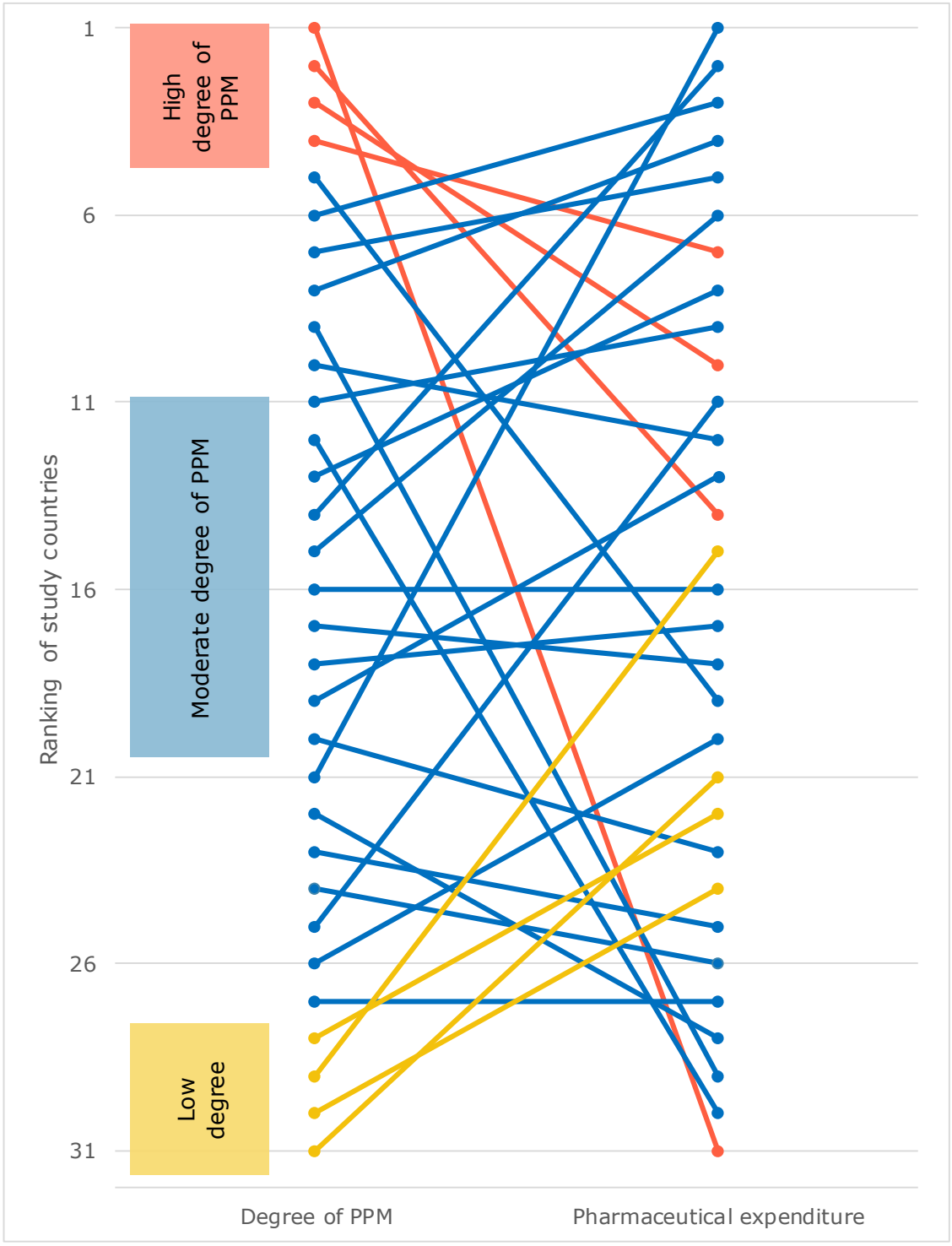
Source: Authors

Figure 9 shows the relationship between **maturity of PPM systems and pharmaceutical expenditure**. Countries with a higher degree of PPM (i.e. countries with more centralised procurement, applying different forms of procurement, using MEAT criteria, and using supporting policies) have higher average public spending on pharmaceuticals (as proportion of total public health expenditure) compared to countries with low degrees of PPM, but not compared to countries with moderate degrees of PPM. This suggests a complex relationship between PPM system and medicines affordability.[27] In fact, the top-6 highest-spending countries all come from the heterogeneous group of countries with moderate degree of PPM. The comparison of countries with high vs. low degrees of PPM suggests that high degrees of PPM are often observed in countries that spend more on pharmaceuticals (see **Chapter 4.2.1** for the analysis of degree of PPM and proxy unit prices). It is important to note that the maturity

[27] Ranking of countries and assignment to groups of high, moderate and low degree of PPM is provided in Annex 9.

of the PPM system, as defined in this study, is linked to other characteristics of the pharmaceutical care set-up which impact on access to medicines, e.g. the systematic use of HTA and horizon scanning. Furthermore, it is likely that other, unmeasured characteristics of more developed pharmaceutical systems are associated with a strategic approach to PPM.

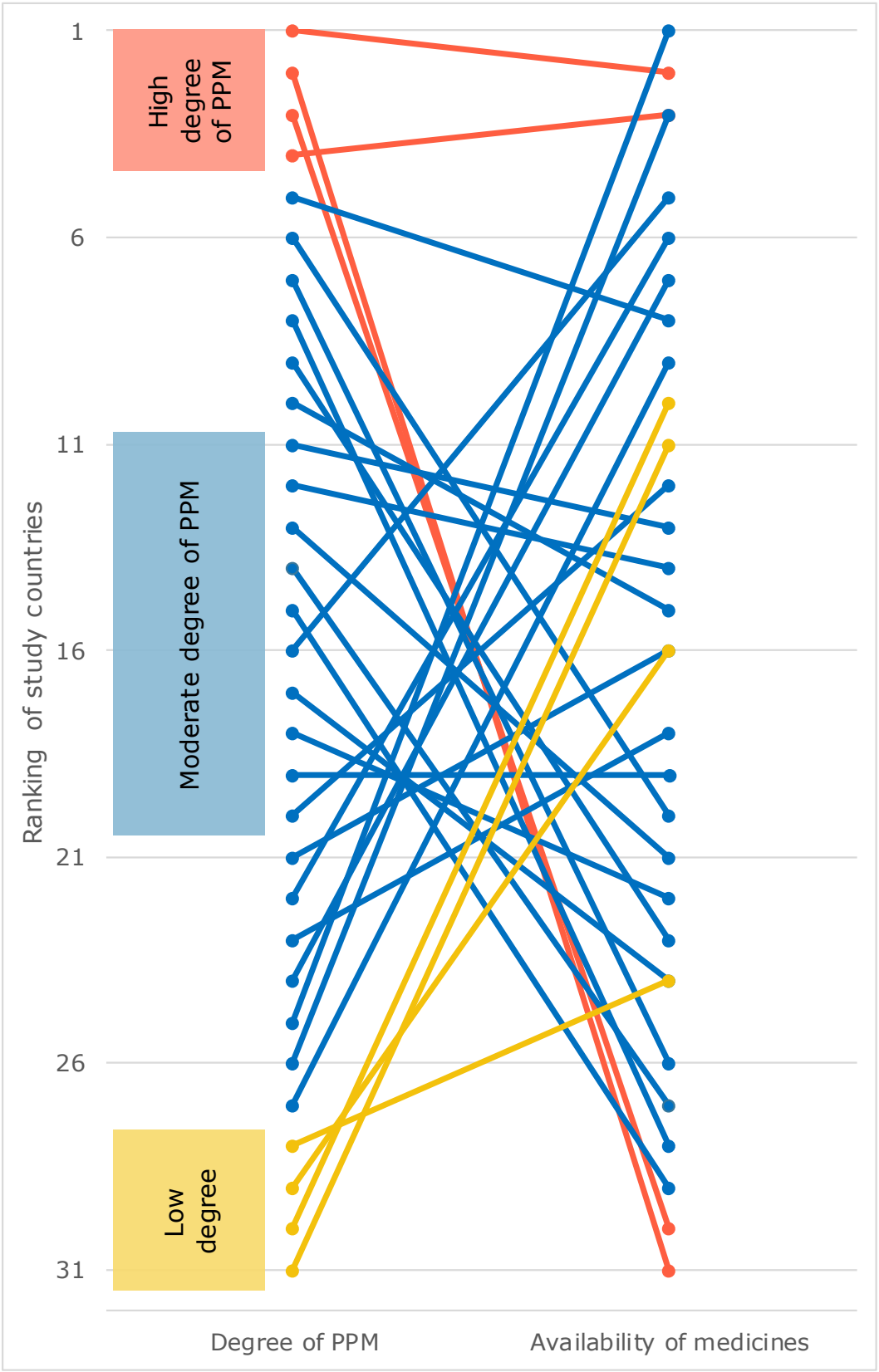
Figure 9: Relationship between degree of PPM and affordability of medicines



Note: Figure shows 31 study countries (no data available for Liechtenstein) ranked by degree of PPM (left column) and corresponding rankings for pharmaceutical spending, measured as the proportion of public health expenditure spent on pharmaceuticals in 2019 (or latest available year).

Source: Authors' analysis based on PPM country fiches and Eurostat [150]

Figure 10: Relationship between degree of PPM and availability of new medicines



Note: Figure shows 31 study countries (no data available for Liechtenstein) ranked by degree of PPM (left column) and corresponding rankings for availability of newly approved medicines in Europe from 2017-2020. Availability typically means that products are included in the reimbursement list in that country. Data on availability were limited for Malta (group of countries with high degree of PPM), Cyprus, and Croatia (both moderate degree of PPM).

Source: Authors' analysis based on PPM country fiches and IQVIA/EFPIA [151]

Figure 10 shows a similarly complex picture of the relationship between **PPM maturity and availability of medicines**. Countries with high degree of PPM had, on average, similar numbers of newly marketed medicines included in their reimbursement lists as countries with moderate or low degree of PPM. This relationship may be impacted by limited data availability for new medicines for Malta, one of the top-ranked country in terms of degree of PPM.[28] When Malta is excluded, the group of countries with high degree of PPM achieved considerably better availability than the other two groups of countries. Nevertheless, the picture remains heterogeneous: of the top-10 ranked countries in terms of availability, two have high degree of PPM, seven moderate degree, and one low degree of PPM.

The notion that countries with high degree of PPM may achieve better availability outcomes is supported by the analysis of stakeholder responses to the online survey conducted as part of this study (**Figure 11**). While authorities from the study countries considered **centralised PPM at national level** to be the most likely to **positively impact on access to medicines** (followed by centralised PPM at regional level), procurers themselves assessed **centralised PPM at regional level** as the organisational form most likely to contribute to access to medicines. The analysis of availability of new medicines (measured as eligibility for reimbursement) appears to support the notion of generally better availability of medicines in countries with more centralised procurement systems compared to countries with highly decentralised systems.[29] Suppliers, on the other hand, often considered **less centralised forms of procurement** to be more beneficial.

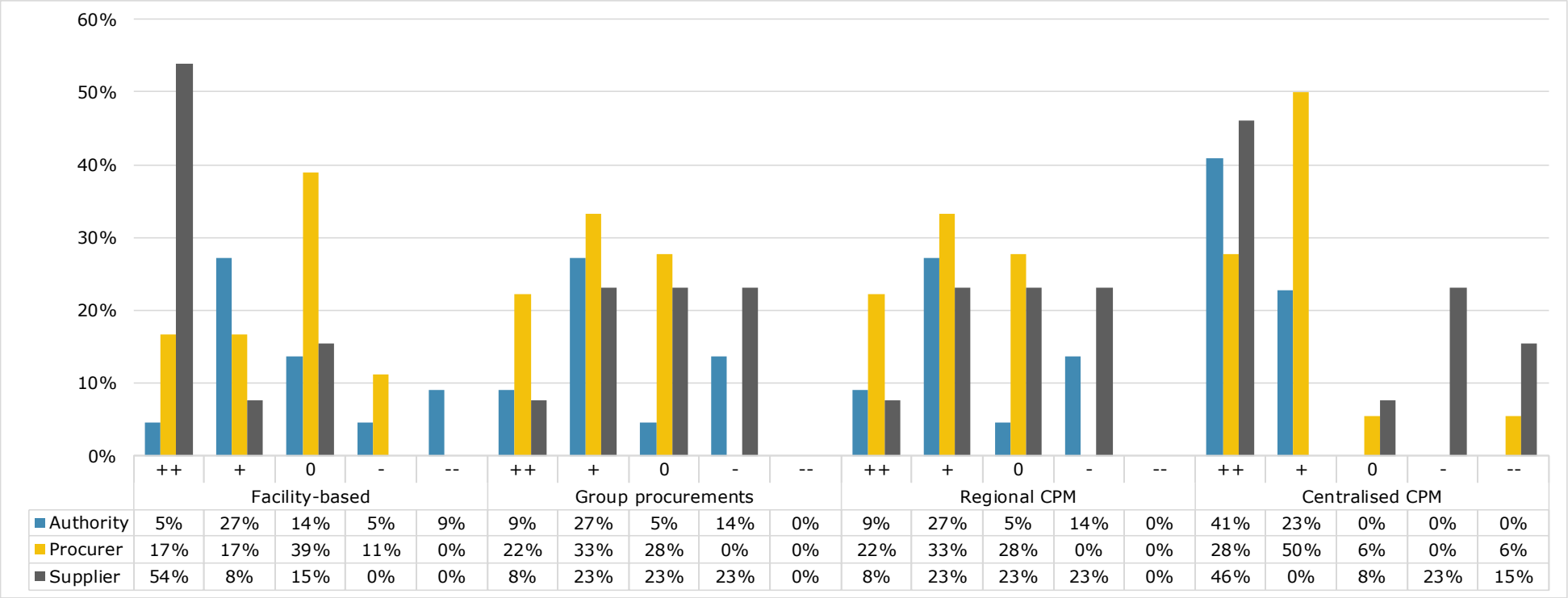
The views of public authorities and procurers as obtained through the online survey were also confirmed through workshops and interviews with stakeholders and procurement experts, as well as documented in the literature. For example, centralised procurement of biosimilars in Norway – accompanied by an institutionalised and well-respected set-up of developing and disseminating treatment recommendations – was found to contribute to lower prices [30]. Similarly, centralised procurement of hospital medicines in Denmark was found to lead to higher numbers of patients being treated with biosimilars [182]. However, centralised procurement does not necessarily result in improved access to medicines. An example is Hungary, where centralised tenders for granulocyte-colony stimulating factors (G-CSFs) conducted by the National Health Insurance Fund Administration (NEAK) resulted in reduced expenditure, but also a slight decrease in the number of patients treated [177]. While the reasons for the decrease in the number of patients treated is not clear, this experience highlights the need for careful implementation of centralised procurement.

The **pharmaceutical industry is sceptical of the contribution of more centralised forms of procurement to access to medicines**. As shown in **Figure 11,** suppliers (representing manufacturers of generic medicines) mostly considered centralised PPM at regional and national level as barriers to access to medicines. Representatives from the research-based industry (who did not participate in the online survey) also do not consider organisational forms of procurement that pool purchases (joint procurement) as suitable for regular procurement and instead view this as procurement instrument for exceptional circumstances [61].

[28] Malta, alongside Cyprus and Luxembourg were included for the first time in the 2021 IQVIA/EFPIA Patient W.A.I.T. survey that are used to measure availability of medicines and submitted an incomplete data set [151].

[29] Figure 10 shows the relationship between availability of medicines and degree of PPM, which includes centralised procurement as a sub-indicator. A similar pattern emerges when restricting the analysis to the organisational forms of procurement used in the study countries (centralised PPM at national level, centralised PPM at regional level, group procurement, facility-based procurement; data not shown).

Figure 11: Level of PPM (within a country) most likely to contribute to access to medicines (responses >3 per stakeholder group), per stakeholder group



	Facility-based					Group procurements					Regional CPM					Centralised CPM				
	++	+	0	-	--	++	+	0	-	--	++	+	0	-	--	++	+	0	-	--
Authority	5%	27%	14%	5%	9%	9%	27%	5%	14%	0%	9%	27%	5%	14%	0%	41%	23%	0%	0%	0%
Procurer	17%	17%	39%	11%	0%	22%	33%	28%	0%	0%	22%	33%	28%	0%	0%	28%	50%	6%	0%	6%
Supplier	54%	8%	15%	0%	0%	8%	23%	23%	23%	0%	8%	23%	23%	23%	0%	46%	0%	8%	23%	15%

Source: Online survey

A positive contribution of PPM to access to medicines can be expected across the spectrum of medicines. In an online survey conducted as part of this study, stakeholders considered a strategic approach to procurement to be almost equally beneficial for access to high-cost medicines, on-patent medicines, off-patent medicines, biosimilars, orphan medicines, oncology medicines, and vaccines (detailed results shown in Annex 7). Furthermore, stakeholders also mentioned potentially positive contributions of PPM for access to medicines with analogue competition (i.e. where therapeutic alternatives exist), older medicines with no alternatives, medicines with low supply volume but that are clinically important, and some specific medicines (anti-infectives and antimicrobials).

4.2. Impact of PPM procedures and practices on affordability of medicines

Affordability of medicines is defined as the ability of a patient or a health system to pay for the medicines they need. Key findings regarding the relationship between PPM practices and affordability are summarised in **Box 4** (detailed results shown below).

Box 4: Key findings: PPM practices and affordability

- Lower average proxy unit prices were generally observed in countries with **higher degrees of PPM** (i.e. using more centralised PPM, using a variety of practices, applying MEAT, and using supporting policies). This is consistent with previous studies which have generally found that joint procurement (e.g. through the use of a CPB) results in lower prices. Within study countries, savings from PPM compared to list prices or historic spending have been reported between 1% and 40-50%.
- While more mature (and centralised) PPM systems appear to be found in countries with lower unit prices, the **relationship between affordability and specific PPM characteristics is not straight-forward**: lower average proxy prices were observed in countries with lower numbers of procedures conducted by CPBs, procedures under framework agreements, and procedures using MEAT criteria to award contracts. However, use of CPBs, framework agreements and MEAT criteria are associated with countries with highly developed pharmaceutical pricing and reimbursement systems with generally higher price levels.
- Stakeholders from the **public sector generally consider PPM to positively impact affordability**. More advanced procurement practices, such as the use of framework agreements, DPS, and application of MEAT criteria were assessed as contributing to improved affordability in an online survey.
- Multiple-winner award procedures were considered to have a positive impact on affordability compared to single winner tenders, as assessed through stakeholder consultation. In particular, suppliers saw potential for a **negative impact** on affordability through some practices, such as **winner-takes-it-all**.
- Stakeholders also stressed the importance of adjusting the use of the different PPM procedures and techniques according to the type of product procured.
- There are possible **trade-offs between affordability and other policy objectives**, in particular greener manufacturing and transport and security of supply.

Source: Authors

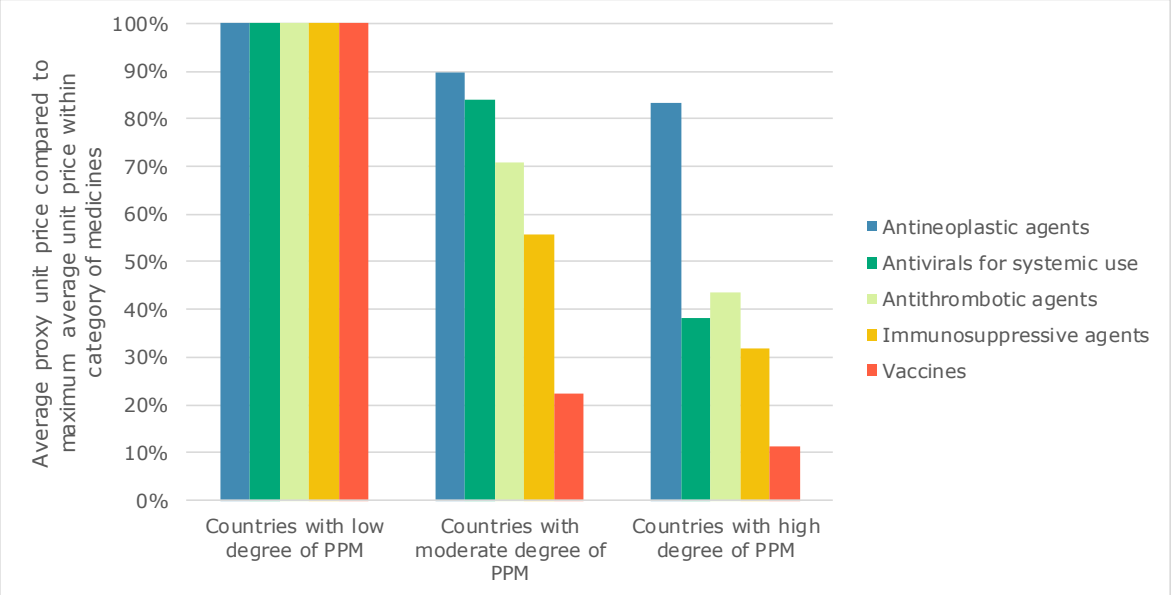
4.2.1. Relationship between centralised procurement and affordability

Pooling of purchase volumes and using PPM practices according to the type of medicine to be procured is expected to lead to reduced prices. Data analysed for this study shows that **lower unit prices were observed in countries with more mature PPM systems** (see **Figure 12**). Approximated unit prices were averaged across countries with low, moderate or high degree of PPM and are displayed in relation to the highest average proxy unit price across these three groups. This mode of presentation was selected to display all five tracer groups together which required accounting for differences in absolute unit prices across product groups. Across all five tracer product groups, the lowest average proxy unit prices were found in the group of countries with high degree of PPM (i.e. using more centralised PPM, using a variety of practices, applying MEAT, and using supporting policies). While the analysis does not account for

other factors that may impact on unit prices, it is in line with most studies assessing the relationship between PPM and affordability of medicines, which have tended to find savings associated with more centralised procurement [41].

Within individual countries, reported savings from centralised procurement ranged from marginal gains to substantial savings. For example, savings from centralised procurement for pharmaceutical and other consumables in hospitals in Croatia amounted to approximately 1% in 2019, whereas the CPBs for hospitals in Denmark and Norway reported average savings of 42.3% and 49%, respectively, compared to retail prices in 2021 [183, 184], and the MoH in Cyprus performing nationally centralised PPM reported savings of 50.7% in 2017 based on tender price compared to lowest wholesale prices (list prices) [18]. In England, the joint procurement of antiretroviral drugs for treatment of HIV/AIDS through joint therapeutic tenders by clinics in London saved 5.2% of annual expenditure on these drugs between 2011 and 2014 [185].

Figure 12: Relationship between degree of PPM and proxy unit prices



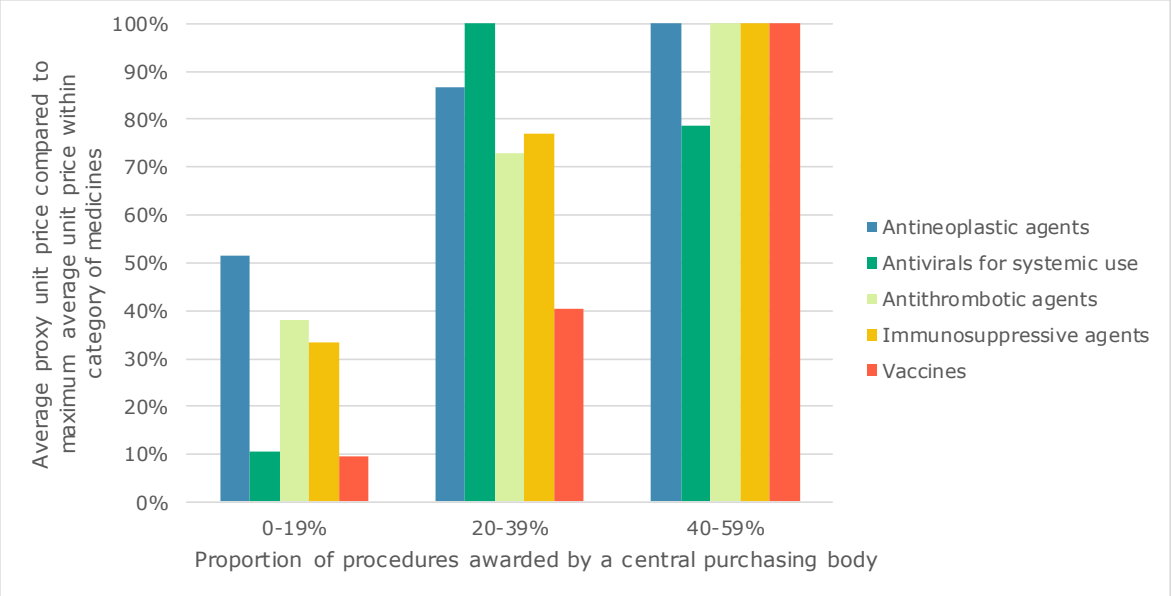
Note: Figure shows aggregated data for 2008-2021 for countries with low, moderate, or high degree of PPM and the average proxy unit price in those countries for five categories of medicines. The vertical axis shows the average approximated unit price for the five categories of medicines in relation to the maximum average approximated unit price within that category (e.g. for antineoplastic agents, the maximum average proxy unit price was observed in countries with low degree of PPM; for this category of medicines, the average proxy unit price in countries with moderate degree of PPM was 90% of that maximum average unit price, etc.). Proportional unit prices were used to avoid distorting the scale of the figure (unit prices varied approximately 200-fold across the different categories of medicines).

Source: Authors' analysis based on IQVIA [145] and PPM country fiches

While proxy unit prices were lowest in countries with more mature PPM systems according to the composite "degree of PPM" indicator, zooming in on specific characteristics of PPM practices reveals the complexities of the relationship between prices and PPM practices. **Countries with a higher share of procurement conducted by CPBs had higher approximated unit prices** (see **Figure 13**). The highest average approximated unit prices for product groups representing medicines with high shares of on-patent products (antineoplastic agents), products with analogue competition (antivirals for systemic use), products with biosimilar competition (immunosuppressive agents), and vaccines were observed in Denmark, the only country with 40-59% of procedures conducted by a CPB, followed by two countries with 20-39% of procedures conducted centrally at national level (Norway and Luxembourg; the latter only procures vaccines centrally). For products with high levels of generic competition (antithrombotic agents), the highest average approximated unit price was observed in

countries with 20-39% of procedures conducted by CPBs, followed by Denmark (40% or more of procedures conducted by a CPB).

Figure 13: Relationship between use of central purchasing body in a country and proxy unit prices



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures awarded by a central purchasing body (CPB) in a country and the average proxy unit price in that country for five categories of medicines. Countries were grouped according to the proportion of procedures awarded by a CPB for each of the five categories of medicines (horizontal axis; no country had more than 59% of procedures awarded by a CPB). Note that the 40-59% category comprises only one country: Denmark. The vertical axis shows the average approximated unit price for the five categories of medicines in relation to the maximum average approximated unit price within that category (e.g. for antineoplastic agents, the maximum average proxy unit price was observed in the country with 40-59% of procedures awarded by a CPB; for this category of medicines, the average proxy unit price in countries with 0-19% procedures awarded by a CPB was 51% of that maximum average unit price, etc.). Proportional unit prices were used to avoid distorting the scale of the figure (unit prices varied approximately 200-fold across the different categories of medicines).

Source: Authors' analysis based on IQVIA [145]and TED data [144]

The finding is at odds with general findings about the price impact of pooling purchase volumes (e.g. through joint procurement or through centralised procurement for multiple contracting authorities) and may be explained by generally higher price levels in countries that use CPBs extensively.[30] This highlights the methodological challenges of the ecological analysis described in **Chapter 2.5.3.3**.

There was limited evidence on **efficiency gains from PPM available from peer-reviewed studies** for most study countries. There is evidence from Italy that central procurement (through a CPB) leads to lower prices for medicines [33], as well as a decrease in health expenditure, although the contribution of pharmaceuticals to an overall decrease in spending may be small compared to other categories [21]. In Cyprus, the largest savings from CPM were observed for generic medicines (94.8% reduction in expenditure for the same volume of products), although savings were also made for branded medicines (33.4% reduction) [16]. Another Italian study found that tendering for biosimilars led to expected results, with prices decreasing as the number of competitors increases [23]. Similarly, a Norwegian study that explored the competition effect of biosimilar entry in centralised tenders for TNF-inhibitors found that in this group prices for biological medicines decreased as more competitors entered the market, and that the Norwegian strategy of promoting biosimilar uptake and thereby

[30] The three countries with the highest use of CPBs according to TED data (Denmark, Luxembourg, Norway) are also the three top-ranking countries in a comparison of pharmaceutical prices across European countries [186].

increased biosimilar market share was accompanied by lower average prices paid [30]. The potential for a centralised system for procuring hospital medicines and implementing system-wide therapeutic changes was also demonstrated through savings of more than 80% after a nation-wide switch from originator adalimumab to biosimilar in Denmark in 2018 [123].

In Spain, regional tenders for **outpatient, off-patent medicines** in Andalusia led to 27% savings on average in 2015, with the potential for savings of between EUR 160 million and 201 million for Andalusia and between EUR 1.08 billion and 1.35 billion for Spain if all procurement was done through such tenders [187]. A Swedish study investigated the tendering-like system of price bids for off-patent medicines in the outpatient setting and found evidence for savings in the short and long term, but at the cost of decreased competition over time [188]. In Germany, the tendering-like system of preferred suppliers for outpatient, off-patent medicines was found to be an effective tool to shift from originators to generic manufacturers [129]. Similarly, the price bidding system for off-patent, outpatient medicines in Hungary was found to have led to decreased expenditures for G-CSFs [177]. Statistics on the Dutch preference price policy published by the Dutch National Health Care Institute highlighted increasing savings for the health insurers due to this tendering policies, amounting to 352 million in 2009, 654 million in 2012 and 679 million in 2014 [116].

There was limited evidence on **procurement of vaccines**. In a comparison of procurement of human papillomavirus (HPV) vaccines across 15 European countries, prices paid for regionally procured vaccines were almost 9-fold higher compared to prices paid at the national level [159]. Other factors, such as purchase volume, number of offers, type of vaccine, and income level of the country were also associated with price differences.

4.2.2. Impact of PPM techniques and award criteria on affordability

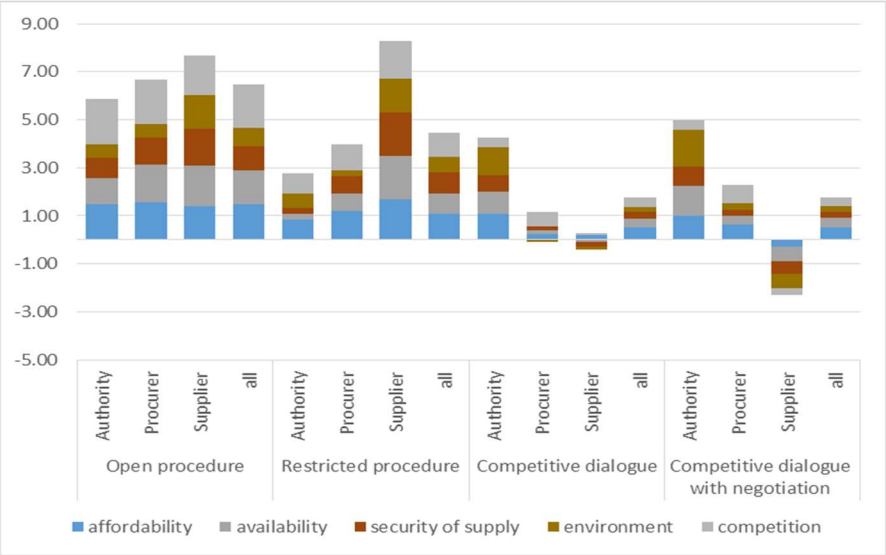
The potential for **PPM procedures and practices to impact on the affordability** of medicines was overall **assessed favourably by stakeholders** participating in an online survey (see **Figure 14**). The procedures included in the EU legislation (i.e. open procedure, restricted procedure, competitive dialogue, competitive procurement with negotiation) were overall considered to be contributing to affordability, although one stakeholder group (suppliers)[31] assessed the impact of competitive procurement with negotiation to be negative. An overall positive assessment of different PPM techniques was also provided in the online survey (see **Figure 15**). **Framework agreements and DPS** were considered to contribute to affordability by all stakeholders, while **electronic auctions and electronic dialogue** were regarded as contributing factors by procurers and authorities, and as barriers by suppliers. Suppliers considered that electronic tools (while rendering the procurement process more efficient) contribute to driving down prices, which can lead to a negative price spiral that – in the view of suppliers – hinders competition.

However, stakeholders also stressed the **importance of using the right procedure and technique for the right product**. Indeed, a more **differentiated picture** emerges when analysing proxy unit prices in relation to the use of **framework agreements** (see **Figure 16**). Higher proxy unit prices were observed in countries with moderate use of framework agreements (20-39% of procedures) for antivirals for systemic use, antithrombotic agents, and vaccines (i.e. in categories where competition can be expected), but for antineoplastic and immunosuppressive agents (both falling into the larger category of antineoplastic and immunomodulating agents) were highest in countries with 60-79% procedures under framework agreements, respectively. A common pattern across all groups of products analysed was that the **lowest proxy unit**

[31] Suppliers participating in the online survey represented the generic medicines industry (representatives from research-based industry decided not to participate in the survey).

prices were observed in countries with low use of framework agreements (less than 20%). Both the use of framework agreements and price levels may be impacted by various characteristics of the countries and health systems in place, therefore no causal link between the two can be established through this analysis.

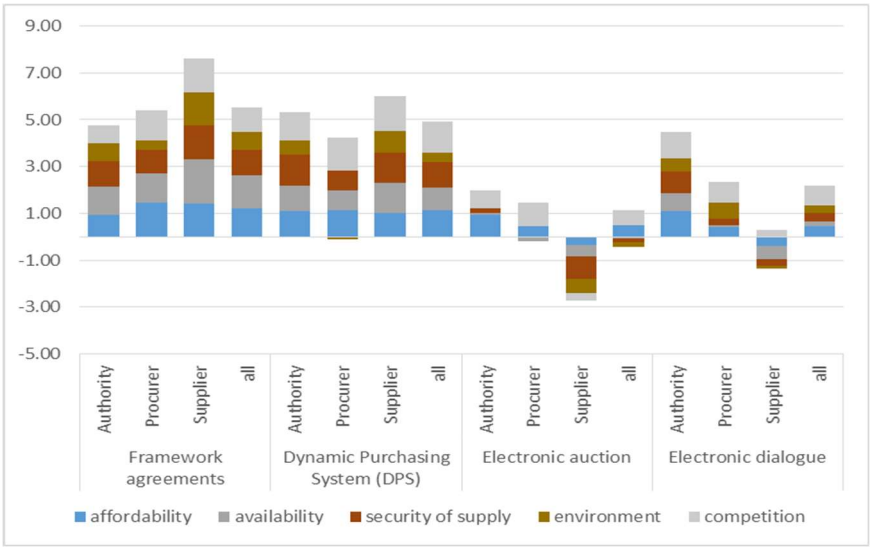
Figure 14: Assessment of potential contribution of PPM procedures to different policy objectives, per stakeholder group



Note: In "all" stakeholders, patients (1 participant), providers non procuring (1 participant) and research (3 participants) are included.

Source: Authors based on online survey

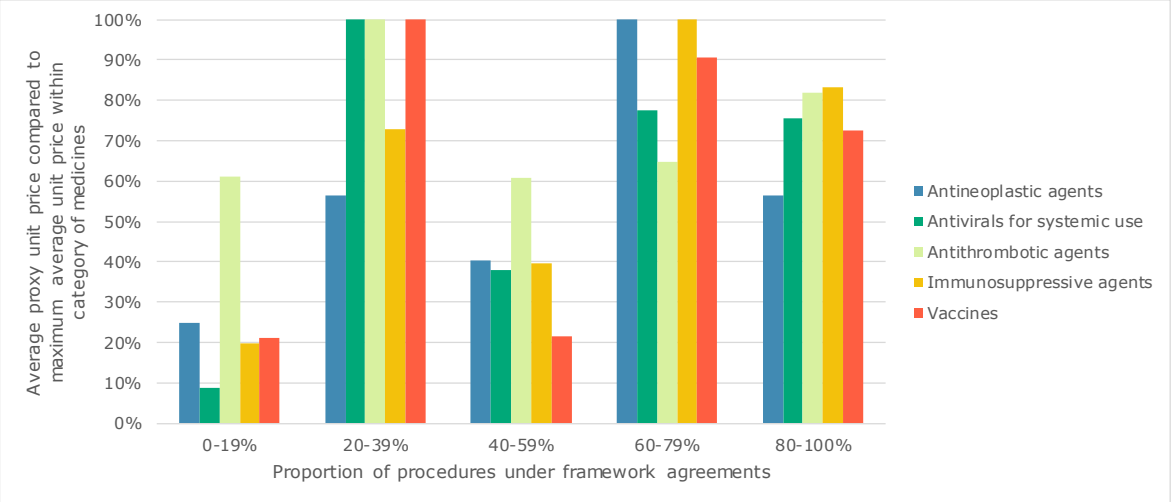
Figure 15: Assessment of potential contribution of PPM techniques to different policy objectives, per stakeholder group



Note: In "all" stakeholders, patients (1 participant), providers non procuring (1 participant) and research (3 participants) are included.

Source: Authors based on online survey

Figure 16: Relationship between use of framework agreements in a country and approximated unit prices



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures conducted under framework agreements in a country and the average proxy unit price in that country for five categories of medicines. Countries were grouped according to the proportion of procedures under framework agreements for each of the five categories of medicines (horizontal axis). The vertical axis shows the average approximated unit price for the five categories of medicines in relation to the maximum average unit price within that category (e.g. for antineoplastic agents, the maximum average proxy unit price was observed in countries with 60-79% of procedures under framework agreements; for this category of medicines, the average unit price in countries with 0-19% procedures under framework agreements was 25% of that maximum average unit price, etc.). Proportional unit prices were used to avoid distorting the scale of the figure (unit prices varied approximately 200-fold across the different categories of medicines).

Source: Authors' analysis based on IQVIA [145]and TED data [144]

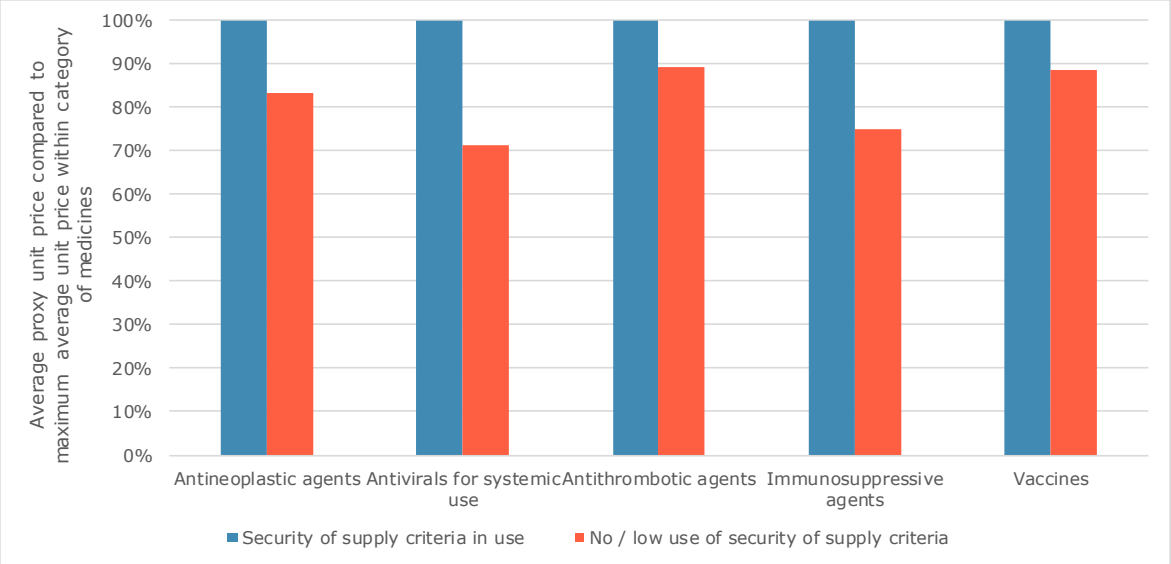
Affordability may not be the only policy objective pursued by procurement. During interviews and workshops, stakeholders have generally stressed that **trade-offs** may need to be made between achieving low prices and other objectives, such as security of supply, promoting green manufacturing and transport, and maintaining sustainable levels of competition in the market. Indeed, **Figure 17** and **Figure 18** suggest that countries that frequently apply **security of supply or environmental criteria** face higher proxy unit prices for medicines. Across all tracer groups, approximated average list prices were between 5% and 29% higher in countries that apply these non-price criteria compared to countries that do not or do not frequently apply the criteria. The analysis did not take into consideration other factors that may impact on prices and therefore only represents an exploratory assessment of the relationship between award criteria and price levels at the aggregate (i.e. country-group) level. Individual countries may have different experiences: for example, Denmark reported that pilot projects applying environmental criteria did not lead to higher unit prices.

Considerations other than the affordability of medicines can be taken into account through the use of advanced award criteria, e.g. through the use of **MEAT criteria**. However, **Figure 19** shows that proxy unit prices tended to be lower in countries that extensively use MEAT criteria, specifically for antineoplastic agents, immunosuppressive agents, and vaccines), although for one group of medicines (antivirals for systemic use), the highest average proxy unit prices were observed in countries with very high use of MEAT. Coincidentally, and somewhat in contrast to qualitative statements provided during interviews and workshops, in the online stakeholder survey, participants ranked MEAT as more important for the policy objective of affordability than any other award criteria, including price only (see **Figure 20**).

These potential trade-offs, in particular in relation to security of supply and maintaining a competitive market, may also be addressed by awarding contracts to multiple winners.

Winner-takes-it-all procedures are seen particularly critically by suppliers (see **Figure 21**).

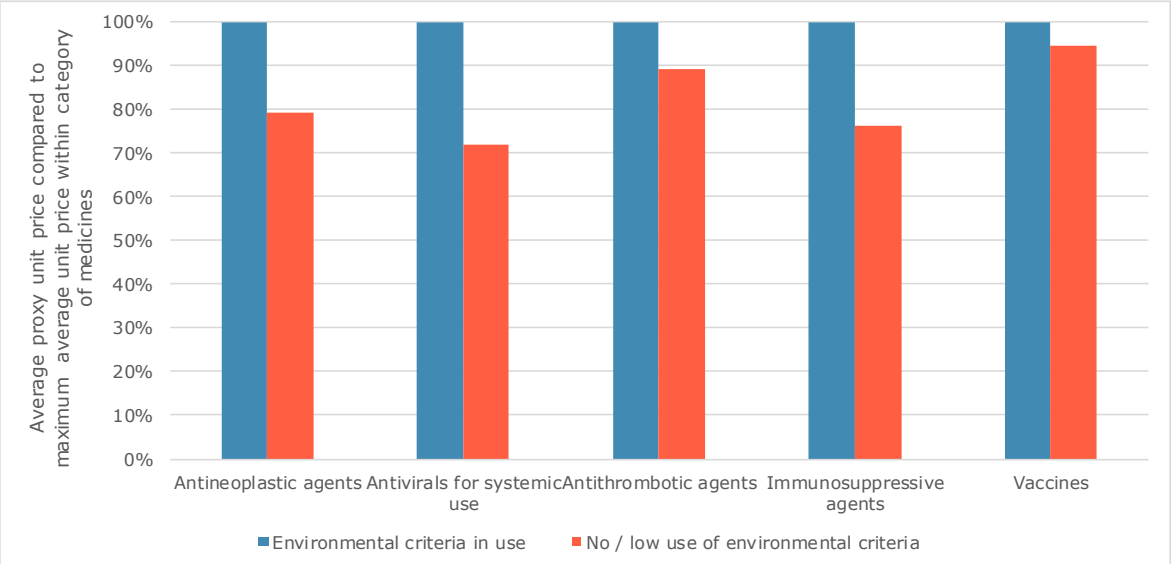
Figure 17: Relationship between use of security of supply criteria and approximated unit prices



Note: Figure shows aggregated data for 2008-2021 for overall application of security of supply criteria in a country and average proxy unit price in that country for five categories of medicines. The vertical axis shows the average approximated unit price for the five categories of medicines in relation to the maximum average unit price within that category (e.g. for antineoplastic agents, the maximum average proxy unit price was observed in countries that regularly use security of supply criteria; for this category of medicines, the average unit price in countries that do not or do not frequently use such criteria was 83% of that maximum average unit price, etc.).

Source: Authors' analysis based on IQVIA [145] and PPM country fiches

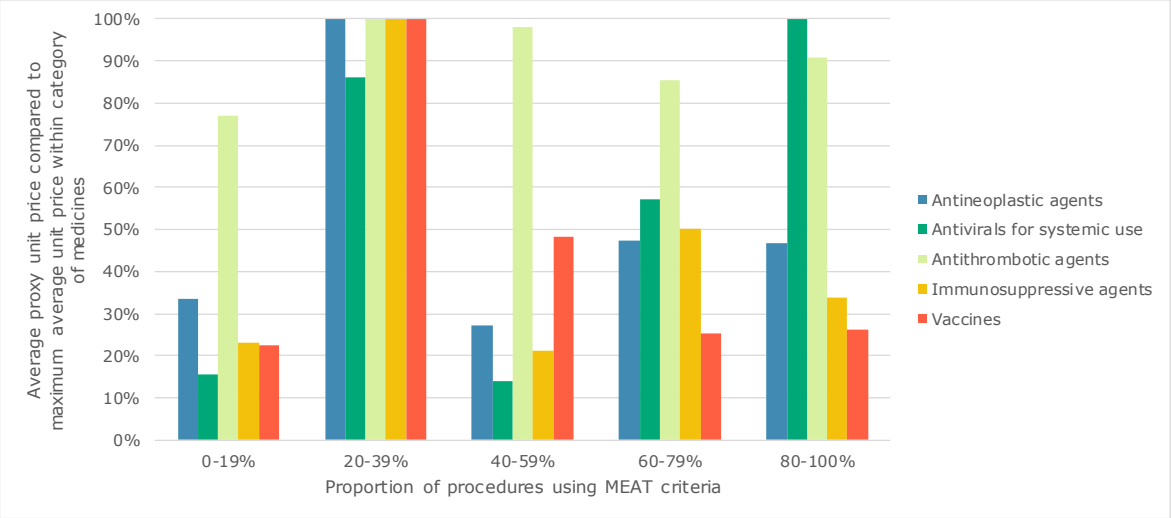
Figure 18: Relationship between use of environmental criteria and approximated unit prices



Note: Figure shows aggregated data for 2008-2021 for overall application of environmental criteria in a country and average proxy unit price in that country for five categories of medicines.

Source: Authors' analysis based on IQVIA [145] and PPM country fiches

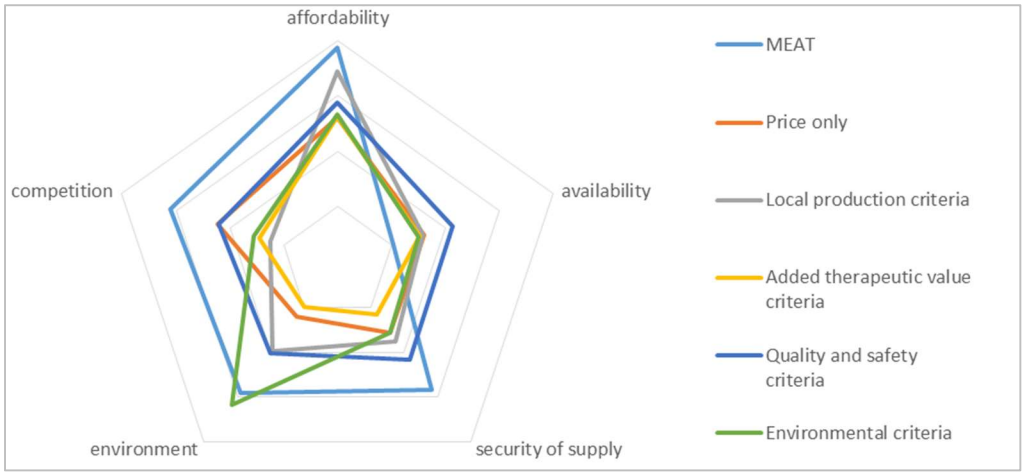
Figure 19: Relationship between use of MEAT criteria in a country and approximated unit prices



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures in a country using MEAT criteria to award contracts and the average proxy unit price in that country for five categories of medicines. Countries were grouped according to the proportion of procedures using MEAT criteria for each of the five categories of medicines (horizontal axis). The vertical axis shows the average approximated unit price for the five categories of medicines in relation to the maximum average unit price within that category (e.g. for antineoplastic agents, the maximum average proxy unit price was observed in countries with 20-30% of procedures using MEAT criteria; for this category of medicines, the average unit price in countries with 0-10% procedures under framework agreements was 34% of that maximum average unit price, etc.). Proportional unit prices were used to avoid distorting the scale of the figure (unit prices varied approximately 200-fold across the different categories of medicines).

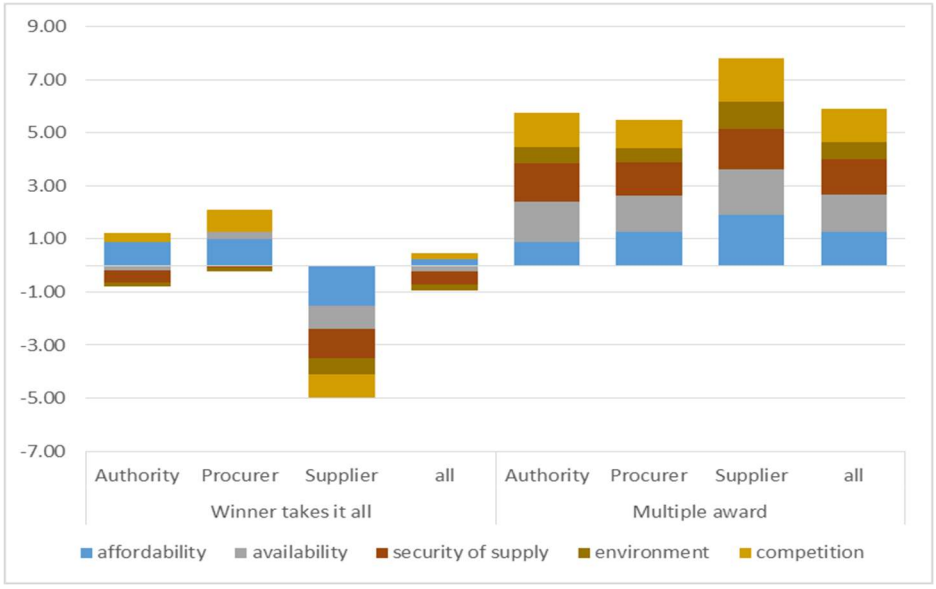
Source: Authors' analysis based on IQVIA [145]and TED data [144]

Figure 20: Ranking of importance of PPM award criteria by policy objective



Source: Authors based on online survey

Figure 21: Assessment of potential contribution of PPM award criteria to different policy objectives, per stakeholder group



Note: In "all" stakeholders, patients (1 participant), providers non procuring (1 participant) and research (3 participants) are included.

Source: Authors based on online survey

4.2.3. Impact of PPM procedures and practices on availability of medicines

Availability of medicines is a key objective for PPM. Availability means that a product is available to patients, which typically involves a valid marketing authorisation and that the product has been launched and is still being marketed in a country, and is covered by a health insurance /national health system, or is available to be purchased by individuals. Key findings regarding the relationship between PPM practices and availability of medicines are summarised in **Box 5** (detailed results shown below).

Box 5: Key findings: PPM practices and availability of medicines

- **Joint procurement** is seen as a tool to improve availability of medicines, in particular for smaller markets that may otherwise not be prioritised by suppliers.
- **Suppliers are critical** of procurement practices that, in their view, reduce competition and subsequently availability of medicines, including joint procurement, awarding single winners, and using price as sole award criterion.
- Stakeholders generally agreed that **awarding multiple winners and using additional criteria** other than price contributes to availability of medicines.
- Globally, studies have generally found joint procurement to contribute to availability of medicines, although studies quantifying the impact of procurement practices on availability from European countries are lacking.

Source: Authors

Potential impacts of PPM on availability have been documented in the literature, although mostly focusing on LMICs. Overall, studies found that pooling volumes through **joint procurement was associated with improved availability of essential medicines**, although potential risks associated with awarding single winners without properly vetting them were also highlighted [14, 41]. There is comparatively little quantitative evidence on availability of medicines in relation to procurement practices in European countries.

Authorities and public institutions participating in workshops for this study considered **joint procurement** as a useful tool to help make small markets more attractive for suppliers, and therefore contributing to availability of medicines that would otherwise

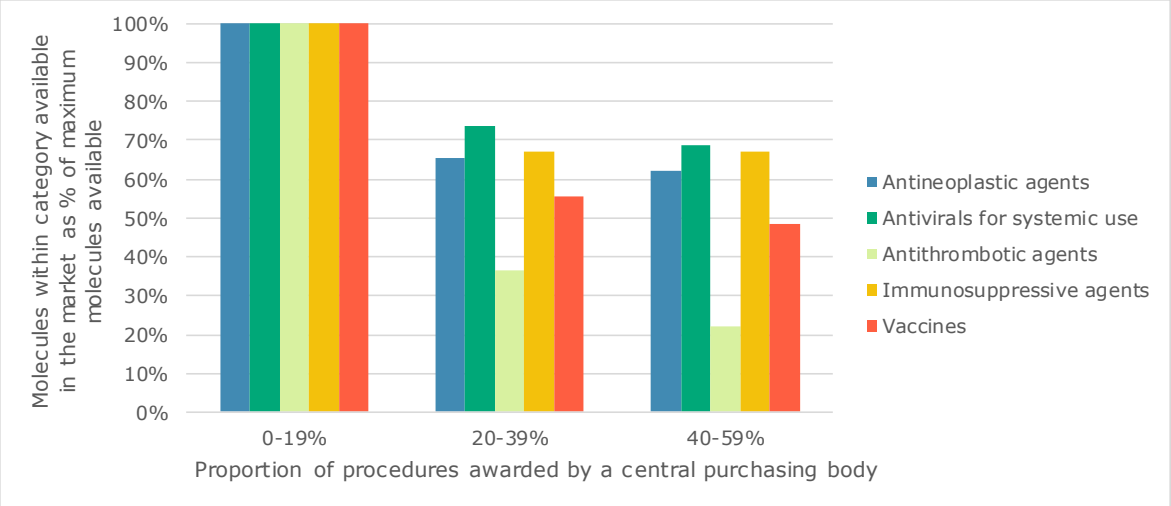
not be supplied. Rather than seeing it as a tool to drive down prices, some procurers consider joint procurement as a key instrument to improve availability of medicines. An example is Iceland, which benefitted from cross-country joint procurement with Denmark and Norway (joint Nordic tenders) to increase the number of medicines available to patients [165]. Suppliers (and some hospital pharmacists), on the other hand, hold a more critical view of joint procurement (intra- or cross-country), warning about the risk of reduced competition and an associated threat to long-term availability of medicines.

Awarding multiple winners (when possible, i.e. for products with competition) was identified as a key PPM technique contributing to availability of medicines in European countries by stakeholders participating in online workshops for this study. This technique was also considered as beneficial to availability by all stakeholders participating in the online survey (see **Figure 21**). Awarding a single winner, on the other hand, was considered a potential barrier to availability.

In terms of award criteria, stakeholders (mainly, but not exclusively, from the supplier side) voiced concerns that the use of **price as sole criterion** presents a threat to availability of medicines in the long term, as suppliers may leave the market. In the online survey, the potential contribution of price as an award criterion towards the policy objective of availability was also most often top-ranked compared to other award criteria (see **Figure 20**).

For the study countries, an inverse relationship between use of a CPB in a country and the availability of medicines was observed (see **Figure 22**). Countries with low use of CPBs recorded sales for the highest **number of individual molecules** within each of the five tracer groups. A similar picture emerged when analysing the use of framework agreements, although for antivirals for systemic use, the highest number of individual molecules was sold in countries with moderate – not low – use of framework agreements (data not shown). There was some variation in availability of individual molecules and the use of MEAT criteria, overall suggesting that fewer individual molecules were sold in countries with higher use of MEAT (see **Figure 23**).

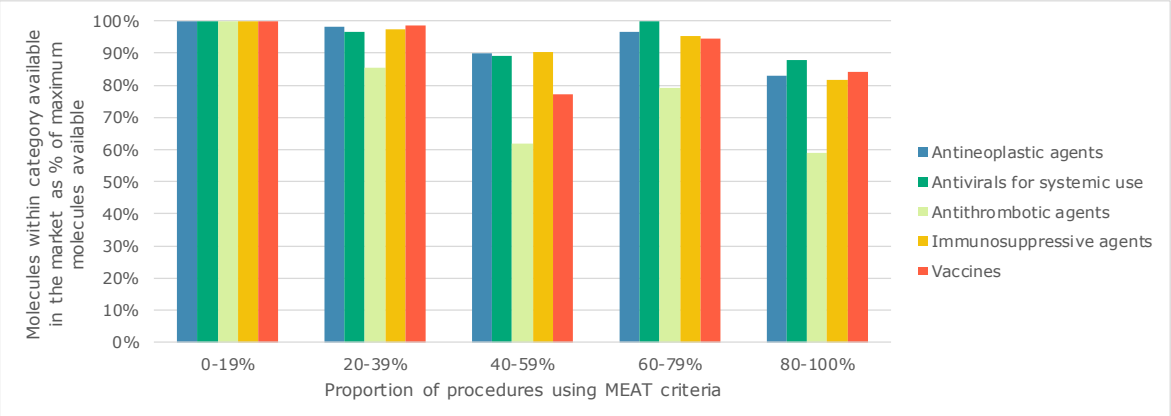
Figure 22: Relationship between use of a central purchasing body and number of molecules within a group of medicines available in a country



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures awarded through a CPB and the number of individual molecules in that country for five categories of medicines. Countries were grouped according to the proportion of procedures awarded by a CPB for each of the five categories of medicines (horizontal axis). The vertical axis shows the number of molecules within each of the five categories of medicines in relation to the maximum number of molecules within that category (e.g. for antithrombotic agents, the maximum number of molecules was observed in countries with 0-19% of procedures using MEAT criteria; for this category of medicines, in countries with 20-39% procedures under framework agreements, only 65% of that maximum number of molecules was available, etc.).

Source: Authors' analysis based on IQVIA [145]and TED data [144]

Figure 23: Relationship between use of MEAT criteria and number of molecules within a group of medicines available in a country



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures in a country using MEAT criteria to award contracts and the number of individual molecules in that country for five categories of medicines. Countries were grouped according to the proportion of procedures using MEAT criteria for each of the five categories of medicines (horizontal axis). The vertical axis shows the number of molecules within each of the five categories of medicines in relation to the maximum number of molecules within that category (e.g. for antithrombotic agents, the maximum number of molecules was observed in countries with 0-19% of procedures using MEAT criteria; for this category of medicines, in countries with 20-39% procedures under framework agreements, only 98% of that maximum number of molecules was available, etc.).

Source: Authors' analysis based on IQVIA [145]and TED data [144]

4.3. Impact of PPM procedures and practices on security of supply

Key findings regarding the relationship between PPM practices and security of supply, defined as the avoidance of or reduction in disruption and shortages in the supply of medicines, are summarised in **Box 6** (detailed results shown below).

Box 6: Key findings: PPM practices and security of supply

- **There may be trade-off between security of supply and other policy objectives**. Maintaining a competitive market with sufficient number of suppliers may reduce the risk of medicines shortages. Stakeholders agreed that **multi-award contracts** contribute to security of supply.
- **Joint procurement** is seen by procurers as a tool to ensure security of supply. Industry representatives, on the other hand, consider joint procurement a barrier to security of supply, in particular when resulting in single winners being awarded.
- **Empirical data** on the impact of PPM on security of supply **are lacking**. Anecdotal reports have linked shortages to awarding single winners.

Source: Authors

There may be trade-offs between security of supply and other policy objectives. As for other policy objectives, stakeholders from the industry as well as others highlight the importance of maintaining a competitive market with sufficient number of suppliers to ensure security of supply in the long term (see Annex 5). A possible reduction in the number of suppliers, possibly due to contracts being consistently awarded to single suppliers and price dominating as award criterion, may carry an increased risk of supply shortages. **Diversifying and having multiple supply sources** in PPM was also recommended as one of the measures to address supply shortages in an EC-commissioned study [156].

Nevertheless, empirically, the **impact of PPM practices on shortages is not clear** as most evidence is restricted to anecdotal reports. For example, shortages have been reported in relation to the procurement of bevacizumab in Italy, where a single supplier was awarded the contract for multiple regions [61]. In the outpatient setting, tendering-like systems exist in some European countries and have been the subject of quantitative studies. For Sweden, the decrease in prices associated with a tendering-like set-up was shown to result in a reduced number of suppliers in the long term [188]. However, shortages were not investigated by the study. In other countries with similar systems, the experience with respect to shortages has been mixed: in Belgium, issues with tender winners not being able to supply required medicines contributed to abandoning tendering in the outpatient sector, and shortages have also been reported in the Netherlands (for both medicines subject to tendering and others), while no supply issues have been reported in Denmark [116]. Related to shortages, analyses found that the Dutch preference price policy highlighted that no suppliers left the market due to this policy [116], while a Swedish study found that fewer suppliers were left in the market in the long term [188].

In the online survey conducted as part of this study, stakeholders assessed potential impacts of PPM practices (see Annex 7 for details). **MEAT and quality/safety were the top-ranked criteria** in terms of their contribution to security of supply (**Figure 20**). Local production was not considered a top priority for ensuring security of supply. There was strong preference among both suppliers and procurers as well as authorities that **multi-award contracts** were best suited to achieve security of supply compared to single-winner awards. In addition, and somewhat related to awarding multiple winners, most participants considered **framework agreements** as contributing to security of supply.

In workshops and reviews of country experiences, **joint procurement emerged as an important tool to address medicines shortages**. Mitigating supply issues for older medicines is seen as an important purpose of cross-country joint procurement collaborations (possibly more so than achieving lower prices), including for the joint procurement of vaccines by the Baltic countries (Baltic Procurement Initiative, see **Chapter 6.2.1.1**) and the joint Nordic tenders (see **Chapter 6.2.1.2**). The Nordic Pharmaceutical Forum initiated joint Nordic tenders for Denmark, Norway, and Iceland in order to overcome restrictions of the comparatively small markets of the individual countries. The experience of the two Nordic tenders conducted so far has been positive, with high participation rates in calls and beneficial prices despite the introduction of

some potentially challenging environmental criteria [165, 189]. The three Baltic countries (Estonia, Latvia and Lithuania) have been collaborating for nearly a decade in the cross-country procurement of vaccines [10, 117]. Potential benefits of joint procurement in addressing medicines shortages are not limited to small countries: in an OECD report on shortages, France was reported to consider international collaborations including joint procurement as strategic pillar to address medicines shortages [149].

Procurers tended not to be directly involved in measures to **mitigate shortages**. Instead, national medicines agencies or other institutions are responsible for monitoring shortages. Procurers may then work with these institutions to address needs arising from shortages. **Collaboration between public institutions** is therefore a key success factor for ensuring security of supply. For example, the Italian body responsible for regionally centralised procurement, Consip, runs a DPS. This is seen as useful infrastructure for efficient procurement. Consip relies on the shortages monitoring system established by the Italian medicines agency, AIFA, to identify possible shortages that need to be address through additional procedures launched through the DPS. Similarly, in Estonia, rapid procurement responses to address potential shortages by the CPB at the Estonian Health Insurance Fund (EHIF) are enabled by information shared between public institutions.

To the best of the study team's knowledge, the impact of PPM policies on medicines shortages has **not been quantitatively assessed in the literature**. This may be related to challenges with consistently measuring and comparing medicines shortages across countries, which have previously been documented [149, 190]. In this study, possible shortages in the study countries based on sales data could only be investigated on a yearly basis (potentially missing shorter periods of products not being available). At this level, no noticeable variation in availability of sales data throughout the study period were detected with respect to PPM techniques and award criteria sued. Products, when grouped at ATC-4 level, were mostly consistently sold across the period 2008-2021 (with the exception of some minor variation for antineoplastic agents), although the three countries with the highest use of nationally centralised PPM (Denmark, Luxembourg, Norway) had larger shares of individual products not being sold in the market compared to other countries.

4.4. Impact of PPM procedures and practices on the environment

Key findings regarding the relationship between PPM practices and the environment are summarised in **Box 7** (detailed results shown below).

Box 7: Key findings: PPM practices and affordability

- The **impact of PPM practices on environmental outcomes is unclear**, as environmental criteria are only starting to be used.
- Including environmental criteria is likely to have the biggest contribution towards sustainable and green manufacturing and supply of medicines, according to stakeholders. Leveraging purchasing power may help implement environmental standards.
- A **trade-off between affordability and use of environmental criteria** is likely. However, experience from the joint Nordic tenders suggests that suppliers are able to fulfil environmental criteria and that price differences are not related to environmental standards.

Source: Authors

Environmental award criteria are only starting to be used in PPM (see **Chapter 3.4**). There is therefore no evidence available on the impact of "green" practices in PPM on environmental outcomes.

In this study, the potential for PPM practices and procedures to impact on the environment was assessed through the online survey since no suitable indicators could be identified to evaluate the actual impact of PPM on the environment. The inclusion of

environmental criteria for awarding contracts was considered most important for achieving environmental aims, but environmental criteria were considered least important for achieving any of the other policy objectives (**Figure 20**). Overall, there was **uncertainty about the possible contribution of specific PPM procedures and techniques** towards the policy objective of sustainable and green manufacturing and supply of medicines. Awarding a single winner may help achieve environmental goals by leveraging the incentive of winning a large contract for the entire market, although possible drawbacks of single-winner procedures (such as risks to the supply of medicines) should be considered.

Stakeholders have pointed out that – similar to security of supply – procurers may have to face a **trade-off** between different policy objectives, namely that the use of environmental criteria may lead to higher prices and/or lower levels of competition. While environment may play an increasingly important role in procurement, addressing patient needs is considered the priority. At the aggregate level, use of environmental criteria appears to be associated with higher approximated unit prices (see **Figure 18**). Countries that frequently use environmental criteria had overall higher proxy unit prices compared to countries that do not or do not frequently use them, with differences of between 17% (for antithrombotic agents) and 79% (for antivirals for systemic use) for average price levels. However, this analysis only considered general use of environmental criteria at the country-level, rather than their use for specific products. **Experience from Scandinavian countries** suggests that the introduction of environmental criteria for tenders conducted by the Danish CPB for hospitals, Amgros, and for joint Nordic tenders by Denmark, Iceland, and Norway, has not negatively impacted on the number of bids submitted, and that differences in prices between bidders were not driven by these criteria [165].

4.5. Impact of PPM procedures and practices on competition

Key findings regarding the relationship between PPM practices and competition in the market are summarised in **Box 8** (detailed results shown below).

Box 8: Key findings: PPM practices and competition

- Creating competition is an **inherent aim of public procurement**. According to stakeholder assessments, PPM processes contributing to competition in the long run include **multi-winner contracts and using MEAT criteria**.
- Countries frequently using MEAT criteria attracted higher number of bids compared to countries that do use MEAT criteria less frequently.
- Competition may be fostered by **pooling purchase volumes** through joint procurement, in particular for markets that were previously underserved by suppliers.

Source: Authors

Tendering, by design, is expected to increase competition. By inviting bids from interested suppliers, incentives are created for economic operators to join the market. The challenge, then, is how to maintain levels of competition. During stakeholder consultations (including in workshops, interviews, and the online survey), industry representatives stressed the importance of several PPM practices to maintain a competitive market, i.e. to incentivise suppliers to remain in the market. These practices include awarding **multi-winner contracts** and using **additional criteria rather than price alone**. Hospital pharmacists also stressed potential risks to maintaining competition in the long term if tendering is based on the lowest price alone. These assessments were generally shared by all stakeholders participating in the online survey: MEAT was the top-ranked criterion contributing to competition, and multi-award contracts were assessed as contributing most towards competition (see **Figure 20, Figure 21** and Annex 7). However, while procurers and authorities also saw positive contributions from single-award contracts (although to a lesser extent than multi-winner

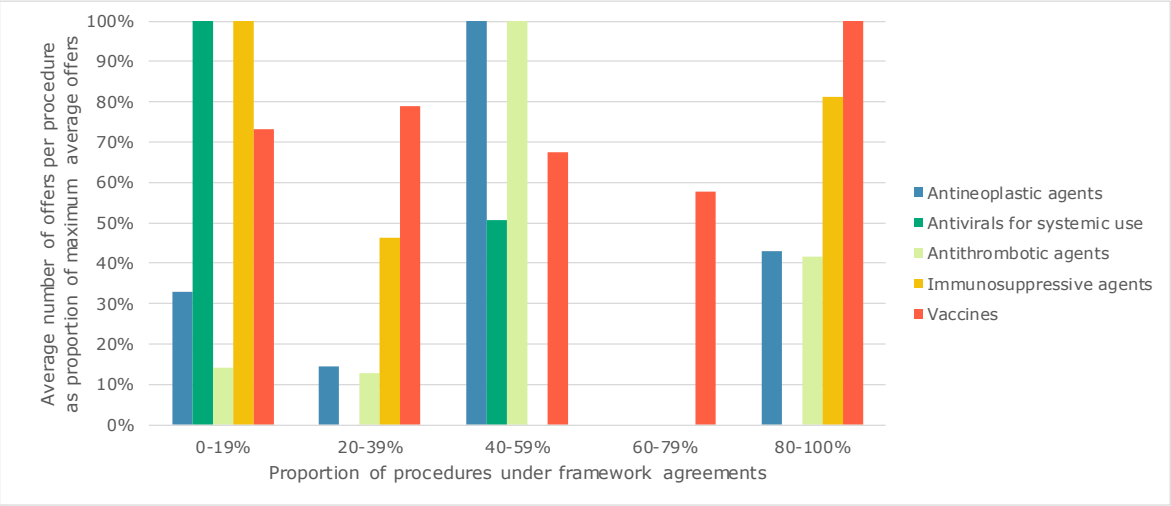
awards), these were seen as barriers to a competitive market by industry representatives.

Given the larger purchase volumes involved and potential focalisation on single suppliers, **joint procurement** is seen as detrimental to competition in the market by industry representatives as well as some procurers at facility level. Compared to procurement conducted at lower levels (e.g. by individual facilities), joint procurement may present fewer opportunities for suppliers to submit bids which may result in some suppliers leaving the market.

However, centralisation may also foster competition. In Italy, the DPS run by Consip as a tool to make procurement for the regions more efficient, allows new suppliers to join the market with relatively low friction cost (see Annex 5). In other countries, joint procurement resulted in the market becoming **more attractive to suppliers** and incentivising them to enter these markets in the first place. The experience of Iceland in joining the joint Nordic tenders demonstrated how a small country can benefit from the increased competition associated with suppliers competing for contracts [165].

Analysis of the use of centralised procurement and levels of competition was not instructive due to lack of relevant data recorded in TED. However, other PPM practices reveal some patterns in relation to the number of bids submitted for procedures. Firstly, different to what may be expected on the basis of framework agreements allowing more companies to supply products, **competition levels and the use of framework agreements** do not appear to follow a systematic trend (see **Figure 24**). While for some groups of medicines, competition levels were highest in countries with low levels of framework agreements (antivirals for systemic use, immunosuppressive agents), they were low in these countries and higher in countries with moderate use of framework agreements for other groups of medicines (antineoplastic agents, antithrombotic agents). Secondly, **competition levels were highest in countries with high use of MEAT criteria** across all groups of medicines (other than vaccines, where number of bids did not vary notably, see **Figure 25**).

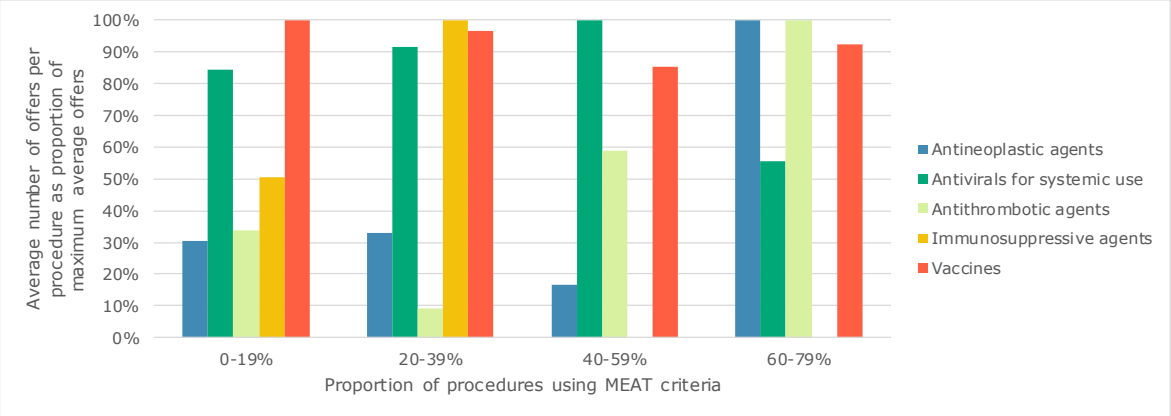
Figure 24: Relationship between use of framework agreements and competition



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures in a country run under framework agreements and the number of bids submitted for procedures for five categories of medicines. Countries were grouped according to the proportion of procedures under framework agreements for each of the five categories of medicines (horizontal axis). The vertical axis shows the average number of bids within each of the five categories of medicines in relation to the maximum average number of bids within that category.

Source: Authors' analysis based on TED data [144]

Figure 25: Relationship between use of MEAT criteria and competition



Note: Figure shows aggregated data for 2008-2021 for the proportion of procedures in a country using MEAT criteria to award contracts and the number of bids submitted for procedures for five categories of medicines. Countries were grouped according to the proportion of procedures using MEAT criteria for each of the five categories of medicines (horizontal axis). The vertical axis shows the average number of bids within each of the five categories of medicines in relation to the maximum average number of bids within that category.

Source: Authors' analysis based on TED data [144]

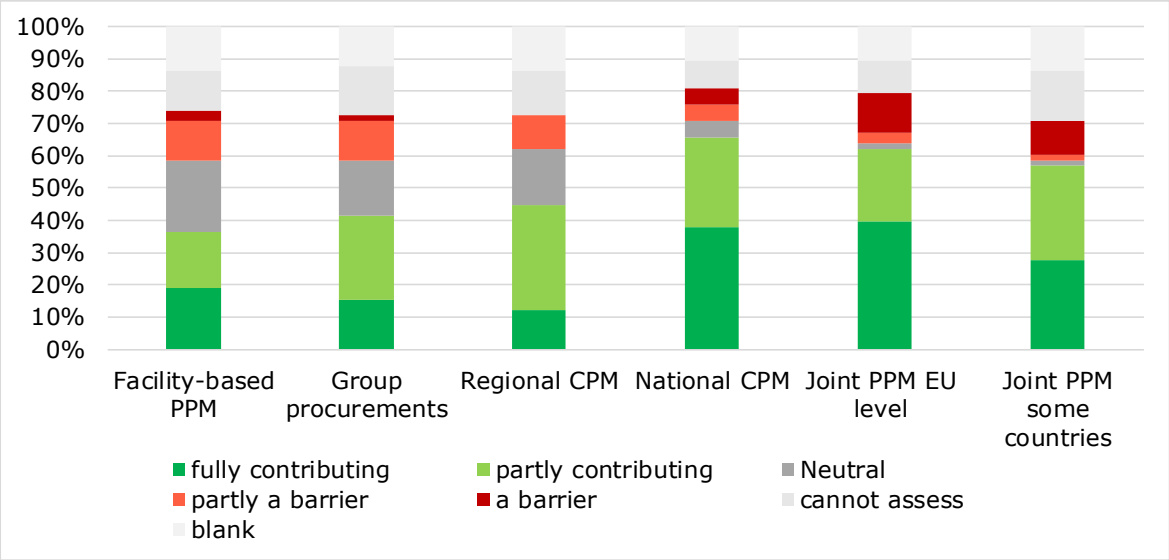
4.6. Impact of PPM procedures and practices on crisis preparedness

Preparedness for health crises and emergencies is a pillar of the European Health Union[32]. It requires anticipation of potential threats and appropriate measures in place to handle them, including procurement of required medicines.

Stakeholders considered well-applied PPM as important tool for crisis preparedness overall. In the study's online survey, participants most often selected vaccines as the category of medicines that would benefit most from crisis preparedness through PPM (see Annex 7 for details). There was variation in the assessment of different forms of PPM for crisis preparedness (see **Figure 26**). **Joint procurement forms at national or cross-national level** (including joint procurement at EU-level) were most favourably assessed overall. This assessment was shared by authorities, most procurers, and some suppliers. However, other suppliers (and individual procurers) considered centralised PPM, and in particular joint PPM at EU or at other cross-national level as detrimental to crisis preparedness.

[32] https://health.ec.europa.eu/health-security-and-infectious-diseases/overview_en

Figure 26: Stakeholder assessment of the level of PPM most likely to contribute to preparedness



Source: Authors based on online survey

Learnings from the joint procurement of COVID-19 vaccines by the EU and the Joint Procurement Agreement are described in **Chapter 6.2.2.**

No quantitative analysis of the relationship between PPM processes and crisis preparedness was conducted since no suitable indicator for this policy objective was identified.

4.7. Issues with data availability to assess impact of PPM

Across study countries, **data availability on savings made from public procurement was comparatively poor**. While procurers may compare prices achieved by their organisation over time to monitor performance, these data are often not made publicly available. As a consequence, few peer-reviewed studies analysing savings made from public procurement were identified by the study team. An example of an organisation that consistently make savings data available on its website is Amgros, the Danish CPB for hospitals. However, even Amgros only publishes aggregate savings and does not provide details on savings achieved in individual tenders.

Monitoring of savings at national level is often hampered by poor data availability. In the hospital setting, individual facilities may regularly analyse their expenditure and potential savings made through optimised PPM, but this information is not shared with other facilities or authorities at the national level. For example, in Belgium, monitoring of prices and savings analysis are done systematically, but individually for each hospital. Countries with centralised procurement system tend to have systematic monitoring of savings in place (e.g. Cyprus, where savings of centrally tendered products compared to list prices are published regularly).

Some of these limitations may be addressed by using routine data on procurement, as recorded in the TED data set. However, the study team encountered challenges in working with TED data, as described in more detail in **Chapter 2.5.1.2.** Briefly, the key challenge relates to the **lack of granularity** in this routine data set which hinders product-level analysis that would be required to better understand the use of specific

procurement practices and their potential impacts.[33] Importantly, lack of granularity about individual products procured creates a challenge for linking TED to other data sets that could provide important insights, e.g. IQVIA data about pharmaceutical sales and volumes. Granular data about individual products being procured may be extracted through data mining processes from the contract notices. However, this is a resource-intensive process that requires identifying relevant product names, potentially in different languages used across the EU, and expert knowledge for processing these data. The lack of coded information about products procured therefore presents an important challenge for routinely using TED data to generate insights into procurement, e.g. for monitoring and benchmarking procurement processes against other countries. In addition to the granularity, there may be issues with data reported in TED not being accurate, requiring data cleaning and verifying to use for analysis.

[33] The suspected main reason for lack of coded data about individual products procured is that the same procedure is used for procuring several products. In these cases, the person responsible for entering data into TED may use the general code for pharmaceuticals rather than entering individual codes for the different products.

5. PHIS HOSPITAL PROCUREMENT UPDATE

The sixth specific objective of the study was to collate and analyse procurement of medicines in the hospital setting. Specifically, the study aimed to update procurement-related aspects of the 2010 PHIS Hospital Pharma report [140] (see below). This work addressed the following study questions: what are current PPM practices in hospitals, and how could they be optimised?

5.1. Background on hospital procurement

Public procurement of medicines is a policy that is of particular relevance for the inpatient sector since, in European countries, most procurements are conducted with the aim to ensure supply to hospitals [6, 118]. Given its importance, hospital procurement is a focus area in this study.

Hospital procurement has some **specificities**. There are different institutional frameworks (for different types of medicines), ranging from individual procurements conducted by hospitals (hospital pharmacy in collaboration with procurement units) at facility level to voluntary collaboration in the form of group purchasing and centralised procurement at regional level (sub-national) or at national level. Furthermore, some medicines used in hospitals are subject to different (stricter) requirements in terms of safety, storage and use compared to outpatient medicines. From the perspective of hospital pharmacists, who are usually strongly involved in procurement, the procurement activities are aimed to contribute to quality assurance, security of supply and cost-containment [189]. The last decade has seen the launch of several new medicines with high price tags that have been a driver for public pharmaceutical expenditure, and some of these new therapies are exclusively or predominantly applied in hospitals [133, 191, 192].

5.1.1. Update of PHIS Hospital report

This chapter presents an update of procurement-related aspects of the PHIS Hospital Pharma Report, published in 2010 [140]. The 2010 report was produced as part of the **Pharmaceutical Health Information System** (**PHIS**) **project**, commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Federal Ministry of Health. One work package of the PHIS project, running from 2008 till 2011, was dedicated to exploring pharmaceutical policies (not exclusively focused on procurement) that are applied in the hospital sector.

The interest in the hospital sector resulted from a recommendation of the **final report of** the 2005–2007 **PPRI** (Pharmaceutical Pricing and Reimbursement Information) project which concluded: "***Pharmaceutical policies in the hospital sector need to be further investigated.*** *The pharmaceutical service in the inpatient sector plays an important role and influences the provision of pharmaceuticals, and also pharmaceutical expenditure, in the outpatient sector. However, pricing policies and practices in the hospital sector have not been addressed by the PPRI project neither have they been the focus of other European research projects. There is a need for paying greater attention to the hospital sector with regard to the intramural rational use of pharmaceuticals and to the interface between the inpatient and the outpatient sector. Therefore, pharmaceutical policies in hospitals shall be surveyed, and, additionally, initiatives for a better cooperation between the inpatient and outpatient sector shall be promoted.*"[193].

The PHIS Hospital Pharma research and network activities resulted in:

- **National PHIS Hospital Pharma Reports** and **a compilation of pharmaceutical policies in the inpatient sector in 27 European countries**, which informed about procurement policies, procedures and award criteria as well as pricing and reimbursement policies in the hospital sector and "interface management" measures to improve collaboration between inpatient and outpatient sectors;
- An investigation of the medicine **price set-up** methodology in hospitals (at macro level), e.g. use of discounts;
- Five in-depth country **case studies**, which comprised a survey of medicines prices, including "real" **discounted prices**, for 12 selected active ingredients;
- Establishment of the **PHIS network of competent authorities** for pharmaceutical pricing and reimbursement policies (already members of the PPRI network established in the previous PPRI project) **and hospital pharmacists and managers** as well as relevant stakeholder associations such as the European Association of Hospital Pharmacists (EAHP) and the European Hospital and Healthcare Federation (HOPE).

While the 2010 PHIS Hospital Pharma Report had a broader focus on all aspects of pharmaceutical care provided in hospitals (including tendering as a tool for procurement), this study's 2022 update focuses specifically on procurement. **Table 12** lists the differences between the 2010 report and its 2022 update.

Table 12: Differences between the 2010 PHIS Hospital Pharma Report and the 2022 PHIS Hospital Procurement Update

Element	2010 Report	2022 Update
Year of survey	2009 – 2010	2022
Countries	27 European countries (25 EU Member States as of 2009, Norway and Turkey)	32 study countries (27 EU Member States, EEA/EFTA countries, UK)
Survey methods	Country reports written by country representatives (alternatively: information filled in a questionnaire) and comparative analysis by the study team	Survey through country fiches (shared for validation with country experts) and comparative analysis by the study team
Project organisation	Project management of 4 institutions (GÖG, Slovak Medicines Agency SUKL, Italian Medicines Agency AIFA, SOGETI) Advisory Board of European and international institutions Network of competent authorities for pricing and reimbursement of medicines and representatives of hospitals (hospital pharmacists and managers) involved as network members in the project ("PHIS network"[1])	Project management: Tetra Tech, GÖ B 4 procurement experts (from Cyprus, Denmark, Estonia and France) and 1 researcher involved in the study as quality assurance Country representatives and further stakeholders not involved in the study as network members but approached as stakeholders
Research on procurement	As part of medicines management in hospitals: Only tendering & negotiations High-level survey of award criteria Optimisation of PPM was not scope	Detailed survey of PPM procedures and techniques as listed in the EU Procurement Directive Analysis of award criteria (supported by TED data) Strategies to optimise PPM to be analysed
Prices	Understanding and interpreting medicines prices in hospitals was a major topic of the study: Price survey in 5 selected countries, including discounted prices	No major topic Price developments analysed (list prices or price proxies as included in IQVIA data)
Consumption	High-level information, no primary data collection	Analysis of IQVIA sales data

Element	2010 Report	2022 Update
Pricing and reimbursement	Surveyed as a major topic	Included to contextualise procurement information Interest in hospital reimbursement / funding
Hospital landscape	Definition of hospital setting was a major topic Hospital pharmacy also a major topic	Definition of hospital setting – not addressed Hospital pharmacy – surveyed as one topic
Interface management	Yes, and it gained importance during the study	Yes
Biosimilar medicines	No	Yes, important elements of analysis
Cross-country collaboration	No	Yes, important elements of analysis

[1] The PHIS network was based on the PPRI network of competent authorities for pharmaceutical pricing and reimbursement, which was established as part of the PHIS-predecessor PPRI project, as well as hospital representatives. Note that "PHIS Hospital Pharma" was one of several work packages in the PHIS project and the sole one specifically related to the hospital setting. The other work packages (e.g. glossary, library of country information, meta-indicators to assess pricing and reimbursement systems, database) related to both outpatient and inpatient sectors [194]. After the official end of the PHIS project co-funded by the European Commission (2011), the activities of the PHIS network continued (e.g. meetings, information of sharing), coordinated by GÖG. At the same time, the activities of the PPRI network also continued low-level after the end of the respective project (2007). Since, to a large extent, same experts were involved in the PPRI and PHIS networks, consolidation was requested by the network members, and it was decided to continue with one network, under the name "PPRI". The authors, involved in the PPRI Secretariat, cannot inform on the institutions that are members of PPRI, since PPRI members requested the PPRI Secretariat to not disclose member organisations. Only public authorities (and some supranational institutions) are eligible for PPRI membership; PPRI members commit to sharing information and providing inputs to their peer colleagues and the PPRI Secretariat [71] but there is no third party funded research project as it were at the time of the initial PPRI project (2005-2007) and the PHIS project (2008-2011).

Source: Authors

The aim of the PHIS Hospital Procurement Update is to characterise public procurement of medicines for hospital use in European countries. A **descriptive approach** was applied which combined **quantitative data about** the **hospital** sector in the study countries with **qualitative data about procurement practices** and other pharmaceutical policies related to procurement of hospital medicines. The PHIS Hospital Procurement Update was based on information obtained through literature review and country expert consultation as part of populating country fiches (see **Chapters 2.2** and **2.3**), workshops with procurement and pharmaceutical pricing and reimbursement experts (including a dedicated workshop on hospital procurement, see **Chapter 2.4.1** and Annex 5), and descriptive analysis of data on pharmaceutical sales, consumption, and the hospital landscape from IQVIA ([145], see **Chapter 2.5.2**), EUROSTAT [150], and OECD [195], respectively.

5.2. Public procurement of medicines in hospitals

Procurement of medicines for hospital use varies greatly across Europe. This variation should be seen against the backdrop of how inpatient care – including pharmaceutical care in hospitals – is organised in each country. This chapter therefore first provides an overview of the landscape of hospitals and hospital pharmacies in the study countries and discusses medicines use in hospitals and how they are paid for, before describing the organisational framework for public procurement of hospital medicines, and which procedures, techniques, and award criteria are used.

5.2.1. Hospital and hospital pharmacy landscape

The **number of hospitals varies** among the study countries. When comparing the number of hospital beds (total hospital beds including acute and chronic care beds), the figures range from less than three (UK, Denmark, Ireland and Iceland) to more than seven beds per 1,000 population (Austria and Germany). Also – as health care systems

are differently organised and financed in the study countries – the percentage of hospitals publicly owned varies (see **Table 13**). There are also hospitals that are privately owned, yet publicly financed.

It should be noted that **hospitals** can be **defined differently** in the study countries. For example, different forms of outpatient care provision may occur in institutions that are defined as hospitals. The OECD includes such care provision in its definition of hospital, which, at its core, states that hospitals "comprise licensed establishments primarily engaged in providing medical, diagnostic and treatment services that include physician, nursing, and other health services to inpatients and the specialised accommodation services required by inpatients." [196].

Table 13: Hospital landscape and ownership in the study countries, 2019

Country	Number of hospitals	Total hospital beds per 1,000 population	Percentage of publicly owned hospitals
Austria	264	7.19	54.17
Belgium	164	5.57	23.17
Bulgaria	n.a	n.a.	n.a
Croatia	n.a	n.a.	n.a
Cyprus	n.a	n.a.	n.a
Czech Republic	258	6.58	61.24
Denmark	n.a	2.59	n.a
Estonia	30	4.53	66.67
Finland	239	3.35	69.46
France	3,008	5.84	45.01
Germany	3,026	7.91	24.79
Greece	270	4.18	45.93
Hungary	163	6.91	n.a
Iceland	8	2.8	100.00
Ireland	86	2.88	77.91
Italy	1,056	3.16	40.91
Latvia	61	5.42	73.77
Liechtenstein	n.a	n.a.	n.a
Lithuania	94	6.35	90.43
Luxembourg	10	4.26	n.a
Malta	n.a	n.a.	n.a
Netherlands	568	3.08	0.00
Norway	n.a	3.47	n.a
Poland	1,236	6.17	60.44
Portugal	238	3.51	46.64
Romania	n.a	n.a.	n.a
Slovakia	129	5.76	n.a
Slovenia	29	4.43	89.66
Spain	777	2.95	44.14
Sweden	n.a	2.07	n.a
Switzerland	281	4.59	n.a
United Kingdom	1,978	2.45	100.00

n.a. = not available

Source: OECD [195]

Information on the **share of public hospitals in the study countries with a hospital pharmacy** was collected and validated in the PPM country fiches. This ranges from around 12% in Germany (of all hospitals, including private) to 100% (see **Table 14**). Hospital pharmacies in most countries are only entitled to serve inpatients (patients admitted to the hospital). Some exceptions exist, which may have been maintained historically or to allow for more "seamless" treatment pathways from the inpatient to outpatient sector for specific conditions (e.g. outpatient cancer care; for interface management measures identified in the study see **Chapter 5.3**) or in cases where medicines are not readily available from community pharmacies. In several countries legislation allows for patients to receive medication for a few days at discharge.

In some countries **hospital pharmacies also serve outpatients** on a more regular basis. In Norway and Sweden, (almost) all hospital pharmacies generally also serve outpatients and in Germany patients visiting outpatient departments in hospitals are

served. In Hungary some dedicated hospital pharmacies serve outpatients (see **Table 14**). However, dispensing to outpatients is often done through a separate pharmacy on the premises of the hospital, with different funding procedures for the medicines dispenses (e.g. the Netherlands, which this practice was allowed around 20 years ago [197]).

Table 14: Relevance of hospital pharmacies and their role in serving patients

Country	% of (public) hospitals with pharmacy	Target customers (inpatients only or also outpatients)	Comment
Austria	~15%	only inpatients, with exceptions	In addition, for historic reasons, five hospital pharmacies also run a community pharmacy on the premises of a hospital for outpatients.
Belgium	100% (mandatory by law)	only inpatients, with exceptions	A few exceptions for outpatient service (e.g. oral anticancer medicines) are made. It is planned to entrust hospital pharmacies with tasks related to the outpatient sector such as medication reconciliation or outpatient antimicrobial therapy.
Bulgaria	73% (2021)	only inpatients	-
Croatia	95%	inpatients and outpatients	-
Cyprus	100%	only inpatients, with exceptions	In exceptional cases (e.g. high-priced medicines) hospital pharmacies may also serve outpatients
Czech Republic	75%	only inpatients, with exceptions	-
Denmark	16%	only inpatients	-
Estonia	n.a.	only inpatients	In some cases, medicines used in the outpatient setting are issued by the hospital (according to the service list financing model)
Finland	low	only inpatients, with exceptions	Outpatients can only receive medicines from the hospital pharmacy at discharge from hospital to ensure continuity of their care.
France	100%	only inpatients, with exceptions	MA specific hospital reimbursement list defines, which medicines may be provided to outpatients.
Germany	~12% (of all hospitals)	inpatients and outpatients	Inpatients visiting outpatient departments may be served by hospital pharmacies.
Greece	90%	only inpatients, with exceptions	Hospital pharmacies dispense to outpatients under special pharmacotherapy (e.g. in cancer treatment) and to patients that receive their medicines free of charge (only from the hospital pharmacies) under social insurance.
Hungary	73%	inpatients and outpatients	Dedicated hospital pharmacies are permitted to serve outpatients on the hospital premises.
Iceland	n.a.	inpatients and outpatients	There are only two hospital pharmacies in Iceland. Other hospitals have contracts with local pharmacies / pharmacists who purchase according to tender agreements made by Landspitali (university hospital).
Ireland	100%	only inpatients, with exceptions	Only medicines that are not readily available in the outpatient sector can be dispensed based on special arrangements.
Italy	95%	only inpatients	-
Latvia	~50%	only inpatients	-
Lithuania	54%	only inpatients, with exceptions	-
Luxembourg	~100%	only inpatients, with exceptions	Only medicines that are not readily available from community pharmacies can be dispensed.
Malta	~100%	inpatients and outpatients	Hospital pharmacies also serve outpatients (mainly recently discharged patients, until outpatient pharmacy services through the Pharmacy of Your Choice Scheme (POYC) take over).

Country	% of (public) hospitals with pharmacy	Target customers (inpatients only or also outpatients)	Comment
Netherlands	~100%	inpatients and outpatients	Hospital-based community pharmacies in the premises of hospitals
Norway	100%	inpatients and outpatients	All hospital pharmacies also serve outpatients.
Poland	~100%	only inpatients	-
Portugal	~100%	only inpatients, with exceptions	Some public hospital pharmacies serve outpatients for specific treatments (specific conditions, without co-payment by the patient) and sometimes for patients of private hospitals.
Romania	~100%	only inpatients	-
Slovenia	~70%	only inpatients	-
Slovakia	~70%	only inpatients	-
Spain	n.a.	only inpatients, with exceptions	Outpatients can receive medicines for hospital use from hospital pharmacies. Outpatient dispensing is limited to hospital prescriptions.
Sweden	100%	inpatients and outpatients	The hospital pharmacy almost always includes an outpatient dispensing
Switzerland	n.a.	n.a.	No legal requirement to employ a pharmacist in a hospital in Switzerland and no mandatory requirements for the provision of clinical pharmacy services.
United Kingdom	n.a.	only inpatients, with exceptions	Hospital pharmacies can serve outpatients who visit hospitals for consultation or treatment without being admitted to a hospital as inpatient

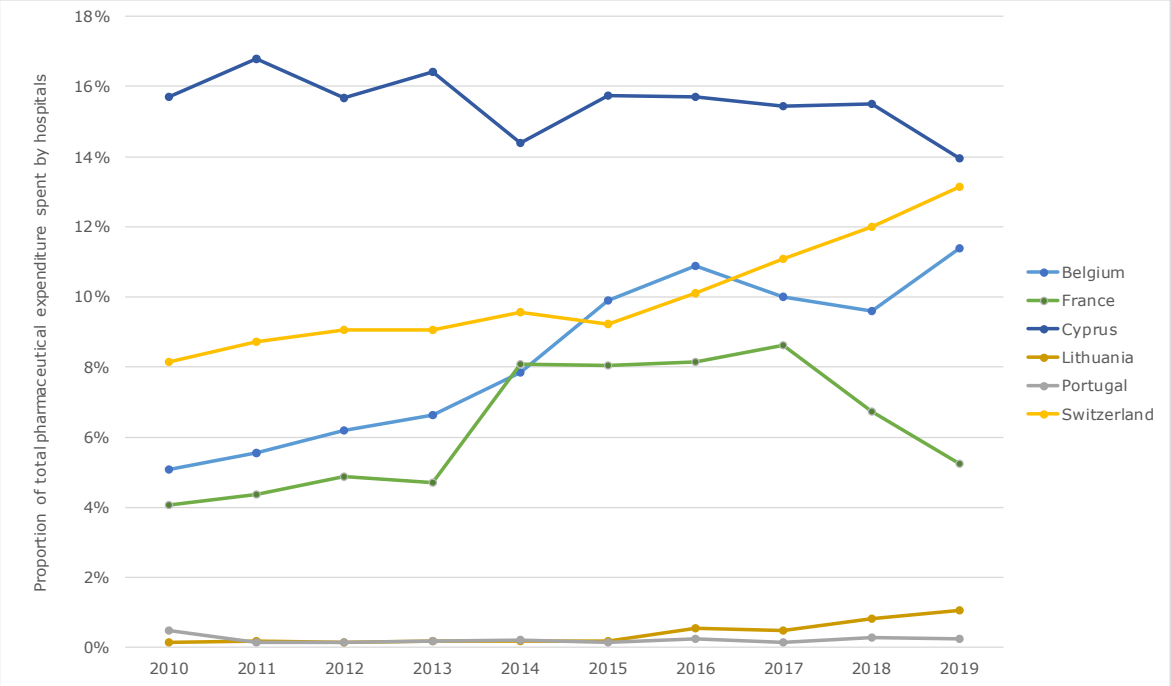
No information available for: Liechtenstein

Source: PPM country fiches; [198]

5.2.2. Medicines in hospitals

Hospital care accounts for the largest proportion of total health expenditure in Europe. In 2019, on average 36.4% of total health expenditure was spent on hospital care [199]. the proportion of total pharmaceutical expenditure that is spent in hospitals is increasing. While this figure varies across countries (ranging from less than 1% to more than 20% within the EU), a trend of **increased spending on hospital medicines** can be observed among countries without breaks in availability of data on hospital expenditure (see **Figure 27**). There are limitations in the reporting of hospital expenditure data [200]. However, the trend of increased spending on hospital pharmaceuticals is observed both in Eurostat data (as displayed in the figure) and OECD data for different sets of countries [201].

Figure 27: Proportion of total pharmaceutical expenditure spent by hospitals, 2000-2019



Note: Figure only shows data for countries without breaks in data availability from 2010-2019. Expenditure includes both pharmaceuticals and other medical non-durable goods.

Source: Eurostat [150]

Higher spending on hospital care is partly driven by hospital medicines, which account for a growing share of hospital expenditure. Hospitals may use medicines that are available in the outpatient sector as well as specialised treatments that can only be administered in inpatient settings. The latter, so-called hospital-only medicines (HOM), are not universally defined. Approximately half of European countries maintain lists of products to be used exclusively in hospitals [140], which can be defined by national medicines agencies or the EMA at the time of marketing authorisation or by pricing and reimbursement authorities when deciding on the reimbursement status (which may be limited to use in hospital settings).

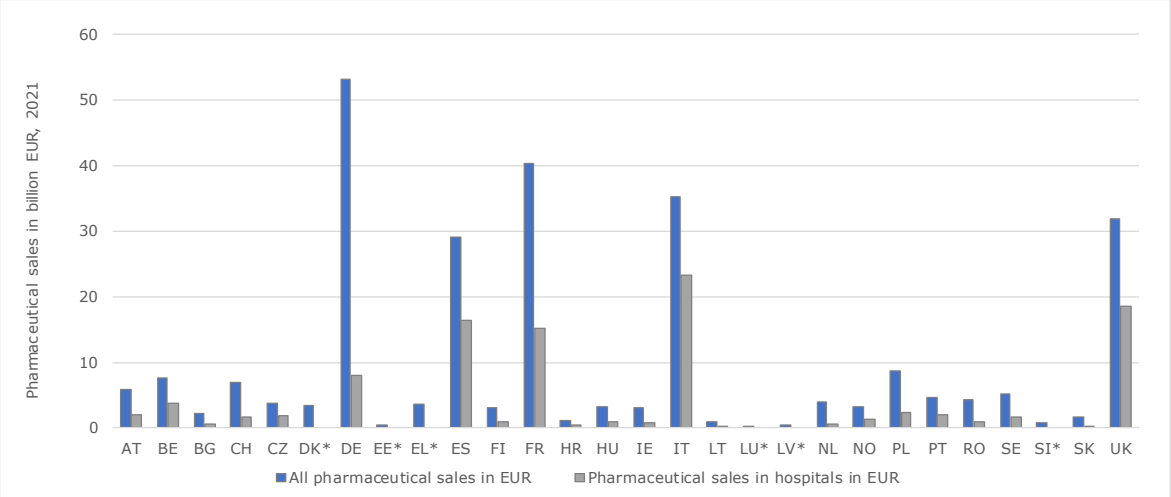
Over the past decade, **spending on medicines used in hospitals has outpaced retail expenditure**, the latter in some countries even contracting in the aftermath of the 2008 financial crisis. An OECD report estimated that the average annual growth rate of pharmaceutical expenditure between 2010 and 2019 was higher in the hospital sector compared to the retail sector in 13 of the 14 countries for which reliable data were available [201]. Annual growth in spending on hospital medicines reached as high as 15.2% in Iceland during that period. This is attributable to medicines with high price tags entering the hospital market.

The growing importance of hospital medicines is also reflected in its market size. In 2019, hospital medicines accounted for more than 50% of all pharmaceutical sales in four of the study countries (Belgium, Italy, Spain, UK) and for more than one-third of sales in five more countries (Czechia, France, Croatia, Norway, Portugal; see **Figure 28**). On the other hand, the share of hospital medicines sales was less than 20% in four of the study countries (Germany, Lithuania, Netherlands, Slovakia).

Figure 28 also demonstrates **vast variation in the size of national markets for hospital medicines**, with the largest five economies (France, Germany, Italy, Spain, UK) recording hospital sales of between EUR 8 billion and EUR 23.4 billion in 2021, while sales in many other countries remained well below EUR 1 billion. This variation indicates

a potential motivation for pooling purchase volumes at the regional, national, or cross-country level for smaller countries, in particular (see also **Chapter 6.1**).

Figure 28: Pharmaceutical market size in EUR billion and share of hospital sector, in total pharmaceutical sales, 2021



Note: No hospital sales data available for DK, EE, EL, LV, LU, SI. No pharmaceutical sales data for IS, LI, MT.

Source: IQVIA [145]

The trend towards increased pharmaceutical spending in hospitals can at least partly be ascribed to more expensive new medicines entering the market which are primarily used to treat inpatients [118]. Some of the most expensive specialty drugs to treat neuromuscular, immunological, and oncological conditions require administration by a health care professional, often provided in hospital settings. In some countries, the high costs of these new medicines provide a **rationale for re-thinking procurement processes**. For example, in Estonia, procurement of high-priced inpatient medicines is set to be delegated from individual hospitals to a central purchasing body, while Sweden uses a system of managed entry agreements for high-priced new medicines.

A key barrier to better understanding the hospital medicines market is the **limited availability of comprehensive data** [118, 201, 202]. In many countries, hospitals are not organised and owned centrally, and data on pharmaceutical consumption and spending are not readily available. In addition, price data are often not available due to confidential arrangements between manufacturers and individual hospitals. International comparisons of hospital pharmaceutical spending are therefore hampered by patchy data and research efforts have tended to focus more on the retail sector. The increase in hospital spending on medicines suggests a bigger focus on hospital medicines is warranted. This includes the need for more systematic monitoring of pharmaceutical consumption, spending, and prices, but also a better understanding of the processes for purchasing medicines in the hospital sector.

5.2.3. Hospital funding of medicines

In the study countries, medicines in hospitals are **usually funded through a diagnosis-related groups (DRG) scheme, or a DRG-like mechanism**. In the design of the national DRG systems, there is heterogeneity across European countries [203]. However, the underlying principle is the same for any DRG or DRG-like system: Hospitals are remunerated for the services (procedures) per patient, and this is independent from what they actually spend. Medicines are included in the bundled financing mechanism of the DRG systems. This is different to the outpatient sector, in which medicines are reimbursed on an individual level.

In some countries, defined medicines are eligible for **special financing schemes** which provide for product-specific reimbursement. As these are exceptions from standard DRG-based financing, they are also called "DRG carve-outs" [204].

Such **"DRG carve-outs"** are known from a few countries, including Austria, France and Germany. The Netherlands and Slovenia used to have such lists (in the Netherlands with cost-sharing between the hospital and health insurer [97], thus an interface management approach, see **Chapter 5.3.2**), but in both countries they were abolished as part of the introduction of new reimbursement mechanisms (such as the "lock system" in the Netherlands).

In addition, special financing schemes also comprise **"(innovation) funds"** for defined medicines, which are expensive but still considered important for patients, so they are financed out of funds that bypass the "standard" reimbursement processes (for medicines used in outpatient and inpatient sectors).

Furthermore, in some countries, some **defined medicines, usually those with high budget impact** (e.g. Onasemnogene abeparvovec / Zolgensma®), are covered by a different payer than the usual one for hospitals, e.g. dedicated funds are made available from the state budget (in some cases linked to state procurement).

Table 15 provides an overview of special financing schemes identified in the study countries. The rationale for these funding schemes is to ensure patient access to medicines that would normally not be possible, as they are unaffordable and/or challenging for the sustainability of the system. These access schemes may be based on payers compromising on funding medicines with limited (evidence of) added therapeutic value (e.g. the English Cancer Drug Fund, in its initial form, was criticised for funding medicines that were assessed as not cost-effective [205, 206]). Special funding systems also create "parallel worlds" to the regular processes and standards for reimbursement. In France, the financing scheme of the "liste en sus" is intended to include medicines on a temporary basis, and with the inclusion of new medicines, others should be transferred back into the DRG system. However, in practice, this happens rather rarely, and as a result, the "liste en sus" has considerably grown [75].

In addition to these pathways, patients may also access medicines through named patient and compassionate use programmes, and hospitals may obtain cost-free provisions of medicines (although these are not allowed in all study countries).

Table 15: "DRG carve-outs", innovation funds, state budget procurement and further special financial schemes for defined medicines used in hospitals

Country	Special financing schemes for medicines used in hospitals
Austria	"Medizinische Einzelleistungen" (MEL / "single medical procedures"): for oncology medicines, inclusion in the MEL list can be requested, through which funding on a product basis is provided (request to be renewed once a year). For some defined medicines, specific funding mechanisms are agreed at regional level between regional sickness funds and regions (hospital owners), see also Box 15. Onasemnogene abeparvovec therapy is funded out of a separate fund.
Belgium	Temporary funding out of the "Special Solidarity Fund" (SSF) for orphan medicines which have not received a positive reimbursement decision under certain conditions (treatment of a rare disease requiring a specific physio pathologic treatment, treatment of a rare disease requiring a continuous and complex treatment, treatment of chronically ill children, involvement of innovative treatment techniques or otherwise requiring medical treatment abroad) and when all of other treatment options have been exhausted. Not limited to medicines used in hospitals.
Bulgaria	Some medicines used in hospitals for treating particular diseases are paid out of the state budget.
Croatia	Some defined medicines (biologicals for the treatment of cancer, autoimmune and rare diseases), which are mainly used in hospital are funded from the "Especially Expensive Medicines Fund" of the health insurance fund.

Country	Special financing schemes for medicines used in hospitals
France	"Liste en sus": Product specific funding for expensive medicines which meet the following criteria: mainly used in hospitals, important therapeutic benefit, added therapeutic benefit, price of the medicine is too high to be covered through DRG system. A second list, the "rétrocession" list, exists for medicines with limitations in supply, dispensing or administration or which require prescription and delivery monitoring; included are e.g. medicines derived from blood, ARV, chronic hepatitis B or C medicines, antibiotics, antifungals, orphan medicines and cancer medicines. Compared to the "liste en sus", the "rétrocession list" is less intended to encourage access and uptake of innovation and instead aims to manage supply limitations (rétrocession list medicines can also be dispensed in community pharmacies).
Germany	Product-specific funding through the NUB list (Neue Untersuchungs- und Behandlungsmethoden / New diagnostic and treatment methods): hospitals can request inclusion of medicines in the NUB list for one year. The rationale is that the consideration of new medicines in updated DRG calculations would take too much time.
Hungary	For high-cost new inpatient medicines, individual product-specific funding (i.e. reimbursement outside the DRG system) is possible. High-cost inpatient medicines which require additional budget and/or legislative adjustments are purchased through centralised tenders. Products that fall under this itemised reimbursement scheme are approved on a case-by-case basis and hospitals receive allocated quotas of the product.
Iceland	A separate budget exists for high-cost new medicines. This budget is used to fund products used in the inpatient and outpatient setting and is held by Landspitali, the only teaching hospital in Iceland. The procurement department at Landspitali conducts centralised procurement for these products.
Italy	New innovation funds of EUR 500 million each (one for cancer medicines, one for other innovative medicines) since 2017, merged into one "innovation fund" in 2020. Included medicines must meet the criteria of unmet medical need, added therapeutic value, robustness of evidence. Not limited to medicines used in hospitals. Eligible medicines are funded out of the funds for a period of 36 months, which frees funding for the regions (which are the payers of medicines.
Latvia	In case of funding limitation of hospitals, some high-cost medicines used in hospitals are funded out of the state budgets. A special fund also exists for the treatment of rare diseases in children.
Netherlands	Some inpatient high-priced medicines can be reimbursed individually upon joint request of the health insurer and the prescriber.
Poland	Some highly specialised therapies (including some medicines) are funded out of the state budget. In addition, a new Medical Fund was launched in 2020 which aims to provide funding for access to products that are innovative or of high clinical value, as well as emergency access to drug technologies (i.e. access to drugs for individual patients when all other treatment options have been exhausted). For the latter, hospitals can now decide whether a patient should receive treatment as part of the emergency access to drug technologies programme (after receiving a positive opinion from a national or provincial consultant), rather than applying for funding from the MoH.
Portugal	Medicines of a defined list of indications (e.g. Multiple Sclerosis, Hepatitis C, Lennox-Gastut syndrome, Cystic fibrosis) which must be supplied by hospital pharmacy to outpatients.
Slovakia	Some medicines (e.g. growth hormone factors, beta-interferons) are procured and funded by sickness funds (these medicines are to be used in specialised centres).
Slovenia	For inpatient medicines not on the formulary, decisions are taken by hospital pharmacy and prescribing physician upon request. For very expensive medicines, approval by the hospital director is needed.
United Kingdom	England: Cancer Drug Fund (CFD): in the beginning (established in 2010) separate funding of cancer medicines that the NHS would normally not cover after the HTA body (NICE) had assessed them as not cost-effective or an HTA had not yet been performed. Not limited to medicines used in hospitals. Reformed in 2016 with a change into a "managed access" mechanism to fund oncology medicines for a maximum period of two years. During this time, the medicines have to undergo an HTA performed by NICE. In 2022, another fund, the "Innovative Medicines Fund" (IMF) was established for potentially lifesaving (e.g. in the areas of spinal muscular atrophy and cystic fibrosis), not limited to medicines in hospital. The IMF shall have the same budget (additional GBP 340 million) as the CDF and shall function according to the principle as the CDF.

Source: PPM country fiches

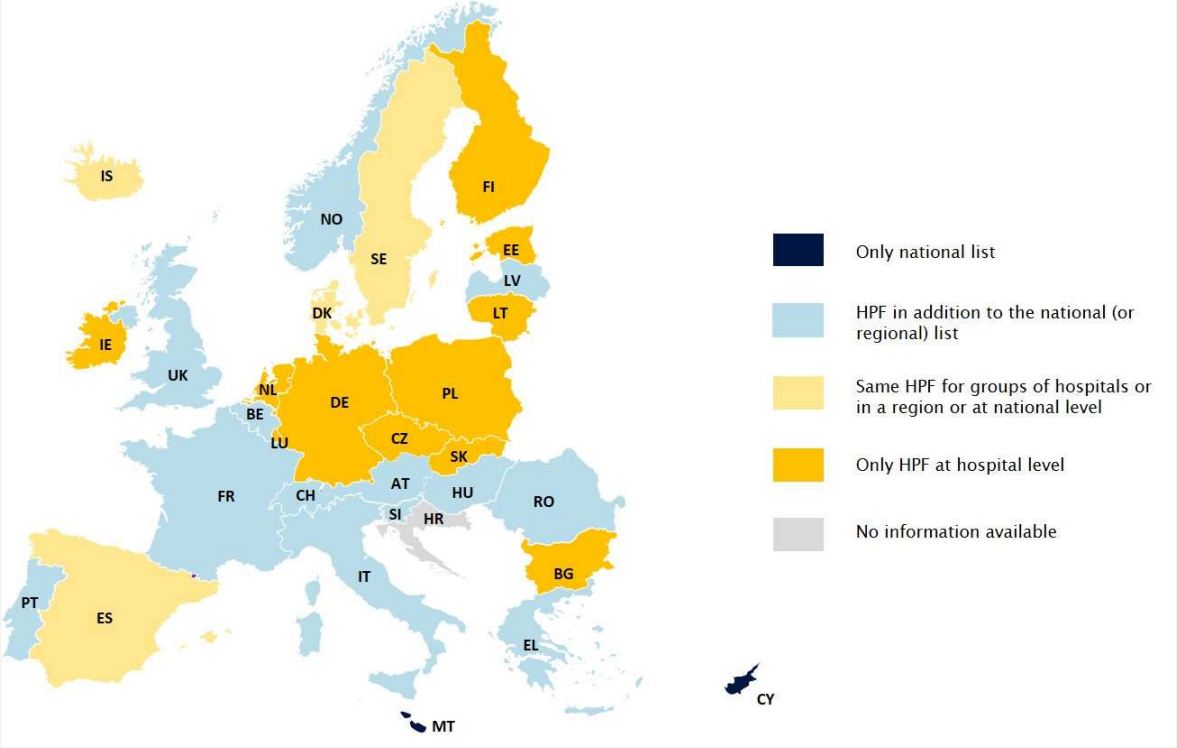
5.2.4. Reimbursement lists for medicines used in hospitals

Usually, only medicines which have been included in the **hospital pharmaceutical formulary (HPF)** are procured. As a principle, only medicines that have been included in these formularies can be procured; however, under certain conditions also medicines which are not on the HPF may be procured. This is also reflected in a statement by the EAHP: "Procurement should be according to the medicine formulary and informed by the formulary selection process. A robust process should also be in place to appropriately procure medicines not included in the formulary where their use is indicated for the safe and effective care of individual patients."[207].

In most study countries, hospitals have their own hospital pharmaceutical formulary (HPF) even if some (or all) medicines used in hospitals are subject to centralised procurement (at national or regional levels within a country). The sole countries with aggregate lists, and no HPF at hospital level, are Denmark, Cyprus and Malta with a national formulary, Iceland with regional list and Sweden with regional prescribing recommendations ("Wise Lists" for rational prescribing, which add to the national larger reimbursement lists). In Norway, there is centralised procurement for all public hospitals, but this is on a voluntary basis, and hospitals may also have their own HPF [208] and procure medicines individually. **Figure 29** visualises at what level HPFs exist in the study countries.

The **individual HPF differ across hospitals, as each hospital decides on its own, in their respective Pharmaceuticals and Therapeutics Committee** (PTC, see **Chapter 5.2.5**). The decision to include medicines in the HPF may be based on an overarching reimbursement decision (joint cross-sector reimbursement list covering the outpatient and inpatient sector). More frequently, the decisions on inclusion of medicines in the HPF are taken irrespective of reimbursement status of medicines in the outpatient sector (for further information see **Chapter 5.2.3**).

Figure 29: Use of hospital pharmaceutical formularies (HPF) in the study countries



Source: PPM country fiches

5.2.5. Pharmaceuticals and Therapeutics Committees in hospitals

Pharmaceuticals and Therapeutics Committees (PTC) are generally **responsible for the maintenance of the HPF** in a hospital, for a group of hospitals, in a region and/or at national level. **Table 16** presents the level of use of PTC in the study countries. In most of the study countries for which information was available, PTC are established at hospital level only (i.e. each hospital has its own PTC). Countries may apply different PTC at several levels.

Table 16: Establishment of Pharmaceuticals and Therapeutics Committees (PTC) in the study countries

Country	All/most hospital have their own PTC	(Additional) PTC of group(s) of hospitals or in a region	(Additional) national PTC
Austria	X	X	-
Belgium	X	-	-
Bulgaria	X	-	-
Cyprus	-	-	X
Czech Republic	X	X	-
Denmark	-	X	-
Estonia	X	-	-
Finland	X	X	-
France	X	X	-
Germany	X	-	-
Greece	X	-	-
Hungary	X	-	X
Iceland	-	-	X
Ireland	X	-	-
Italy	X	-	-
Latvia	-	-	X
Lithuania	X	-	-
Luxembourg	X	-	-
Malta	-	-	X
Netherlands	X	-	-
Norway	X	-	-
Poland	X	-	-
Portugal	X	X	X
Romania	X	-	-
Slovenia	X	-	-
Slovakia	X	-	-
Spain	X	X	-
Sweden	-	X	-
Switzerland	X	-	-
United Kingdom	X	-	-

Note: No information available for Croatia and Liechtenstein

Source: PPM country fiches

5.2.6. Use of MEAs by hospitals

Managed entry agreements (MEAs) are arrangements about access to new medicines subject to pre-specified conditions. They are typically concluded for products with high prices and / or uncertain evidence about therapeutic benefit. Arrangements can take many different forms but can generally be categorised into financial-based (e.g. price-volume agreements) and performance-based contracts (e.g. payment conditional on patients achieving a specified outcomes) [169, 171].

MEAs are in place for inpatient medicines in almost all study countries, with the exceptions of Hungary and Latvia (MEAs in the outpatient setting only) (see **Table 17**).

MEAs include as contract partners the manufacturer of a product on one side and a health care payer or another institution responsible for access of the population to new

medicines, such as a regional health authority, HTA body, or health care provider, on the other. In most countries, **MEAs are only concluded by the national competent authority or the CPB**. In some countries, MEAs form part of the procurement process: in Denmark, Iceland, and Malta, the CPBs (Amgros, procurement department at Landspitali, and CPSU, respectively) are concluding an MEA. More commonly, however, are models where the pricing and reimbursement authority concludes the MEA. For example, in Cyprus, the Health Insurance Organisation (HIO) started entering into financial- and performance-based MEAs in both inpatient and outpatient settings for selected, high-cost medicines. Similarly, the HSE in Ireland concludes MEAs for selected medicines, e.g. for nusinersen (Spinraza®) and patisiran (Onpattro®).

An MEA can also be concluded between manufacturers and **individual hospitals**, and this was a common model across study countries. Hospitals or hospital groups may be able to conclude MEAs with manufacturers after the public authority has made their decision on pricing and / or reimbursement of the product, including any potential MEA at national / regional level. This is the case in France, where hospitals or CPBs for the hospital sector can conclude an MEA after the pricing and reimbursement decision was taken at the national level. In the United Kingdom, MEAs (patient access schemes) are concluded by the National Health Service (NHS), but hospitals are also free to procure medicines directly from manufacturers and obtain discounts. Confidential discounts and rebates are also the most common form of MEAs in Austria, where the focus was shifted away from earlier performance-based contracts (payment by results) due to their large administrative burden.

In some other countries, there are no MEAs concluded by the national competent authority for pricing and reimbursement, but such arrangements can be concluded at a lower level. For example, in Sweden, procurement of hospital medicines is conducted by the regions and any MEA for inpatient medicines would also be concluded by the regions. Since 2014, the Council for New Therapies (NT-rådet) has provided guidance to the regions on the introduction of new medicines, and has also concluded some MEAs on their behalf.

Table 17: Use of managed entry agreements in hospitals

Contractual arrangements including managed-entry agreements (MEAs)	Countries
Hospitals conclude specific arrangements (e.g., MEAs) after the pricing and reimbursement decision of the public authority (which may include conclusion of an MEA)	Austria, Finland, Greece, Romania, Slovakia, Slovenia, Switzerland, United Kingdom
No MEAs conducted by the national competent authority for pharmaceutical pricing and reimbursement but there are contractual arrangements including MEAs in hospital procurement	Bulgaria, Czech Republic, Luxembourg, Sweden
No MEAs in hospital procurement are concluded but there are MEAs concluded by the national competent authority for pharmaceutical pricing and reimbursement	Belgium, Cyprus, Denmark, Estonia, Iceland, Ireland, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Spain
MEAs are used in the inpatient setting (no further details available)	Croatia, Germany, France, Poland
No MEAs are used in the inpatient setting	Hungary, Latvia

Note: In Denmark, Iceland, and Malta, MEAs are not concluded by the national competent authority for pricing and reimbursement, but by the responsible CPBs. In Spain MEAs can either be concluded at national or regional level. In Cyprus MEA are concluded by the Health Insurance Organisation for a few very expensive medicines. No information available for Liechtenstein.

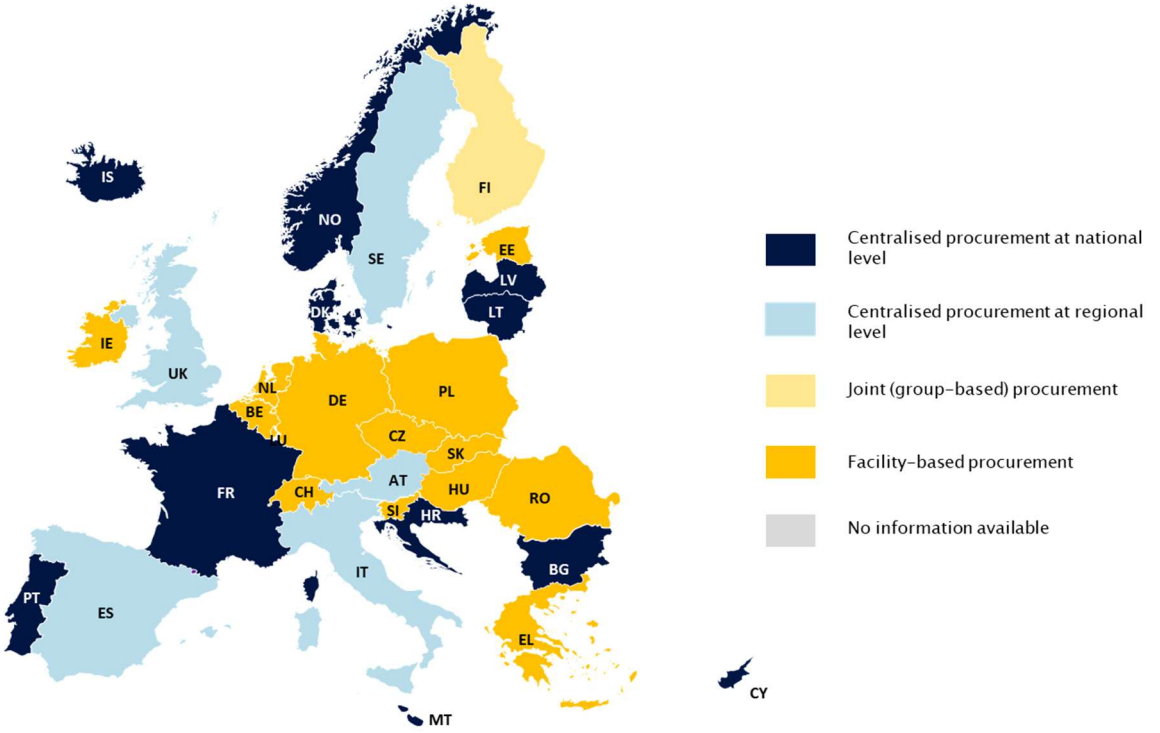
Source: PPM country fiches

5.2.7. Organisational framework for PPM in hospitals

PPM may be organised at different levels, including at the facility level, through voluntary group (joint) procurement, or centrally at regional (within-country) or national level. As discussed in **Chapter 3.2**, key forms of procurement in the inpatient sector are facility-based PPM and procurement through a CPB (at national or regional level).

Figure 30 gives an overview on which main route study countries use for procurement of medicines in their (public) hospital setting. Table 18 elaborates on whether besides the main route further routes of PPM are applied in a study country.

Figure 30: Main route for procurement of medicines in hospital setting



Note: France uses both regional and national-level centralised procurement as main procurement route.

Source: PPM country fiches

Table 18: Organisation of PPM (main and other routes of PPM) in hospitals in the study countries

Country	Main route(s) for procurement of medicines for inpatient use	Additional route(s) for procurement of inpatient medicines
Austria	Centralised procurement at regional level	In some cases, individual hospitals may conduct their own procurement. In addition, when Austria was involved in the Joint Procurement Agreement of the EU with regard to COVID-19 medicines, procurement was done by the Federal Ministry of Social Affairs, Health, Long Term Care and Consumer Protection and medicines where then distributed to hospitals with COVID-19 patients.
Belgium	Facility-based procurement	Procurement through regional CPBs ((e.g. MercurHosp).
Bulgaria	Centralised procurement at national level	No
Croatia	Centralised procurement at national level	Yes, facility-based procurement for products outside the List of Medicinal Products prescribed by law, medicines from emergency import and new medicines that have not yet been contracted at the national level.

Country	Main route(s) for procurement of medicines for inpatient use	Additional route(s) for procurement of inpatient medicines
Cyprus	Centralised procurement at national level	No
Czech Republic	Facility-based procurement	Joint (group-based) procurement
Denmark	Centralised procurement at national level	No
Estonia	Facility-based procurement	The procurement unit at EHIF, acting as a quasi-CPB, has conducted pilot projects for centralised procurement of selected inpatient medicines (products with larger cost containment potential and biosimilars). The role of centralised procurement of inpatient medicines is expected to increase over time.
Finland	Joint (group-based) procurement	Facility-based procurement (and for novel medicines procurement at national level by one of the hospital pharmacies)
France	Centralised procurement at national (or regional) levels	Centralised procurement through national CPBs such as Resah and UniHA and regional CPB. Joining these CPBs is voluntary, and use of these services are also voluntary. Thus, hospital may procure themselves some medicines and some others through the CPB.
Germany	Facility-based procurement	Some hospitals have joined (private) hospital purchasing companies or form group purchasing organisations.
Greece	Facility-based procurement	Centralised procurement at national and regional level. Since 2012, PPM has been gradually shifted towards the regional level and to the central level, as – as part of the bail-out programme – a CPB for health service was established in 2018.
Hungary	Facility-based procurement	There is centralised tendering for some hospital medicines, including high-cost medicines that are not covered by the DRG system (conducted by the National Health Insurance Fund Management, NEAK), but most procurement is done by individual facilities. As part of a reform to centralise health care in Hungary, hospitals were put under state ownership, and synergies were expected to be realised from centralised procurement (conducted by the Directorate-General for Public Procurement and Supply, KEF). Some medicines are therefore also procured via KEF, but hospitals are not obliged to participate in procedures organised by KEF.
Iceland	Centralised procurement at national level	Facility-based procurement is also possible since not all medicines are tendered, and centralised procurement is only mandatory for high-cost medicines. For other medicines, other hospitals may procure through Landspitali (where tenders are issued), but are not obliged to. When not subject to tendering, medicines are purchased at the registered price by hospital pharmacy/pharmacies.
Ireland	Facility-based procurement	Groups of 2-4 hospitals have started to pool volumes for the purchase of biosimilars.
Italy	Centralised procurement at regional level	Facility-based procurement (through Consip DPS) for every kind of medicine.
Latvia	Centralised procurement at national level	Facility-based procurement for all medicines not on the list of centrally tendered products. Health care institutions are responsible for their own procurement.
Lithuania	Centralised procurement at national level	Facility-based procurement: hospitals also carry out procurement procedures themselves using the tools of the Central Portal of Public Procurements if medicines are not available in the catalogue of the Central Procurement Organization (CPO LT). In exceptional cases (for example low value procurements, very urgent simplified procurements) hospitals may not use the tools of Central Portal of Public Procurements.
Luxembourg	Facility-based procurement	Voluntary group procurements
Malta	Centralised procurement at national level	No

Country	Main route(s) for procurement of medicines for inpatient use	Additional route(s) for procurement of inpatient medicines
Netherlands	Facility-based procurement	Some hospitals (e.g. university teaching hospitals) do group purchasing. For medicines with high budget, prices are negotiated by the Ministry of Health. Welfare and Sports
Poland	Facility-based procurement	No
Portugal	Centralised procurement at national level	Facility-based procurement. Procurements centrally conducted by SPMS based on a needs assessment by public hospitals. Hospitals may procure based on framework agreements negotiated at national level and individually if necessary (e.g. at the beginning of the year when CPM not yet conducted or medicines not available through framework agreements)
Romania	Facility-based procurement	No
Slovenia	Facility-based procurement	No
Slovakia	Facility-based procurement	In addition, for some high-cost cost medicines (e.g. blood derivatives, beta interferons) there is centralised procurement by the Vseobecná Zdravotná Poistovña (VsZP) / General Health Insurance or other sickness funds. In hospital groups owned by Territory Regional Units joint procurement is used.
Spain	Centralised procurement at regional level	Facility-based procurement (by hospital) and for some medicines central procurement.
Sweden	Centralised procurement at regional level	Procurement may also be done by informal groups of individual hospitals or groupings of counties.
Norway	Centralised procurement at national level	Hospitals may also procure medicines on their own, at different prices than the ones negotiated by LIS.
Switzerland	Facility-based procurement	(Joint) group procurements (e.g. in Zurich) and in two regions (cantons) Vaud and Geneva centralised regional procurement.
United Kingdom	Centralised procurement at regional level	Hospitals can also conduct their own procurement. Hospitals may procure products individually to address specific needs or to cover short-term demand.

No information available for Liechtenstein

Source: PPM country fiches

Centralised procurement at national level refers to a national CPB (or any other central authority or institution acting as a CPB, such as a Ministry of Health) performing all or most of the procurements for the (public) hospital sector. Nine of the study countries (Bulgaria, Cyprus, Denmark, Iceland, Latvia, Lithuania, Malta, Norway, Portugal) use centralised procurement at national level as the main (or only) route for procurement of medicines in the hospital setting. **Box 9** provides an overview of how the central purchasing bodies (CPB) are organised in some of these countries.

Box 9: Central procurement bodies (CPB) at national level in the study countries

Some central procurement bodies may purchase not only medicines but other services and goods for the public sector. When such body is responsible for PPM, these are referred as central PPM bodies. Several study countries perform (at least parts) of their PPM at a national level through a central PPM body.

Bulgaria and Cyprus – MoH departments responsible for PPM in hospital sector

In Bulgaria and Cyprus, the central PPM body is incorporated in the services of the Ministry of Health (MoH), e.g. by establishment of a dedicated department for procurement.

After joining the EU in 2007, public procurement in **Bulgaria** underwent major changes to comply with EU legislation, resulting in a new national public procurement legislation. A **CPB** was **established at the MoH** in 2015 for procurement in the public health care sector. The CPB is responsible for the procurement of medicines included in the positive medicinal list used by medical establishments (various types of inpatient care facilities).

For centralised PPM of hospital medicines, the CPB concludes **framework agreements** on behalf of individual contracting authorities (the health care providers). Individual procurement procedures are then conducted as **electronic auctions** at the facility level.

Similar to Bulgaria, in **Cyprus** the central procurement body is established in the form of a **specific department for PPM at the MoH** – the Purchasing and Supply Services Department. The MoH purchases medicines under the mandate of the Health Insurance Organisation (HIO)[34] or medicines which have not been reimbursed by the HIO for mainly the inpatient (and formerly outpatient sector) at a central level. The centralised national PPM system is obligatory, no parallel procedures on other levels (such as regional or facility-based) are performed, except for outpatient medicines by private pharmacies.

The procurement procedures applied – either **open procedure tenders** or **competitive procurement with negotiations** - depend on the type of the medicine. Open procedure tenders account for around 75% of procedures and are mainly used for off-patent medicines with increased competition and biosimilars, while competitive procurement with negotiations is applied for on-patent and innovative medicines with competition (around 25% of all medicines).

Norway and Denmark – Central procurement bodies owned by regions

In Denmark and Norway, the central PPM body is owned by regions and performs PPM for public hospitals with different degrees of obligation for hospitals to participate (Denmark mandatory, Norway voluntary).

Procurement of medicines for public hospitals in **Norway** is performed centrally by **Legemiddelinnkjøpssamarbeid (LIS)/ Norwegian Drug Procurement Cooperation**. LIS was established in 1995 as a cooperation for procurement between some counties and was later integrated into the hospital procurement body **Sykehusinnkjøp**. As of today, all publicly funded hospitals are members of LIS. Its role in procurement for specialist medicines has grown considerably since then, and notably so since the funding for medicines previously reimbursed through the national insurance scheme was transferred to hospitals.

In a narrow sense, procurement activities by LIS (**tendering and negotiations**) only relate to the **price** of medicines, which is then communicated to public hospitals. Purchase decisions, including whether the lowest-priced medicine should be bought and at what volume, are made by the hospitals and their owners, the four regional health authorities. However, an important part of LIS' procurement set-up is the establishment of expert groups for different groups of medicines. These groups, comprising nationally renowned specialists in their respective therapeutic areas, prepare tenders and – based on the results – **issue treatment recommendations**. Take-up of these recommendations (while not mandatory) is high and ensures that the winning product is widely used. Nevertheless, hospitals are **not obliged to participate in the centralised procurement**, and they may deviate from LIS' guidance by choosing different medicines for their patients than the ones recommended. However, there is evidence on higher prices from individual procurements.

In Denmark, the central purchasing/procurement body, **Amgros**, is **jointly owned by the five Danish regions**. Amgros is responsible for procurement and price negotiations for inpatient medicines on behalf of the regions. Nearly all (98%) of medicines used in public hospitals are purchased through tenders organised by Amgros.

Tendering (i.e. use of formal and competitive procurement methods) is the most commonly used procurement procedure for medicines with analogue competition (i.e. interchangeable medicines within the same therapeutic area), generic and biosimilar medicines. Four different types of tender contracts are used: **framework contracts, fixed volume tender contracts, regional tender contracts and contracts for new products**.

[34] The HIO – responsible for PPM since 2020 - is still using the Purchasing and Supply Services Department (formerly responsible for PPM) for tendering procedures due to its high expertise in this field. Further to that the Purchasing and Supply Department of the MOH is responsible for the public procurement of medicines without market interest in Cyprus or even without marketing authorization in the EU.

Amgros also performs **other services than PPM** that contribute to providing the right medicines for patients in public hospitals, including horizon scanning activities, logistic services, consultancy for the government, and collaboration with the Danish Health Technology Assessment (HTA) institute.

Portugal – central procurement as a shared service between the ministries of health and finance

The **ministries of health (MoH) and finance (MoF)** are responsible for strategy development and budgeting for the PPM activities performed. The Serviços Partilhados do Ministério da Saúde / Shared Services of the Ministry of Health (SPMS) is the central procurement body and performing Centralised PPM and concluding framework agreements for the National Health Service (SNS) institutions both in the inpatient sector for public hospitals and the outpatient sector for Regional Health Administrations (ARS). SPMS was created in 2010 and is a public enterprise. The **Central Administration of the Health System (ACSS) commissions and pays** for the activities of SPMS.

SPMS performs both **open procedure tenders** (called centralised procurement of medicines - CPM) based on a list of medicines as of 2016 and negotiates **framework agreements** (mainly for a duration of four years) for both the outpatient and inpatient sectors. In addition, users of PPM (hospitals and ARS) may conduct **individual procurement at facility level** if neither CPM or framework agreements cover the medicine or are (temporarily) not (yet) available through CPM or framework agreements (e.g. at the beginning of calendar years).

SPMS is a service provider to the users of PPM (hospitals and ARS) and serves as key contact to suppliers. Its work goes **beyond medicines** (procurement of services for example, provision of IT services and representation in eHealth cross-border activities).

Latvia – a central procurement body at National Health Service (NHS) for some products

Public procurement of medicines in Latvia is centralised for a **defined list of products**. Procurement for these products is organised by the **Procurement Division of the National Health Service** (Iepirkumu nodaļa) which acts as a centralised purchasing body. For inpatient medicines on the list of centrally tendered products, individual hospitals enter contracts with suppliers on the basis of framework agreements created by the CPB. For other medicines, hospitals (with the hospital pharmacies being responsible for PPM) conduct their own procurement.

Open tenders are the main procurement procedure for centrally tendered inpatient medicines. Upon conclusion of the open tender, **framework contracts** are created with suitable suppliers as the basis for subsequent supply contracts with individual hospitals.

Source: PPM country fiches; [19, 89, 120, 211-217]

A distinct form is **centralised procurement by a regional CPB**. These bodies exist for hospitals in 13 study countries. However, their use is often limited and only represents the main route for procurement of hospital medicines in five countries (Austria, Italy, Spain, Sweden, UK; see Table 18). In four of these countries (all except the UK), regional procurement is aligned with the regional administrative responsibility for inpatient care, i.e. regions are responsible for organising (and partly also financing) hospital care. However, this responsibility does not necessarily translate into procurement structures at the same level in other countries: in Denmark and Norway, where hospital care is also organised by regions, procurement of hospital medicines was centralised at national level through a CPB that is jointly owned by and operates on behalf of the regions (see **Box 9**).

In most of the other study countries, **public hospitals procure medicines individually** (i.e. at hospital level). However, for certain medicines and in certain situations, the hospitals **collaborate in** voluntary **group purchasing**. Some public hospitals have joined established group procurement collaborations or companies.

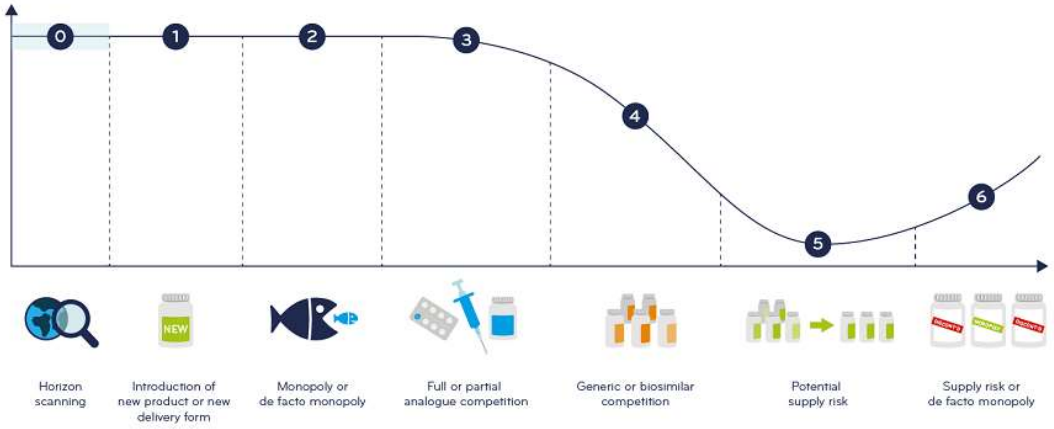
5.2.8. Procedures and techniques applied in hospital procurement

Procurement procedures describe **award procedures** that are defined by law to conduct a procurement, such as open procedure tenders, restricted procedure tenders, competitive dialogue procedures, and competitive procedures with negotiation as defined by EU Public Procurement law [68], whereas procurement techniques relate to different **methods for managing a procurement procedure**, e.g. by making use of e-procurement or repetitive calls for recurring purchases. See also **Chapter 3.3** for

descriptions of the various procedures and techniques and their use for PPM as well as the "Glossary for procurement terms" compiled for this study (Annex 3).

The use of the different procurement procedures and techniques depends on the type of medicines, in particular with regard to its location in the product life cycle. The CPB Amgros, which is responsible for procuring medicines for public hospitals in Denmark (see **Box 9**), has been stressing the **product "life cycle" approach** to procurement [152]: while monopoly medicines are procured via negotiations (which may involve the conclusion of MEAs, see **Chapter 5.2.6**), more competitive procedures and techniques may be used when alternatives in the same therapeutic area (analogous competition), or even competitors based on the same active substance (generics and biosimilars) become available (see **Figure 31**). Competition is therefore leveraged not only for products with direct competitors that use the same active substance, but also for products with therapeutic alternatives. This model is based on close collaboration between Amgros and other institutions, including the Danish Medicines Council, which conducts HTA and issues treatment guidelines that are aligned with the results of the tenders [218].

Figure 31: Product life cycle approach applied and promoted by the Danish CPB Amgros



Source: Amgros [152]

In the study countries, a mix of procurement procedures and techniques is being used for purchasing medicines used in hospitals. Overall, hospital procurers follow the Amgros pharmaceutical life cycle approach, with frequent application of (mainly open) tender procedures, framework agreements and negotiations, depending on the type of medicines. Given that potentially innovative medicines in areas with unmet need (i.e. where no alternative treatment exists) are typically relevant for specialist care provided in hospital settings, hospital procurers may rely on **competitive dialogue** procedures or **competitive procurement with negotiations** for these products. However, such procurements are comparatively rare and other procedures are more frequently used. The most common procedure are **open tenders** which are used across all types of medicines in the hospital setting (see **Table 19** and **Chapter 3.3.1**). Open procedures may also be used to find suitable suppliers for a **framework agreement**. Additional details on the use of framework agreements in study countries is available in **Chapter 3.3.2.1**.

Table 19: Use of open procedures for procurement of hospital medicines in the study countries

Country	Use of open procedures
Austria	Applied in centralised PPM at regional level and in facility-based PPM. May be used to award contracts or to find suppliers for a framework agreement

Country	Use of open procedures
Belgium	Most commonly used procedure for procurement in the inpatient setting, including for centralised PPM at national and regional levels, group procurement, and facility-based procurement
Bulgaria	Used for the majority of procedures for medicines. Open procedures are used in centralised national PPM (by the CPB for the health sector) to conclude framework agreements on behalf of the contracting authorities for medicines included in the positive medicinal list, and by individual facilities for procurement of medicines not included in the list (and for which therefore no framework agreements exist).
Cyprus	Most commonly applied procedure in centralised PPM at national level. Used mainly for off-patent medicines with increased competition and biosimilar medicines. Worldwide calls for tenders (often at ATC-5 level, and sometimes at ATC-4 level) are issued by the MoH every two years.
Czechia	Used for procurement at facility-level.
Denmark	Applied in centralised PPM at national level.
Estonia	Most commonly form of procedure in centralised PPM at national level for medicines used for national health programmes, hospital medicines with large cost containment potential, and biosimilars. Open procedure tenders (every 1-2 years) are the only form of procurement used in facility-based PPM.
Finland	Applied in group and facility-level procurement for all medicines used in hospitals (apart from novel medicines that may be procured centrally by one of the hospital pharmacies).
France	Applied in all forms of hospital procurement, including national, regional, group-based and facility-level procurement.
Croatia	Most commonly used form of procurement for all medicines used in inpatient settings (applied in centralised PPM at national level and for facility-based procurement).
Hungary	Used when there is more than one potential supplier for centrally tender inpatient medicines, including high-cost medicines not covered by the DRG when there is more than one potential supplier (tenders conducted by NEAK), and other centrally tendered inpatient medicines (tenders conducted by KEF). Tenders are generally conducted every 1-2 years.
Iceland	Mandatory use of tenders for products where there is competition in the market.
Ireland	Applied in group-based or facility-level PPM for off-patent hospital medicines (medicines with more than one possible supplier).
Italy	Applied in regional centralised PPM
Lithuania	Applied in national centralised PPM for procurement of high-cost medicines and in facility-level procurement for all medicines used in hospitals.
Latvia	Main procedure for centralised national PPM to identify suppliers for framework agreements (centrally tendered inpatient medicines include vaccines, standard tuberculin, peritoneal dialysis products, products for phenylketonuria and other genetic disorders, immunobiological preparations, and parenterally administered oncological medicines). 4-6 tenders are conducted annually. At facility-level, hospitals also use annual open procedures for medicines not subject to central tendering.
Malta	Used in appr. 80% of procedures conducted at the central national level.
Norway	Most commonly used procedure for procurement of medicines used in specialist care, which is typically conducted at central national level. Facility-based procurement is rarely used, but when individual hospitals conduct their own procurement, they use open procedure tenders.
Poland	At central level, open procedures are used for medicines for bleeding disorder, treatment of HIV/AIDS, and some other medicines. For facility-based and joint (group-based) PPM, open procedures are used for all inpatient medicines.
Portugal	Applied in national centralised PPM for inpatient medicines. Tenders are conducted annually.
Romania	Applied in national centralised PPM and facility-level PPM.
Sweden	Applied in regional centralised PPM and group-based (joint) PPM. At regional level, tendering is done for all inpatient medicines (including biologicals). Tenders can be molecule-based (for biologicals) or therapeutic indication-based, and are typically conducted every 1-2 years.
Slovenia	Applied in facility-based PPM for inpatient medicines. For some years (2017-2019) hospitals performed PPM within a centralised PPM system. Currently, hospitals carry out their own procurements according to tenders issued by the procurement department.
Slovakia	Used for on-patent medicines for centralised PPM at national level and at facility level.
United Kingdom	Applied in centralised regional PPM for procurement of generic medicines, including products that just came off-patent, branded medicines, and biologicals. Open procedure tenders are used to establish framework contracts for branded medicines and biologicals (including biosimilars). Individual hospitals may also use open procedures to address short-term needs.

Note: While no details on open procedure use for hospital medicines were available for the remaining countries, it is likely that open procedures are still used for at least some medicines.

Source: PPM country fiches

In addition, use of new techniques such as electronic auctions and DPS (see **Box 10** for use in Italy) has also been observed in some of the countries (e.g. use by a CPB at national and regional levels).[35]

Box 10: Dynamic purchasing system (DPS) for medicines in Italy

Consip is the CPB at national level which is responsible for procurement of any goods and services in the public sector (voluntary use for the hospitals). Consip uses DPS (in Italian: Sistema dinamico di acquisto (Sdapa)) as a major procurement technique. Introduced in 2011, more than 300 competitive tendering procedures were launched as part of the DPS since then. For instance, in 2021, there were 62 DPS procedures amounting to a total of about 8 billion euros.

According to their needs, hospitals can call negotiated procedures through the DPS provided by Consip or they can also join on-going procedures at regional levels. Consip does not perform any needs assessment or aggregation but offers the technical environment, in particular an e-platform hosted by the Ministry of Economy.

Consip has made very favourable experiences with DPS and considers this technique as the ideal procurement technique for homogenous medicines. A well-functioning e-procurement platform is prerequisite.

Source: PPM country fiche for Italy based on national data and literature [9]

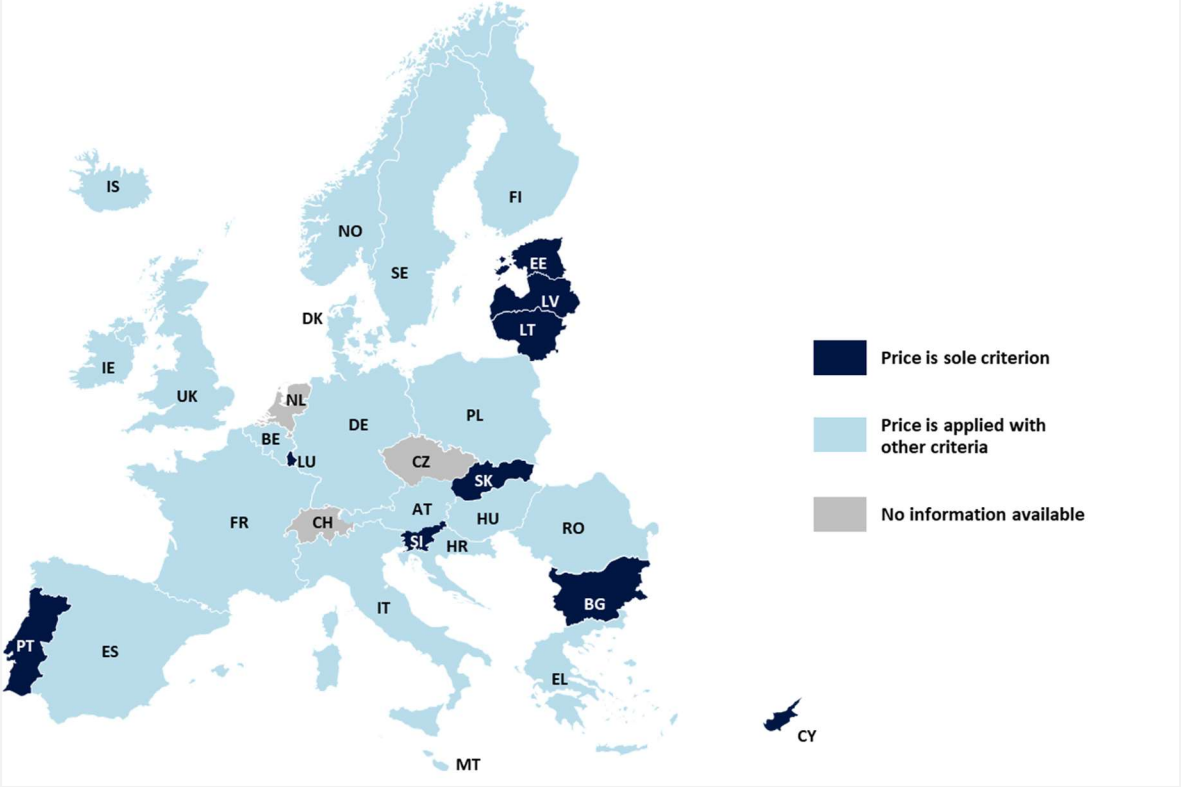
5.2.9. Award criteria in hospital procurement

Details on the use of different award criteria in the study countries, including MEAT, price only, security of supply, local production, environment, and added therapeutic value are described in **Chapter 3.4**.

In all study countries for which information was available, **price is used as an award criterion in hospital procurement procedures** (independent of which main route of procurement is implemented). Most study countries apply price in combination with other criteria, which could include environmental, social, quality or other aspects. A few study countries use price as sole criterion without generally taking into account other criteria. However, among countries labelled as using price together with other criteria in the figure are some that would use price only in some circumstances. For example, the regions in Sweden generally use price as the main criterion for biosimilars because these are considered interchangeable with respect to other characteristics. Similarly, Hungary uses price as the main criterion for central national tenders of biosimilars.

[35] A wide range of procurement procedures and techniques – much more than the ones described in Chapter 4.2.1 of the 2010 PHIS Hospital Pharma report [140] – are applied.

Figure 32: Study countries applying price as sole criterion for PPM in hospitals



Source: PPM country fiches

MEAT criteria come into increasing use in the study countries, allowing the combination of price and other criteria. Specifically for smaller markets, where security of supply can be a challenge and competition in tenders is low, such criteria help to mitigate these risks. While the use of MEAT would generally be taken to mean that several criteria are used, MEAT can also be based on price or cost alone. The following countries apply MEAT in (at least some of) their procurement procedures in the inpatient setting:

- In Austria, MEAT is used in some procedures.
- In Belgium, MEAT is implemented through the use of additional criteria for quality/safety, supply, environment, among others.
- In Croatia, MEAT is dominated by price which makes up 90% of the weight (with the remaining 10% being used for delivery date and environmental criteria so far).
- In Denmark, MEAT is used for centralised PPM at national level, where national tenders are obliged to award contracts to the MEAT as per the respective EU Directive and the Danish Act on Public Procurement. Yet, Denmark also uses price as criterion in some cases in combination with quality criteria (weighted at >50%).
- In Finland, MEAT is the preferred approach to award contracts and includes criteria such as price, usability, patient and work safety, and expenses for switching from formerly used products. Price only is used as criterion for 'less sophisticated' medicines.
- In France, MEAT is supported by procurers. A range of criteria are used, including price.

- In Greece public contracts may be awarded on the basis of MEAT criteria, which can be identified either on the price or cost, or on the basis of the best price-quality ratio.
- In Ireland tenders issued by individual hospitals or groups of hospitals, as well as tenders for national health programmes state that the MEAT criteria will be applied, and that this will be based on the criteria indicated in the tender documents.
- In Iceland, price is always used together with other criteria.
- Romania applies MEAT criteria for all levels of PPM. Out of 17,856 procedures for which contracts have been concluded in 2019, 3,492 used MEAT as award criteria.
- In Spain, MEAT are most commonly used to award contracts.
- In the UK, MEAT criteria are used to award most contracts. This includes cost as well as other criteria.

In some countries, MEAT is reported to be widely used. Note that the reported use may differ from actual use as recorded in the TED database (see **Figure 8** for a breakdown of MEAT vs. price only across procedures (inpatient and outpatient) in the study countries). **Box 11** describes some challenges in implementing MEAT criteria in the study countries.

Box 11: Challenges in implementing MEAT criteria in PPM

Some study countries are trying to implement MEAT criteria in their PPM systems and procedures, but they face some challenges in increasing its use:

- In Malta, the Central Procurement & Supplies Unit (CPSU) within the Ministry of Health, which procures all medicines for the public hospitals, aimed for the introduction of MEAT criteria in tendering. As authorities were hesitant and reluctant to use MEAT, the best price-quality-ratio (which still represents an integral part of MEAT criteria) was defined as sole criterion.
- Latvia applies MEAT criteria for a small percentage of procurement procedures. Overall (across all sectors, not specifically health sector), MEAT criteria were applied in 20% of procedures in 2014.
- In Portugal the Public Procurement Code (PPC), which translated the EU Procurement Directive into national law, would allow the application of MEAT criteria, but it is in practice rarely applied.
- Austria applies MEAT criteria depending on the product only at facility-based PPM level.
- In Estonia and Lithuania, MEAT has so far only been used for procurement of vaccines, not for medicines used in the hospital sector.

Source: PPM country fiches

For all non-price criteria that may be applied, examples are provided in **Table 20.** Note that the table only provides a non-exhaustive list of the application of these criteria. Award criteria may vary between individual procurers within a country, and not all possible applications of all criteria may be reflected in the table.

Environmental criteria are gaining in importance and some countries have started applying or are considering applying these criteria, either directly in specific tenders and/or by piloting environmental criteria in tenders. Aspects of environmental criteria include for example waste reduction (packaging, plastic use etc.), water recycling, principles of fair trade or ethical requirements with respect to the environment. **Box 12** provides an overview of green procurement of hospital medicines in the Nordic countries, while additional information on use of environmental criteria in PPM in the study countries can be found in **Chapter 3.4**.

Box 12: Use of environmental criteria in Nordic tenders for hospital medicines

Denmark

In line with its "green agenda", the first national (Danish) tenders with environmental criteria were launched in 2021. For the development of environmental criteria for hospital procurement, Amgros included expert opinion from the technical university, public authorities and stakeholders. Environmental criteria include packaging and transport criteria. Amgros received similar response rates as to previous tenders (without environmental criteria). Environmental criteria accounted for around 20% of the award criteria in these tenders. Even if the number of bidders was comparable to tenders without environmental criteria, resources to assess the bids increased significantly.

Norway

Regarding environmental criteria inclusion Norway is active and has performed pilot studies on antibiotics and hormones.

The Nordic Pharmaceutical Forum

The cross-country collaboration "Nordic Pharmaceutical Forum" of Denmark, Norway, Finland, Iceland and Sweden conducted two successful Nordic tenders for medicines used in hospitals (for details and learnings see relevant **Chapter 6.2.1.2** on cross-country procurement).

There was some concern that tenders would not generate enough response from suppliers, but this fear did not materialise. Even though new criteria were included in the tenders (such as security of supply or environmental criteria), competition was not affected, yet prices increased. Environmental award criteria were weighted at 30% of the overall award criteria in the second joint tender.

Environmental criteria in the Nordic tenders included:

- following good practice to ensure zero carbon emissions and clean wastewater at the bidder's and their sub-suppliers' production sites;
- documentation on environmental certification;
- documentation of eco-friendly transport (reducing greenhouse gas emissions)

Source: literature and workshops with procurement experts

Examples of other criteria are provided in **Table 20.** **Social criteria** are not commonly used in the study countries. Social criteria are mainly indirectly used as part of MEAT criteria. Social criteria seem as well to be interconnected with environmental criteria (ethical requirements, fair trade, etc.). **Quality and safety of product** are used together with other criteria in some study countries. It may include various aspects from packaging to storage and clinical and literacy aspects. **Security of supply** criteria are used together with other criteria in some study countries. For example, in Ireland, security of supply was used for procuring hepatitis C medicines in a national tender and in a tender on trastuzumab and infliximab. **Added therapeutic value** criteria are used together with other criteria in some study countries. Denmark for example uses the criterion for new hospital medicines.

Table 20: Examples for application of criteria other than price in the hospital sector (non-exhaustive list)

Award criteria	Example
Environmental criteria	• AT: In Austria, a pilot about including environmental criteria in the tender was performed. The difficulty was to include it as award criteria without running risk of appeals while in commercial negotiations it is easier to consider such criteria. • BE: Belgium applies environmental criteria such as waste reduction or water recycling. • CY: Cyprus partly applies environmental criteria. There is a provision in the tendering documents and in contracts establishing environmental issues.

Award criteria	Example
	• CZ: Czech Republic uses environmental criteria. Legislation on Public Procurement (Act 134/2016 Coll, and Act. 543/2020 Coll.) makes it mandatory for every public contracting authority to consider possible environmental, social and also innovative potential of every tender. Implementation is attained through e.g. setting special conditions for participation using labels to have environmental or social criteria proven, or by using a quality evaluation criterion. • DK: Denmark uses the criterion for centralised PPM at cross-country level and has also launched its first national tender with environmental criteria in 2021 for products in ATC groups G and H. Criteria focused on packaging and transport. • EL: In Greece, in principle, legislation provides for consideration of environmental and/or social aspects in MEAT criteria. • ES: tenders launched by national CPBs have included environmental criteria. • FR: Environmental criteria in relation to logistics are used. • HR: For centralised procurement at national level, implementation of an environmental management system according to ISO 14001 was used as part of MEAT criteria (price making up 90% of the weight). • IE: Environmental criteria are used for all PPM through the DPS. Varying award criteria for suppliers to provide medicines in recyclable packaging. • IS: Bidders are required to describe their environmental strategy. Iceland is working on improving environmental criteria. • NO: Norway uses environmental criteria for centralised PPM at national level. The use of environmental criteria for the procurement of new antibiotics was a pilot project. LIS engaged with the regional health authorities, the Norwegian Association of Pharmaceutical Manufacturers (LMI), representatives from generic suppliers, the Norwegian Medicines Agency, and colleagues in Sweden to include environmental criteria. • RO: Romania applies the environmental criterion as sub criterion for all levels of PPM. The Governmental Decision on National Strategy for Sustainable Development for Romania (GD 877/2018) provides a strategic framework for including environmental factors into procurement (e.g. principles of fair trade, ethical requirements). • SE: There is a legal requirement to include environmental criteria in publicly awarded contracts. *No use of environmental criteria: Estonia, Finland, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovenia, Switzerland* *Unclear whether environmental criteria are used for hospital procurement: Bulgaria* *No information on use of environmental criteria: Germany, Liechtenstein, Netherlands*
Social criteria	• CZ: Legislation on Public Procurement (Act 134/2016 Coll, and Act. 543/2020 Coll.) makes it mandatory for every public contracting authority to consider possible environmental, social and also innovative potential of every tender. Implementation is attained through e.g. setting special conditions for participation using labels to have environmental or social criteria proven, or by using a quality evaluation criteria. • EL: In Greece, in principle, legislation provides for consideration of environmental and/or social aspects in MEAT criteria. • *No use of social criteria or no information available for all other study countries.*
Quality / safety of product criteria	• AT: Austria applies qualitative criteria such as storage, supply conditions, availability of different dosage forms (e.g. for children) in national and regional PPM. • BE: Different criteria in the field of quality and safety linked to the subject of the tender are used (e.g. data matrix scanning, stability, clinical evidence, indications, clarity of packaging and labelling, patient education). • DK: In Denmark qualitative criteria may be used together with other criteria for centralised PPM at national level. Examples of quality criteria used previously include storage life, safe administration of products or routes of administration that minimise risk of dosing errors, production processes that minimise the contamination of container surfaces (safety for staff handling products), product quality including packaging (container design that minimises risk of mix-up), and compatibility with existing products. • FR: Quality criteria usually make up 50% of the criteria and may include solubility, quality of the packaging, differentiation in the strengths, identification of the medicine on the unit dose, data matrix on the vial or the unit dose, among others. • HU: Hungary applies the Quality / safety of product criterion for centralised PPM and facility-based PPM. Award criteria for inpatient medicines include price, as well as some quality aspects like supply conditions, storage, etc. • IE: Ireland uses qualitative criteria together with other criteria for all levels of PPM. Quality criteria included shelf life, reported side effects, presentation, and treatment dosage and duration (jointly, 10% of total weight). Quality criteria were also used in tenders for hospital medicines conducted by individual hospitals or groups of hospitals (e.g. product suitability, supply chain, and support services contributed jointly over 50% to tenders for infliximab).

Award criteria	Example
	• IT: Italy applies the quality / safety of product criterion for centralised PPM at regional level. In some rare cases the regional body awarded tenders which also considered qualitative elements, such as the number of dosages available and the quality of customer service. • LV: Latvia applies qualitative criteria for national PPM. Quality aspects such as delivery terms and quality of the product may be used together with price and other criteria. • PL: According to public procurement legislation, the contract shall be awarded on the basis of quality criteria and the price or cost. • SE: Sweden applies the quality / safety of product criterion for centralised PPM at national level. • UK: Award criteria applied in the hospital sector are price and quality (jointly, these constitute MEAT criteria). • In some countries, quality and safety of a product is indirectly considered through the existence of a marketing authorisation: Iceland, Portugal, Slovenia, Switzerland • Other countries applying this criterium without further detail: Germany, Greece, Slovakia, Spain *No use of quality / safety of product criterion: Bulgaria, Cyprus, Estonia, Finland, Luxembourg, Malta (not as a criterium per se but as part of the BPQR), Norway, Romania* *No information available: Croatia, Czech Republic, Liechtenstein, Lithuania, Netherlands*
Security of supply criteria	• BG: Provisions to require documentation on security of supply from suppliers were challenged and overturned in court. • DK: Denmark uses the criterion for centralised PPM at cross-country level. (e.g. used for the 2021 joint Nordic procurement, together with price and environmental criteria. • FR: Stock levels are used as criterion for major therapeutic medicines. • IE: Ireland uses the Security of supply criterion for all levels of PPM. Was used together with other criteria (cost, quality of product, other contract management criteria) for procuring hepatitis C medicine in a national tender (security of supply was weighted at 3%). Other examples include 5% weighting for a tender on trastuzumab (criteria included confirmation of number of months of buffer stock in Ireland, details on previous stock-out situations, and details on number of manufacturing sites) and 12% on a tender for infliximab. • IS: Requirement to have 2 months' supply in a warehouse. • Other countries applying this criterium without further detail: Belgium, Latvia, Norway, Spain, Sweden, Switzerland • NL uses security of supply criteria for outpatient medicines in its preferential pricing system. *No use of security of supply criterion: Austria, Cyprus, Estonia, Finland, Hungary, Italy, Lithuania, Luxembourg, Malta (only indirectly through delivery times specifications), Poland, Portugal, Slovenia* *No Information available: Croatia, Czech Republic, Germany, Greece, Liechtenstein, Romania, Slovakia, UK*
Added therapeutic value criteria	• BE: Belgium asks for additional clinical evidence (however: the therapeutic value has been established by the national authority in the evaluation for market acceptance). • DK: Denmark uses the criterion for centralised PPM at national level. For new hospital medicines, added value (in six categories ranging from major added value to non-demonstrable added value) is assessed by the Danish Medicines Council and informs the price negotiations conducted by Amgros. Added therapeutic value indirectly features as a criterion for procurement of newly introduced medicines as it informs price negotiations and is used to determine an acceptable price range. • NO: Norway applies added therapeutic value as criterion. It has been used for selected tenders (effects of medicine as well as side-effects). • SE: Sweden applies this criterion for centralised PPM at regional level. Priority is given to quality aspects of the tender, i.e. the medical and pharmaceutical value, although price also features. • Other countries applying this criterium without further detail: Germany, Netherlands, Slovakia, Spain. Switzerland • EE: Estonia has used added therapeutic value for procurement of vaccines, not for hospital medicines. *No use of added therapeutic value as criterion: Austria, Bulgaria, Cyprus, Finland, France, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia* *No Information available: Croatia, Czech Republic, Greece, Ireland, Liechtenstein, UK*

Award criteria	Example
Other criteria	• IE: Ireland uses other criteria: Value-added services. Some element of value-added services was included in all tenders for infliximab, including as core criterion or additional consideration. In one example from a hospital in Dublin, patient-support resources (i.e. age-appropriate information material for children and self-management tools) and therapeutic drug monitoring (TDM), antibody, and calprotectin measurements were weighted at 15% of the award criteria. • NO: Norway uses other criteria: User-friendliness, packaging and product range for centralised PPM at national level and service for centralised PPM at national level. • FR: France considers considering the local production criterion in next tenders, to support security of supply.

Source: PPM country fiches

5.3. Interface management

In several cases, a therapy is started when a patient is admitted to the hospital and continues after her/his discharge, frequently resulting in a long-term continuous therapy in the outpatient setting.

Thus, the **medicines selected for the start of the therapy can have a major impact on the follow-up prescribing**. For instance, when a hospital therapy starts with the prescribing of a high-cost medicine, such as the originator (biological) medicine, despite availability of equivalents and alternatives (e.g. generics or biosimilars), outpatient physicians may experience the switch to a lower-priced medicine as challenging. Even if doctors in the outpatient sector are obliged (or at least encouraged) in many countries to switch to a lower-priced alternative in line with (prescribing) guidelines of the social health insurance or NHS, this may entail additional communication with the patient to ensure switches are understood and do not negatively impact on adherence. There is empirical evidence (from France) that hospital medicine use impacts pharmaceutical consumption in the outpatient sector [219].

In this context, hospital procurement plays an important role. Compared to reimbursement lists (positive lists, formularies) applied in the outpatient sector which usually include several equivalents per active ingredient, in addition to originator and/or reference medicine, hospital pharmaceutical formularies are narrower and frequently only contain one medicine per active ingredient. As a result of marketing strategies of pharmaceutical companies (higher discounts and even cost-free provision in countries where it is allowed), medicines with, in principle, higher price tags (in the subsequent outpatient use) are procured in hospitals, because they are provided at lower costs for them [220]. This practice of offering so-called **loss leaders**, mainly for chronic diseases, to hospitals, with the expectation of companies for a return on investment in the outpatient sector in the long-term run, has been documented in previous research [219, 221] and has been investigated by competition authorities due to the effect of impeding market entry and uptake of generic and biosimilar products [180, 222]. In addition, prescribers in hospitals have a stronger role (through their application to, and possible involvement in the PTC) in what is being procured compared to the interaction of outpatient physicians in decisions on the inclusion of medicines in the reimbursement list.

Thus, what is procured and subsequently prescribed in hospitals has an impact on the outpatient sector and eventually the whole health and pharmaceutical system. **Savings for hospital procurers may result in overall higher pharmaceutical expenditure borne by the taxpayers.**

The outpatient and inpatient pharmaceutical (procurement) systems differ, with different mechanisms, regulations, policies, institutional and organisational set-up and sometimes also differ funding bodies (even if eventually it is all public money). In **Chapter 5.2**, the specificities of hospital procurement were described. In contrast,

public procurement generally plays a less important role in the outpatient sector. There are exemptions: some smaller countries use PPM for almost all their medicines needs (e.g. Cyprus for all inpatient medicines, the outpatient sector is private [16, 18], Malta for all medicines both in the inpatient and outpatient sector). Additionally, some countries apply tendering or tendering-like policies for off-patent medicines in the outpatient setting: public payers invite bids per active ingredient, and the product of the winning bidder (and in some cases also of the second and third winner) is included in the reimbursement list and must be prescribed (e.g. the "Preferential Pricing Policy" in the Netherlands, "discount contracts in Germany, the "product of the month" in Sweden, a tendering-like system with changes every two weeks in Denmark [116, 127, 223]; see also **Box 1**). Normally, for a medicine used in the outpatient sector, the public payer decides whether or not a medicine is reimbursed (positive list) and will thus be publicly funded (at least to some extent). Physicians are expected to prescribe, according to the guidelines, medicines included the reimbursement list, unless the patient is willing to pay out-of-pocket for a non-funded medicine.

Given the interconnectivity of the inpatient and outpatient sectors that are frequently organised in separated settings, there has been for long a call for collaboration mechanism to bridge between the two sectors. In the PHIS Hospital Pharma Report 2010, this mechanism was called "interface management", a term that was subsequently used by the management and the members of the PHIS network (a network of competent authorities for pharmaceutical pricing and reimbursement information resulting from the PPRI network plus hospital managers), and by the WHO that followed up on this concept. In the literature, further terms, in particular "seamless care" and "continuity of care" were also used (see Box 13). For this study, which follows on the PHIS work, the term "interface management" continues to be used.

Box 13: "Interface management" – definitions and concepts

For the purpose of this study, the term "interface management" is used, and it is defined as followed: "Mechanisms of cooperation between the hospital and the outpatient sector" [142].

Further commonly used concepts to this cross-sector collaboration include:

- Seamless care: "the desirable continuity of care delivered to a patient in the health care system across the spectrum of care and their environments. Pharmacy care is carried out without interruption such that when one pharmacist ceases to be responsible for the patient's care, another pharmacist or healthcare professional accepts responsibility for the patient's care" [224], cited in [225].
- Integrated care (comprehensive care, transmural care): "Integrated care is a concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency"[226].
- Continuity of care: Continuity is "the degree to which a series of discrete healthcare events is experienced as coherent and connected and consistent with the patient's medical needs and personal context" [227].

The concepts and definitions of seamless care, integrated care and continuity of care are a focus on the "care" aspect, involving the health professionals offering services. The term "interface management" is broader as it aims to also consider features of the institutional, organisational and funding framework (e.g. pharmaceutical policies).

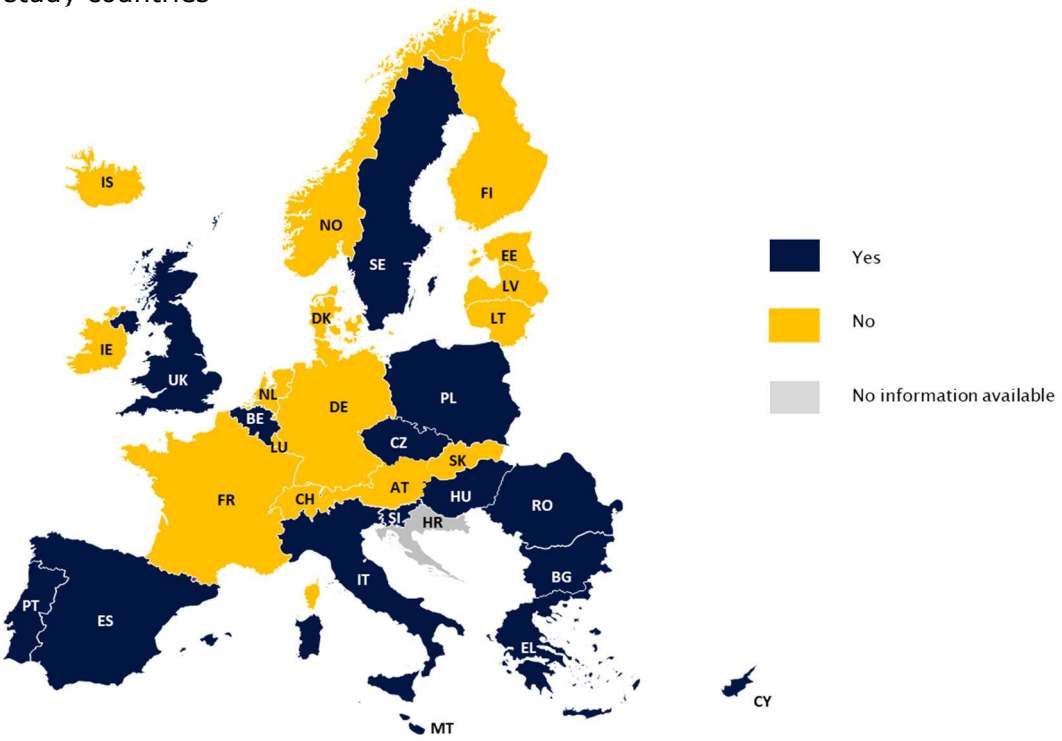
Identified policies and measures in the study countries include reimbursement lists applicable for both sectors, joint reimbursement committees, specific funding mechanisms to avoid incentivising the transfer of financial responsibility between the sectors, supporting instruments to generate evidence implemented from a holistic point of view, capacity building and networking (collaboration) activities of health professionals, discharge programmes to support seamless care, and IT projects.

5.3.1. Cross-sectoral formularies and formulary committees

In the majority of the study countries, reimbursement lists (formularies) relate mainly to the outpatient sector, while hospitals have national, regional and/or facility-based hospital pharmaceutical formularies (see also **Chapter 5.2.4**). As described above, sector-specific formularies imply that prescribers and procurers do not consider the needs of those responsible for procurement, inclusion into reimbursement and prescribing in the other sector (usually the outpatient setting, which is the "downstream" sector). Cross-sectoral formularies, or at least involvement of representatives of the "other sector" in the formulary management, are a key instrument to address this barrier.

Several countries (Belgium, Bulgaria, Cyprus, Czech Republic, Greece, Hungary, Malta, Italy, Portugal, Romania, Slovenia, Sweden, UK (applying only to Scotland)) have a **joint formulary for outpatient and inpatient sectors** (see **Figure 33**). It should be noted that in some countries (e.g. Bulgaria, Czech Republic, Hungary, Portugal, Slovenia) a comprehensive **cross-sector reimbursement list** is in place, which is **supplemented by HPF**. **Box 14** reports in more detail some cases of such cross-sectoral reimbursement lists.

Figure 33: Cross-sectoral (joint inpatient and outpatient) reimbursement lists in the study countries



AT: Specific HPF, no joint reimbursement list.
BE: In addition to the cross-sectoral formulary in place, HPF are applied.
BG: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF). Medicines included in the cross-sectoral formulary are reimbursed. However, there may be differences with regard to medicines that may be used in the outpatient sector (based on ICD codes) and the inpatient sector (based on authorised indications).
CH: Specific HPF, no joint reimbursement list
CY: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF). Until end of August 2020 a formulary of medicines (positive list) was maintained by the Ministry of Health advised by the Medicines Council for the inpatient sector separately from the general reimbursement list which was then integrated to the responsibilities of the Social Insurance (HIO) and its committees.
CZ: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF). SÚKL has been processing and publishing the list of reimbursed medicines and foods for special medicinal purposes. The list is processed on the basis of decisions about maximum prices and conditions and levels of reimbursements. This list constitutes the basis for reimbursement in the inpatient sector and can be supplemented by HPF.

DE: Specific HPF, no joint reimbursement list.
DK: Specific HPF, no joint reimbursement list.
While no cross-sectorial formularies exist for the outpatient and inpatient sectors, inclusion of medicines in the regional HPF takes into consideration potential price differences between the two sectors (low price inpatient vs. high price outpatient).
EE: Specific HPF, no joint reimbursement list.
EL: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF). The Greek pharmaceutical systems regulates maximum hospital prices, which are set in relation to ex-factory prices of products included in the positive list. Hospitals usually have their additional own formularies, but the regulated prices of the positive list serve as a ceiling for PPM.
ES: Specific HPF, no joint reimbursement list.
FI: Specific HPF, no joint reimbursement list (or only partly on municipality level).
FR: Specific HPF, no joint reimbursement list. The national reimbursement list consists of two distinct parts: one list of reimbursable medicines used in the outpatient sector (liste des medicaments remboursables agréés aux assurés sociaux) and another list for the hospital sector (liste des médicaments agréés aux collectivités or réserve hospitalière).
HR: No Information available.
HU: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF).
There is a single process for applying for inclusion of new medicines in the reimbursement list for both inpatient and outpatient sectors. For most medicines, the National Health Insurance Fund (NEAK) decides on the inclusion of medicines in the cross-sector reimbursement list. For some high-cost medicines, the ministries of health and national economy are involved.
IS: Specific HPF, no joint reimbursement list.
IE: Specific HPF, no joint reimbursement list.
IT: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF).
Medicines to be included in the HPF must have been included in the national positive list (PNF – applicable for both outpatient and inpatient sectors). Additionally, there is formulary "hospital – outpatient" - of direct distribution (Prontuario Ospedale – Territorio PHT) which lists medicines that can be supplied "in direct distribution", i.e. directly by local health authorities for community pharmacies which dispense these medicines to the patients, discharged from hospitals. The rationale is that health authorities may get lower prices. There has been some discussion since it has not been regularly updated.
LI: No Information available.
LT: Specific HPF, no joint reimbursement list.
LU: Specific HPF, no joint reimbursement list.
LV: Specific HPF, no joint reimbursement list.
MT: Joint reimbursement lists for outpatient and inpatient sector, no HPF.
There is a Government Formulary List (free of charge / covered by social health system for patients), yet in addition there are also separate lists for the outpatient and inpatient sectors.
NL: Specific HPF, no joint reimbursement list.
NO: Specific HPF, no joint reimbursement list.
PL: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF).
The positive reimbursement list for outpatient medicines informs procurement decisions in the inpatient sector.
PT: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF), but the HPF at hospital level play a more important role, kindly confirm.
RO: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF).
SK: Specific HPF, no joint reimbursement list.
SE: Joint reimbursement lists for outpatient and inpatient sector, no HPF.
The Stockholm "Wise List" aims to improve prescribing practices in the Stockholm area by providing a single set of recommendations across inpatient and outpatient settings. Similar initiatives exist in other regions.
SI: Joint reimbursement lists for outpatient and inpatient sector, plus hospital pharmaceutical formulary (HPF).
A positive list (full coverage), a positive list with up to 30% co-payment and an intermediate list (with higher co-payments) are in place.
UK: While there is no national joint reimbursement list in England, Scotland has introduced such a list to improve quality and safety of prescribing (including considerations about polypharmacy). Cost considerations increasingly played a role and a single budget for inpatient and outpatient care was introduced. Joint medicines lists (formularies) are developed by drug and therapeutics committees which comprise physicians from both sectors. The joint formularies are informed by joint guidelines for both sectors, which are developed based on recommendations by the Scottish Medicines Consortium (SMC), the Scottish HTA body.
In England, several initiatives have developed joint formularies between inpatient and outpatient sectors through Regional Medicines Optimisation Committees.

Source: PPM country fiches

Box 14: Cross-sectoral formulary management in Sweden and Scotland

The "Wise List" in Stockholm – a cross-sector formulary managed by a joint committee

Sweden has a decentralised pharmaceutical system, with the regions paying for medicines. To ensure rational use of prescribing, the Stockholm region developed the so-called "Kloka Lista" (translated as "Wise List"). The "Wise List" contains those medicines which physicians are encouraged to prescribe; it is a selection of medicines that have been assessed by the National Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket / TLV) as eligible for reimbursement. Regular information activities targeted at physicians aim to enhance prescribing compliance with the "Wise List" which is closely monitored, and in case of deviated prescribing behaviour prescribers are approached. The "Wise List" is also actively communicated to the patients, with a booklet in laypeople's language.

Introduced in 2000, the "Wise List" was first intended to target prescribing in the outpatient sector. However, in the course of further developing the "Wise List", it was expanded in 2006 to also cover medicines used in the hospitals.

The "Wise List" is updated on an annual basis, based on suggestions that expert panels developed and submit to the PTC of the Stockholm region. Given the cross-sector character of the "Wise List", the Committee comprises experts from different fields, to be able to cover both medicines for hospital and outpatient use.

The "Wise List" recommends around 200 medicines for treating common diseases in outpatient and hospital care and additional 100 medicines for specialised care.

While the Stockholm region pioneered the "Wise List" concept, the other regions have similar lists in place.

Cross-sectoral formularies and committees for primary and hospital care in Scottish regions

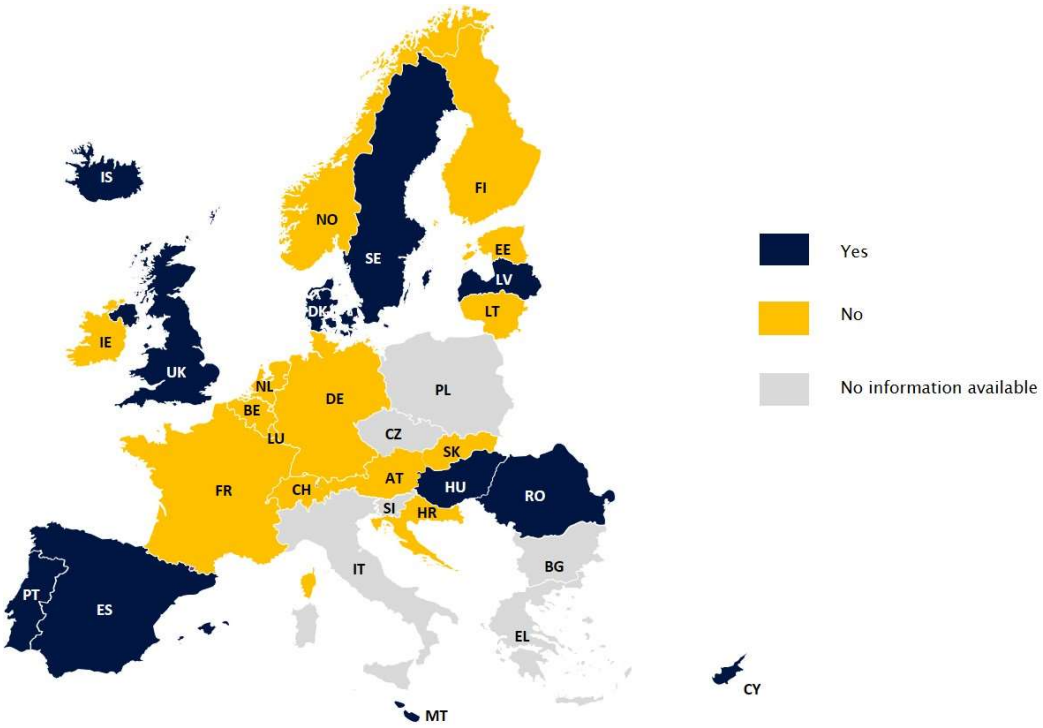
Scottish regions have a joint list of medicines that are recommended for outpatient and inpatient use. For instance, in Lothian (one region), the Area Drug and Therapeutic Committee (ADTC) formed a Formulary Subcommittee to produce a Lothian Joint Formulary, which was first launched in 2001. The concept of joint formularies even dates back to the 1980s, with the Health Board of the Grampian region to introduce a joint formulary in 1993. In 1993, the Scottish Office advised that each health board in Scotland should produce a similar joint formulary covering both primary and hospital care, with the aim to improve the quality and cost-effectiveness of prescribing.

In the regional PTC, physicians of the outpatient and inpatient setting are involved to develop recommendation and guidelines. Formulary guidance aims to apply equally to outpatient and hospital care, and no "carte blanche" is given to specialist care. Prescribing medicines that are not included in the formularies is only permitted if a justification is provided by the prescriber.

Source: Sweden [228, 229], Scotland [228, 230, 231]

Cross-sectoral reimbursement committees are not frequently used in the study countries and have mostly been established in the countries with cross-sectoral formularies (see **Figure 34**). In Austria for example, there are no reimbursement committees across the sectors but in the PTC a representative of the sickness fund (i.e. payer for outpatient medicines) is involved, however without voting rights. Still, this change which was legally implemented more than a decade ago helped create a better understanding of all members of the PTC for the other sector [232]. In addition, Austria established (and then put on hold) a "Medicines Commission" of representatives of the outpatient and inpatient sector with the aim of better coordination between sectors (see **Box 15** for further information, as this Commission was part of a large interface management initiative).

Figure 34: Cross-sectoral reimbursement committees in the study countries



AT: Representatives of sickness funds (payer for medicines used in the outpatient sectors) are members without voting right in the PTC of hospitals.

BE: Social health insurance decides on the reimbursement of medicines both for outpatient and inpatient sectors.

CY: The Advisory Committee on medicines assesses the application and makes a recommendation to the HIO Board of Directors on whether the pharmaceutical product should or should not be reimbursed.

DK: Joint implementation committee /clinical task force for biosimilar stakeholders.

ES: Some committee with representation of outpatient and inpatient sectors.

FI: Cross-sectoral reimbursement committees only partly on municipality level.

FR: CEPS (Interministerial Economic Committee for Health Products) negotiates the prices of medicines used in hospitals and part of the DRG system (instead included in the national reimbursement lists applicable for medicines in the hospital). CEPS also negotiates the prices of medicines included in the outpatient list.

IS: The same PTC (based at the national hospital, Landspitali) is responsible for assessing new medicines and determining their benefit to patients in the inpatient and outpatient sector.

LV: The same committee is responsible for defining the lists of reimbursed medicines in the inpatient and outpatient sectors.

MT: The Government Formulary List Advisory Committee (GFLAC) and Advisory Health Care Benefits Committee (ACHBC).

SE: The Stockholm "Wise List" model includes a joint committee making recommendations about essential medicines to be used in the inpatient and outpatient sectors.

UK: Cross-sectoral committees are implemented at regional level in Scotland only.

Source: PPM country fiches

Box 15: Interface management initiatives in Austria

Long-term cross-sector health reform agenda

In Austria, a reform process has been on-going for more than a decade to improve the interface management in several areas of health care (so-called "Zielsteuerung Gesundheit" (ZSG) process, with the three ZSG partners: federal state (represented by the Ministry of Health), the regions (main owner of hospital), and social health insurance (funding outpatient services including medicines used in the outpatient sector).

The legal framework is based provided by the Federal ZSG Agreements (resulting in ZSG Agreements at regional levels), one running from 2013 till 2016 followed by another from 2017 till 2021 (negotiations for a new Agreement currently taking place). The agreements define numerous reform project to improve collaboration between the three ZSG partners and thus also at the interface of outpatient and hospital sectors.

Cross-sector "Medicines Commission" for high-cost medicines

The 2013-2016 agreement provided for the establishment of a "Medicines Commission" for outpatient and inpatient care to determine the "point of care" (POC) of a medicine based on the medical-therapeutic, health care and security of supply criteria. Members of this "Medicines Commission" were delegates of the social health insurance and the regions as well as scientific experts nominated by the federal state who chaired the Commission. The social health insurance or a region could submit an application for an eligible medicine (only medicines with high budget impact or speciality medicines) to the Commission to ask for clarity on the POC and thus the funding responsibility.

The "Medicines Commission" was established and received some applications, but eventually the project was discontinued as no aggregate consumption data (both outpatient and inpatient sector) for the first medicine discussed could be collated, which could have been needed for taking an informed decision.

Procurement practitioners' conference

To improve the exchange and collaboration between the outpatient and inpatient sectors, a meeting of ZSG partners, the central procurement agency and procurers at facility-level (hospital pharmacists) was organised in 2016. A key-note speaker of the Danish CPB Amgros reported about their experience with centralised procurement. Similar follow-up conferences are considered.

Cross-sector joint procurement plans

The 2017-2021 ZSG agreement listed the intention to establish the necessary organisational and legal prerequisites to conduct joint procurements across the sectors (outpatient and inpatient), across regions and across EU Member States. The project has been put on hold.

Source: ZSG Agreements [233, 234], information of involved experts

5.3.2. Funding mechanisms

In countries with a fragmented pharmaceutical system, with different payers for the outpatient and inpatient sectors, **funding mechanisms bridging between or aligning the two sectors constitute a major interface management measure**. One funding measure (also presented in the 2010 PHIS Hospital Pharma Report [140]) that used to serve this aspect was one of the two "DRG carve-out lists" (see also **Chapter 5.2.3**) applied in Dutch hospitals. Medicines included in the "NZa list of expensive medicines" were largely (80%) funded by the social health insurance, but 20% had to be paid by the hospitals out of their budget, with the explicit aim "to stimulate hospitals to use these medicines in an efficient way" [235]. This funding mechanism in the Netherlands was meanwhile abolished and replaced a different system. The "H prescriptions" in Norway (see **Box 16**) is the only mechanism of funding for the "other" sector with the aim to strengthen awareness and financial responsibility that had been identified in the study countries. While it should be noted that high-priced medicines (e.g. Onasemnogene abeparvovec / Zolgensma®, see **Chapter 5.2.3**) can be covered by a different payer than the standard funding routine, this appears to be based rather on financial considerations (to ensure access to medicines which the regular payers, e.g. regions, would not be able to afford) and was thus not classified as an interface management measure.

Box 16: "H prescriptions" in Norway – paying for the medicine use in the other sector

In Norway, hospitals pay for medicines that are used by patients in the outpatient sector, usually medicines whose initial therapy is started in a hospital and then continued in outpatient care. With this measure, a shift of funding responsibility from social health insurance (regular payer for outpatient medicines) to the hospitals took place for defined medicines. The rationale was and is to incentivise hospital doctors to prescribe more economically, as the subsequent expenditure has to be borne by the hospitals.

At its start in 2006, medicines under the "H prescriptions" measure were tumour necrosis factor (TNF) inhibitors and Multiple Sclerosis medicines. However, it was extended over the years to also include some oncology medicines and medicines for the treatment of HIV, Hepatitis B and Hepatitis C.

Source: PPM country fiches; [92, 114, 228]

5.3.3. Further interface management measures

Further measures to improve the collaboration regarding pharmaceutical care at the interface of hospital and outpatient sectors are described below. Given the lack of a clear definition of what constitutes an interface management measure, these are intended to provide an overview of possible initiatives, rather than aiming to provide an exhaustive list of all existing measures.

Extend (supporting) policies from the outpatient to the inpatient sector or vice versa:

- Netherlands: The "lock" system to assess expensive medicines used in hospitals (see **Box 17**).
- Norway: Extension of the "Nye Metoder" system for the managed introduction of new health technologies, including medicines, which was introduced for specialist health services (hospital care) in 2013, to the outpatient sector in 2016. The "Nye Metoder" system provides for conducting HTA (different types, such as mini-HTA, single technology assessment or full HTA, depending on the findings of a preceding horizon scanning exercise)

Box 17: "The lock" system in the Netherlands to assess high-budget impact medicines for hospital use

The Netherlands used to perform an HTA only for medicines included in the outpatient reimbursement list. With the advance of an increasing number of new medicines with high price tags to be procured by the hospitals and thus publicly funded, without an evaluation of their evidence, the government introduced the "lock" system in 2014.

Medicines intended for the hospital sector and whose budget impact is estimated to amount to more than EUR 40 million for all patients or to EUR 50,000 per patient annually plus total cost of EUR 10 million per patient over the years are blocked from the previously applied "automatic funding" and are put in the "lock". This means that a full HTA will be conducted, and its findings will determine the subsequent processes (e.g. decision in favour or against funding, price negotiations, possible conclusion of an MEA).

Source: [236, 237]

Examples of **IT projects** / cross-sector collection and exchange of data include the following:

- Cyprus: Electronic system fed by data of the social health insurance and the Purchase and Supply Services of the Ministry of Health with comprehensive data including stocks and prescriptions
- Spain: In Catalonia, an electronic system allows sharing of clinical data between outpatient and hospital medical records
- Sweden: Pharmaceutical sales in inpatient and outpatient sectors are monitored by the Swedish eHealth agency (E-hälsomyndigheten). The agency collects data on

sales from all pharmacies, retailers and wholesalers who are obliged by law to supply the data

Examples of measures and programmes with regard to **discharge of patients** from hospitals:

- Austria: The discharge letter (in some regions) indicates the recommended therapy by its International Non-Proprietary Name (INN) to facilitate subsequent prescription of lower-priced medicines, if available (overall, as a rule, neither INN prescription nor generic substitution is allowed in Austria)
- Czech Republic: Patients receive medicines prescribed in hospitals and needed after discharge from the hospitals in order to avoid that patients fill the prescription elsewhere
- Portugal: Patients with ambulatory surgery are entitled to free medication (for up to five days) after discharge

Initiatives that aim to provide **treatment recommendations**, and foster **capacity-building and collaboration**:

- Italy: Collaborative SIFO-FARE project of outpatient and inpatient procurers: SIFO (Società Italiana di Farmacia Ospedialiera e dei Servizi Farmaceutici delle Aziende Sanitaria / Italian Society of Hospital Pharmacists) and FARE (Federazione delle Associazioni Regionali Economi e Provveditori della Sanità / Italian Federation of Regional Association of Public Buyers in Healthcare) launched a collaboration project to jointly further develop the procurement rules (the 2014 EU Procurement Directive [68] was transposed into Italian law in 2016), while fully accepting the interprofessionality (different background of the two professions). There were capacity-building events and four publications regarding to the further development of PPM.
- Latvia: Adding to a cross-sectorial committee to decide on the inclusion of medicines in the lists of outpatient and sectors (see **Chapter 5.3.1**) hospitals are responsible for developing and issuing treatment recommendations for outpatient care.
- Spain / regional of Andalusia: There are so-called "integrated areas" ("Areas Integradas" (Integrated areas) where the manager of the Area is both the manager / director of the hospital and the community centers in the area.
- Sweden (Stockholm): Training and education for prescribers to inform about the concept and context of the "Wise List" (see **Box 14**)
- UK: Area Prescribing and Medicines Management Committees (APC) with outpatient and hospital care commissioners and providers to discuss medicines management approaches, including prescribing issues.

5.3.4. Developments in the last decade

Since the 2008/2009 survey conducted for the PHIS Hospital Pharma Report [140], no major changes in terms of organisational and funding measures to improve the interface management have taken place. To the knowledge of the authors, as far as observable in literature and the country surveys, no further countries introduced joint reimbursement lists and committees or funding mechanisms to disincentivise the shifting of financial responsibility between the outpatient and inpatient sector. With regard to the latter, Norway extended its list of "H prescription" medicines, and Austria aimed to implement an interface management project which was eventually discontinued.

In the last decade, some further measures to improve bridging between the sectors were taken, and they can be classified into two overarching categories:

- **Supporting policies**: In light of pressure on public budgets of new medicines with high price tags and uncertainty, supporting instruments such as horizon scanning and HTA to generate evidence required for decision-making have gained importance. These instruments are introduced and/or further developed with a holistic view of the pharmaceutical system; examples from some countries (the Netherlands, Austria) highlight increased political interest in the hospital sector.
- **Collaboration projects**: Some projects were launched to improve processes at the discharge of patients (discharge letter, exchange between health professionals of the two sectors) as well as collaboration initiatives between community and hospital pharmacists with the aim to learn more about the other sector.

These measures are no procurement activities per se, but are part of the package of policies and initiatives to support equitable patient access to affordable medicines from a holistic point of view.

5.4. Biosimilar use and procurement in hospitals

Biological medicines are based on a biological substance that is more complex compared to other, non-biological medicines. Biologicals are used in patients with often seriously debilitating and life-threatening conditions which are typically treated in hospitals, including in oncology, neurological degenerative diseases, and rheumatoid arthritis, among others. Biosimilar medicines are biological medicines that are similar in their active substance to a reference product and can only enter the market once the patent of the reference product has expired [142].

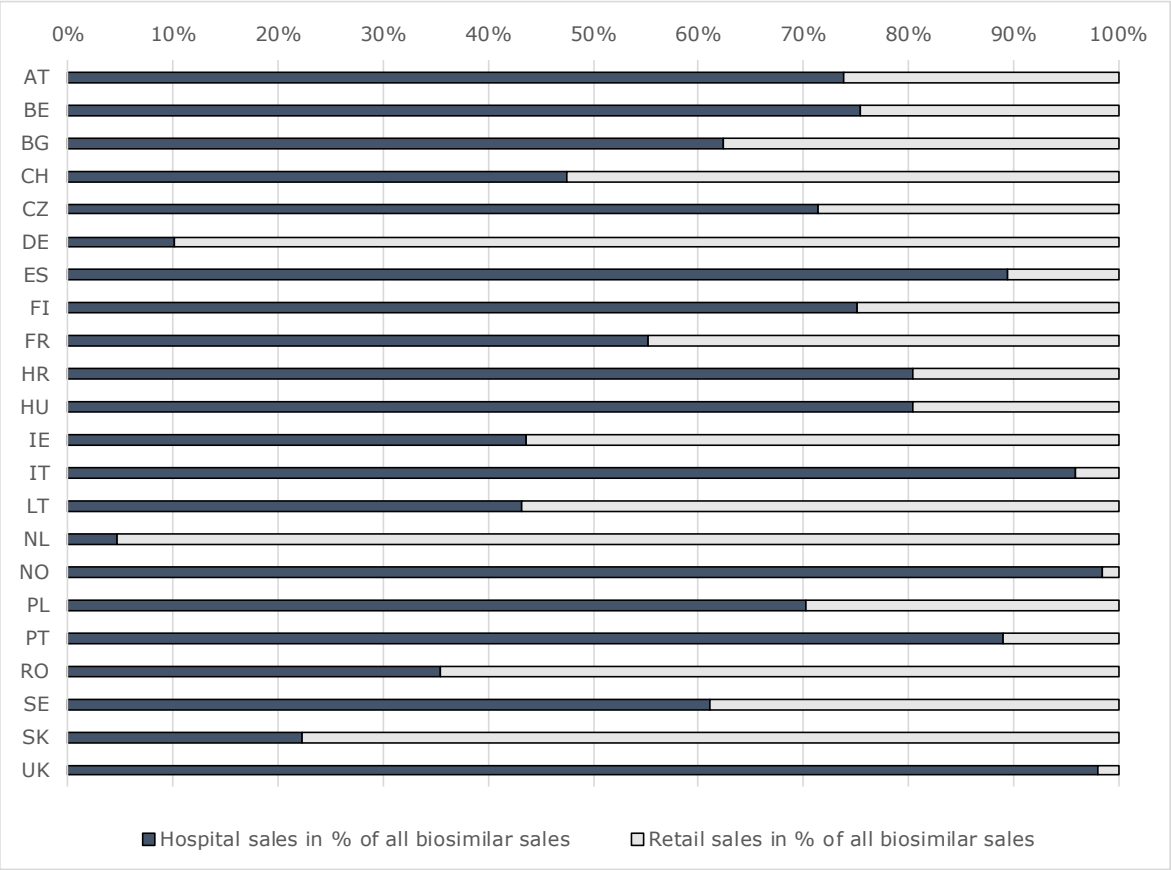
Use of biosimilar medicines has seen consistent annual growth since the first products entered the market in 2006. As of June 2020, biosimilar medicines accounted for 9% of the sales value of biological medicines in Europe, while list prices in markets with biosimilar competition have decreased by almost one-third [238]. Due to the typically **high prices charged for biological medicines**, creating competition for their markets through the introduction of biosimilar versions can generate substantial cost savings [239].

This chapter provides an overview of how biosimilar medicines are used in inpatient care in European countries, how hospitals conduct procurement of these products, and what factors contribute to or hinder more widespread uptake.

5.4.1. Biosimilar use in hospitals

The potential for substantial savings makes biosimilar medicines an attractive target for optimising procurement policies. This is particularly relevant for the hospital sector, which accounts for the lion share of biosimilar medicines in most European countries. In 2021, the share of biosimilar medicines sales in hospitals (as opposed to the retail sector) was 50% or greater in 15 of the study countries, and seven countries had a larger share of sales in the retail setting (see Figure 35).

Figure 35: Share of biosimilar medicines sales in the hospital vs. retail sectors, 2021

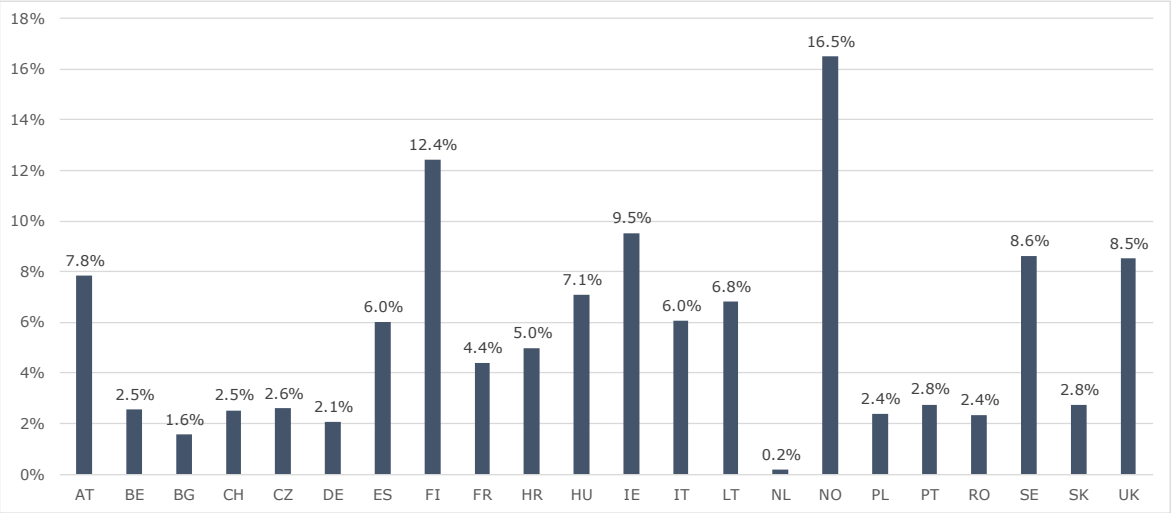


Note: Only retail sector data available for DK, EE, EL, LV, LU, SI. No pharmaceutical sales data for IS, LI, MT.

Source: IQVIA [145]

Uptake of biosimilar medicines varies greatly, both between European countries and within. At the national level, the share of sales of biosimilar medicines among all pharmaceutical sales in hospitals ranged from less than 2% in Bulgaria and the Netherlands to 8% and more in Finland, Ireland, Norway, Sweden, and the UK (see **Figure 36**). Norway, which invested heavily in generating and disseminating evidence about safety of switching patients to biosimilar medicines and where procurement of hospital medicines is conducted centrally, had the highest proportion of biosimilar sales at 16.5% of hospital pharmaceutical sales (see **Box 18** for description of the tendering system for biosimilars in Norway).

Figure 36: Share of biosimilar medicines in total hospital pharmaceutical sales, 2021



Note: No hospital sales data available for DK, EE, EL, LV, LU, SI. No pharmaceutical sales data for IS, LI, MT.

Source: IQVIA [145]

Substantial variation in biosimilar uptake may also occur **within countries**. While biosimilar uptake overall is comparatively high in Sweden, this varies greatly by individual region. In 2017, the market share of biosimilar infliximab ranged from 18% to 96% across the 21 counties [240]. In Hungary, there was wide variation in biosimilar uptake across different products, with biosimilars dominating the market for G-CSFs while for indications where infliximab was used, originator products continued to be prescribed after biosimilar infliximab became available [241, 242].

Variation may be partly explained by the use of different **policies to encourage uptake**, including how procurement is done, but may also occur due to **other factors that act as barriers and facilitators for uptake**, respectively. A Swedish study found that variation in uptake of biosimilar infliximab was partially explained by differences in prices between originator and biosimilar products, as well as the views of key opinion leaders, local guidelines, and hospital initiatives [240]. **Lack of trust** in the safety and efficacy of biosimilars was also identified as a potential key barrier to biosimilar uptake in other countries. In Norway, this was addressed by generating evidence on safety through a large, state-sponsored randomised controlled trial and regular communication with prescribers about biosimilar safety and efficacy through seminars [128, 243]. Other **examples of barriers** for the uptake of biosimilar medicines from study countries include the transactional costs associated with switching treatments (including the need for enhanced communication with the patient), lack of knowledge about biosimilars among patients and physicians, regulations around the timing of switching a patient (in Portugal, this is only allowed after six months[120]), lack of a biosimilar substitution policy (which means that only the prescribing physician could initiate a switch to a biosimilar), and lack of clear guidance steering prescribers towards the cheapest available alternative. Finally, **suppliers may take actions to impede market entry or uptake of biosimilars**, including through contract clauses that disincentivise hospitals to switch to biosimilars, restricting supply conditions to ensure their product wins a tender, and legal actions (see **Chapter 3.6** and **Box 2**).

Box 18: Biosimilar tendering in Norway

In Norway, procurement of medicines for public hospitals, including biosimilar medicines, is organised through a central tendering system by Sykehusinnkjøp (LIS) / Norwegian Drug Procurement Cooperation. While LIS' tenders only relate to the price of the product (hospitals decide individually which product and how much to procure, and doctors are not bound by the results of the tenders), the organisation has established a system to ensure widespread uptake of the winning bids. Firstly, there is close involvement of clinicians, pharmacists, patient organisations, and other relevant stakeholders in preparing tenders and communicating their results. For each category of medicines, an expert group is formed to provide input for the design of the tenders (e.g. an expert group for TNF-inhibitors was convened to prepare a tender for these products). The panel then endorses the results of the tender by issuing recommendations indicating the preferred treatment choice. Secondly, the results of tenders are disseminated to clinicians through seminars that are seen as key resources to learn about recommended treatments. The seminars are particularly important to educate prescribers about efficacy and safety of biosimilar medicines. Part of this evidence (specifically, the effects of switching patients from originator to biosimilar infliximab) comes from a national, state-funded randomized clinical trial (NOR-SWITCH study) that was initiated as part of Norway's process to accelerate uptake of biosimilars.

An example of significant savings achieved through central tendering that attracted international attention was the 2015 tender for biological medicines to treat rheumatological conditions, and stomach, intestinal and skin diseases. Biosimilar infliximab was offered at a price that was 69% lower than that of the originator, starting a process of replacing the originator from the market for TNF-inhibitors. Within two years of market entry, the market share of biosimilar had increased to 40%.

Source: [30, 244, 245]

Box 19: Mandatory multi-winner contracts for biosimilar medicines in Italy

Given the concern that the "winner-takes-it-all" approach may lead to availability issues, Italy introduced in 2017 the obligation to grant multi-award contracts for off-patent biological medicines if three or more medicines of an active substance have been marketed. All bidders are granted a defined quote. This "multi-winner approach" is obligatory for outpatient and hospital sectors.

There has been some research on biosimilar tenders in Italy (as of 2012, before the multi-winner contract obligation was introduced, and no limited to hospital), and it showcased the association between limited number of bidders (low competition) and difficulty to achieve low prices. The practice of splitting up large tenders into many lots also contributed to lower competition.

Source: multi-winner award contracts [100, 246], research on biosimilar tendering [22, 23]

5.4.2. Biosimilar procurement in hospitals

Procurement practices for biosimilar medicines vary across study countries (see **Table 21**). While biosimilar medicines are not part of regular tendering processes for hospital medicines in some countries (Croatia, Latvia), the **vast majority of study countries includes biosimilars in public procurement activities**. In most countries, the same organisational framework applies as for the procurement of other medicines (see **Chapter 5.2.7**). For example, regardless of the type of medicine (biosimilar or other), procurement of hospital medicines is organised at the facility level in Belgium, at the regional level in Italy, and the national level in Norway (see **Table 21** for descriptions of other countries). However, due to the potentially significant budget impact of biosimilar medicines, deviations from standard procurement practices exist. In Estonia and Hungary, procurement of biosimilar medicines is conducted through central tenders while the main route for other medicines is facility-based procurement. In Estonia, centralised procurement of biosimilars forms part of a wider transition of procurement activities from individual facilities to the procurement unit at the Estonian Health Insurance Fund (EHIF).

The case of Estonia highlights the scope for **biosimilar procurement as catalyst for optimising PPM** (see also **Chapter 3.6**). Due to the cost-saving potential of biosimilars, they provide an opportunity to try out new PPM practices. In Estonia, centralised procurement of some biosimilars paved the way for an expanded role for the CPB at EHIF in the inpatient setting. Having experienced benefits from centralised procurement for biosimilars in pilot projects, individual hospitals are welcoming further joint procurements. In Ireland, where procurement of medicines in hospitals is also

predominantly done at the facility-level, groups of hospitals have started joint procurements of biosimilars. Irish hospitals have also started using the newly introduced DPS for biosimilars.

In some countries, public procurement of biological medicines is conducted only **at ATC-5 level** (i.e. separate procedures are conducted for each active substance, e.g. Hungary, Ireland). In contrast, some other countries include biosimilar medicines in **tenders by therapeutic indication** when there is analogue competition (i.e. several product have a valid marketing authorisation for a specific indication and could therefore win the tender). For example, in Cyprus, tendering for biosimilars is done both at active substance (ATC-5) level and at therapeutic indication level. The Czech Republic and Norway also conduct therapeutic tenders for biosimilar medicines.

What is common to countries that use tendering for biosimilar medicines in hospitals is that some consideration is given during the procurement process to the specificities of these products and how their use can be increased (see also **Chapter 3.6** for additional details on biosimilar procurement practices in the study countries). Details on other, non-procurement related measures to encourage uptake of biosimilars are presented in **Chapter 5.4.3**.

Firstly, even though biosimilars have been in use for almost two decades, knowledge gaps about the safety, efficacy, and product quality of biosimilar medicines still exist among physicians and there is **a need to build trust so they feel comfortable prescribing biosimilars**. This can be achieved through general educational activities (see **Chapter 5.4.3**) but also through **engagement with prescribers during the procurement process and provision of clear treatment guidelines**. Denmark had a pioneering role in achieving cost savings through centralised tenders for biosimilars, ensuring their swift uptake through early engagement with prescribing doctors and preparing nationwide switches from originator to biosimilar products (see **Box 20**). Following this model, Norway established a national system of expert panels who are involved in preparing the tender and subsequently issue treatment recommendations about the preferred product (the winner of the tender, see **Box 18**). In other countries, procurement is done at the facility level where involvement of physicians and other health care professionals for procurement decisions is good practice to ensure buy-in. For biosimilars in particular, engagement with the prescribing doctors at the facility prior to conducting procurement procedures can ensure that the procured product is better received. PTC often play an important role in procurement decisions and are influential in steering prescribing behaviour.

Secondly, procurers need to be mindful of the **trade-off between cost savings from awarding a contract based on the lowest price and possible additional costs** incurred by switching to a new product. In theory, these trade-offs should be addressed by using MEAT criteria, but there are challenges with implementing this (see **Box 11**). In addition, there may be concerns about the impact of frequent switching on patients. In Ireland, where procurement is generally done at a facility-level, a group of hospitals created harmonised treatment protocols and conducts joint procurement for biosimilars. A key principle of the procurements is to avoid subjecting patients to too many switches. As a result, tenders are awarded for two years. In Malta, contracts for biosimilars are awarded in four years cycles.

Finally, considerations about **creating a sustainable competitive environment** also apply to biosimilars [42]. During a workshop on procurement of hospital medicines conducted as part of this study (see Annex 5), participants discussed potential risks of single-winner procedures to security of supply and long-term price levels if these lead to a monopoly situation where only one supplier remains in the market for a given biosimilar. Some countries have therefore introduced multi-award procedures where the tender is split between suppliers if they are ranked sufficiently close to each other (e.g. if prices of the second-ranked supplier fall within a specified range of the winning bid).

The example of Italy, where multi-winner contracts are mandatory for biosimilar medicines, is described in **Box 19**.

Table 21: Biosimilars procurement in hospitals in the study countries

Country	Biosimilars procurement in hospitals
Austria	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level). The PTC is the central body in which decisions on the inclusions of medicines on the hospital formulary are taken, and guidelines on the purchasing of and handling of medicines are developed. Promoting the use of biosimilars is mainly dependant on the position of the persons in the PTC. No official guidelines exist regarding the use of biosimilars in the inpatient sector, but due to the Austrian DRG system hospitals and hospital owners have an incentive to encourage the use of biosimilars.
Belgium	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level). However, there are no specific procedures used for biosimilars. When biosimilars enter the market, a procurement file is published and the awarded product is procured by hospital pharmacists. Awarding is in cooperation with prescribing physicians. Switch rules are determined by each hospital individually, through the Medical Pharmaceutical Committee which determines which medicines can be used within the hospital. No specific process for procurement of biosimilars is in place in hospitals. Switching from biological to biosimilar medicines is prohibited for hospital pharmacists.
Croatia	Biosimilars are not included in tender processes.
Cyprus	Biosimilars are mainly purchased through open tendering commonly at the ATC-5 level and sometimes at the ATC-4 level (analogue competition).
Czech Republic	HPF are based both on the choice of active ingredient (from a certain ATC group) and on the choice of a particular medicine. Hospital pharmacies buy pharmaceuticals based on the results of public procurement or negotiations. In case of medicines with identical active substance, the selection of the provider most often depends on the best offer (the lowest price). If requested by health insurance companies or by manufacturers / wholesalers, SUKL CZ is authorised to announce competition for the lowest retail price of the medicine in specific reference group (group of different active substances with similar effect).
Denmark	Amgros, the procurement body for public hospitals, uses tenders for biosimilar medicines.
Estonia	Procurement of hospital medicines in general is conducted at the facility-level. However, for some high-priced medicines and biosimilars, centralised procurement by the Estonian health Insurance Fund (EHIF) was initiated. Successful pilot projects for the procurement of monoclonal antibodies helped convince individual hospital to conduct more centralised procurement in the future.
Finland	Tendering is used for procurement of biosimilar medicines (as for most hospital medicines) in the hospital setting (at the hospital level, but hospitals may create procurement pools).
France	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level or through joint procurement at the regional level).
Germany	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level).
Hungary	Tendering for biological medicines (at ATC-5 level) is done centrally every two years.
Iceland	Tendering is used for procurement of biosimilar medicines in the hospital setting.
Ireland	Individual hospitals conduct tenders for biosimilars approximately every two years. Some hospitals also conduct group procurement for biosimilars. Tendering is done at ATC-5 level (same substance), rather than at therapeutic level. There is no HTA for biosimilars.
Italy	Tendering at the regional level is used for procurement of biosimilar medicines. Mandatory use of multi-award contracts for biosimilars (if more than 3 in the market) is also relevant for hospitals. Each Region has its own guideline for prescribers (e.g.: use of the cheapest drug for all patients/ use of the cheapest drug for new patients in compliance with therapeutic continuity).
Latvia	Biosimilars are not subject to tendering.
Malta	Biosimilars procurement in hospitals represents a challenge for the CPB in Malta. However, with horizon scanning and evidence-based decision making, CPSU looks out for managing upcoming biosimilars and awards in a 4-year cycle to avoid changeovers.
Netherlands	Tenders are used to procure biosimilar medicines by individual hospitals, groups of hospitals, or in collaboration with insurance companies.
Norway	Biosimilar procurement for hospitals is conducted through centralised, national tenders (using the same system as for other medicines). An expert group consisting of clinicians, and a researcher, pharmacist, patient representative, health economist, and medicines

Country	Biosimilars procurement in hospitals
	agency representative provides input for the design of tenders and issues treatment recommendations about preferred products based on the results of the tender. Tenders are at the therapeutic level. For active substances with bioequivalent competition, two winners may be announced to address risk of shortages.
Portugal	No specific processes applied in comparison to other hospital medicines.
Romania	A central task of the hospital's PTC is to analyse opportunities to modify specific therapeutic protocols based on documents provided from the hospital pharmacy. This includes the enhanced use of biosimilars in hospitals
Slovakia	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level).
Slovenia	The use of biosimilars is encouraged. In tenders usually one slot is reserved for original medicines and the other(s) for biosimilars. If more than one biosimilar is used, there are several slots for biosimilars provided in the tender.
Spain	Tendering is used for procurement of biosimilar medicines in the hospital setting (at the hospital level).
Sweden	Sweden uses tendering as the regular procurement method for biosimilars in the inpatient setting. This is done at the level of the regions, although the regions may also collaborate in the procurement of medicines. Switching to biosimilars is encouraged but not mandatory. Prescribing physicians may decide that switching is not appropriate for individual patients. Councils applied different strategies to switching from originator to biosimilar infliximab, including rapid switch to the biosimilar winning a tender based on lowest price (Skåne), delayed switch after gradually introducing the biosimilar (Stockholm), and no switch when there was no price difference between originator and biosimilar (Västra Götaland).
Switzerland	Most hospitals procure medicines at facility level (i.e. for their hospital pharmacy only).
United Kingdom	Biosimilar medicines are subject to central tenders by the NHS.

No information available for: Bulgaria, Greece, Liechtenstein, Lithuania, Luxembourg, Poland

Source: PPM country fiches

5.4.3. Measures to enhance the uptake of biosimilar use

As shown in **Chapter 5.4** and also highlighted by hospital pharmacists participating in a workshop on hospital procurement conducted as part of this contract (see Annex 5), ensuring the uptake of biosimilar medicines is a **major prerequisite to make use of the efficiency potential** of biosimilar medicines. If the use of biological medicines cannot be shifted from originator to biosimilar products, any savings due to procurement policies are not sufficiently exploited. Thus, the WHO Guideline of Country Pharmaceutical Pricing Policies recommends promoting off-patent medicines, where available, and the 2020 update of the guideline [2] explicitly mentions biosimilar medicines (not included in the original 2013 /2015 version [247]).

To enhance the uptake of biosimilars, two linked approaches are necessary. First, the legal framework to implement appropriate policies needs to be created. Relevant practices include **prescribing (and switching) recommendations for biosimilars, switching, INN prescribing and substitution**. Second, but equally important, **awareness-raising and capacity-building measures** are required to ensure implementation and enforcement of policies to encourage biosimilar uptake, in particular when they were introduced on a voluntary basis. These include training, education and information activities, which should complement legal provisions.

5.4.3.1. Guidelines for biosimilar prescribing (including switches)

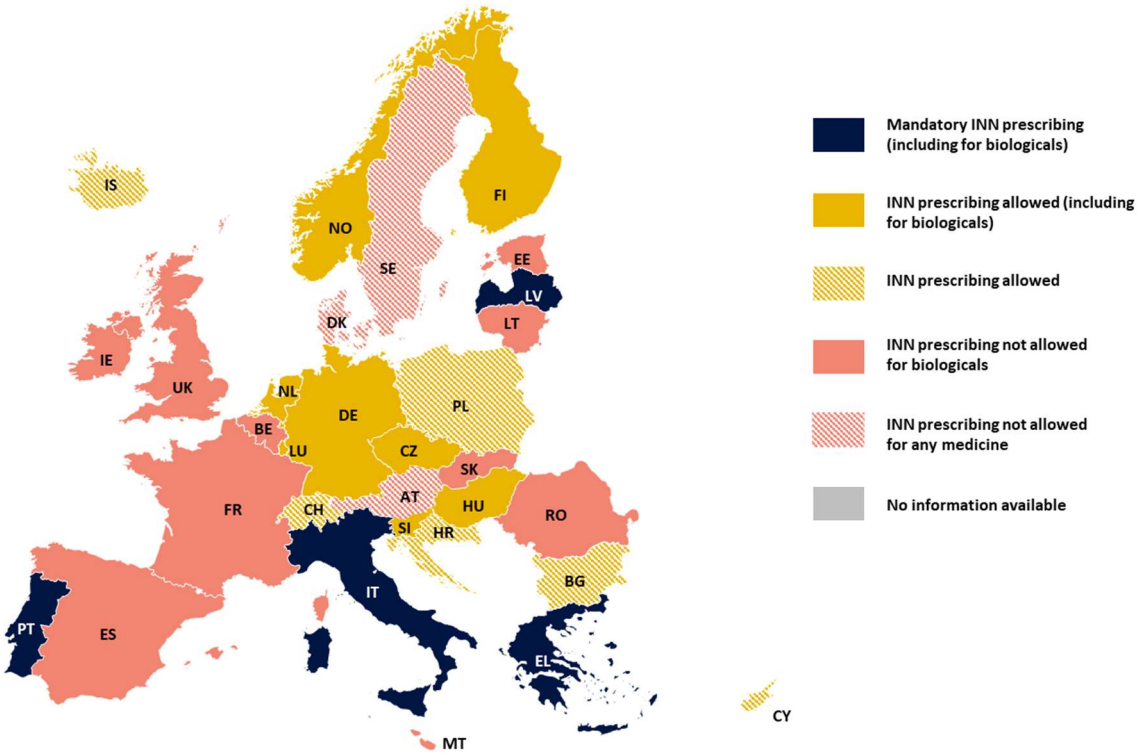
Most study countries support prescribing of biosimilars: usually prescribing guidelines **recommend starting with a biosimilar** (unless some justified reasons exist to not do so) **for treatment-naïve patients**. Switching from the biological reference to a biosimilar or between biosimilars is, in principle, allowed but should, as a rule, follow specific prerequisites (e.g. monitoring, consultation with patients). In any case, it is also

the responsibility of the doctors to manage the process of switching and identify any potential reasons not to switch a patient. There may also be active substance-specific treatment or switching recommendations: for instance, in Hungary, doctors have to switch patients to the tender winner product for infliximab, but there is no recommendation for a switch for other biosimilars.

5.4.3.2. INN prescribing

Some hesitancy with regard to biosimilars has also been seen with regard to the regulation for INN prescribing (see **Figure 37**). In all of the study countries except for Austria, Denmark and Sweden, INN prescribing is in place, and it is mandatory in ten countries (although this may be restricted to treatment-naïve patients, as is the case in Latvia). However, **some countries excluded biologicals from INN prescribing**, including some where INN prescribing is mandatory for other medicines (France, Lithuania, Malta, Romania, Slovakia, Spain) and others where INN prescribing is voluntary (Belgium, Estonia, Ireland, UK).

Figure 37: INN prescribing policies for biological medicines in the study countries



Note: In Latvia, INN prescribing is mandatory for newly diagnosed patients and indicative (voluntary) for others.

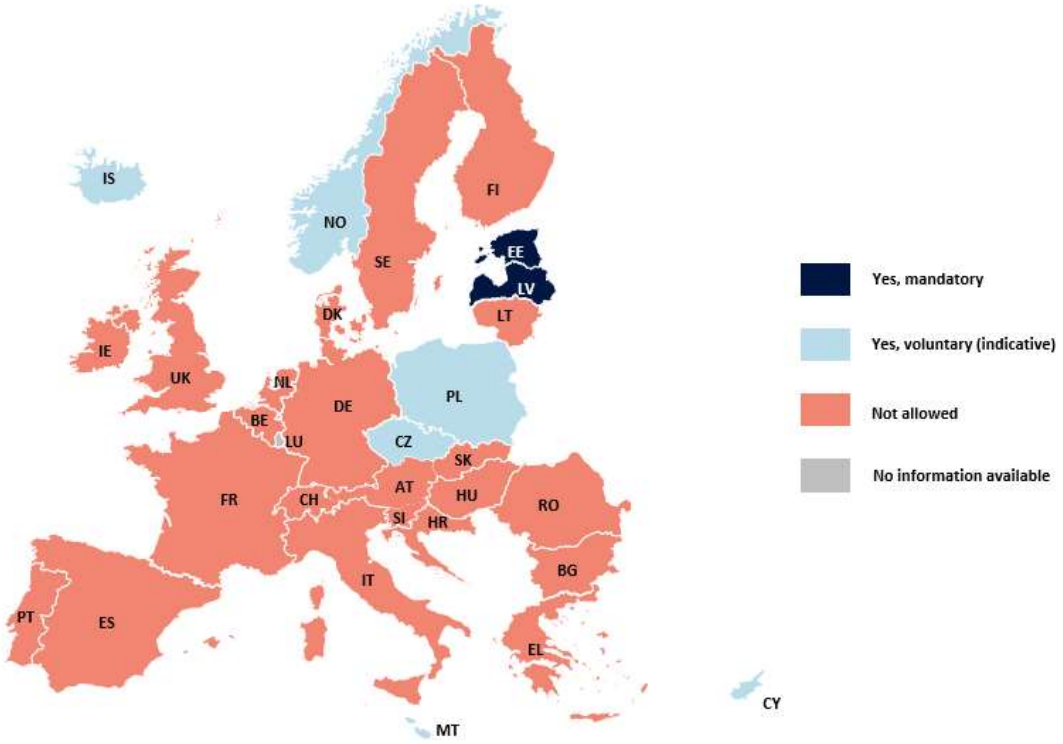
Source: PPM country fiches

5.4.3.3. Substitution

Generic and biosimilar substitution is usually a measure targeting community pharmacists. While generic substitutions is in place in ten of the study countries (thereof mandatory in two countries), it is not allowed in 20 countries (no information available for Liechtenstein and Luxembourg; see **Figure 38**).

These policies can also impact substitution by hospital pharmacists. Overall, there are mixed positions on biosimilar substitution. In the workshop on hospital procurement [189], the possibility of automatic biosimilar substitution in the hospital setting was raised once sufficient experience with a product has been gained.

Figure 38: Biosimilar substitution policies in the study countries



In Germany, introduction of biosimilar substitution is planned for summer 2022.

Source: PPM country fiches

5.4.3.4. Information and education activities

Knowledge gaps about the safety, efficacy, and product quality of biosimilars remain. Information and education activities are therefore needed to address these gaps and possible associated concerns about initiating and / or switching to biosimilars. In a workshop with hospital pharmacists, public procurement agencies, pricing and reimbursement authorities, and representatives from the pharmaceutical industry, educating physicians was identified as the single most promising route for promoting uptake of biosimilars.[36]

Efforts are underway in the study countries to address this gap. In Norway, the hospital drug procurement cooperation, LIS, is actively involved in information and education activities by setting up regular **seminars** on biosimilars. The seminars are used as general education channels for biosimilars in general but also to communicate the results of centralised tenders, so prescribers are aware of what the recommended treatments will be in the coming year (see **Box 18** for an overview of biosimilar procurement in Norway). The need for engagement with prescribers has also been recognised in other countries. In Ireland, the national health service, HSE, is implementing a strategy to achieve a biosimilar prescribing rate of 50% by working with clinical pharmacists and clinical teams. **Early engagement with prescribers** was also instrumental for the success of a rapid, nationwide switch from originator to biosimilar adalimumab in Denmark, where biosimilars effectively replaced the originator within a few weeks (see **Box 20**). In the Danish example, these activities were not limited to

[36] Other important routes were generating evidence on effectiveness and safety of biosimilars, and making changes to treatment guidelines.

doctors. A biosimilar task force also provided patients with information and engaged in a dialogue with patient organisations.

Box 20: Denmark: successful switch of adalimumab within six weeks

Denmark has held a pioneering role in achieving cost savings through widespread biosimilar uptake. This was made possible through the systematic approach to procurement of medicines by the CPB for Danish hospitals, Amgros, which involves close collaboration with all stakeholders, including prescribers, hospital pharmacists, the Danish Medicines Council, suppliers, and – for some activities – patients (see **Box 9** for a description of how Amgros operates and its product life cycle approach to procurement). The Danish model for achieving cost savings is built on generating competition among suppliers, either within the same active ingredient or within therapeutically analogue alternatives, and the ability to influence prescribing patterns throughout the country with evidence-based, standardised treatment guidelines.

Denmark's experience of moving from originator to biosimilar adalimumab provides an example of a successful nationwide switch over a short time period. While biosimilar substitution is not allowed in Denmark, the system of centralised procurement through Amgros coupled with a well-established system for issuing treatment recommendations by the Danish Medicines Council resulted in a near-complete switch of patients treated with adalimumab to biosimilars.

Upon patent expiry of the originator in October 2018, most patients were immediately switched to one of three biosimilars (one for children, and two products used for adults in different regions). Within just six weeks, the market share of biosimilars increased to 95.1%. While the total number of patients treated increased over the following year, the total costs of adalimumab were cut to approximately one-fifth of the expenditure before market entry of biosimilars.

Success factors for the near-complete switch to biosimilar adalimumab included engagement with clinical staff as well as patients to prepare for the switch (a biosimilar task force prepared information material for patients), clear guidelines issued by the Danish Medicines Council that prescribing physicians could rely on, the expectation of significant savings from the switch (cost reductions of 87% were reported ahead of the switch), and the existence of an experienced CPB with market knowledge to conduct successful tenders.

Sources: [123, 182, 218, 248]

6. COLLABORATIONS IN PPM

6.1. Reasons for conducting joint procurement and variants

Joining forces in public procurement – not necessarily focusing on health care or medicines – has been promoted **for long in public administration**, under different terms (e.g. collaborative purchasing, alliance purchasing, bundled purchasing, collaborative purchasing, collective purchasing, combined purchasing, joint purchasing, mutual purchasing, shared purchasing) [122, 249-254]. The predominant argument in favour of joint (or pooled) procurement is to achieve **lower prices** due to higher volumes (improved economies of scale) and thus also becoming a more attractive client. Other reasons for conducting pooled procurement are to improve **availability of medicines**, ensure access to **high-quality products**, and more efficiency in procurement due to **reduction of transaction costs** [41]. Another frequently mentioned argument supporting joint procurement concerns the ability to **strengthen the bargaining power** of the purchasers and their **capacity** (see also an EC commissioned study [138] which maps the administrative capacity of public procurement across the EU member states), including improvement in **transparency, accountability and anti-corruption** [21, 34, 40, 255, 256].

These arguments have also been brought forward when it comes to pooling in public procurement in health care, including for medicines. A seminal work by Huff-Rousselle [7] more than a decade ago stressed the benefits of pooled (or joint) PPM, which go beyond savings for the public budgets (see **Box 21**).

Box 21: Benefits of joint PPM

Based on a literature review and experience with pooled PPM intra-country and cross-country, with a focus on LMIC, Huff-Rousselle identified the following benefits:

- Reduction in purchase prices,
- Improved quality assurance,
- Improved rational choice through better-informed selection and standardisation,
- Reduction in operational costs and administrative burden,
- Creation of a professional network and increased equity between the members of procurement collaboration
- Strengthening the role of the host organisation,
- Improved supply of commodities to populations in needs.

In a recent study on intra-country collaboration in European countries (national centralised PPM), these benefits were largely confirmed. Some additional (partially overlapping) benefits were identified:

- Improved governance and enhanced transparency (e.g. on processes and methods),
- No discrimination between the suppliers,
- Opportunity to develop measures to improve the attractiveness of the market,
- Building capacity,
- Increasing competition,
- Improved data availability and generation,
- Accelerated processes and avoidance of waste (e.g. stockpiling)

Source: Authors' compilation based on Huff-Rousselle 2012 [7] and Vogler et al. 2022 [9]

Pooled (or joint) PPM can be designed **intra-country or cross-country** [7], and this can be implemented through collaboration between different public procurers or through procedures conducted by a designated procurement body (e.g. a CPB) as defined lead procurer (see also **Chapter 1.1**). Implementation of intra-country collaboration in PPM (e.g. national or regional centralised PPM, group procurements) has been mapped for

the study countries in this report (see **Chapters 3.1, 3.2**, and **5.2.7**); details on collaboration in PPM (including intra-country and cross-country) are provided in the country fiches (see Annex 4.1-4.32). A recently published study on national centralised PPM system in six European countries confirmed the challenges identified by Huff-Rousselle [7] and identified a few further advantages (see also **Box 21**), while also acknowledging challenges which need to be addressed appropriately from the very beginning [9].

This chapter presents some cross-country collaborations in PPM in the study countries and examples of other initiatives. This information presented is informed by literature and information provided by experts involved (e.g. during the workshops in the course of this study, validation of documents by procurement experts).

6.2. Cross-country collaborations in PPM and learnings

Globally, procurement has been an important area of cooperation between countries. In Europe, where pricing, reimbursement and also procurement are, to a major extent, national competences of the EU MS, collaborative approaches in the peri-launch phase (i.e. between marketing authorisation and launch of a product into the market) have emerged more recently, mostly in the last decade. Cross-country collaboration in Europe was prompted by an increasing emergence of new medicines with very high price tags (challenging financial sustainability) and frequently subject to uncertainty about their therapeutic value, and by emergency situations such as pandemics.

6.2.1. Cross-country collaborations in the study countries

Currently, there are **five collaborations established at the initiative of national governments**, in which study countries are involved and whose (planned) areas for collaboration include PPM or related activities such as joint price (or reimbursement) negotiations. **Table 22** provides an overview of these five initiatives as well as two further government-initiated collaborations, with related areas of collaboration that are relevant for procurement. Three initiatives that have conducted joint procurements or price negotiations are described in more detail in **Chapters 6.2.1.1-6.2.1.3.** Learnings about challenges and best practices for cross-country collaborations in PPM from these initiatives are also taken up in **Chapter 7**.

Table 22: Government-initiated cross-country collaborations in the study countries

Initiative	Start	Countries	Areas of collaboration		Status of PPM
			PPM	Further activities	
Baltic Procurem. Initiative	2010[1]	EE, LV, LT	Yes	Lending of medicines and medical devices in case of non-availability	**Joint vaccines tenders successfully concluded**
Beneluxa Initiative	2015	BE, NL, LU, AT, IE	No, but joint nego-tiations	Horizon scanning HTA Price and reimbursement negotiations Information sharing	Not appl. for PPM **Joint negotiations successfully concluded**
FAAP	2017	CZ, HU, LT, PL, SK	Yes	HTA Price and reimbursement negotiations Information sharing	No joint tender / negotiation yet started
FINOSE	2018	FI, NO, SE	No	HTA	Not appl.
IHSI	2019	BE, NL, DK, IE, NO, PT, CH, SE	No	Horizon scanning	Not appl.
Nordic Pharma. Forum	2015	DK, IC, NO, SE	Yes	Horizon scanning Manufacturing Security of supply	**Two joint tenders successfully conducted**
Valletta Declaration	2017	HR, CY, EL, IE, IT, MT, PT, RO, SI, ES	Yes	HTA Price negotiation	No joint tender / negotiation yet started

FAAP = Fair and Affordable Pricing, IHSI = International Horizon Scanning Initiative, not appl. = not applicable, Pharma. = pharmaceutical, Procurem. = pharmaceutical, for country abbreviations see the respective list of abbreviations
[1] Task force started in 2010, the partnership agreement was signed in 2012

Source: [10, 48, 117], updated by authors

In addition, there are indications of further (planned) and examples of previous (unsuccessful) joint procurement initiatives between individual countries, such as between Bulgaria and Romania, or between Spain and Portugal. In case of the latter, plans for joint PPM were eventually postponed due to other priorities during the management of the COVID-19 pandemic. Due to lack of robust information on these additional procurement initiatives, no further details are presented in this report.

To note that there are additional collaborative networks in Europe, in which competent authorities for pricing and reimbursement and/or public payers are involved, such as the Pharmaceutical Pricing and Reimbursement Information (PPRI) network [71] or the Piperska group [257]. These networks are focused on information-sharing but do not collaborate technically in procurement, pricing or reimbursement. In addition, there is the Network of Competent Authority Responsible for Pricing and Reimbursement (NCAPR), which is coordinated by the European Commission in coordination with EU MS [258]. Still, they are of relevance for the exchange and possible dissemination of experience of collaborations. Further platforms for sharing of information and practices include European associations of public procurers (e.g. European Health Public Procurement Alliance (EHPPA) [259], or payers (e.g. European Social Insurance Platform (ESIP)).

6.2.1.1. Baltic Procurement Initiative

The Baltic Procurement Initiative started in 2012 based on a partnership agreement signed by the competent authorities (ministries of health, or of social affairs, respectively) of the three Baltic countries Estonia, Latvia, and Lithuania. This agreement followed up on the political mutual understanding of the government of three countries, expressed by their prime ministers in 2010 by establishment of a task force [117].

The Baltic Procurement Initiative has **two objectives** [117]:

- Joint procurement of medicines (by now, this joint endeavour only related to vaccines that are in the immunisation schedule of at least two of the three countries);
- Lending of medicines and medical devices among the countries without charging any costs in cases of shortages.

The Baltic Procurement Initiative has **successfully concluded some joint tenders**. The lead partner is defined on a case by case basis for each procurement; the lead partner receives the official (written) mandate by the other countries to proceed on their behalf. The procurement is conducted in accordance with procurement legislation of the lead partner's country. The identification of the candidate vaccines for joint PPM is done jointly by all three countries. In some cases, only two of the countries procure jointly, where required vaccines included in national immunisation schedule match. For the future, moving to joint procurement of other medicines beyond vaccines is considered.

The initiative faced a steep learning curve. The first joint tender, launched by all three countries, for the bacille Calmette-Guerin (BCG) vaccine against tuberculosis in 2015 had to be declared unsuccessful since no bids were received. There was only one BCG vaccine that was authorised in all three countries. This unsuccessful joint PPM highlighted the importance of market research.

In the following years, the initiative conducted **four successful tenders**:

- rotavirus vaccine in 2016 (involvement of Estonia and Latvia),
- pneumococcal conjugate vaccine in 2017 (Latvia and Lithuania),
- rotavirus vaccine, and a hexavalent vaccine in 2018 (Estonia and Latvia), and
- again a rotavirus vaccine, and a hexavalent vaccine in 2018 (all three countries) in 2021.

In all procurements, open procedures were used, and except for one procurement, price was considered as the key evaluation criterion. Apart from one case, the prices achieved in the joint PPM were lower than in national procedures.

Another important step was the move to more strategic action, with the development of the first strategic procurement plan for the Baltic Procurement Initiative in 2019, which also ended the years of a pilot phase.

Key lessons learned from the Baltic Procurement Initiative include the following:

- **Political support:** This collaboration was set up as a high-level political initiative. Having the political support was important for the technical experts who reported that the interest of their political leaders who asked about the progress was important especially in the early years when no successful procurement had yet been performed.
- **Mutual understanding and trust:** Building trusting between the experts was considered as a key prerequisite to good cooperation. However, a high number of face-to-face meeting slowed down the process in the beginning. As soon as trust and clarity on division of work and processes has been achieved, collaboration went much smoother. Face-to-face meetings were reduced to minimum one meeting per year; email correspondence is an important communication channel.
- **Clear responsibilities (role of lead procurer):** The Baltic Procurement Initiative moved from representation of all three participating countries (in the first unsuccessful tender) to a working model based on a lead procurer for each joint procurement. Under this model, the country being the lead procurer takes a major

responsibility and a large share of the workload in the respective joint tender. The lead procurer is given a strong mandate by the other countries, which is important for the conduct of the procedure. Given the workload, rotation of the lead procurer proved to be useful.

- **Flexibility and alignments to country specificities:** Countries can decide on a case-by-case basis whether or not they want to participate in the joint tender. Usually, the criterion as to whether the vaccine to be procured is in the national immunisation schedule will be the decision criterion. While there is this flexibility to decide on a voluntary basis whether or not to participate, it is clear that as soon as the decision in favour of participation has been taken, it is a commitment.
- **Relevance of market research:** The failure of the first joint tender highlighted the importance of knowing the markets. Market feasibility analyses, including exploring the capacity of possible bidders to supply, was a major learning from this first failure.
- **Simplification of procedures and clarity (language):** Legal issues and processes should be clarified before the tender is launched. Value is seen in keeping the PPM procedures, and also documents, as simple as possible. As a practical learning, the Initiative aims to keep the procurement documents short (with a maximum length of ten pages). From the second joint tenders, the Baltic Procurement Initiative produced the procurement documents in English, which facilitated collaboration. For the terminology, the Initiative moved from using English translations of the national public procurement law to the ones used in the EU Public Procurement Directives.
- **Learnings over the years (move to strategic procurement):** The beginning of the collaboration, with slow progress (no successful tender in the first year) was difficult, but there were learnings over time, and it becomes easier each time. After a pilot phase, the Initiative developed further towards improved professionalism and strategic approaches.

6.2.1.2. Nordic Pharmaceutical Forum

The Nordic Pharmaceutical Forum started as a cross-country collaboration in 2015, initiated by the Danish CPB for public hospitals, Amgros, as a bottom-up initiative (in contrast to other, more politically-driven collaborations). The Nordic Pharmaceutical Forum is a collaboration of Denmark, Norway, Iceland, Sweden and Finland.

The initiative was founded to provide a **platform for exchange between the Nordic countries** on issues related to access to medicines and identify areas for collaboration. Joint action areas include horizon scanning, manufacturing, logistics, security of supply, and joint procurement and negotiations.

By joining forces, the initiative **aims to increase purchasing power and to ensure security of supply**. Joint procurement of medicines has been one of the objectives of the Nordic Pharmaceutical Forum from the beginning, as the involved procurement agencies from Denmark and Norway were the respective CPBs for the hospital sector. However, Sweden could not get involved in the hospital procurement because of its fragmented hospital sector (hospital procurement is done by the regions, see **Chapter 5.2.7**).

In the beginning, the member countries had the intention to work together on new high-priced medicines which put pressure on public health budget. However, the focus increasingly shifted towards security of supply, as all involved countries experienced supply issues. Individually, the Nordic markets were considered too small and unattractive to be served with both new as well as "old", well-established medicines. Aiming to address the security of supply issue, the collaboration focused on procuring "old" medicines which usually have rather low prices.

The Nordic Pharmaceutical Forum has **concluded two successful joint tenders for off-patent medicines** (including ampicillin, anagrelide, ceftazidime, ceftriaxone, cefuroxime, ciprofloxacin, gentamicin, meropenem, methotrexate, metronidazole, ondansetron, paracetamol, vancomycin). All of these products fall into the final two phases of the pharmaceutical life cycle (consisting of six phases, ranging from newly introduced products to products at risk of or with actual supply security issues; for the Amgros life cycle approach see **Figure 31**).

- First preparations for the joint procurement date back to the summer of 2017 when members of the collaboration met to discuss options for a pilot joint procurement exercise.
- In September 2018, the Nordic Pharmaceutical Forum conducted a market survey with the aim to collect potential suppliers' views on a preliminary list of suitable products.
- This was followed by six weeks of hearings with potential suppliers to consult with them on the draft call for tender.
- The call for the first Nordic tender was launched in April 2019, with agreements for the deliveries starting in February 2020.
- Based on the overall success of the first tender, the Nordic Pharmaceutical Forum published a second call in June 2021. Bids were awarded, and the procurement period for these tenders will run from April 2022 till March 2024.

Adding to the security of supply focus, the Nordic Pharmaceutical Forum also included environmental criteria as award criteria (see **Chapters 3.4, 5.2.9** and **Box 12**).

Key lessons learned from Nordic Pharmaceutical Forum include the following [10, 117, 165]:

- **Joint procurement can improve access to medicines and security of supply for smaller countries**, as evidenced by the positive experiences with the joint Nordic tenders.
- **Excellent knowledge of the market** and market research is a prerequisite.
- The **extensive dialogue with the suppliers** helped to improve the procurement documents and ensure adequate participation rate.
- Need to **budget sufficient resources for planning and preparing**: compared to "regular", national tenders, more time resources were required (minimum one full-time member of staff).
- Participating countries could leverage **the expertise of experienced agencies** in hospital procurement (with experience from national centralised procurement).
- **Technical expertise** is required at operational levels (bottom-up initiative), complemented by high-level political support.
- **New, potentially challenging award criteria** (e.g. environmental criteria) could be successfully used in the procurement and did not impact on participation rate of bidders.
- Logistic aspects (e.g. delivery of the products) needs to be considered at an early stage.

6.2.1.3. Beneluxa Initiative

The Beneluxa Initiative was initiated by the health ministers of Belgium and the Netherlands in 2014. The two countries were joined by Luxembourg and Austria in 2015 and 2016, respectively, giving the Initiative its name ("BeNeLuxA"). Ireland joined as fifth member country in 2018.

The overarching **aim of the initiative** is to ensure sustainable access to innovative medicines at affordable costs [260]. Member countries cooperate in the following four action areas:

- **Horizon scanning:** collaboration to identify newly emerging – typically high-cost – medicines, resulting in horizon scanning reports. This action area has resulted in a spin-off (IHSI) with additional participants.
- **HTA**: joint assessments are performed and participating countries also re-use existing HTA reports from the other countries. This action area is expected to grow in the future and a joint template for HTA is being developed.
- **Information sharing:** member countries engage in regular exchange on topics of interest. This may result in joint statements, e.g. recently on methodological considerations for assessment of CAR-Ts.
- **Price and reimbursement negotiations:** Joint price and reimbursement negotiations are linked to the other action areas (e.g. informed by horizon scanning and HTA).

Differently to the other two initiatives described above, Beneluxa is focusing on high-cost, potentially innovative medicines and does not conduct joint procurement. However, member countries have conducted **joint price negotiations**. After an initial unsuccessful joint negotiation for the combination product lumacaftor / ivacaftor in 2017, two of the member countries (Belgium and the Netherlands) successfully conducted price negotiations for nusinersen (Spinraza®), a high-cost medicine for treatment of spinal muscular atrophy. The price was kept confidential and may have differed between the two countries, as final price and reimbursement decisions remain at the national level (e.g. slightly different reimbursement conditions were applied in Belgium and the Netherlands).

Key lessons learned from the Beneluxa Initiative include the following [10]:

- **A holistic view on the pharmaceutical value chain** is required to understand issues with access to innovative medicines and address them. The initiative therefore cooperates on horizon scanning, HTA, and negotiations.
- **Accept country differences and collaborate where possible:** pricing and reimbursement decisions are made at the country level, and countries may have different requirements for medicines and different thresholds for what they are willing and able to pay. The initiative has therefore accepted that its joint actions, including joint price negotiations, may lead to different outcomes in participating countries.
- **Key challenges in cross-country collaboration** are due to differences in the legal set-up and the different pricing and reimbursement processes. These differences need to be acknowledged.
- **Successful price negotiations require time and buy-in from all parties.** Convincing manufacturers to participate in joint price negotiations with several countries may be challenging and therefore require a value proposition for all participating parties. For manufacturers, this may be to base negotiations on added value of the product, rather than price alone.

6.2.2. European initiatives for joint public procurement in crisis response

Crisis preparedness was highlighted as a key action area for the EU in the COVID-19 pandemic. In response, a new Directorate-General, the European Health Emergency preparedness and Response Authority (HERA), was set up in October 2021. HERA therefore has taken up the task of the implementation of the previously established mechanism for joint procurement (JPA, see below) and other measures taken by the EU to address security of supply, such as central stockpiling among others.

6.2.2.1. Joint procurement agreement

The Joint Procurement Agreement (JPA) for medical countermeasures was developed following the H1N1 pandemic influenza, in which weaknesses in access and purchasing capacity of EU MS to procure needed medicines and medical devices became evident.

The Council Conclusion of 13 September 2010 requested the EC to **develop a mechanism to jointly procure medical countermeasures**, which would support fair and equitable access to, and distribution of, pandemic influenza vaccines for the future. In response, the EC developed the JPA [261], with the aim to improve the preparedness of the MS to serious cross-border threats to health.

In 2014, the EC approved the JPA, and soon signed it together with more than half of the EU MS at the time. As of April 2020, the JPA has been signed by 37 countries, including all EU MS [262].

The JPA is a **voluntary mechanism**. A joint procurement procedure can be initiated if at least four EU MS and the EC are willing to participate. In parallel, countries may launch a national public procurement procedure on the same subject matter, as well as to engage in negotiations with the same companies participating in a joint procurement procedure.

The scope of the JPA is defined by medical countermeasures, such as vaccines and antivirals. In the beginning, there was discussion as to whether the JPA instrument could also be used to jointly procure high-priced medicines (such as orphan medicines, oncology medicines). However, this was not possible since the legal basis of the JPA only allows procuring medical countermeasures for cross-border health threats.

Before the COVID-19 pandemic, the EC considered the **signature of the framework contracts for pandemic influenza vaccines** in March 2019 as a major achievement under the JPA.

During the **COVID-19 pandemic**, the JPA was used in a number of joint procurement procedures to purchase medical equipment and therapeutics. Medicines procured through the JPA included remdesivir (Verklury ®), medicines used in intensive care units, including the corticosteroid dexamethasone, and monoclonal antibodies including sotrovimab (Xevudy ®), and the combination products casirivimab / imdevimab (Regn-COV2 ®) and bamlanivimab / etesevimab. For the procurement of remdesivir, 36 countries (all EU MS and nine others) participated. The procedure was conducted as a negotiated procedure without prior publication as justified by the urgency of the pandemic situation. A framework agreement was created that allowed participating countries to purchase the product from the manufacturer.

In 2022, the European Commission launched a study to assess the functioning of the JPA. In particular, the evaluation will look into the effectiveness, efficiency, relevance, coherence, and added value of both the legal framework and the implementation of the Agreement against the underlying policy objectives defined in the legal framework in two different periods and contexts (i.e. until and since the COVID-19 pandemic). The results are expected before the end of 2022.

6.2.2.2. EU COVID-19 vaccines procurement

While the JPA was used for joint procurement of COVID-19 therapeutics and medical equipment, it was not used to **purchase vaccines**. The JPA, designed as preparedness mechanism with set roles for the MS and the EC, was not seen as suitable in the situation of extreme urgency and global competition for a scare resource of strategic importance (a COVID-19 vaccine) which had not yet been developed when the pandemic started.

The procurement of COVID-19 vaccines by the EU was **overall seen as success** by stakeholders participating in the workshops conducted for this study (see Annex 5). MS authorities, procurers, patient and public representatives, and hospital pharmacists (although not industry representatives) considered the joint procurement as **example of how MS can collaborate**, and some participants expected this experience to be used for joint procurements in other areas as well. At the same time, concerns were raised about a lack of transparency about the EU vaccines procurement process, including lack of transparency on prices, and failure to tackle pertinent issues around intellectual property rights.

6.2.3. International collaborations in PPM of relevance

Other examples of successful international PPM collaborations, with different mandates and focus areas, include the PAHO Revolving and Strategic Fund and the joint procurement activities of the Gulf Health Council. These initiatives have been conducting joint procurements since the 1970s.

The **PAHO Revolving Fund** has been operating since 1975 as a cooperation mechanism for producing vaccines and related supplies for countries in **Latin America and the Caribbean**. The Fund is coordinated by the Pan American Health Organization (PAHO), the regional office of the WHO for the America, and has 41 participating countries who delegate the authority to conduct **procurement of vaccines** on their behalf. The "revolving" nature of the fund is an important aspect of the procurement initiative, as it allows PAHO to pay suppliers before being reimbursed by participating countries, which may occur in local currency, thus supporting weaker economies [8]. In 2021, the Fund procured 47 vaccines from 38 suppliers [263]. The Fund pools the needs of participating countries and issues joint tenders for required supplies of vaccines. Estimates for required quantities are either supplied by the countries or developed jointly with the Fund as part of its supporting activities. The Fund not only organises the joint tenders, but it also monitors deliveries and helps countries with other issues related to the roll-out of vaccination campaigns.

The **Gulf Health Council** conducts joint procurement of medicines and other medical goods for member countries of the **Gulf Cooperation Council** (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates) and Yemen. Among other activities in the health sector, the Gulf Health Council has been running a joint procurement programme since 1976. The scope of the programme includes pharmaceuticals, sera, vaccines, and medical devices for human and veterinary use. Tenders are conducted in different therapeutic areas, typically once per year [264]. Differently from the PAHO Revolving Fund, the Gulf Health Council's role is limited to organising the tenders, selecting suppliers and adjudicating the process, but does not purchase the products itself. Instead, member countries conduct their own procurement on the basis of the tenders selected by the Council [8].

Joint procurement received additional attention during the **COVID-19 pandemic**. The **COVAX facility**, a new procurement initiative, was founded by the WHO, Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi, initiated the **COVAX facility** as mechanism to equitable distribution of COVID-19 vaccines around the world. COVAX is the vaccines pillar of the WHO Accelerator, which aims to accelerate the development and production of COVID-19 vaccines, tests, and treatments. COVAX was founded in response to concerns about unequitable access to vaccines during the H1N1 influenza pandemic, when resource-poor countries were unable to purchase vaccines in the quantities needed as supply was bought up by high-income countries. In the early stages of the COVID-19 pandemic, COVAX aimed to implement a formula for equitable distribution of vaccines, allowing all participating countries to initially secure enough doses to vaccinate 20% of their population before purchasing more doses [265]. However, while high-income countries were willing to donate vaccine doses to COVAX, they did not adhere to principles of equitable distribution and instead sought other routes to procure vaccines for their population.

7. POLICY IMPLICATIONS OF THIS STUDY

Based on the analysis of available evidence, key barriers to and best practices for optimisation of PPM were identified. These serve as **policy implications of this study**: what issues need to be addressed and how in order to optimise PPM? The following chapter addresses the relevant study questions related to specific objectives 4 (what are the barriers to optimising PPM?) and 5 (what are best practices to optimising PPM?).

7.1. Key barriers for optimising PPM

The barriers analysis is based on multiple sources. For country-specific input, barriers were included as a topic in the **country fiches** which were shared with country experts for validation. Identified country-specific barriers were pre-filled for validation. Thus, the section on "barriers" in all country fiches contained a standardised list of potential barriers that may exist in PPM, with the aim to encourage respondents assessing the relevance of these barriers in their national contexts. These barriers were largely **identified based on literature** [9, 60, 120]. Additional information about barriers was obtained in some interviews and in particular in the three multi-stakeholder **workshops** (see Annex 5). Barriers relating to cross-country procurement were mainly identified from literature [7, 10, 60, 117] as well as the stakeholder workshops.

Barriers can be identified **at several levels**: they can relate to limitations in PPM policy and practices which could be addressed through optimisation of procedures; or to challenges in the context of PPM in the broader sense, including potential impacts of PPM on policy objectives such as availability, affordability and similar. Furthermore, barriers can be considered solely from the procurers' perspective, from the perspective of other stakeholders (e.g. suppliers), or from a broader public health perspective. **Table 23** provides a summary of key findings of the barrier analysis and the relevance of the challenges identified in the study countries for different levels, and for different stakeholders. These barriers are further analysed according to whether they relate to product-specific challenges or setting-specific challenges below.

Table 23: Barriers, constraints and challenges with regard to the PPM in the study countries

Barriers / challenges	Relevance	Description and comments
External factors		
Small volumes	Frequent (due to facility-based PPM in the inpatient sector in many countries; even with centralised PPM country markets might be too small to be attractive)	Small volumes limit the bargaining power of procurers and may result, in a worst case, in not attracting any bids.
No competitors marketed	Frequent	More competitive procurement procedures and techniques are possible if a higher number of alternatives is available. Monopoly products may come with high price tags.
Disruption in the supply chain	Increasingly frequent	Due to circumstances in the production and/or transportation, independent from the procurement process, supply issues exist.

Barriers / challenges	Relevance	Description and comments
PPM practice and policy		
Non-transparency, corruption, and issues with good governance	Indication on issues for a few countries according to literature [31, 33, 34, 211, 255, 266], no further information obtained	In principle, PPM is a policy that contributes to improved governance, accountability, and transparency. Appropriate legislation supports the application of these principles. Still, literature suggests issues in a few countries, such as reporting on "direct conflicts of interest, biased decision-making and clientelistic networks" [266] in health sector procurement and "collusion" of suppliers resulting in limited levels of competition [31]. This may result in low trust in public procurement [211].
High administrative burden, cumbersome legislation	Mentioned in particular with regard to joint procurement	Procurers and "users" (e.g. hospitals, which order through a CPB) consider some workflows as time-consuming. Differences across cross-specific legislation are considered a major challenge for cross-country PPM.
Lengthy procedures, insufficient flexibility to adapt to new situations	Mentioned in particular with regard to some procedures (e.g. open or restricted tenders) Limited use of "new" PPM techniques, as provided by the EU Procurement Directive [68], was observed in some countries	Depending on the type of product, different PPM procedures and techniques are to be selected, and some are less flexible and require long preparation period. Lengthy procedures and slow response rates hinder use of these practices in emergency situations.
Low participation rate in bids	Reported from several countries, in case of limited number of competitors	No or low participation of bidders may result in failure of a tender. This also restricts the procurement techniques that can be used (e.g. winner-takes-it-all by default).
Appeals	Some countries	For some procedures, bidders launched an appeal.
Paper-based PPM / limitations in e-procurement	E-procurement has been implemented in all study countries. In some countries, e-procurement needs to be improved.	E-procurement has considerably improved, facilitated and accelerated PPM processes, and allows some of the "newer" PPM techniques such as DPS. However, optimisation potential may still exist.
Lack of knowledge on efficiency and impact of PPM	In several countries, data are missing to monitor the impact of PPM, and PPM monitoring and evaluation are not conducted on a regular basis.	Lack of monitoring hinders targeted and appropriate development and optimisation of PPM. Policy makers (and the public and further stakeholders) miss the information whether or not PPM has been able to achieve identified PPM policy.
Lack of political vision and guidance	Not known, indication of issues from a few countries	Further development of PPM, piloting of "new" PPM policy and practices may be difficult for procurement bodies if the vision and policy objectives of the policy makers are not known.
Lack of budgets, delayed payments	Indication from some countries, in particular at facility-based PPM	Limited funds weaken the bargaining power and attractiveness of the procurers. Delayed payments and debts with suppliers damage the relationship between procurers and suppliers (no trust).
Lack of mitigation strategies in case of failures	Several countries	If suppliers cannot deliver as agreed, strategies to mitigate the risk of shortage would be needed.
Limited tools to ensure enforcement of legal obligations	Several countries	If suppliers fail to meet the contractual obligations, mechanisms to provide sanctions and/or ensure avoidance of such situations would help in the longer run.

Barriers / challenges	Relevance	Description and comments
Related to procurers, suppliers and other stakeholders		
Limited capacity of procurers (e.g. understaffing, low and inappropriate skills)	Frequent: understaffing is an issue in some countries, indications of lack of PPM-specific qualifications	Capacity is required in both quantitative as well as qualitative terms. PPM, in particular in specific settings (e.g. specialised hospital care), may require very specific (clinical) knowledge. Legal and procurement expertise is not sufficient for PPM; further staff with specific qualifications (e.g. suppliers management, communication) is also needed and is frequently missing.
Supplier action impeding market entry and uptake of competitor products	Some countries	There have been cases of suppliers engaging in practices that impede market entry or uptake of competitor products, in particular biosimilars. Practices include contractual agreements and pricing structures that lock contracting authorities into continued use of the originator product or shut out competition from tenders, as well as schemes to tie patients to the product [179, 180, 222, 267].
Limited interaction with suppliers	In some countries, due to staff and time restraints	Low participation rate may also result from limited capacity (e.g. limited skills) on behalf of suppliers (e.g. in case of new PPM practices, such as consideration of social and environmental awarded by the contracting authority, tender of cross-country collaboration)
Limited interaction of procurers with other public institutions (e.g. pricing and reimburse-ment authorities, competition authorities)	Identified as an issue in some countries (concerns both "users" in case of centralised PPM as well as further public authorities)	Limited interaction hinders exchange of required data and information to inform preparation of PPM procedures.
Limited interaction with prescribers	Some countries	Prescribers would be needed to support use and uptake of off-patent medicines (e.g. biosimilar medicines). They need to understand why certain medicines were procured and should (must) be prescribed as preferred products.

Source: Analysis done by authors

7.1.1. Product-group specific barriers

For **off-patent products**, an important barrier to efficient procurement are practices by suppliers to **impede market entry and uptake of competitor products**, in particular for biosimilar products. Examples of such practices include pricing structures that lock hospitals into continued use of higher-priced originators, "loss leader" practices to initiate treatment with a specific product in hospital at reduced price followed by higher prices for treatment continuation in the outpatient setting, subsidising out-of-pocket payments for patients to continue using the product, as well as practices to impede the chances of competitor products being selected as winners in tenders (see also **Box 2** for descriptions of cases investigated by competition authorities in the Netherlands and Romania) [179, 180, 222, 267].

Another challenge of particular relevance for **biosimilar products** is the lack of uptake which may be due to **lack of interaction between procurers and prescribers**. Challenges with gaps in knowledge about the efficacy and safety of biosimilars still exist (see also **Chapter 5.4.3**). Successful procurement of a lower-priced biosimilar product (which may allow treatment of more patients) therefore partly depends on the uptake of that product: if prescribers are hesitant to switch patients to the biosimilar product, then procurement of that product will not be considered supportive to providing patients with access to medicines. Procurers therefore need to work with prescribers to ensure that procured products meet the needs of patients and are being prescribed.

Supply issues are particularly prominent for off-patent products, and more commonly encountered in smaller countries. In the debate, there has been the assumption that prices were too low to be attractive for suppliers, which may contribute to supply issues. Commercial reasons for non-supply (i.e. small volumes in small markets which are considered not to be attractive) may also apply to on-patent medicines. Measures to mitigate shortages were not always implemented or successful, also because shortages and supply limitations are a multi-faceted issue.

Lack of funding is a frequently encountered challenge. This may pose particular problems for procuring **high-cost, potentially innovative medicines** which have significant budget implications for the health care sector [268]. Several countries have introduced specific funding mechanisms that operate outside the regular system (see **Table 15** for an overview of these schemes in the study countries in the hospital setting). However, budgetary constraints generally apply to procurement of all medicines: as pharmaceutical expenditure grows, spending constraints become more likely. In some countries, hospitals have reported difficulties to procure with available budgets [269, 270].

7.1.2. Setting-specific barriers

An important barrier to optimising PPM for the **hospital sector** is the **lack of (comprehensive) data** about procurement practices and prices paid by individual hospitals, and the **lack of cooperation and information sharing** due to fragmentation in the hospital setting. In many countries, hospitals are owned by the regions and/or operate as independent health care facilities and are therefore responsible for their own procurement. Without institutionalised collaboration (e.g. through joint procurement organised by CPBs, as is the case in Denmark and Norway), individual hospitals may not know what other hospitals are paying for the same products and may therefore find themselves in a weakened negotiating position. Nevertheless, individual procurers may engage in informal exchange.

The decentralised organisation of hospital care in many countries also impedes the possibility for implementing a **strategic approach to procurement**. While individual hospitals may develop their own procurement strategies, these may not reflect the priorities of the health system overall. Short-term goals, such as securing the required supplies for the next year within the available budget, are more likely to trump long-term considerations when a strategic approach is missing. Centralising the procurement for the hospital sector may help address the lack of strategic vision, but this faces barriers in itself, notably that hospitals may perceive centralised procurement as a threat to their autonomy.

Lack of a joined-up approach to formulary development across inpatient and outpatient sectors and different funding mechanisms per sector can create a barrier to continuation in the uptake of medicines (seamless care) and access to medicines. These challenges at the **interface between inpatient and outpatient care** and possible measures to address them were described in **Chapter 5.3.** While individual procurers may not perceive the interface between the two sectors as challenge (typically, procedures would only be conducted for one sector, and in many cases only for an individual contracting authority in that sector), lack of cross-sectoral thinking poses a challenge from a health system perspective, also because of incentives to shift medication (and patients) from one sector to the other. Importantly, procurement decisions in the inpatient setting may have implications for the outpatient sector with respect to the continuation of a specific therapy that was initiated in the hospital.

7.1.3. Cross-country specific barriers

Additional challenges have been identified for cross-country collaborations. These are informed by more detailed descriptions of learnings from cross-country initiatives described in **Chapter 6.2.1**. Key challenges that cross-country initiatives have faced included the following:

- Differences in national **legislation and procedures** (related to PPM as well as pricing and reimbursement processes and supporting tools such as HTA),
- More **resource-intensive and time-consuming** than national procurements and lack of investment in resources in quantitative and qualitative terms,
- **Fragmented health systems** may limit or prevent country's participation in cross-country procurement (who would be the country representative for procuring a hospital medicine if in the country procurement is done at facility level?),
- Lack of clarity about **leadership** and lead procurer,
- Lack of **political support** to address above-mentioned barriers,
- **Suppliers' hesitancy** to respond to calls for a cross-country tender,
- **Language** issues due to different countries and legislations (including regarding the packaging of procured medicines).

7.2. Best practice toolbox

Given the heterogeneity of health care systems across Europe, best practices might not be applicable to all countries. Nevertheless, identifying possible best practices can help procurers and policy makers select suitable approaches for adaptation in their country.

The methodical approach to identify best practices was similar to the one applied in the barriers analysis (see **Chapter 7.1**). Information was mainly gained from the PPM **country fiches** and the **stakeholder workshops**, as well as the stakeholder survey and analysis of IQVIA and TED data. In the country fiches, good practices were outlined in a section of its own, which contained pre-filled categories of good practice areas. Information about cross-country procurements were sourced from literature [7, 10, 117] as well as previous projects conducted by the study team.

7.2.1. Implementation of best practices in the study countries

Table 24 shows the frequency with which different best practices are applied in the study countries. These practices can address several of the policy objectives of interest in this study: access to medicines (having medicines available at affordable prices), security of supply, creating a competitive market, protecting the environment, and strengthening crisis preparedness.

Table 24: Best practices applied in the study countries

Best practice	Number of countries
Cross-country collaboration	23
e-procurement, IT projects	20
Use of specific supporting policies (e.g. negotiations, horizon scanning, HTA)	19
Seminars (webinars), capacity-building measures	19
Use of specific procurement practices, procedures and techniques (e.g. market research, MEAT, framework agreements)	17
Dialogue with suppliers (e.g. in preparation of calls)	17
Legal change(s)	15
(Systematic) collaboration of public procurers of medicines	14
Specific projects to encourage uptake of biosimilar medicines	13

Best practice	Number of countries
Internal rules and procedures, procurement contacts (administration management)	12
Strengthening of clinical hospital pharmacy	11
Leadership in centralised procurement agency or other procuring institution	10
Specific funding schemes	9
Specific projects to improve collaboration at the interface of hospital and outpatient sector	9
Institutional change(s)	8
Logistics management	8

Note: Table only lists best practices mentioned for more than one country.

Source: PPM country fiches

Most widely used were **cross-country collaborations**, although these varied in scope. Some, as described in **Chapter 6.2.1**, engage in joint procurement (Baltic Procurement Initiative, Nordic Pharmaceutical Forum) or joint price negotiations (Beneluxa Initiative, Valletta Declaration) while others are primarily used to exchange information and provide a platform for potential closer collaboration on issues related to access to medicines. Going beyond lower prices achieved through pooled purchase volumes, cross-country collaborations provide benefits to participating countries by pooling expertise and information. In interviews, workshops and reviews, procurement experts and other national technical experts (e.g. of pricing and reimbursement authorities) stressed the importance of collaboration which goes beyond the technical aspects of joint PPM, but the exchange of experiences, motivation through meeting of people working in similar areas and with similar mind-set and capacity-building is seen as a major value.

E-procurement was also commonly mentioned. Today, e-procurement is considered common in many European countries, but procurers remember the time of paper-based procurement. E-procurement helped facilitate and speed up processes, was a prerequisite for application of certain techniques (e.g. DPS) and increased transparency and accountability.

Use of **supporting policies and the linkage of PPM to pricing and reimbursement policy** (see **Chapter 3.5**) were also widely reported. In Norway, centralised procurement of medicines used in hospitals is integrated into the "system for introducing new health technologies" (so-called "Nye metoder"). This includes horizon scanning and HTA (the HTA method, i.e. rapid review or full HTA, is determined by the outcome of horizon scanning), followed by tendering and pricing negotiations of LIS. Another best practice example is the Danish CPB for hospitals, Amgros, which aims to have mechanisms in place to follow medicines used in hospitals at each stage of the product life cycle, including horizon scanning to identify emerging medicines, price negotiations with suppliers about newly marketed medicines on the basis of a clinical and health economic assessment of the Danish Medicines Council regarding the potential role of the treatment in Danish hospitals, as well as **using specific procurement procedures and techniques** for products with analogue competition and generics. Other countries also use supporting policies along the pharmaceutical value chain (e.g. Netherlands, Sweden, UK).

Investment in human resources in quantitative and qualitative terms is needed to achieve best results. Ensuring sufficient capacity (staffing) and appropriate training are considered a prerequisite for good PPM. Appropriate staffing of a procurement body is not limited to legal expertise; technical experts in the subject matter (in the case of PPM: pharmacists, ideally with clinical knowledge in specific disease areas), IT specialists (for data monitoring) and communication experts are required, to name a few.

Dialogue with suppliers was highlighted as a key best practice in preparation of specific procedures and can take various forms. Some procurers also consider dialogue

with suppliers a prerequisite for successful procurement. At a minimum, procurement plans should be communicated to potential bidders, e.g. through annual procurement plans published on the websites of contracting authorities (mandatory in some countries). More advanced forms of supplier dialogue include direct engagement, e.g. through questionnaires and interviews to elicit feedback on procurement plans and award criteria. Finally, supplier dialogue may not only be used in preparation of calls but also to shape the procurement system more generally.

Institutional and legal changes are comparatively rare but carry significant potential. Optimisation of PPM was reported in some countries after appropriate changes in legislation. This included institutional changes such as the set-up of a dedicated procurement body (e.g. Bulgaria, Denmark, Norway) with appropriate mandate, funding and staffing. In addition, some legal changes helped or even permitted introduction of some PPM policies. Use of DPS in Italy required, however, the legal basis in national legislation (see also **Chapter 3.3.2.2**). In the Czech Republic 2020 adaptions in the Waste Act and the End-of-Life Products Act completed the transformation towards sustainable public procurement as legislation requires to consider environmental and innovative aspects in the award criteria. Experience from the Nordic countries suggests that the inclusion of environmental criteria does not impact negatively on competition. However, there seems to be agreement among stakeholders, as voiced at the workshops, that environmental criteria may lead to higher prices. This is not necessarily the case, as Cyprus reported no impact of adding environmental criteria to tenders on prices.

Such changes require **a political vision and strategy** for PPM. This enables the development (e.g. to strengthen the PPM system, e.g. optimising it in terms of efficiency and resilience) and to test more "innovative" approaches. In addition to political leadership, **leadership at the level of the procurement body** is required. Amgros, for instance, piloted environmental criteria because, among others, the company's leadership urged to move forward this direction.

Collaboration of procurers and sharing of information informally and also formally through joint tenders is considered as a major asset. This can be done intra-country and cross-country. For instance, some procurers mentioned the usefulness of the EC Government Experts Group on Public Procurement (EXPP), Subgroup on Health Public Procurement.

Communication by the procurers with users of procurement is key. In case of centralised PPM, interaction with the users (e.g. hospital pharmacists) ensures better understanding, acceptance and uptake of centrally procured medicines. Thus, a helpdesk should be sufficiently staffed; communication to users should be pro-active and may contain capacity-building elements. In Norway, the procurement body holds annual seminars about the procured medicines which should be used as a priority.

7.2.2. Optimising PPM policy and practices

Adding to the best practice examples documented for the study countries summarised in the previous chapter (for details see the country fiches), several features, approaches and principles relating to PPM and the overall pharmaceutical policy framework have been mentioned in literature, the workshops organised in the frame of this study, interviews and the stakeholder survey. Some key optimisation proposals are presented in this chapter. It is important to note that they may address more than one of the best practices explained above, and they are sometimes cross-cutting topics.

In PPM, a range of policy objectives can be of interest, notably access to medicines, as well as ensuring availability of effective and safe medicines, creating a competitive market in the long term, ensuring security of supply, supporting environmental protection, and strengthening resilience and crisis preparedness. **MEAT criteria** can be

used to incorporate various award criteria and can therefore be seen as a tool to promote policy objectives other than affordability (i.e. price or cost alone).

The use of a **life cycle approach** to procurement, as pioneered by Amgros (see **Figure 31**), emerged as a best practice to **address multiple policy objectives**. There is no one size-fits-all approach in procurement but PPM procedures and techniques have to be well selected. Awareness of a product's position in the life cycle helps identify suitable procurement processes and set procurement goals. For example, negotiating an affordable price is most relevant for products without competitor to ensure that such a potentially innovative medicine is available to patients, while procedures that leverage competition between suppliers (including open tenders) are of interest when there are alternatives either through other treatments (analogue competition) or through generic or biosimilar products (after patent expiry). This approach also highlights the need to be aware of market entry of competitor products, which can be achieved through systematic horizon scanning. Knowledge of upcoming competitor products allows for leveraging the new competitive environment through timely issued tenders. Finally, the life cycle approach makes it clear that security of supply should be built into procurement as products approach the later stages of their life cycle. MEAT criteria may be tilted towards security of supply for these products, as price becomes less of a concern compared to the risk of shortages.

Market research and engaging in **dialogue with suppliers** are also suited to addressing multiple objectives. The EU Procurement Directive [68] encourages preliminary market consultations between contracting authorities and suppliers with the aim of facilitating better specifications, better outcomes and shorter procurement times. Firstly, this ensures knowledge of the market, including the number of potential suppliers and their interest in winning contracts in the planned procurement period. Market research can therefore avoid availability issues through a situation where no or few suppliers are willing or able to submit bids. Secondly, supplier dialogue can help prepare tenders with relevant award criteria to support participation from sufficient numbers of suppliers to create a competitive environment. Before launching their first joint Nordic tender call, Amgros held six weeks of hearings with suppliers, which helped strengthen the procurement documents [10]. Engaging with suppliers was also seen as key success factor for introducing environmental criteria in the joint Nordic tenders by Denmark, Iceland, and Norway (see **Box 12**). Finally, market research is required to implement a strong prequalification process where applicable to mitigate risks of shortages: robust pre-qualification criteria should be used, and sanctions may be imposed for suppliers who do not comply with their contractual obligations.

Awarding contracts to multiple winners can help to address security of supply and maintaining a competitive environment for products with off-patent competition. Multi-winner contracts are used for all or at least some off-patent medicines in most study countries in order to mitigate supply risks. Multi-winner contracts have been particularly recommended for biosimilars [42]. Sometimes these are used only for products where shortages would have a critical impact (e.g. in Austria for antibiotics and immunoglobulin G), but some countries aim to apply multi-award contracts wherever possible (Portugal). Some countries also use multi-award contracts for procurement of vaccines for national immunisation programmes (e.g. Ireland). Industry representatives also stress the importance of awarding multiple winners to maintain a competitive market with multiple suppliers operating.

In the outpatient setting, **tendering-like systems** based on regular price bids and preferential reimbursement status for the winning product may combine the economic incentive for suppliers to win a contract for the entire market (for a limited period of time, i.e. until the next round of bidding starts) with considerations for security of supply by building in a mechanism that allows the second- or third-ranked bidder to step in when there are supply issues.

Related to multi-winner contracts is the use of **framework agreements**. Concluding a framework contract with multiple suppliers allows the contracting authority flexibility in addressing its needs and provides some security should one of the suppliers fail to deliver. Framework agreements can therefore address security of supply concerns. Framework agreements may also be welcomed by suppliers as they can provide them with some flexibility for efficient manufacturing and delivery (e.g. by shifting between countries according to demand rather than being locked into contracts with set volumes). Framework agreements were also the procurement technique of choice for joint procurement at the EU level for pandemic preparedness through the JPA.

For successful PPM to achieve its goals, monitoring and evaluation through selected **Key Performance Indicators (KPIs)** is important. Some CPBs (e.g. AMGROS in Denmark, Resah in France, for details see the country fiches) are applying a strategic set of KPIs. Still, this good practice of selecting a set of useful KPIs has apparently not been fully implemented in all study countries.

While not strictly related to procurement, some **interface management measures** may also help address issues with access to medicines. These measures are intended to bridge the gap between inpatient and outpatient care, addressing, among others, issues of affordability and availability of medicines (where high-cost therapies are initiated in the hospital setting without consideration of future treatment after discharge). One such measure is to introduce **cross-sectoral formularies** (reimbursement lists) and committees. In the majority of the study countries, formularies relate mainly to the outpatient sector, while hospitals have national, regional and/or most commonly facility-based hospital pharmaceutical formularies. However, several countries have a cross-sectorial formulary for outpatient and inpatient sectors. Some of these countries also have **cross-sectoral committees** to define formularies. Other interface management initiatives include **funding mechanisms** to disincentivize transfer of treatment across sectors for financial reasons (e.g. in Norway), extending policies from the outpatient to the inpatient sector or vice versa, **IT** projects / cross-sectoral collection and exchange of data, programmes with regard to discharge of patients from hospitals, issuing treatment recommendations, and engaging in capacity-building and collaboration.

7.2.3. Best practices for joint procurement

Potential benefits of joint procurement (within-country or cross-country) are described in **Chapter 6.1** and in the impact analysis (**Chapter 4.3**). Briefly, these include achieving lower prices, better availability of high-quality medicines and improved security of supply, as well as fewer tangible benefits such as capacity building for procurers, improved standards and efficiency of the procurement process, and better transparency and accountability.

From existing cross-country initiatives in Europe (see **Chapter 6.2.1**), key learnings on prerequisites and good practice for **cross-country joint procurement** can be drawn:

- There is a need to **budget sufficient time for planning and preparing**; as compared to "regular" national tenders, more time resources are required;
- **Technical expertise** is required at operational levels (bottom-up initiative), complemented by high-level political support;
- **Mutual understanding** of the country representatives involved is considered as a key success factor; clarity of all general provisions and technical procedures before conducting the procurement is needed and may require frequent communication between participating countries;

- Clear, well-defined and yet simple and not too long **procurement documents**;
- There is a need to **define the lead partner** who will be responsible and has to take leadership;
- **Similar processes in pricing and reimbursement** are helpful (e.g. in the case of vaccine procurement, to have the vaccine in the vaccination schedule of the countries involved),
- **Logistical aspects** (e.g. delivery of the products) need to be considered at an early stage.
- In relation to joint procurement at EU level in the context of the COVID-19 pandemic, an important learning is that **communication between EC and MS is key**.

There is some overlap in learnings and best practices for **within-country joint procurement**, in particular in relation to the need for technical expertise, shared understanding of the goals and technical specifications of the procurement, and the need to consider logistical aspects.

Similarly to cross-country joint procurement, having a designated lead for the joint procurement within a country is needed. This may be a CPB, which might be most suitable to the role of a **"service provider"** – a key asset in ensuring joint procurement is of benefit to the contracting authorities.

It is acknowledged that joint procurement is a major challenge, in particular in the beginning, when processes are yet to be defined across jurisdictions given legal and institutional complexities (see **Chapter 6.1**). At the same time, collaborative procurement models are among the most prominent best practice examples. In joint procurement, **pooling** is not restricted to **purchase volumes** (making markets more attractive), but includes **pooling of knowledge and expertise**, which increases bargaining power. Literature has confirmed advantages of joint procurement in its different formats (group procurement of hospitals, centralised procurement at intra-country regional level or national level, cross-country collaboration). Major benefits were lower prices and thus savings of public expenditure [9, 14, 19, 271-274] and with regard to further policy objectives (mainly availability due to the prospect of larger markets, security of supply as well as accountability, standardisation of quality) [7, 9, 10, 14, 26, 32, 273, 275-277]. It should be noted that suppliers are hesitant towards joint procurement as default option, predicting availability issues and limited competition in the long term.

7.3. Policy recommendations

Based on the findings regarding overarching approaches to PPM as well as PPM practices at operational level (including examples described in the best practices toolbox), the study concludes by proposing a set of policy **recommendations targeted at policy-makers**:

1. Policy-makers are encouraged to **develop a procurement-related strategy**, which considers different aspects of PPM (e.g. PPM procedures and techniques, award criteria) aligned to the policy objectives to be achieved. Evidence on impact of different PPM policy and practices, as identified in this study, should be taken into consideration.
2. In the development of the procurement strategy, policy-makers are encouraged to apply a **holistic perspective**, in which PPM is one component of the toolbox for improving patient access to medicines. Using such an approach, accompanying tools and techniques related to procurement as well as further policies can have an important role in the overall pharmaceutical policy development.

3. Policy-makers are encouraged to **communicate** their strategic **vision of PPM** to procurers (contracting authorities), users, suppliers and also to the public, and to **invest in changes** needed to implement and operationalise the procurement strategy (e.g. changes in legislation, institutional reforms, etc.).
4. As part of the investment into an optimisation of PPM, policy-makers are encouraged to provide for **sufficient funding** to foster these optimisation processes, and to ensure sufficient **capacity-building** of procurers and users of PPM. Capacity-building should consider transfer and gaining of knowledge in operational skills, procedures and techniques which were identified to be beneficial.
5. Applying and optimising PPM as one important instrument of pharmaceutical policy to improve equitable and sustainable access to affordable medicines for patients, policy-makers are thus encouraged to **adjust the procurement strategy**, if needed, based on regular monitoring and evaluation conducted on a regular basis, to account for changes of policy objectives and reductions in the impact of PPM policies and practices resulting from changes in the environment.
6. In developing and optimising the PPM strategy, policy-makers are encouraged to consider **collaboration as a guiding principle**, both intra-country (across regions, facilities and cross-sectorial) as well as cross-country, as well as for procurement and further policy implementation.

At a more **technical-operational level**, the study findings suggest considering the following policy and practices in a PPM strategy and action plan:

- Availability (in legal basis and technical capacity) of a **range of PPM policies and practices**, with clear understanding of most appropriate conditions of use for each of them,
- Application of the **MEAT criteria**, to allow for consideration of further criteria in a strategically well-defined mix,
- Awarding contracts to **multiple winners** instead of pursuing a single-winner approach,
- Move to more centralised PPM or, at least, through voluntary **collaboration** through group procurements and cross-country PPM involving several contracting authorities,
- Developing **joint formularies and treatment recommendations** for at least some medicines, which are used in both outpatient and inpatient settings,
- Introduction of **regular interchange** (meetings, seminars) in an institutionalised format between procurers and suppliers, as well as between centralised contracting authorities (CPBs) and users,
- Ensuring transparent, clear processes,
- Continuation and optimisation of the **IT environment** of supporting PPM (e-procurement),
- Definition of required information in preparation of a call (e.g. market research, knowledge of upcoming patent expiries), during the procedure and after awarding the contract, and ensuring systematic **collection of** these **data and regular analysis** and communication of key findings to policy-makers,
- **Communication with prescribers**, to inform about (the rationale) of procured medicines, in particular with regard to biosimilar medicines, to support their support in prescribing and switching.

The study confirmed that there is large potential in optimising PPM, but for some improvements and novel routes, projects are yet evolving or in a pilot phase. The **European Commission** could support in this context by facilitating information-sharing and exchange of experience through:

- Organisation of targeted meetings and seminars of **PPM practitioners to discuss** plans and implementations of new PPM methods ("how does it work in practice?"),
- Documentation on updated **experiences of PPM practitioners** and development of training materials to facilitate knowledge brokerage to further countries interested,
- **Communication to other stakeholders in pharmaceutical policy** (e.g. pricing and reimbursement authorities, HTA body) about new developments to improve vertical collaboration between policy-makers and technical experts.

8. CONCLUSIONS

Procurement is a key **pharmaceutical policy that can help achieve better access to medicines**, including making more medicines available at lower prices. Procurement practices vary across European countries, often reflecting the heterogeneity in health care systems. In terms of optimising public procurement of medicines, **no one size fits all**, and procurement policies need to be integrated into the national set-up of the healthcare system. A **life cycle approach** to procurement which considers the place of a medicine along the pharmaceutical value chain can help determine which procurement procedure (less vs. more competitive) to use and what award criteria are most relevant. Understanding the market can be helped by thorough market research and engagement with suppliers ahead of the launch of procurement procedures.

Importantly, through its leverage as key area for procurement, PPM can help address further policy objectives, including security of supply and crisis preparedness for the health sector, a competitive market for pharmaceuticals, as well as environmental objectives. However, not all objectives may be simultaneously attainable. A strategic approach to pharmaceutical procurement is therefore needed.

Policy-makers are encouraged to put **attention to PPM** and to (further) develop a **PPM vision and strategy**, which can be then operationalised based on learnings on how to **optimise PPM in technical terms**.

9. REFERENCES

[1] European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Pharmaceutical Strategy for Europe. COM/2020/761 final. 25 November 2020. Brussels, 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761 (accessed 17 January 2021).

[2] WHO. WHO Guideline on Country Pharmaceutical Pricing Policies. Second edition. Geneva: World Health Organization, 2020. Available from: https://apps.who.int/iris/rest/bitstreams/1309649/retrieve (accessed 20 December 2020).

[3] European Commission. Public Procurement in Healthcare Systems. Opinion of the Expert Panel on effective ways of investing in Health (EXPH). Brussels 2021. Available from: https://op.europa.eu/en/publication-detail/-/publication/0fa5efff-b138-11eb-8307-01aa75ed71a1/language-en (accessed 7 August 2021).

[4] Leopold C, Habl C, Vogler S. Tendering of Pharmaceuticals in EU Member States and EEA countries. Results from the country survey. Vienna: ÖBIG Forschungs- und Planungsgesellschaft mbH, 2008. Available from: http://whocc.goeg.at/Literaturliste/Dokumente/BooksReports/Final_Report_Tendering_June_08.pdf (accessed 24 November 2021).

[5] Maniadakis N, Holtorf AP, Otávio Corrêa J, Gialama F, Wijaya K. Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage. Appl Health Econ Health Policy. 2018;16(5): 591-607. Epub 2018/07/11.

[6] Vogler S, Zimmermann N, Haasis MA. PPRI Report 2018: Pharmaceutical pricing and reimbursement policies in 47 PPRI network member countries Vienna: WHO Collaborating Centre for Pricing and Reimbursement Policies, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), 2019. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI%20Report2018_2nd_edition_final.pdf (accessed 25 October 2021).

[7] Huff-Rousselle M. The logical underpinnings and benefits of pooled pharmaceutical procurement: a pragmatic role for our public institutions? Social Science & Medicine. 2012;75(9): 1572-80.

[8] DeRoeck D, Bawazir SA, Carrasco P, Kaddar M, Brooks A, Fitzsimmons J, et al. Regional group purchasing of vaccines: review of the Pan American Health Organization EPI revolving fund and the Gulf Cooperation Council group purchasing program. The International journal of health planning and management. 2006. Available from: http://dx.doi.org/10.1002/hpm.822 (accessed 03 March 2021);21(1): 23-43.

[9] Vogler S, Bauer E, Habimana K. Centralised pharmaceutical procurement – learnings from six European countries. Applied health economics and health policy. 2022: https://doi.org/10.1007/s40258-022-00729-w.

[10] Vogler S, Haasis MA, van den Ham R, Humbert T, Garner S. European collaborations on medicine and vaccine procurement. Bulletin of the World Health Organization. 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8477421/# (accessed 21.09.2022).

[11] WHO. Operational principles for good pharmaceutical procurement. Geneva: World Health Organization, 1999. Available from: https://www.who.int/3by5/en/who-edm-par-99-5.pdf (accessed 2 August 2021).

[12] Diaconu K, Chen YF, Cummins C, Jimenez Moyao G, Manaseki-Holland S, Lilford R. Methods for medical device and equipment procurement and prioritization within low- and middle-income countries: findings of a systematic literature review. Global Health. 2017;13(1): 59. Epub 2017/08/20.

[13] Puig-Junoy J. [Policies encouraging price competition in the generic drug market: Lessons from the European experience]. Gac Sanit. 2010;24(3): 193-9. Epub 2010/03/02. Políticas de fomento de la competencia en precios en el mercado de genéricos: lecciones de la experiencia europea.

[14] Seidman G, Atun R. Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceuticals, vaccines or health products? A systematic review of evidence from low-income and middle-income countries. BMJ Global Health. 2017;2(2): e000243.

[15] Acosta A, Ciapponi A, Aaserud M, Vietto V, Austvoll-Dahlgren A, Kösters JP, et al. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database Syst Rev. 2014;2014(10): Cd005979. Epub 2014/10/17.

[16] Petrou P, Talias MA. Tendering for pharmaceuticals as a reimbursement tool in the Cyprus Public Health Sector. Health Polcy and Technology. 2014;3(3): 167-75.

[17] Petrou P, Talias MA. Price Determinants of the Tendering Process for Pharmaceuticals in the Cyprus Market. Value in Health Regional Issues. 2015. Available from: https://www.sciencedirect.com/science/article/pii/S2212109915000618?via%3Dihub (accessed 16 July 2020);7C: 67-73.

[18] Panayiotopoulou E. A, Charalambous G, Kaitelidou D, Jelastopulu E. Assessment of Effectiveness of Tendering Procedure in Pharmaceuticals: The Cyprus Experience. Annals of Pharmacology and Pharmaceutics. 2020;5(2): 1179.

[19] Bartels D. Centralizing Procurement of Medicines to save costs for Denmark. Eurohealth. 2016. Available from: https://apps.who.int/iris/bitstream/handle/10665/332708/Eurohealth-22-2-42-44-eng.pdf?sequence=1&isAllowed=y (accessed 03 September 2021);22(2): 42-3.

[20] Kastanioti C, Kontodimopoulos N, Stasinopoulos D, Kapetaneas N, Polyzos N. Public procurement of health technologies in Greece in an era of economic crisis. Health Policy. 2013;109(1): 7-13. Epub 2012/04/17.

[21] Ferraresi M, Gucciardi G, Rizzo L. Savings from public procurement centralization in the healthcare system. European Journal of Political Economy. 2021;66: 101963.

[22] Curto A, Van de Vooren K, Garattini L, Lo Muto R, Duranti S. Regional tenders on biosimilars in Italy: potentially competitive? Generics and Biosimilars Initiative (GaBI) Journal. 2013;2(3): 123-7.

[23] Curto S, Ghislandi S, van de Vooren K, Duranti S, Garattini L. Regional tenders on biosimilars in Italy: an empirical analysis of awarded prices. Health Policy. 2014;116(2): 182-7.

[24] Ferraresi M, Gucciardi G, Rizzo L. Does purchase centralization reduce health expenditure? Evidence from the Italian health-care system. 2019.

[25] Clark R, Coviello D, De Leverano A. Centralized procurement and delivery times: Evidence from a natural experiment in Italy. ZEW-Centre for European Economic Research Discussion Paper. 2021(21-063).

[26] Dubois P, Lefouili Y, Straub S. Pooled Procurement of Drugs in Low and Middle Income Countries. 2020. Available from: http://publications.ut-capitole.fr/32228/1/wp_tse_999.pdf (accessed 24. July 2020).

[27] Moye-Holz D, van Dijk JP, Reijneveld SA, Hogerzeil HV. The Impact of Price Negotiations on Public Procurement Prices and Access to 8 Innovative Cancer Medicines in a Middle-Income Country: The Case of Mexico. Value in health regional issues. 2019;20: 129-35.

[28] Toulemon L. Regional Purchasing Groups and Hospital Medicine Prices: Evidence from Group Creations. Health economics. 2018;27(9): 1380-93.

[29] Gavurová B, Belás J, Rowland Z, Kubák M. The impact of agreement on government procurement use on the competition in Slovak healthcare sector. Administratie si Management Public. 2021(36): 102-15.

[30] Dalen DM, Strøm S, Locatelli M. Biosimilar bidding in centralized tenders in Norway. Nordic Journal of Health Economics. 2021;9(1): 11-23.

[31] Nemec J, Kubak M, Krapek M, Horehajova M. Competition in Public Procurement in the Czech and Slovak Public Health Care Sectors. Healthcare. 2020;8(3): 201.

[32] Vogler S, Habimana K, Haasis MA. Purchasing medicines for the public sector: Evaluation of the performance of centralised procurement in Portugal. The International journal of health planning and management. 2022;n/a(n/a).

[33] Baldi S, Vannoni D. The impact of centralization, corruption and institutional quality on procurement prices: an application to pharmaceutical purchasing in Italy. Carlo Alberto Notebooks. 2014;379.

[34] Baldi S, Vannoni D. The impact of centralization on pharmaceutical procurement prices: the role of institutional quality and corruption. Regional Studies. 2017;51(3): 426-38.

[35] Mackey TK, Cuomo RE. An interdisciplinary review of digital technologies to facilitate anti-corruption, transparency and accountability in medicines procurement. Global Health Action. 2020;13(sup1): 1695241.

[36] Chokshi M, Farooqui HH, Selvaraj S, Kumar P. A cross-sectional survey of the models in Bihar and Tamil Nadu, India for pooled procurement of medicines. WHO South-East Asia

journal of public health. 2015. Available from: https://apps.who.int/iris/bitstream/handle/10665/329690/seajphv4n1p78.pdf?sequence=1&isAllowed=y (accessed 13 March 2021);4(1): 78-85.

[37] Stuurman AL, Rizzo C, Haag M. Investigating the procurement system for understanding seasonal influenza vaccine brand availability in Europe. PloS one. 2021;16(4): e0248943. Epub 2021/04/09.

[38] Carradinha H. Tendering short-term pricing policies and the impact on patients, governments and the sustainability of the generic medicines industry. Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector. 2009;6(4): 351-61.

[39] Kohler JC, Mitsakakis N, Saadat F, Byng D, Martinez MG. Does Pharmaceutical Pricing Transparency Matter? Examining Brazil's Public Procurement System. Globalization and Health. 2015. Available from: https://doi.org/10.1186/s12992-015-0118-8 (accessed 24 July 2020);11(1): 34.

[40] Kohler JC, Dimancesco D. The risk of corruption in public pharmaceutical procurement: how anti-corruption, transparency and accountability measures may reduce this risk. Global Health Action. 2020. Available from: https://www.tandfonline.com/doi/full/10.1080/16549716.2019.1694745 (accessed 24 July 2020);13(sup1): 1694745.

[41] Parmaksiz K, Pisani E, Bal R, Kok MO. A systematic review of pooled procurement of medicines and vaccines: identifying elements of success. Global Health. 2022;18(1): 59. Epub 2022/06/12.

[42] Barbier L, Simoens S, Soontjens C, Claus B, Vulto AG, Huys I. Off-Patent Biologicals and Biosimilars Tendering in Europe-A Proposal towards More Sustainable Practices. Pharmaceuticals (Basel). 2021;14(6). Epub 2021/06/03.

[43] Rintoul A, Colbert A, Garner S, Kotwani A, Vogler S, Bouvy J, et al. Medicines with one seller and many buyers: strategies to increase the power of the payer. BMJ. 2020. Available from: https://www.bmj.com/content/bmj/369/bmj.m1705.full.pdf (accessed 25 November 2021);369: m1705.

[44] Ferrario A, Dedet G, Humbert T, Vogler S, Suleman F, Pedersen HB. Strategies to achieve fairer prices for generic and biosimilar medicines. BMJ. 2020. Available from: https://www.bmj.com/content/bmj/368/bmj.l5444.full.pdf (accessed 25 November 2021);368: l5444.

[45] Modisakeng C, Matlala M, Godman B, Meyer JC. Medicine shortages and challenges with the procurement process among public sector hospitals in South Africa; findings and implications. BMC Health Services Research. 2020;20(1): 234.

[46] Miller FA, Lehoux P, Peacock S, Rac VE, Neukomm J, Barg C, et al. How procurement judges the value of medical technologies: a review of healthcare tenders. International journal of technology assessment in health care. 2019. Available from: https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/abs/how-procurement-judges-the-value-of-medical-technologies-a-review-of-healthcare-tenders/AA8D1B91D00FD8BED54F1634995422DB (accessed 13 March 2021);35(1): 50-5.

[47] Iwu CJ, Jaca A, Abdullahi LH, Ngcobo NJ, Wiysonge CS. A scoping review of interventions for vaccine stock management in primary health-care facilities. Hum Vaccin Immunother. 2019;15(11): 2666-72. Epub 2019/05/23.

[48] Vogler S. "Ready for the future?"–Status of national and cross-country horizon scanning systems for medicines in European countries. GMS German Medical Science — an Interdisciplinary Journal. 2022;22: Doc05.

[49] European Commission. Impact Assessment - Strengthening of the EU Cooperation on Health Technology Assessment (HTA). Brussels; 2018.

[50] Dylst P, Vulto A, Simoens S. Demand-side policies to encourage the use of generic medicines: an overview. Expert Review of Pharmacoeconomics and Outcomes Research. 2013;13(1): 59-72.

[51] Klasa K, Greer SL, van Ginneken E. Strategic Purchasing in Practice: Comparing Ten European Countries. Health Policy. 2018;122(5): 457-72.

[52] European Commission. Strategic Public Procurement. Brussels, 2017. Available from: https://ec.europa.eu/growth/single-market/public-procurement_en (accessed 1 February 2022).

[53] European Commission. Recommendation on the professionalisation of public procurement. Brussels, 2021. Available from: https://ec.europa.eu/growth/single-market/public-procurement_en (accessed 27 January 2022).

[54] European Commission. "Buying Social - a guide to taking account of social considerations in public procurement (2nd edition)". Brussels, 2021. Available from: https://ec.europa.eu/docsroom/documents/45767/attachments/1/translations/en/renditions/native (accessed 27 January 2022).

[55] European Commission. Report on the implementation and best practices of national procurement policies. Brussels, 2021. Available from: https://ec.europa.eu/growth/single-market/public-procurement_en (accessed 27 January 2022).

[56] European Commission. Guidance on Innovation Procurement. Brussels, 2021. Available from: https://ec.europa.eu/docsroom/documents/45975 (accessed 01 February 2022).

[57] European Commission. Making socially responsible public procurement work. Luxembourg: Publications Office of the European Union, 2020. Available from: https://op.europa.eu/en/publication-detail/-/publication/69fc6007-a970-11ea-bb7a-01aa75ed71a1 (accessed 01 February 2022).

[58] OECD. Government at a Glance 2015; Paris: OECD Publishing; 2015.

[59] Ferrario A, Humbert T, Kanavos P, Pedersen HB. Strategic procurement and international collaboration to improve access to medicines. Bulletin of the World Health Organization. 2017;95(10): 720-2.

[60] WHO Europe. Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. Copenhagen: World Health Organization Regional Office for Europe, 2016. Available from: https://www.euro.who.int/__data/assets/pdf_file/0003/323598/Challenges-opportunities-improving-access-medicines-efficient-public-procurement.pdf (accessed 14 April 2022).

[61] EFPIA. On the effectiveness of public procurement of medicines in the EU. Brussels: European Federation of Pharmaceutical Industries and Associations, 2022. Avaliable from: https://www.efpia.eu/media/636671/efpia_white-paper_public-procurement.pdf (accessed 18 February 2022).

[62] Medicines for Europe. Lessons learned from the joint procurement of Intensive Care Unit medicines. Brussels, 2021. Available from: https://www.medicinesforeurope.com/publications/?t=reports (accessed 6 April 2022).

[63] Medicines for Europe. Joint procurement. Brussels, 2020. Available from: https://www.medicinesforeurope.com/publications/?t=reports (accessed 4 April 2022).

[64] Medicines for Europe. Procurement and security of supply. Brussels, 2019. Available from: https://www.medicinesforeurope.com/publications/?t=reports (accessed 6 April 2022).

[65] Medicines for Europe. Best procurement practices - position paper_final version. Brussels, 2015. Available from: https://www.medicinesforeurope.com/publications/?t=reports (accessed 6 April 2022).

[66] Medicines for Europe. Position Paper on cross-border joint procurement. Brussels, 2015. Available from: https://www.medicinesforeurope.com/publications/ (accessed 6 April 2022).

[67] EAHP. EAHP Position Paper on Procurement Advocating for the involvement of hospital pharmacists in procurement. Brussels: European Associations of Hospital Pharmacists, 2020. Available from: https://www.eahp.eu/sites/default/files/eahp_position_paper_on_procurement_1.pdf (accessed 30 July 2022).

[68] European Commission. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. Brussels, 2014. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0024-20180101 (accessed 3 September 2021).

[69] Janssen Daalen JM, den Ambtman A, Van Houdenhoven M, van den Bemt BJF. Determinants of drug prices: a systematic review of comparison studies. BMJ Open. 2021;11(7): e046917. Epub 2021/07/17.

[70] Vulto AG, Vanderpuye-Orgle J, van der Graaff M, Simoens SRA, Dagna L, Macaulay R, et al. Sustainability of Biosimilars in Europe: A Delphi Panel Consensus with Systematic Literature Review. Pharmaceuticals (Basel). 2020;13(11). Epub 2020/11/21.

[71] Vogler S, Leopold C, Zimmermann N, Habl C, de Joncheere K. The Pharmaceutical Pricing and Reimbursement Information (PPRI) initiative–experiences from engaging with pharmaceutical policy makers. Health Policy and Technology 2014;3(2): 139–48.

[72] Vogler S, Zimmermann N, Haasis MA, Babar Z-U-D, Busse R, Balbino JE, et al. Abstracts from the 4th International PPRI Conference 2019: Medicines access challenge – The value of pricing and reimbursement policies. Journal of Pharmaceutical Policy and Practice. 2019;12(3): 34.

[73] Andre G, Semerdjiev I. PHIS Pharma Profile Bulgaria. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Pharma_Profile_Bulgaria_Oct2010_4.pdf (accessed 02 February 2022).

[74] Özer S, Thomsen E, Schüder P. PHIS Pharma Profile Denmark. Vienna: Pharmaceutical Health Information System (PHIS), 2011. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/V9_DK%20PHIS%20Pharma%20Profile_final_1.pdf (accessed 02 February 2022).

[75] Lopes S, Marty C, Berdai D. PHIS Pharma Profile France. Vienna: Pharmaceutical Health Information System (PHIS), 2011. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Pharma%20Profile%20FR_2011_final_1.pdf (accessed 02 February 2022).

[76] Martini N, Folino Gallo P, Montilla S. PPRI Pharma Profile Italy. Pharmaceutical Pricing and Reimbursement Information (PPRI), 2007. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Italy_PPRI_2007_4.pdf (accessed 1 February 2022).

[77] Festøy H, Yu LM, Aanes T, Ognøy AH, Gregersen T. PHIS Pharma Profile Norway. Vienna, 2011. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Pharma%20Profile%20Norway%20Nov11_2.pdf (accessed 27 August 2021).

[78] Martinez Vallejo M, Ferré de la Peña P, Guillo Izquierdo MJ, Lens Cabrera C. PHIS Pharma Profile Spain. Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Spain_PHIS_PharmaProfile_2010_4.pdf (accessed 2 February 2022).

[79] Kullman D. PHIS Pharma Profile United Kingdom. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Pharma%20Profile%20UK%20Feb2011_5.pdf (accessed 02 February 2022).

[80] Zimmermann N, Vogler S. PPRI/PHIS Pharma Profile Austria. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI) / Pharmaceutical Health Information System (PHIS), 2012. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_PHIS%20Pharma%20Profile%20Austria_2012_final_3.pdf (accessed 02 February 2022).

[81] Zimmermann N, Vogler S. PHIS Hospital Pharma Report Austria. Vienna: Pharmaceutical Health Information System (PHIS), 2009.

[82] Antonissen Y, De Swaef A. PHIS Hospital Pharma Report Belgium. Vienna: Pharmaceutical Health Information System (PHIS), 2009.

[83] Andre G, Semerdjiev I. PHIS Hospital Pharma Report Bulgaria. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Bulgaria%20Hospital%20Pharma%20Report%202009_5.pdf (accessed 02 February 2022).

[84] Panagiotis P. PHIS Hospital Pharma Report Cyprus. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Hospital%20Pharma%20Report%202009%20Cyprus_3.pdf (accessed 02 February 2022).

[85] Pavlena Z. PHIS Hospital Pharma Report Czech Republic. Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Hospital%20Pharma%20Czech%20Republic%202009_5.pdf (accessed 02 February 2022).

[86] Er S. PHIS Hospital Pharma Report Denmark. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Denmark%20Hospital%20Pharma%20Report%202009_2.pdf (accessed 2 February 2022).

[87] Närhi U. PHIS Hospital Pharma Report Finland. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Finland_Hospital%20Pharma_Report%202009_5.pdf (accessed 02 February 2022).

[88] Lopes S, Marty C, Berdai D. PHIS Hospital Pharma Report France. Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Hospital%20Pharma%20France%202009_2.pdf (accessed 02 February 2022).

[89] Anda G, Jānis I, Atis M. PHIS Hospital Pharma Report Latvia. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Latvia%20Hospital%20Pharma%20Report%202009_6.pdf (accessed 02 February 2022).

[90] Krukiene G, Alonderis T, Knasiene D, Jankauskiene O. PHIS Hospital Pharma Report Lithuania. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/4%20Hospital%20Pharma%20Report%20Lithuania_draft_for_publication_revised_1.pdf (accessed 02 February 2022).

[91] Zahra Pullis I. PHIS Hospital Pharma Report Malta. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Malta%20Hospital%20Pharma%20Report%202009_4.pdf (accessed 02 February 2022).

[92] Aanes T, Ognøy AH, Festøy H. PHIS Hospital Pharma Report Norway. Vienna: PHIS Pharmaceutical Health Information System, 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Norway%20Hospital%20Pharma%20Report%202009_3.pdf (accessed 11 January 2022).

[93] Mazag J, Bilančíková B, Vogler S, Leopold C. PHIS Hospital Pharma Report Poland. 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Hospital%20Pharma%20Poland%202009_1.pdf (accessed 02 February 2022).

[94] Caldeira S, Furtado C, Vieira I, Baptista A. PHIS Hospital Pharma Report Portugal. Vienna: Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (Austrian Health Institute), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Hospital%20Pharma%20Portugal%202010_5.pdf (accessed 01 February 2022).

[95] Mazag J. PHIS Hospital Pharma Report Slovakia. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/7%20Slovakia%20Hospital%20Pharma_2.pdf (accessed 2 February 2022).

[96] Svensson J. PHIS Hospital Pharma Report Sweden. 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/V5%20PHIS%20Hospital%20Pharma%20report%20SE_final%20version_6.pdf (accessed 02 February 2022).

[97] Storms H, Schreurs M. PHIS Hospital Pharma Report The Netherlands. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20NL%20Hospital%20Pharma%20Report%202009_5.pdf (accessed 2 February 2022).

[98] James D, Kullman D. PHIS Hospital Pharma Report United Kingdom. Vienna: Pharmaceutical Health Information System (PHIS), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/UK%20Hospital%20Pharma%20Report%202009_6.pdf (accessed 02 February 2022).

[99] Zimmermann N, Haasis MA. PPRI Pharma Brief: Cyprus 2021. Vienna: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), 2021. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Pharma_Brief_Cyprus_2021_final_bf.pdf (last accessed 20 May 2022).

[100] Vogler S. PPRI Pharma Brief: Italy 2021. Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series. Vienna: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), 2021. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Pharma_Brief_Italy_2021_final_bf..pdf (accessed 4 January 2022).

[101] Antonissen Y, De Swaef A. PPRI Pharma Profile Belgium. 2008.

[102] Pudersell K, Vetka A, Rootslane L, Mathiesen M, Vendla K, Laasalu K. PPRI Pharma Profile Estonia 2007. Vienna: Austrian National Public Health Institute / Gesundheit Österreich GmbH (GÖG), 2007. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Estonia_PPRI_2007_4.pdf (last accessed 20 may 2022).

[103] Mäntyranta T, Martikainen J, Kivioja A, Paldán M. PPRI Pharma Profile Finland 2007. Vienna: Austrian National Public Health Institute / Gesundheit Österreich GmbH (GÖG), 2007. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Finland_PPRI_2007_6.pdf (last accessed 20 May 2022).

[104] Stargardt T, Busse R, Dauben HP. PPRI Pharma Profile Germany 2008. Vienna: Austrian National Public Health Institute / Gesundheit Österreich GmbH (GÖG), 2008. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Germany_PPRI_2008_6.pdf (last accessed 20 May 2022).

[105] Vardica A, Kontozamanis V. PPRI Pharma Profile Greece 2007. Vienna: Austrian National Public Health Institute / Gesundheit Österreich GmbH (GÖG), 2007. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Greece_PPRI_2007_1.pdf (last accessed 20 May 2022).

[106] Kovacs T, Rozsa P, Szigeti S, Borcsek B, Lengyel G. PPRI Pharma Profile Hungary; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2007.

[107] Elliot D, Byrne G. PPRI Pharma Profile Ireland; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2007.

[108] Behmane D. PPRI Pharma Profile Latvia; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2007.

[109] Krukiene G, Alonderis T. PPRI Pharma Profile Lithuania; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2008.

[110] Janiszewski R, Bondaryk K. PPRI Pharma Profile Poland; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2007.

[111] Teixeira I, Vieira I. PPRI Pharma Profile Portugal; Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2008.

[112] Mazag J, Segec A. PPRI Pharma Profile Slovakia. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI), 2007.

[113] Pontén J, Rönnholm G, Skiöld P. PPRI Pharma Profile Sweden. Stockholm / Vienna: Dental and Pharmaceutical Benefits Agency / Pharmaceutical Pricing and Reimbursement Information (PPRI), 2017. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Pharma_Profile_Sweden_2017_5.pdf (accessed 8 September 2021).

[114] Weise N, Festoy H, Hagen C, Gregersen T, Andreassen E, Sivertsen C. PPRI Pharma Profile: Norway 2018. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI), 2018. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI%20Norway%202018.pdf (accessed 20 June 2020).

[115] Vogler S, Fischer S. How to address medicines shortages: Findings from a cross-sectional study of 24 countries. Health Policy. 2020. Available from: https://www.sciencedirect.com/science/article/pii/S0168851020302256 (accessed 20.09.2022);124(12): 1287-96.

[116] Vogler S, Gombocz M, Zimmermann N. Tendering for off-patent outpatient medicines: lessons learned from experiences in Belgium, Denmark and the Netherlands. Journal of Pharmaceutical Health Services Research. 2017;8(3): 147-58.

[117] Vogler S, Haasis MA, van den Ham R, Suleman F, Humbert T, Garner S. Cross-Country Collaborations to improve access to medicines and vaccines in the WHO European Region. Word Health Organization Regional Office for Europe, 2020. Available from: https://apps.who.int/iris/bitstream/handle/10665/332933/9789289055031-eng.pdf (accessed 31 January 2022).

[118] Vogler S, Paris V, Panteli D. Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? European Observatory on Health Care Systems. Copenhagen: WHO Regional Office for Europe, 2018. Available from: http://www.euro.who.int/__data/assets/pdf_file/0009/379710/PolicyBrief_AUSTRIA_PB30_web_13082018.pdf (accessed 29 January 2021).

[119] Vogler S, Schneider P, Zuba M, Busse R, Panteli D. Policies to Encourage the Use of Biosimilars in European Countries and Their Potential Impact on Pharmaceutical Expenditure. Frontiers in Pharmacology. 2021. Available from: Policies to Encourage the Use of Biosimilars in European Countries and Their Potential Impact on Pharmaceutical Expenditure - PMC (nih.gov) (accessed 21.09.2022);12(625296).

[120] Sabine V, Katharina H, Eveli B, Peter S, Alexander HM. Assessment of Centralised Procurement of Medicines in Portugal. Vienna: Gesundheit Österreich, 2021. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/GOe_FP_PT_CPM_Full%20Report_total_bf.pdf (accessed 28 April 2022).

[121] WHO Europe. Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. Copenhagen: World Health Organization Regional Office for Europe, 2016. Available from: http://www.euro.who.int/__data/assets/pdf_file/0003/323598/Challenges-opportunities-improving-access-medicines-efficient-public-procurement.pdf?ua=1 (accessed 20 August 2020).

[122] Albano GL, Racca G. Collaborative Public Procurement and Supply Chain in the EU Experience. SSRN Electronic Journal. 2011. Available from: https://www.researchgate.net/publication/228286155_Collaborative_Public_Procurement_and_Supply_Chain_in_the_EU_Experience (accessed 15 June 2021): 31.

[123] Jensen TB, Kim SC, Jimenez-Solem E, Bartels D, Christensen HR, Andersen JT. Shift From Adalimumab Originator to Biosimilars in Denmark. JAMA Internal Medicine. 2020.

[124] Ferrario A, Kanavos P. Dealing with uncertainty and high prices of new medicines: a comparative analysis of the use of managed entry agreements in Belgium, England, the Netherlands and Sweden. Social Science & Medicine. 2015;124: 39-47.

[125] Wouters OJ, Kanavos P, McKee M. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. The Milbank Quarterly. 2017;95(3): 554-601.

[126] Wouters OJ, Sandberg DM, Pillay A, Kanavos PG. The impact of pharmaceutical tendering on prices and market concentration in South Africa over a 14-year period. Social science & medicine. 2019. Available from: https://www.sciencedirect.com/science/article/pii/S0277953618306634 (accessed 27 July 2020);220: 362-70.

[127] Dylst P, Vulto A, Simoens S. Tendering for outpatient prescription pharmaceuticals: What can be learned from current practices in Europe? Health Policy. 2011;101(2): 146-52.

[128] Moorkens E, Vulto AG, Huys I, Dylst P, Godman B, Keuerleber S, et al. Policies for biosimilar uptake in Europe: an overview. PloS one. 2017;12(12): e0190147.

[129] Blankart CR, Stargardt T. Preferred supplier contracts in post-patent prescription drug markets. Health Care Manag Sci. 2016.

[130] Callea G, Armeni P, Marsilio M, Jommi C, Tarricone R. The impact of HTA and procurement practices on the selection and prices of medical devices. Social science & medicine. 2017. Available from: https://www.sciencedirect.com/science/article/pii/S027795361630658X (accessed 27 July 2020);174: 89-95.

[131] Kanavos P. Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands and Germany. European Medicines Information Network (EMINet), 2012 (accessed 24 November 2021).

[132] OECD. Methodology for assessing procurement systems (MAPS). Paris: Organisation for Co-operation and Development, 2018. Available from: http://www.mapsinitiative.org/methodology/MAPS-methodology-for-assessing-procurement-systems.pdf (accessed 21 October 2019).

[133] OECD. Pharmaceutical Innovation and Access to Medicines. Paris: Organisation for Economic Co-operation and Development, 2018. Available from: https://www.oecd-ilibrary.org/content/publication/9789264307391-en (accessed 10 February 2021).

[134] OECD. Centralised Purchasing Systems in the European Union. SIGMA Papers, No. 47. Paris: OECD, 2011. Available from: https://www.oecd-ilibrary.org/governance/centralised-purchasing-systems-in-the-european-union_5kgkgqv703xw-en (last accessed 6 April 2022). Report No.: 20786581

[135] Simoens S, Cheung R. Tendering and biosimilars: what role for value-added services? Journal of Market Access & Health Policy. 2020;8(1): 1705120.

[136] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. PPRI country information. 2022. Available from: https://ppri.goeg.at/index.php/ppri_country_information (last accessed 16 May 2022).

[137] European Oberservatory on Health Systems and Policies. Health Systems and Policy Monitor (HSPM). Brussels, 2022. Available from: https://eurohealthobservatory.who.int/monitors/health-systems-monitor/overview# (accessed 29 April 2022).

[138] European Commission. Stock-taking of administrative capacity, systems and practices across the EU to ensure the compliance and quality of public procurement involving European Structural and Investment (ESI) Funds. Brussels: European Commission, 2016. Available from: https://op.europa.eu/en/publication-detail/-/publication/d1082259-0202-11e6-b713-01aa75ed71a1 (accessed 26 January 2022).

[139] OECD. Publications on Public Procurement. Paris: Organisation for Economic Co-operation and Development, 2022. Available from: https://www.oecd.org/gov/public-procurement/publications/ (accessed 26 January 2022).

[140] Vogler S, Habl C, Leopold C, Mazag J, Morak S, Zimmermann N. PHIS Hospital Pharma Report. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Hospital%20Pharma_Report_2.pdf (accessed 4 January 2022).

[141] Gesundheit Österreich Beratung GmbH. Glossary of public procurement terms. Working definitions of public procurement terms for the "Study on Best Practices in Public Procurement of Medicines". Vienna: Gesundheit Österreich, 2022. Available from: https://ppri.goeg.at/public_procurement_glossary (accessed 5 April 2022).

[142] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. Glossary of pharmaceutical terms. Vienna: Gesundheit Österreich (GÖG / Austrian National Public Health Institute), 2022. Available from: https://ppri.goeg.at/ppri-glossary (accessed 5 January 2022).

[143] OECD. MAPS Glossary. Paris: Organisation for Economic Co-operation and Development, 2018. Available from: https://www.mapsinitiative.org/methodology/MAPS-glossary.pdf (accessed 5 November 2021).

[144] European Commission. Dataset: Tenders Electronic Daily (TED) (csv subset) – public procurement notices. Belgium: European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), 2022. Available from: https://data.europa.eu/data/datasets/ted-csv?locale=en (last accessed 18 May 2022).

[145] IQVIA. Dataset: MIDAS Quantum Quarterly Sales. IQVIA, 2021.

[146] Backman G, Hunt P, Khosla R, Jaramillo-Strouss C, Fikre BM, Rumble C, et al. Health systems and the right to health: an assessment of 194 countries. The Lancet. 2008;372(9655): 2047-2047-85.

[147] Perehudoff SK, Alexandrov NV, Hogerzeil HV. Access to essential medicines in 195 countries: A human rights approach to sustainable development. Glob Public Health. 2019;14(3): 431-44. Epub 2018/09/07.

[148] United Nations. Sustainable Development Goals (SDG). Geneva, 2020. Available from: https://www.un.org/sustainabledevelopment/health/ (accessed 23 August 2020).

[149] Chapman S, Dedet G, Lopert R. Shortages of medicines in OECD countries. OECD Health Working Paper No. 137. Paris: OECD, 2022. Available from: https://www.oecd-ilibrary.org/docserver/b5d9e15d-en.pdf?expires=1648119612&id=id&accname=guest&checksum=FE38C68153D37B055E9C30B77660A821 (last accessed 24 March 2022).

[150] Eurostat. Dataset: Expenditure for selected health care functions by health care providers. Luxembourg: Eurostat, 2021. Available from https://ec.europa.eu/eurostat/databrowser/view/HLTH_SHA11_HCHP/default/table?lang=en&category=hlth.hlth_care.hlth_sha11.hlth_sha11_cross (last accessed 29 April 2022).

[151] Newton M, Scott K, Troein P. EFPIA Patients W.A.I.T. Indicator 2021 Survey. IQVIA, 2022. Available from: https://www.efpia.eu/media/636821/efpia-patients-wait-indicator-final.pdf (last accessed 2 August 2022).

[152] Amgros. Price negotiations and tendering. Copenhagen: Amgros, 2020. Available from: https://amgros.dk/en/pharmaceuticals/price-negotiations-and-tendering/ (accessed 16 July 2020).

[153] European Medicines Agency. Dataset: European public assessment reports (EPAR). Amsterdam: EMA, 2022. Available from: https://www.ema.europa.eu/en/medicines/download-medicine-data (last accessed 2 August 2022).

[154] Amgros. Therapeutic areas with analogue competition. 2022. Available from: https://amgros.dk/en/pharmaceuticals/price-negotiations-and-tendering/therapeutic-areas-with-analogue-competition/ (last accessed 2 August 2022).

[155] Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to medicines from a health system perspective. Health Policy Plan. 2013;28(7): 692-704. Epub 2012/11/24.

[156] de Jongh T, Becker D, Boulestreau M, Davé A, Dijkstal F, King R, et al. Future-proofing pharmaceutical legislation: study on medicine shortages: final report. Brussels: European Commission Directorate-General for Health Food Safety, Publications Office, 2021. Available from: https://data.europa.eu/doi/10.2875/211485 (accessed 25 December 2021).

[157] Vogler S, Panteli D, Busse R. Biologika und Biosimilars in Deutschland und im europäischen Vergleich – Marktsteuerungsmechanismen und Preisvergleich. In: Ludwig W-D, Mühlbauer B, Seifert R, Eds. Arzneiverordnungs-Report 2021. Berlin, Heidelberg: Springer Berlin Heidelberg; 2021. p. 75-107.

[158] HSE National Drugs Management Programme. Strategy for Procurement of Medicines in Acute & non-Acute Hospitals. Dublin: Health Service Executive, 2019. Available from: https://www.hse.ie/eng/about/who/national-drugs-management-programme/procurement-of-medicines-strategy-document.pdf (last accessed 8 February 2022).

[159] Qendri V, Bogaards JA, Berkhof J. Pricing of HPV vaccines in European tender-based settings. The European Journal of Health Economics. 2019;20(2): 271-80.

[160] BMKUEMIT. Aktionsplan & Kernkriterien für die Beschaffung nachhaltiger Produkte und Leistungen [Action plan and core citeria für sustainable procurement of goods and services]. Vienna: Bundesministerium für Klimaschutz, Umwelt, Energie, Mobilität, Innovation und Technologie, 2021. Available from https://www.nabe.gv.at/wp-content/uploads/2021/06/naBe-Aktionsplan_barrierefrei.pdf (last accessed 25 July 2022).

[161] European Commission. Buying green - A handbook on green public procurement, 3rd Edition. 2016. Available from: https://ec.europa.eu/environment/gpp/buying_handbook_en.htm (accessed 01 February 2022).

[162] UVO Green Public Procurement Working Group. Green Public Procurement Working Group. Bratislava: Úrad pre verejné obstarávanie (Office for Public Procurement), 2022. Available from: https://www.uvo.gov.sk/legislativametodika-dohlad/zodpovedne-verejne-obstaravanie/pracovna-skupina-pre-zelene-verejne-obstaravanie-5d0.html (accessed 4 April 2022).

[163] Michal P, Vladislav V, Cristina dC, Gabriela V, František O, Markéta Š. Stewardship and administrative capacity in green public procurement in the Czech Republic: evidence from a large-N survey. 2021. Available from: https://enveurope.springeropen.com/articles/10.1186/s12302-021-00534-7 (accessed 27 January 2022).

[164] Sykehusinnkjøp. New environmental criteria for the procurement of pharmaceuticals. 2019. Available from: https://sykehusinnkjop.no/nyheter/new-environmental-criteria-for-the-procurement-of-pharmaceuticals (last accessed 4 January 2022).

[165] Amgros. Second Joint Nordic Tendering Procedure for Medicines completed. 2022. Available from: https://amgros.dk/en/knowledge-and-analyses/articles/second-joint-nordic-tendering-procedure-for-medicines-completed/ (accessed 1 February 2022)

[166] NHS England, NHS Improvement. NHS commercial framework for new medicines. London: NHS England, 2021. Available from: https://www.england.nhs.uk/publication/nhs-commercial-framework-for-new-medicines/ (last accessed 12 May 2022).

[167] European Commission. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282&from=EN (last accessed 14 September 2022).

[168] Ferrario A, Arāja D, Bochenek T, Čatić T, Dankó D, Dimitrova M, et al. The implementation of managed entry agreements in Central and Eastern Europe: findings and implications. Pharmacoeconomics. 2017;35(12): 1271-85.

[169] Ferrario A, Kanavos P. Managed entry agreements for pharmaceuticals: The European experience. London: London School of Economics (LSE), 2013.

[170] Pauwels K, Huys I, Vogler S, Casteels M, Simoens S. Managed Entry Agreements for oncology drugs: lessons from the European experience to inform the future. Frontiers in pharmacology. 2017;171(8).

[171] Wenzl M, Chapman S. Performance-based managed entry agreements for new medicines in OECD countries and EU member states: How they work and possible improvements

going forward. OECD Health Working Papers, No. 115. Paris: OECD Publishing, 2019. Available from: https://doi.org/10.1787/6e5e4c0f-en (accessed 13 August 2021).

[172] Salisbury NHS Foundation Trust. Procurement and Commercial Services Strategy. Salisbury: Salisbury NHS Foundation Trust, 2019. Available from: https://www.salisbury.nhs.uk/media/ixgk411x/procurementandcommercialservicesstrategy7march2019.pdf (last accessed 27 June 2022).

[173] Oxford University Hospitals NHS Foundation Trust. Procurement & Supply Chain Strategy 2018 – 2021. Delivering Value from Procurement & the Supply Chain – A New Approach. Oxford: Oxford University Hospitals NHS Foundation Trust, 2018. Available from: https://www.ouh.nhs.uk/contact/non-clinical/procurement/documents/supply-chain-strategy.pdf (last accessed 27 June 2022).

[174] Frimley Health NHS Foundation Trust. Procurement Strategy 2016 – 2019. Frimley: Frimley Health NHS Foundation Trust, 2016. Available from: https://www.fhft.nhs.uk/media/2251/procurement-strategy-16-19.pdf (last accessed 27 June 2022).

[175] European Medicines Agency, Heads of Medicines Agencies. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. Amsterdam: EMA, 2022. Available from: https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf (last accessed 26 September 2022).

[176] NHS England. Commissioning framework for biological medicines (including biosimilar medicines). London: NHS England, 2017. Available from: https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf (last accessed 11 May 2022).

[177] Hornyak L, Nagy Z, Ilku L, Talos Z, Endrei D, Agoston I, et al. Price competition and reimbursement of biosimilar granulocyte-colony stimulating factor in Hungary. Expert Rev Pharmacoecon Outcomes Res. 2019;19(6): 725-31. Epub 2019/02/15.

[178] Van de Wiele VL, Kesselheim AS, Sarpatwari A. Barriers To US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation. Health Aff (Millwood). 2021;40(8): 1198-205. Epub 2021/08/03.

[179] Biosimilar Development. The Competition Council Sanctioned Roche Romania With Fines Of 128 Million Euro. 2020. Available from: https://www.biosimilardevelopment.com/doc/the-competition-council-sanctioned-roche-romania-with-fines-of-million-euro-0001 (last accessed 8 August 2022).

[180] Authority for Consumers & Markets. Drug manufacturer Pfizer to discontinue its steering pricing structure for Enbrel following discussions with ACM. 2022. Available from: https://www.acm.nl/en/publications/drug-manufacturer-pfizer-discontinue-its-steering-pricing-structure-enbrel-following-discussions-acm?utm_source=POLITICO.EU&utm_campaign=5ded7c77d7-EMAIL_CAMPAIGN_2022_02_14_06_00&utm_medium=email&utm_term=0_10959edeb5-5ded7c77d7-190517957 (Last accessed 8 August 2022).

[181] Agence fédérale des médicaments et des produits de santé. Circulaire No. 646: À l'attention des hopitaux, des officines hospitalières, des fabricants et distributeurs en gros de médicaments et des fabricants importateurs et distributeurs de dispositifs médicaux [Circular No. 646: To the attention of hospitals, hospital pharmacies, manufacturers and wholesale distributors of drugs and manufacturers importing and distributing medical devices]. 2019. Available from: https://www.afmps.be/sites/default/files/content/DC-CT/20190625151638.pdf (last accessed 26 September 2022).

[182] Jensen TB, Bartels D, Sædder EA, Poulsen BK, Andersen SE, Christensen MMH, et al. The Danish model for the quick and safe implementation of infliximab and etanercept biosimilars. European Journal of Clinical Pharmacology. 2020;76(1): 35-40.

[183] Amgros. Amgros website landing page. 2022. Available from: https://amgros.dk/en/ (last accessed 1 February 2022).

[184] Sykehusinnkjøp. Tall fra divisjon legemidler siste 12 måneder, oppdatert for oktober 2021 [Figures from the pharmaceutical division last 12 months, updated for October 2021]. Vadsø: Sykehusinnkjøp HF, 2021. Available from: https://sykehusinnkjop.no/Documents/Legemidler/Statistikk/tall%20til%20nettsiden%20-%20oppdatert%20for%20oktober%202021.pdf (last accessed 27 January 2022).

[185] HIV i-base. London Therapeutic Tender Implementatioon: Guidance for Clinical Use. London: HIV i-Base, 2015. Available from: https://i-base.info/wp-content/uploads/2015/01/London-NHSE-guidance-14Jan2015.pdf (last accessed 14 April 2022).

[186] Vogler S, Schneider P, Fischer S, Haasis A, Heindl B, Zimmermann N, et al. Preisvergleich ausgabenstarker Arzneispezialitäten 2019 [Price comparison of high-cost medicines 2019]. 2020.

[187] Casanova J, Jorge Mestre-Ferrandiz J, Espín-Balbino J. Competition in the off-patent medicine market in Spain: The national Reference Pricing System versus the Regional System of Tendering for Outpatient Prescription Medicines in Andalusia. Health Policy. 2018;122(12): 1310-5.

[188] Bergman MA, Granlund D, Rudholm N. Squeezing the Last Drop Out of Your Suppliers: An Empirical Study of Market-Based Purchasing Policies for Generic Pharmaceuticals. Oxford Bulletin of Economics and Statistics. 2017;79(6): 969-96.

[189] Vogler S, Habimana K, Salcher-Konrad M. Workshop for the Study on Best Practices in the Public Procurement of Medicines. Summary Report (unpublished). Gesundheit Österreich Beratungs GmbH. Commissioned by the European Commission, 2022.

[190] Troein P, Newton M, Wasik A, Coucoravas C, Scott K. IQVIA White Paper: Reporting of Medicine Shortages in Europe. IQVIA, 2020. Available from: https://www.iqvia.com/library/white-papers/reporting-of-medicine-shortages-in-europe (last accessed 9 February 2022).

[191] Belloni A, Morgan D, Paris V. Pharmaceutical Expenditure And Policies. Paris: Organisation for Economic Cooperiaton and Development, 2016.

[192] OECD. Spending on Health: Lastest Trends. Paris: Organisation on Economic Cooperation and Development, 2018. Available from: https://www.oecd.org/health/health-systems/Health-Spending-Latest-Trends-Brief.pdf (accessed 23 April 2022).

[193] Vogler S, Habl C, Leopold C, Rosian-Schikuta I, de Joncheere K. PPRI Report. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI), 2008. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Report_final_3.pdf (accessed 29 January 2021).

[194] Hoebert J, Mantel-Teuwisse A. PHIS Evaluation Report. Utrecht: Pharmaceutical Health Information System (PHIS), 2011. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20evaluation%20report_2.pdf (accessed 12 June 2022).

[195] OECD. Dataset: Health Care Resources. Paris: OECD, 2021. Available from: https://stats.oecd.org/index.aspx?r=456782 (last accessed: 3 May 2022).

[196] OECD. OECD Health Statistics 2021: Definitions, Sources and Methods: Hospitals. Paris: OECD, 2021. Available from: https://stats.oecd.org/FileView2.aspx?IDFile=74208f2a-5431-4d15-bbf7-50bb917944eb (last accessed 3 May 2022).

[197] Kroneman M, Boerma W, van den Berg M, Groenewegen P, de Jong J, van Ginneken E, et al. Netherlands: health system review. 2016. Report No.: 1817-6127

[198] EAHP, HOPE. Hospital Pharmacies in the European Union. Oosterzele-Bal / Leuven: European Association of Hospital Pharmacists (EAHP) / Standing Committee of the Hospitals of the European Union (HOPE), 2002. Available from: https://www.hope.be/wp-content/uploads/2015/11/63_2002_OTHER_Hospital-pharmacies-in-the-European-Union.pdf (last accessed 4 May 2022).

[199] Eurostat. Healthcare expenditure statistics. Luxembourg: Eurostat, 2021. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics#Healthcare_expenditure_by_provider (last accessed 2 May 2022).

[200] Morgan D, Xiang F. Improving data on pharmaceutical expenditure in hospitals and other health care settings. OECD Health Working Papers No. 139. Paris: OECD, 2022. Available from: https://www.oecd-ilibrary.org/docserver/6c0d64a2-en.pdf?expires=1664195424&id=id&accname=guest&checksum=C15963E4EF684AAA150B6CA305F259D0 (last accessed 26 September 2022). Report No.: 18152015

[201] OECD. Health at a Glance 2021: OECD Indicators. Paris: OECD, 2021. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2021_ae3016b9-en (last accessed 8 February 2022).

[202] Hawlik K, Devalière A. Access to High-priced Medicines in Hospital Settings in Europe: A Study in Four European Countries. 2016.

[203] Geissler A, Quentin W, Busse R. Heterogeneity of European DRG systems and potentials for a common EuroDRG system Comment on "Cholecystectomy and Diagnosis-Related Groups (DRGs): patient classification and hospital reimbursement in 11 European countries". International journal of health policy and management. 2015;4(5): 319-20.

[204] Gotham D, Moja L, van der Heijden M, Paulin S, Smith I, Beyer P. Reimbursement models to tackle market failures for antimicrobials: Approaches taken in France, Germany, Sweden, the United Kingdom, and the United States. Health Policy. 2021;125(3): 296-306. Epub 2021/01/07.

[205] Grieve R, Abrams K, Claxton KP, Goldacre B, James N, Nicholl J, et al. Cancer Drugs Fund requires further reform: reliance on "real world" observational data undermines evidence base for clinical practice. British Medical Journal. 2016.

[206] Chamberlain C, Collin S, Stephens P, Donovan J, Bahl A, Hollingworth W. Does the cancer drugs fund lead to faster uptake of cost-effective drugs? A time-trend analysis comparing England and Wales. British Journal of Cancer. 2014;111(9): 1693-702.

[207] EAHP. The European Statements of Hospital Pharmacy. Eur J Hosp Pharm. 2014;21(5): 256–8.

[208] Björkhem-Bergman L, Andersén-Karlsson E, Laing R, Diogene E, Melien O, Jirlow M, et al. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. European Journal of Clinical Pharmacology. 2013;69(1): 73-8.

[209] European Commission. Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. 2004. Available from: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=celex%3A32004L0018 (last accessed 10 August 2022).

[210] OECD. Central purchasing bodies; 2015.

[211] World Bank. Assessment of the Public Procurement System in Republic of Bulgaria. World Bank Group, 2019. Available from: https://elibrary.worldbank.org/doi/abs/10.1596/34184 (last accessed 17 February 2022).

[212] OECD. General guide on the public procurement legislative environment in Bulgaria. Paris: OECD, 2016. Available from: https://www.oecd.org/gov/public-procurement/publications/guide-public-procurement-legislation-bulgaria.pdf (last accessed 17 February 2022).

[213] EY. The Norwegian processes for implementation of medicinal products and the associated tenders. 2019. Available at https://heatinformatics.com/sites/default/files/images-videosFileContent/B18022no-Implementation-Medical%20products_07LR_final.pdf (accessed 24 January 2022). EYGM Limited, 2019.

[214] Hostenkamp G. The market for hospital pharmaceuticals in Denmark. Nordic Journal of Health Economics. 2012;1(1): 83-97.

[215] Vogler S, Habimana K, Haasis MA, Bauer E. Addressing Gaps in Centralised Procurement of Medicines in Portugal. Deliverable D3 of the project "Evaluating the centralised public procurement of medicines in Portugal". Vienna: Gesundheit Österreich, 2020. (accessed 05 October 2020).

[216] SPMS. Servicos Partilhados do Ministerio de Saude. Who we are. Available from: https://proempower-pcp.eu/who-we-are/spms-portugal.html (accessed on 1 November 2019).

[217] Behmane D, Dudele A, Villerusa A, Misins J, Kļaviņa K, Mozgis D, et al. Latvia: Health system review. Health Systems in Transition. 2019;21(4): 1-165.

[218] Christensen E, Hirsch NC, Andersen JV, Ehlers LH. The analogue substitution model: Introducing competition in the absence of generic substitution in Danish hospitals. Health Policy. 2022;126(9): 844-52. Epub 2022/06/22.

[219] Gallini A, Legal R, Taboulet F. The influence of drug use in university hospitals on the pharmaceutical consumption in their surrounding communities. Br J Clin Pharmacol. 2012;7(10): 1365-2125.

[220] Vogler S, Zimmermann N, Leopold C, Habl C, Mazag J. Discounts and Rebates Granted for Medicines for Hospital Use in Five European Countries. The Open Pharmacoeconomics & Health Economics Journal 2013.;5: 1-10.

[221] Vogler S, Zimmermann N, Habl C, Mazag J. The role of discounts and loss leaders in medicine procurement in Austrian hospitals - a primary survey of official and actual medicine prices. Cost Effectiveness and Resource Allocation. 2013;11(1): 15.

[222] Austrian Federal Competition Authority [Bundeswettbewerbsbehörde]. Merck Sharp & Dohme GmbH and AFCA reach agreement before the Cartel Court on commitments to end proceedings on abuse of a dominant position in relation to the sale of a Temozolomide drug. 2021. Available from: https://www.bwb.gv.at/en/news/detail/merck-sharp-dohme-gmbh-and-afca-reach-agreement-before-the-cartel-court-on-commitments-to-end-proc (last accessed 10 August 2022).

[223] Kanavos P, Seeley L, Vandoros S. Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium. European Medicines Information Network (EMINet), 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/EMINet_Report%20on%20Preference%20Policy%20and%20Rebate%20PolicyFINAL_1.pdf (accessed 21 April 2022).

[224] Canadian Society of Hospital Pharmacists and Canadian Pharmacists, editor. Proceedings of the seamless care workshop. 1998; Ottawa.

[225] Nickerson A, MacKinnon NJ, Roberts N, Saulnier L. Drug-therapy problems, inconsistencies and omissions identified during a medication reconciliation and seamless care service. Healthc Q. 2005;8(special issue)): 65-72.

[226] Gröne O, Garcia-Barbero M. International Journal of Integrated Care. Policy Paper. World Health Organization, 2001. Available from: https://www.ijic.org/articles/10.5334/ijic.28/ (accessed 23 April 2022).

[227] Haggerty JL, Reid RJ, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: a multidisciplinary review. BMJ. 2003;327(7425): 1219-21. Epub 2003/11/25.

[228] Björkhem-Bergman L, Andersén-Karlsson E, Laing R, Diogene E, Melien O, Jirlow M, et al. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. European Journal of Clinical Pharmacology. 2013.;69(Suppl 1): 73-8.

[229] Gustafsson LL, Wettermark B, Godman B, Andersen-Karlsson E, Bergman U, Hasselstrom J, et al. The 'wise list'- a comprehensive concept to select, communicate and achieve adherence to recommendations of essential drugs in ambulatory care in Stockholm. Basic Clin Pharmacol Toxicol. 2011;108(4): 224-33. Epub 2011/03/19.

[230] Matusewicz W, Godman B, Pedersen HB, Furst J, Gulbinovic J, Mack A, et al. Improving the managed introduction of new medicines: sharing experiences to aid authorities across Europe. Expert Rev Pharmacoecon Outcomes Res. 2015;15(5): 755-8. Epub 2015/09/15.

[231] Herms S, Rutledge P. The Lothian Joint Formulary: overcoming the barriers to formulary success. Pharmacy in Practice. 2002;12(6): 279-85.

[232] Vogler S, Zimmermann N. How do regional sickness funds encourage more rational use of medicines, including the increase of generic uptake? A case study from Austria. Generics and Biosimilars Initiative Journal (GaBI Journal). 2013;2(2): 65-75

[233] Federal Ministry of Health, Main Association of the Austrian Social Health Insurance institutions, Austrian provinces. Zielsteuerungsvertrag auf Bundesebene. Zielsteuerung-Gesundheit 2013-2016 (Target control agreement at federal level. Target control - Health 2013-2016). Vienna, 2013. Available from: https://www.parlament.gv.at/PAKT/VHG/XXV/III/III_00038/imfname_336346.pdf (accessed 13 January 2022).

[234] Federal Ministry of Health and Women, Main Association of the Austrian Social Health Insurance institutions, Austrian provinces. Zielsteuerungsvertrag auf Bundesebene. Zielsteuerung-Gesundheit 2017-2021 (Target control agreement at federal level. Target control - Health 2017-2021). Vienna, 2017. Available from: https://www.sozialministerium.at/dam/jcr:ae2cd2c2-dc03-44ba-9a15-47826081189f/Zielsteuerungsvertrag%20auf%20Bundesebene%20Stand%2005.05.2017%20BF1.pdf (accessed 13 January 2022).

[235] Harrie S, Margreet S. PHIS Pharma Profile The Netherlands. Vienna: Pharmaceutical Health Information System (PHIS), 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20NL%20Hospital%20Pharma%20Report%202009_5.pdf (accessed 2 February 2022).

[236] Angelis A, Lange A, Kanavos P. Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. The European Journal of Health Economics. 2017: 1-30.

[237] Chamova J. Mapping of HTA national organisations, programmes and processes in EU and Norway. AB S. Brussels: European Commission, 2017.

[238] IQVIA. The Impact of Biosimilar Competition in Europe. London, 2020. Available from: https://ec.europa.eu/health/sites/default/files/human-use/docs/biosimilar_competition_en.pdf (accessed 10 December 2021).

[239] Farfan-Portet M-I, Gerkens S, Lepage-Nefkens I, Vinck I, Hulstaert F. Are biosimilars the next tool to guarantee cost-containment for pharmaceutical expenditures? The European Journal of Health Economics. 2014;15: 223-8.

[240] Moorkens E, Simoens S, Troein P, Declerck P, Vulto AG, Huys I. Different Policy Measures and Practices between Swedish Counties Influence Market Dynamics: Part 1-Biosimilar and Originator Infliximab in the Hospital Setting. BioDrugs. 2019;33(3): 285-97. Epub 2019/04/05.

[241] Harsanyi A, Csanadi M, Marky K, Vincziczki AZ, Kalo Z, Inotai A. Influence of biosimilar infliximab launch on the utilization pattern of biological medicines: the case of Hungary. Expert Rev Pharmacoecon Outcomes Res. 2020;20(6): 653-9. Epub 2019/09/13.

[242] Remuzat C, Kapusniak A, Caban A, Ionescu D, Radiere G, Mendoza C, et al. Supply-side and demand-side policies for biosimilars: an overview in 10 European member states. J Mark Access Health Policy. 2017;5(1): 1307315. Epub 2017/07/26.

[243] Jørgensen KK, Olsen IC, Goll GL, Lorentzen M, Bolstad N, Haavardsholm EA, et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. The Lancet. 2017;389(10086): 2304-16.

[244] Mack A. Norway, biosimilars in different funding systems. What works? Generics and Biosimilars Initiative Journal (GaBI Journal). 2015. Available from: http://gabi-journal.net/norway-biosimilars-in-different-funding-systems-what-works.html (accessed 03 September 2021);4(2): 90-2.

[245] Initiative GO-GaB. Huge discount on biosimilar infliximab in Norway. 2015. Available from: http://www.gabionline.net/Biosimilars/General/Huge-discount-on-biosimilar-infliximab-in-Norway (accessed 4 September 2021).

[246] Repubblica Italiana. Legge 11 dicembre 2016. n. 232. Bilancio di previsione dello Stato per l'anno finanziario 2017 e bilancio pluriennale per il triennio 2017-2019. (16G00242). Roma, 2016. Available from: https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=57356&completo=true (accessed 17 April 2022).

[247] WHO. WHO Guideline on Country Pharmaceutical Pricing Policies. Geneva: World Health Organization, 2015. Available from: https://digicollections.net/medicinedocs/#d/s21016en (accessed 4 April 2022).

[248] Amgros. New international record for switch to biosimilar. 2019. Available from: https://amgros.dk/en/knowledge-and-analyses/articles/new-international-record-for-switch-to-biosimilar/?report=reader (last accessed 12 Sept 2022).

[249] Patrucco AS, Walker H, Luzzini D, Ronchi S. Which shape fits best? Designing the organizational form of local government procurement. Journal of Purchasing and Supply Management. 2019;25(3): 100504.

[250] Walker H, Schotanus F, Bakker E, Harland C. Collaborative Procurement: A Relational View of Buyer–Buyer Relationships. Public Administration Review. 2013;73(4): 588-98.

[251] Walker H, Essig M, Schotanus F, Kivistö T. Cooperative purchasing in the public sector. Public Procurement: Routledge; 2012. p. 353-70.

[252] Bakker E, Walker H, Schotanus F, Harland C. Choosing an organisational form: the case of collaborative procurement initiatives. International journal of procurement management. 2008;1(3): 297-317.

[253] Bakker E, Walker H, Harland C. Organizing for collaborative procurement: An initial conceptual framework. In: Piga G, Thai KV, Eds. Advancing public procurement: Practices, innovation and knowledge-sharing: PrAcademics Pres; 2007. p. 14-44.

[254] Emerson K, Nabatchi T, Balogh S. An integrative framework for collaborative governance. Journal of public administration research and theory. 2012;22(1): 1-29.

[255] Ferwerda J, Deleanu I, Unger B. Corruption in Public Procurement: Finding the Right Indicators. European Journal on Criminal Policy and Research. 2017;23(2): 245-67.

[256] Cohen J, Mrazek M, Hawkins L. Tackling corruption in the pharmaceutical systems worldwide with courage and conviction. Clinical Pharmacology & Therapeutics. 2007;81(3): 445-9.

[257] Garattini S, Bertelé V, Godman B, Haycox A, Wettermark B, Gustafsson L, et al. Enhancing the rational use of new medicines across European health care systems. European Journal of Clinical Pharmacology. 2008;64(12): 1137-8.

[258] Pani L, Montilla S, Németh G, Russo P, Viceconte G, Vogler S. Balancing access to medicines and sustainability in Europe: An analysis from the network of competent authorities on pricing and reimbursement (CAPR). Pharmacological research. 2016;111: 247-50.

[259] EHPPA. European Health Public Procurement Association. An alliance of public and non-profit group procurement organisations specialised in the health & care sector. European Helath Public Procurement Alliance, 2022. Available from: https://www.ehppa.com/accueil.aspx (accessed 1 August 2022).

[260] Beneluxa Initiative. Beneluxa Initiative on Pharmaceutical Policy. 2022. Available from: https://beneluxa.org/ (accessed 4 March 2022).

[261] European Parliament and Council of the European Union. Decision No 1082/2013/EU of the European Parliament and Council of the European Union of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (Text with EEA relevance). Brussels, 2013. Available from: https://health.ec.europa.eu/system/files/2016-11/decision_serious_crossborder_threats_22102013_en_0.pdf (accessed 26 September 2022).

[262] European Commission. Joint Procurement Agreement to procure medical countermeasures. 2022. Available from: https://ec.europa.eu/health/health-security-and-infectious-diseases/preparedness-and-response/signing-ceremonies-joint-procurement-agreement_de (accessed 14 February 2022).

[263] Pan American Health Organization. PAHO Revolving Fund. 2022. Available from: https://www.paho.org/en/revolvingfund (last accessed 5 August 2022).

[264] Gulf Health Council. Gulf Health Council - Joint procurement. 2020. Available from: https://ghc.sa/en/joint-procurement/ (last accessed 11 August 2022).

[265] Wouters OJ, Shadlen KC, Salcher-Konrad M, Pollard AJ, Larson HJ, Teerawattananon Y, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. The Lancet. 2021;397(10278): 1023-1023-34.

[266] Gavurová B, Mikeska M, Huculova E. Evaluation of selected determinants of public procurement in the health sector. Administratie si Management Public. 2020;34: 45-63.

[267] OECD. Competition issues in the distribution of pharmaceuticals: Contribution from Hungary. DAF/COMP/GF/WD(2014)18. Paris: OCED, 2014. Available from: https://www.gvh.hu/pfile/file?path=/gvh/elemzesek/oecd_hozzajarulasok/oecd-hozzajarulasok-2014/elemzesek_oecd_hozzajarulasok_pharmaceuticals&inline=true (last accessed 7 April 2022).

[268] WHO. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. Copenhagen: World Health Organization Regional Office for Europe, 2015. Available from: https://www.euro.who.int/__data/assets/pdf_file/0008/306179/Access-new-medicines-TR-PIO-collaboration-research.pdf (accessed 23 December 2020).

[269] Pawłowska I, Krzyzaniak N, Pawłowski L, Kocić I. Beyond clinical care: the pharmacoeconomic and research roles of pharmacists in Poland. Acta Poloniae Pharmaceutica - Drug Research. 2019;76(2): 381-381-5.

[270] Mandják T, Simon J, Szalkai Z. Understanding Institutional Markets from a Network Perspective: Empirical Findings about the Hospital Market in Hungary. Milan: 22nd IMP-conference, 2006. Available from: https://www.impgroup.org/uploads/papers/5757.pdf (last accessed 7 April 2022).

[271] Castro VA, Centeno BL, Palacios JP, Casasempere IM, Martin AG, Oyarzabal AA, et al. 2SPD-027 Centralised purchasing as a strategic line for the rationalisation of pharmaceutical expenditure in a regional health service. European Journal of Hospital Pharmacy. 2018. Available from: https://ejhp.bmj.com/content/ejhpharm/25/Suppl_1/A21.2.full.pdf (accessed 24 July 2020);25(Suppl 1): A21-A2.

[272] Millington K, Bhardwaj M. Evidence and experience of procurement in health sector decentralisation. Brighton: K4D Helpdesk Report, 2017. Available from: https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/13078 (accessed 24 November 2021).

[273] Vončina L, Sagan A. New joint hospital procurement programme in Croatia. Eurohealth. 2014. Available from: https://apps.who.int/iris/bitstream/handle/10665/332841/Eurohealth-20-2-29-32-eng.pdf (accessed 21 September 2021);20(2): 29-32.

[274] Barbosa K, Fiuza EPS. Demand aggregation and credit risk effects in pooled procurement: evidence from the Brazilian public purchases of pharmaceuticals and medical supplies. FGV EESP - Textos para Discussão / Working Paper Series. 2012. Available from: http://hdl.handle.net/10438/10009 (accessed 24 July 2020).

[275] Sreeramareddy CT, Sathyanarayana T. Decentralised versus centralised governance of health services. Cochrane Database of Systematic Reviews. 2013(11).

[276] Bare A, Kopczak L. Pooled Procurement in the Vaccine Market: UNICEF's Experience. Available from: https://marketbookshelf.com/wp-content/uploads/2017/06/WDI_MDSI_Pooled-Procurement-Case-Study_12.9.2015.pdf (accessed 24 July 2020).

[277] Domfeh KA. Pooled procurement program in the quality improvement of medicines of the National Catholic Health Service in Ghana: using the Donabedian model. Journal of Pharmaceutical Health Services Research. 2021. Available from: https://doi.org/10.1093/jphsr/rmaa030 (accessed 21 September 2021);12(2): 133-41.

10. LIST OF ANNEXES

Annex 1: List of study questions
Annex 2: Country fiche template
Annex 3: Glossary of public procurement terms
Annex 4: PPM country fiches
- Annex 4.1: PPM country fiche Austria
- Annex 4.2: PPM country fiche Belgium
- Annex 4.3: PPM country fiche Bulgaria
- Annex 4.4: PPM country fiche Croatia
- Annex 4.5: PPM country fiche Cyprus
- Annex 4.6: PPM country fiche Czech Republic
- Annex 4.7: PPM country fiche Denmark
- Annex 4.8: PPM country fiche Estonia
- Annex 4.9: PPM country fiche Finland
- Annex 4.10: PPM country fiche France
- Annex 4.11: PPM country fiche Germany
- Annex 4.12: PPM country fiche Greece
- Annex 4.13: PPM country fiche Hungary
- Annex 4.14: PPM country fiche Iceland
- Annex 4.15: PPM country fiche Ireland
- Annex 4.16: PPM country fiche Italy
- Annex 4.17: PPM country fiche Latvia
- Annex 4.18: PPM country fiche Liechtenstein
- Annex 4.19: PPM country fiche Lithuania
- Annex 4.20: PPM country fiche Luxembourg
- Annex 4.21: PPM country fiche Malta
- Annex 4.22: PPM country fiche Netherlands
- Annex 4.23: PPM country fiche Norway
- Annex 4.24: PPM country fiche Poland
- Annex 4.25: PPM country fiche Portugal
- Annex 4.26: PPM country fiche Romania
- Annex 4.27 PPM country fiche Slovakia
- Annex 4.28: PPM country fiche Slovenia
- Annex 4.29: PPM country fiche Spain
- Annex 4.30: PPM country fiche Sweden
- Annex 4.31: PPM country fiche Switzerland
- Annex 4.32: PPM country fiche United Kingdom

Annex 5: Summary report of workshops conducted for the PPM study
Annex 6: Full questionnaire of online survey
Annex 7: Full report of online survey
Annex 8: TED data cleaning and identification of relevant CPV codes
Annex 9: Degree of PPM in study countries
Annex 10: Categorisation of CPV and ATC codes into main medicines groups
Annex 11: Ex post review by procurement experts

HW-04-22-229-EN-N

Publications Office
of the European Union