PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Report 2018

Pharmaceutical pricing and reimbursement policies

in 47 PPRI network member countries

Gesundheit Österreich GmbH

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Report 2018

Pharmaceutical pricing and reimbursement policies
in 47 PPRI network member countries

Authors:

Sabine Vogler
Nina Zimmermann
Manuel Alexander Haasis

Supported by:

Margit Gombocz
Valentin Kandler

Project assistant:

Romana Landauer

Data validated by PPRI network members

Suggestion for citation: Vogler Sabine, Zimmermann Nina, Haasis Manuel Alexander (2019): PPRI Report 2018 – Pharmaceutical pricing and reimbursement policies in 47 PPRI network member countries. WHO Collaborating Centre for Pricing and Reimbursement Policies, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna

Vienna, October 2019

Owner, editor and publisher: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Stubenring 6, 1010 Vienna, Austria, Tel. +43 1 515 61, websites: www.goeg.at and https://ppri.goeg.at

Gesundheit Österreich
GmbH

Foreword

In 2005, the *Pharmaceutical Pricing and Reimbursement Information (PPRI)* project started, based on the vision to bring together technical experts working in competent authorities for pharmaceutical pricing and reimbursement and thus to contribute to more affordable access to (essential) medicines. On behalf of the PPRI secretariat, we use multiple pathways: We have been offering a space for the PPRI network members to exchange experience of policy implementation, we have been providing capacity-building, and we have been documenting the policies that governments use to price medicines and decide on their funding.

The latter is done through PPRI Pharma Profiles that report country-specific information, country posters, country system presentations at PPRI meetings and conferences, policy evaluations based on the input of PPRI network members and comparative analyses of pharmaceutical policies. In 2008, we published the *PPRI Report 2008* that contained 21 indicators to survey, measure and compare pharmaceutical pricing and reimbursement information, fed by the data of PPRI network members at that time (27 countries).

Since then, several changes have been observed in Europe and globally related to access to safe, effective, quality and affordable essential medicines. New opportunities have emerged, and new challenges have to be met, and this requires careful reconsideration of policy options. PPRI has also changed: its membership has increased to 47 countries, and the PPRI secretariat responded to the members' request to address specific areas such as hospital medicines (done through the Pharmaceutical Health Information System / PHIS project) and medical devices (such as setting up a PPRI sub-group).

Still, the need for knowledge of the policies applied in other countries has not changed. Thus, the PPRI secretariat prepared an updated *PPRI Report 2018* which reflects the changes that occurred in pharmaceutical pricing and reimbursement over the last decade.

This *PPRI report 2018* is the result of the close collaboration within the PPRI network since most pieces of information are based on input provided by the PPRI network members.

We hope that this report is of interest for PPRI network members as well as for any person interested in pharmaceutical pricing and reimbursement policies.

The PPRI secretariat

Abstract

Background and objective

To facilitate affordable and equitable access to essential and cost-effective medicines for patients, governments can use a mix of policy measures. For the implementation and optimisation of such policies, policy-makers benefit from information and evidence of appropriate measures in other countries and their impacts.

This *PPRI Report 2018* aims to provide information of currently existing pharmaceutical pricing and reimbursement policies in the 47 PPRI member countries.

Methodology

Information and data of pharmaceutical policies (as of December 2018) were predominantly obtained through primary surveys from the competent authorities in 47 PPRI network member countries.

Results

42 PPRI network member countries have mechanisms in place to set medicine prices at the ex-factory (or sometimes wholesale) price level, mostly targeting reimbursable medicines or prescription-only medicines. 41 countries apply external price referencing (i.e. referencing to prices in other countries). The EPR methodology (e.g. reference countries, benchmark calculation) varies across the countries. Several but not all PPRI countries have regulated distribution remuneration such as mark-ups (32 countries with regulated wholesale remuneration and 43 countries with regulated pharmacy remuneration).

46 PPRI network member countries have one or more reimbursement lists for outpatient medicines in place, and in 31 PPRI countries the reimbursement lists relate to both outpatient and inpatient sectors. In addition, hospital pharmaceutical formularies are managed at the level of hospitals in most PPRI countries. At least 43 countries charge co-payments for outpatient reimbursable medicines (frequently percentage co-payments, but also a prescription fee and/or a deductible). All these 43 countries apply exemptions from or reductions of co-payments for vulnerable and other defined population groups.

Internal price referencing, which considers the prices of identical or similar medicines in the same country, is a pricing policy applied for off-patent medicines (32 PPRI countries set the generic price at a defined percentage of the originator price, and 23 countries determine the biosimilar price based on the price of the reference medicine). A reference price system, with defined reimbursement amounts for similar or identical medicines, is applied in 32 PPRI countries. Prescribing by International Non-proprietary Name (43 PPRI countries) and generic substitution (43 countries) are commonly used.

To assess the value of new medicines, health technology assessments (HTA) and pharmacoeconomic evaluations are used to support reimbursement decisions of new medicines. Among the PPRI countries, Sweden is the only country with a full-fledged value based pricing system. To manage the market entry of new medicines with possibly high price tags an increasing number of countries (at least 33 PPRI countries) have been applying managed-entry agreements (MEA).

Conclusion

Since the implementation of pricing and reimbursement policies is the national competence of governments, the design of policies used varies from country to country.

Executive Summary

Background

In line with the Sustainable Development Goals (target 3.8), governments have committed to achieve universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all. This should not compromise the financial sustainability of the health care system and further public health and also industry goals. In doing so, they can use a mix of measures, including policies in the areas of pricing and reimbursement of medicines.

Knowledge of appropriate measures, including methodological aspects and practice experience, in other countries as well as evidence of their impacts are of major importance for policy-makers who intend to introduce new measures and/or to optimise their policy framework.

As of 2019, the Pharmaceutical Pricing and Reimbursement Information (PPRI) network comprises national competent authorities for pharmaceutical pricing and reimbursement in 47, mainly European, countries as well as European and international institutions (e.g. European Commission, Organisation for Economic Co-operation and Development (OECD), World Health Organization). Published a decade ago, the 'PPRI Report 2008' provided an overview of pharmaceutical pricing and reimbursement policies in the then 27 PPRI network member countries. Given the lack of updated data of policies in pharmaceutical pricing and reimbursement for a large number of countries, this study aims to close this gap by providing an update for an extended number of countries.

Objective

The study aims to offer a comprehensive, concise and up-to-date comparative analysis of pharmaceutical pricing and reimbursement policies implemented in the outpatient and inpatient sectors in the 47 member countries of the PPRI network.

Methodology

Information and data of pharmaceutical policies were predominantly obtained through primary surveys from the competent authorities in 47 countries that are involved in the PPRI network. In addition, general data were retrieved from international statistics (e.g. Eurostat, OECD); and some information presented is based on literature.

The 47 PPRI network member countries are the 28 Member States of the European Union, plus Albania, Armenia, Belarus, Canada, Iceland, Israel, Kazakhstan, Kosovo, Kyrgyzstan, Moldova, North Macedonia, Norway, Republic of Korea, Republic of Serbia, Russian Federation, South Africa, Switzerland, Turkey, and Ukraine. Information of the pharmaceutical policy framework relates, in general, to December 2018.

Results

Almost all PPRI countries (42 countries) have mechanisms in place to set medicine prices at the ex-factory (or sometimes wholesale) price level, mostly targeting reimbursable medicines or prescription-only medicines. Some countries without this kind of price regulation (e.g. Kosovo, Kyrgyzstan) are currently working on the introduction of price regulation.

A commonly used pricing policy is external price referencing (EPR) in which prices are determined based on the prices in other countries. 41 PPRI member countries apply EPR to derive a benchmark for setting national medicine prices, at least for some of the medicines. The EPR methodology varies across the countries: For instance, the number of countries included in the country baskets ranges from 1 (Luxembourg) to 39 countries (Kazakhstan), and 18 of the EPR-applying PPRI countries apply an average or median benchmark price, whereas 9 countries relate to the lowest price of the reference countries.

Internal price referencing considers the prices of identical or similar medicines in the same country. It is a policy for off-patent medicines. 32 PPRI countries apply a so-called generic price link (i.e. the generic price is set at a defined percentage of the originator price), and 23 countries use this policy for biosimilar medicines.

Among the PPRI countries, Sweden is the only country with a full-fledged value based pricing policy for new medicines. In at least 37 PPRI countries, health technology assessments (HTA) and pharmacoeconomic instruments are used to support mainly reimbursement decisions of new medicines. To be prepared for the possible market entry of new, potentially high-priced medicines, 11 countries reported to perform horizon scanning activities. Since it is resource-intensive, this exercise is also on the agenda of cross-country collaborations (such as the Beneluxa initiative, the 'Valletta Declaration') that were established in the last years.

A policy which is increasingly used to manage the market entry of new medicines with possibly high price tags is the use of managed-entry agreements (MEA); 33 PPRI countries reported to have concluded such arrangements. The number of MEA in a country ranges from less than ten to several hundred. Financially-based MEA are more commonly used than performance-based MEA.

In the hospital sector, some of the medicines are usually procured via tendering procedures; 23 countries apply it as the predominant procurement method for medicines used in hospitals. Tendering of medicines particularly plays a role in Central Asian and in smaller countries. In 18 PPRI member countries, tendering, or tendering-like, processes, are used for off-patent medicines as a competitive policy in the outpatient sector.

Overall, different pricing policies are applied for different types of medicines (e.g. for new medicines, for generics), and, in addition, for some medicines price regulation implies the application of several policies on one product (e.g. starting with EPR, performance of a HTA as supportive information-base, and conclusion of an MEA).

In the supply chain, several PPRI countries regulate the add-ons allowed to the distribution actors. In 32 countries, wholesale remuneration is regulated, usually through maximum mark-ups or margins for the wholesalers. 43 PPRI countries regulate the remuneration for community pharmacies, also through – mainly regressive – mark-ups or margins, but increasingly also through a dispensing fee which is not linked to the medicine price. Usually, a value-added tax (VAT) is applied on medicines (some countries exempt medicines, or certain groups of medicines, from VAT), which tends to be lower than the standard VAT in most countries.

46 PPRI member countries have one or more reimbursement lists for outpatient medicines in place; of those 41 apply solely positive lists (i.e. explicitly indicating those medicines that are included in reimbursement). The reimbursement lists for inpatient medicines (hospital pharmaceutical formularies) are usually managed at the level of hospitals or hospital groups. In 31 countries, the national reimbursement lists relate to both the outpatient and inpatient sectors, independently from further formularies at hospitals' levels. The (added) therapeutic benefit of a medicine, medical need, financial considerations such as budget impact and the cost-effectiveness are key criteria to inform the decision about the inclusion of a medicine in reimbursement.

32 PPRI countries apply a reference price system (RPS), which defines the same reimbursement amount for similar or identical medicines in a cluster which are established at ATC-5 level in 18 countries and broader in the remaining RPS-applying countries. In addition to pricing and reimbursement policies targeted at off-patent medicines, demand-side measures aim to enhance the uptake of these medicines: 43 PPRI countries have prescribing by International Non-proprietary name in place (25 countries – obligatory, and 18 countries – indicative), and 43 countries implemented generic substitution (29 countries – obligatory, and 13 countries – indicative). Biosimilar substitution, however, is only in place in 15 countries.

At least 43 PPRI countries apply co-payments for outpatient reimbursable medicines, in the form of a prescription fee (20 countries), a percentage co-payment of the medicine price (30 countries) or a deductible (9 countries; some countries have more than one co-payment in place). All of these PPRI network member countries apply exemptions from or reductions of co-payments for defined population groups. Common reasons for exemption or reduction mechanisms on co-payments include defined diseases, age (mainly children), low income and social disadvantage. In the inpatient sector, medicines are usually provided free of charge to the patients.

Conclusion

PPRI network member countries use similar pricing and reimbursement policies, such as external price referencing, regressive mark-up schemes to regulate the remuneration for wholesalers and pharmacies, positive lists and percentage co-payments. Specific policies are applied for some groups of medicines (e.g. managed-entry agreements for high-priced medicines and demand-side measures to increase the uptake of generic and biosimilar medicines). However, there are differences with regard to the details in the design of these policies across countries.

Table of contents

List of tables

List of figures

List of abbreviations

AESGP	Association of the European Self-Medication Industry
ATC	Anatomical Therapeutic Chemical (classification of the WHO)
DRG	Diagnosis Related Groups
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPR	External price referencing
EU	European Union
EUnetHTA	European network for health technology assessment
FAAP	Fair and Affordable Pricing
GDP	Gross domestic product
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HMO	Health maintenance organization
HPF	Hospital pharmaceutical formularies
HTA	Health Technology Assessment
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INN	International Non-proprietary Name
MEA	Managed-entry agreement(s)
mio.	million(s)
MoH	Ministry of Health
NHS	National Health Service
NPM	Non-prescription medicine(s)
OECD	Organisation for Economic Co-operation and Development
PMPRB	Patented Medicine Prices Review Board (Canada)
POM	Prescription-only medicine(s)
PPP	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information
PPRS	Pharmaceutical Price Regulation Scheme
R+D	Research and development
RPS	Reference price system

SDG	Sustainable Development Goal(s)
SFK	Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics (the Netherlands)
SHA	System of Health Accounts
SHI	Social health insurance
TLV	Tandvårds- & läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency (Sweden)
USD	United States dollar
VAT	Value-added tax
VBP	Value based pricing
WHO	World Health Organization

List of country abbreviations

Country abbreviations of PPRI network members

AL	Albania	KZ	Kazakhstan
AM	Armenia	LT	Lithuania
AT	Austria	LU	Luxembourg
BE	Belgium	LV	Latvia
BG	Bulgaria	MD	Moldova
BY	Belarus	MK	North Macedonia
CA	Canada	MT	Malta
CH	Switzerland	NL	Netherlands
CY	Cyprus	NO	Norway
CZ	Czech Republic	PL	Poland
DE	Germany	PT	Portugal
DK	Denmark	RO	Romania
EE	Estonia	RU	Russian Federation
EL	Greece	RS	Republic of Serbia
ES	Spain	KR	Republic of Korea
FI	Finland	SE	Sweden
FR	France	SI	Slovenia
HR	Croatia	SK	Slovakia
HU	Hungary	TR	Turkey
IE	Ireland	UA	Ukraine
IL	Israel	UK	United Kingdom
IS	Iceland	XK	Kosovo
IT	Italy	ZA	South Africa
KG	Kyrgyzstan		

Abbreviations of other countries

AU	Australia	LI	Liechtenstein
BA	Bosnia and Herzegovina	ME	Montenegro
CL	Chile	NZ	New Zealand
JP	Japan	US	United States of America

Acknowledgments

This report would not have been possible without the support of numerous people in the past fourteen years, in particular in the course of the last 15 months.

We express our genuine appreciation to the members of the PPRI network who have been providing updated information on the pharmaceutical pricing and reimbursement policies in their country over the years. Based on their constant input, data and information were available for a draft report that has been subject to and benefitted from an extensive review within the PPRI network.

In particular, we sincerely thank the experts involved in the PPRI network who were generously available to validate and update the information provided in this report for their country and to fill data gaps: these were PPRI network members from 41 countries (Albania, Armenia, Austria, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Kosovo, Latvia, Lithuania, Malta, Moldova, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom).

Furthermore, we would like to acknowledge the scientific guidance on the PPRI Advisory Board, and we appreciate the comments provided by the European Commission and World Health Organization on a draft version of this report.

Last but not least, we are grateful to the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, which has been financially supporting the activities of the PPRI secretariat, for their long-lasting trust and commitment.

1 Introduction

1.1 Background and aim

The development, implementation and monitoring of pharmaceutical pricing and reimbursement policies is a national competence of governments even if the country is a member of a cross-country collaboration or a supranational (economic) area (e.g. the European Union / EU). Hence, policy-makers introduced and have adapted a mix of relevant policy measures at national levels, with the aim of achieving universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all, as defined in the Sustainable Development Goals (SDG) agenda in target 3.8 (United Nations 2019). Striving for affordable and equitable access to medicines should not compromise the financial sustainability of the health care system as well as further public health and also industry goals (e.g. rewarding research-oriented industry, encouraging local generic industry).

The policy implementation is informed by the evidence of appropriate measures (including the design of the regulation) in other countries and their impacts. Countries with yet limited experience in pharmaceutical regulation require such knowledge, as they progress towards universal health coverage. Given current challenges (e.g. market entry of medicines with high price tags, shortages of ➲ essential medicines, limited evidence about the therapeutic benefits of new medicines in real-world environments), policy-makers in high-income countries, whose pharmaceutical systems have been well-developed, also benefit from information about policies in other countries.

Literature on pharmaceutical pricing and reimbursement policies tends to be focused on analyses in a single country or a few countries and on descriptive cross-country overviews of a specific policy measure. Countries covered are mainly high-income countries in Europe, North America or Asia-Pacific with large pharmaceutical markets, and information published in peer-reviewed literature frequently relates to situations some years ago.

Against this backdrop, this report aims to provide a comprehensive, concise and updated overview of pharmaceutical pricing and reimbursement policies implemented in the 47 member countries of the PPRI (Pharmaceutical Pricing and Reimbursement Information) network (cf. chapter 1.3). This 'PPRI Report 2018' follows up on the PPRI Report 2008 (Vogler et al. 2008) that was published a decade ago.

The report was produced with the support of representatives of competent authorities responsible for pharmaceutical pricing and reimbursement (cf. chapter 1.2), and policy-makers are considered as the key target audience of this study. In addition, the report aims to inform researchers, regulators in related areas (e.g. marketing authorisation), patients, health professionals (e.g. doctors, pharmacists) and stakeholders of the pharmaceutical market (e.g. industry) as well as anyone interested in pharmaceutical policy.

1.2 Methodology

The scope of the study is pharmaceutical policies, mainly in the area of pricing and reimbursement, for the medicines used in the outpatient and inpatient sectors (where applicable).[1] Some policies and tools that complement pricing and reimbursement policies (see chapter 3.1) are also reported. Furthermore, the report offers some general key data on the health care and pharmaceutical systems and markets in the countries.

The study covers a total of 47 countries, which is all PPRI network member countries (Figure 1.1).

The information (particularly on pharmaceutical policies) relates to the year 2018 (describing the situation as of December 2018) unless indicated differently.

Information and data were collected by the authors from several sources, including databases (as indicated in the respective chapters). The key source of the information presented in the report is the PPRI network. Over the years, the PPRI secretariat has been collecting data and information on pharmaceutical pricing and reimbursement policies in the course of several surveys and monitoring exercises from PPRI network members. A draft version of the PPRI report based on available and previously shared information and data among the PPRI network was sent for validation to the PPRI network members in May 2019. The information provided in the draft report was validated by 41 PPRI countries (Albania, Armenia, Austria, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Kosovo, Latvia, Lithuania, Malta, Moldova, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom).

Definitions of relevant terms (indicated with the following label ➲ in their first time use and in special cases also in repeated use) can be found in the Glossary in the Annex to this report (cf. Annex 1). It is based on the Glossary of the Pharmaceutical Terms of the World Health Organization (WHO) Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2019).

Policies bearing the same name might be designed differently. Thus, it is acknowledged that in some cases decisions had to be taken to make information comparable to allow for an overview covering the large range of 47 countries.

---

[1] Some policies are, however, only applicable in one sector.

This study is a descriptive pharmaceutical systems comparative research. The reported policies have benefits and limitations, but their discussion is beyond the scope of this study.[2]

1.3 PPRI network

The PPRI network is a collaboration of pharmaceutical pricing and reimbursement authorities of 47 largely European countries as well as international and European institutions. The aim of this network is to facilitate exchange between public officials (including personal networking meetings), supported by scientific evidence and a common understanding of pharmaceutical policy issues, with the aim to achieve SDG target 3.8 on access to safe, effective, quality and affordable essential medicines.

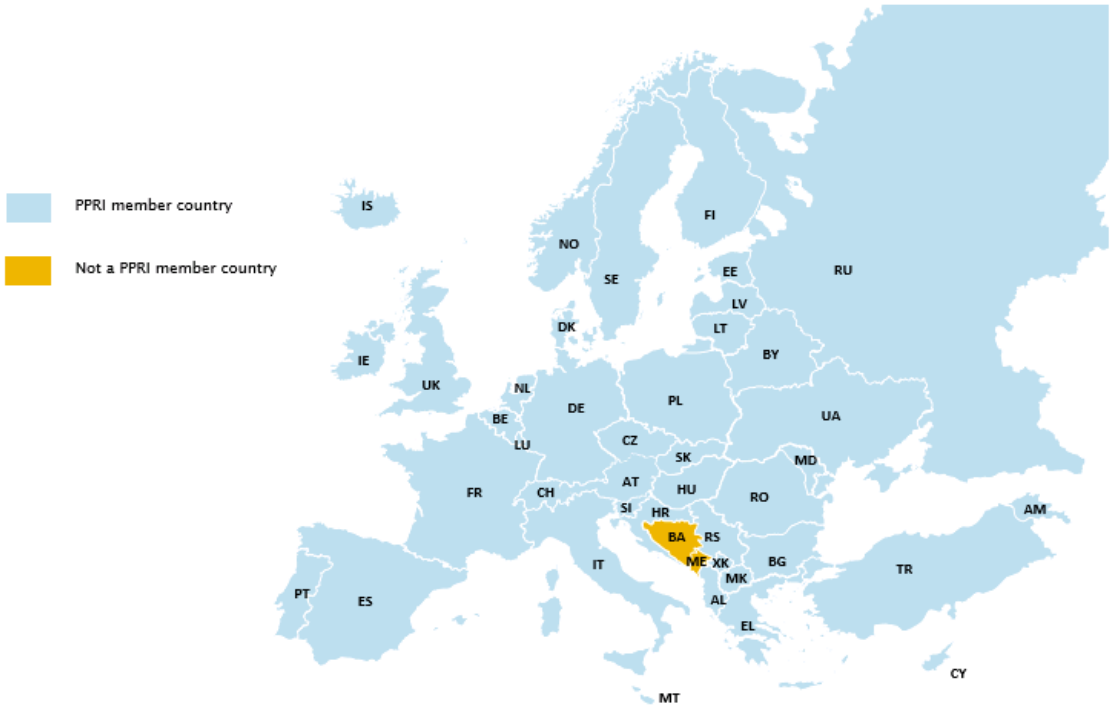
As of December 2018 (date of the information provided in this report), the PPRI network comprises more than 90 competent authorities for pharmaceutical pricing and reimbursement from a total of 47 countries, thereof 44 in the WHO European Region[3]. PPRI network member countries are: Albania (AL), Armenia (AM), Austria (AT), Belarus (BY), Belgium (BE), Bulgaria (BG), Canada (CA), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Iceland (IS), Ireland (IE), Israel (IL), Italy (IT), Kazakhstan (KZ), Kosovo (XK), Kyrgyzstan (KG), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Moldova (MD), Netherlands (NL), North Macedonia (MK), Norway (NO), Poland (PL), Portugal (PT), Republic of Korea (KR), Republic of Serbia (RS), Romania (RO), Russian Federation (RU), Slovakia (SK), Slovenia (SI), South Africa (ZA), Spain (ES), Sweden (SE), Switzerland (CH), Turkey (TR), Ukraine (UA), United Kingdom (UK), see also Figure 1.1. In addition, European and international institutions (e.g. European Commission services and agencies, Organisation for Economic Co-operation and Development (OECD), WHO Headquarters and Regional Office for Europe) are members of PPRI. Most of the European and international organisations and competent authorities of a few selected countries (on a rotation basis) are involved in the PPRI Advisory Board.

---

2 Pharmaceutical policy analyses based on input provided by PPRI network member countries can be found at https://ppri.goeg.at/studies_analyses.

3 The WHO European Region comprises a total of 53 countries, including Israel and countries of the former Soviet Union in Central Asia. PPRI member countries outside the WHO European Region are Canada, Republic of Korea and South Africa.

Figure 1.1:
Introduction – Map of PPRI network member countries, 2018



Not shown in the maps of this PPRI report: PPRI member countries Canada (CA), Israel (IL), Kazakhstan (KZ), Kyrgyzstan (KG), Republic of Korea (KR), South Africa (ZA)
Information of these countries will be provided in the notes accompanying the maps

Source: PPRI secretariat

2 Key figures of PPRI network member countries

This chapter presents demographic and economic figures and data of the organisation of the health care system in the countries studied to offer contextual background information.

2.1 Population figures and economic situation

Table 2.1:
Key figures – Total population in PPRI network member countries in million, 2018

Country	Population in million	Country	Population in million	Country	Population in million
Albania	2.87	Hungary	9.77	Poland	37.98
Armenia	2.95	Iceland	0.35	Portugal	10.28
Austria	8.85	Ireland	4.85	Republic of Korea	51.64
Belarus	9.49	Israel	8.88	Republic of Serbia	6.98
Belgium	11.42	Italy	60.43	Romania	19.47
Bulgaria	7.02	Kazakhstan	18.28	Russian Federation	144.48
Canada	37.06	Kyrgyzstan	6.32	Slovakia	5.45
Croatia	4.09	Kosovo	1.85	Slovenia	2.07
Cyprus	1.19	Latvia	1.93	South Africa	57.78
Czech Republic	10.63	Lithuania	2.79	Spain	46.72
Denmark	5.80	Luxembourg	0.61	Sweden	10.18
Estonia	1.32	Malta	0.48	Switzerland	8.52
Finland	5.52	Moldova	3.55	Turkey	82.32
France	66.99	Netherlands	17.23	Ukraine	42.27
Germany	82.93	North Macedonia	2.08	United Kingdom	66.49
Greece	10.73	Norway	5.31		

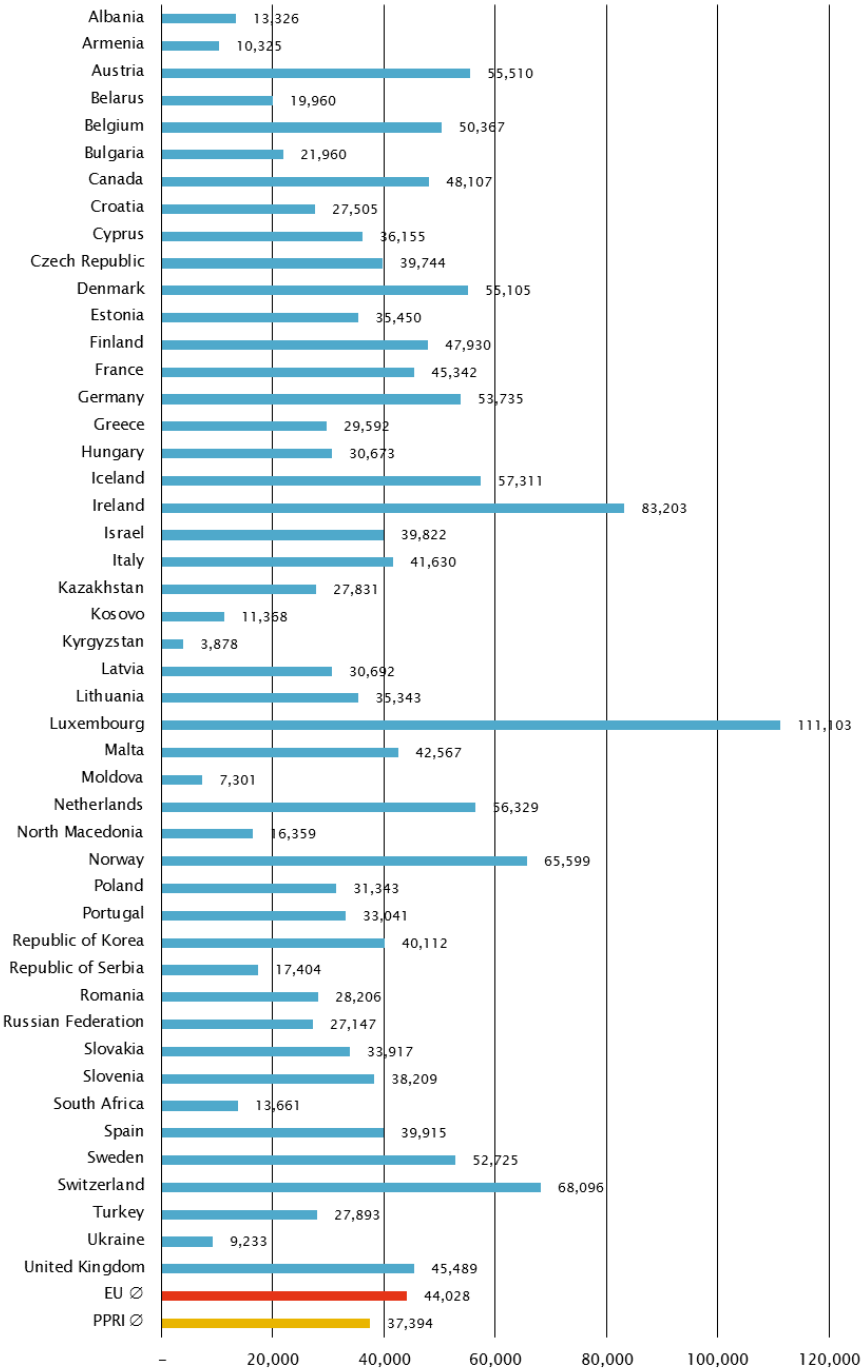
Source: for Ukraine: Ukraine's Central Statistical Office 2019; for the remaining countries: World Bank 2019a

In total, the 47 PPRI network member countries cover more than 1 billion people (1,006 million). PPRI is predominantly a network of European countries (44 of the 47 member countries are in the WHO European region, see chapter 1.3) but has member countries in almost all WHO regions (except the South-East Asian and Eastern Mediterranean regions). The gross domestic product (GDP) per capita ranges from 3,878 United States dollars Purchasing Power Parities (USD PPP)[4] (Kyrgyzstan) to 111,103 USD PPP (Luxembourg).

4

Gross domestic product (GDP) based on Purchasing Power Parities (PPP) is the GDP converted to international dollars using purchasing power parity rates. An international dollar has the same purchasing power over GDP as the US dollar has in the United States. Data are in current international dollars based on the 2011 International Comparison Program round of the World Bank. This conversion step is used in the international comparison of values to take into account the fact that in countries with lower (or higher) price levels more (or less) products can be purchased with a given amount of money.

Figure 2.1:
Key figures – Gross domestic product per capita in Purchasing Power Parities (current international US dollars) in PPRI network member countries, 2018



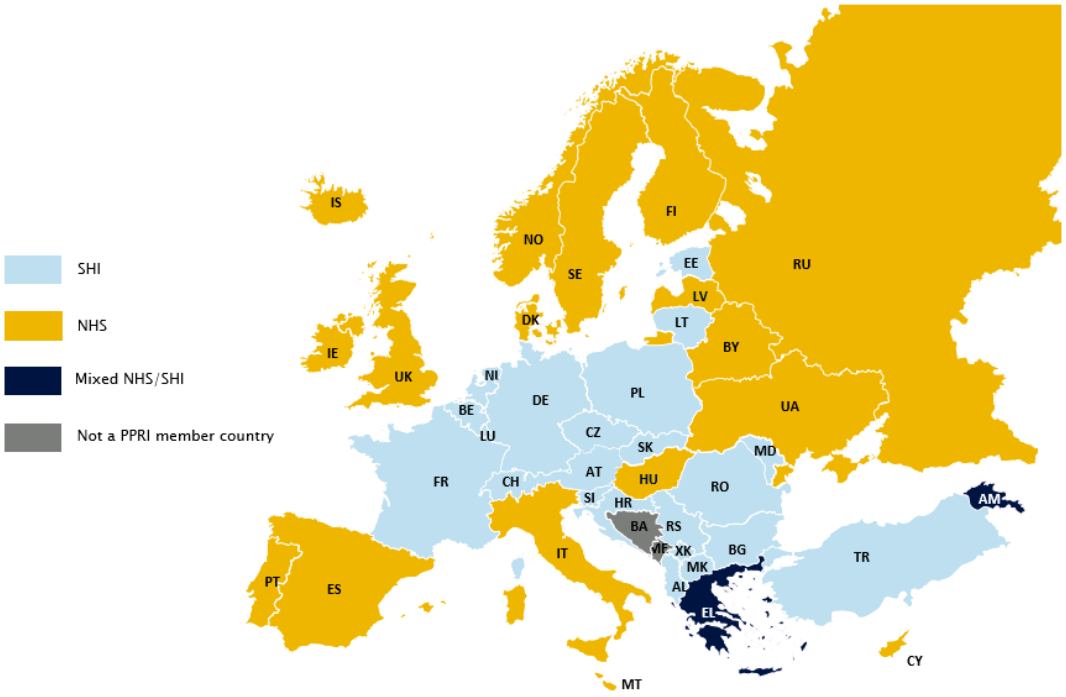
Cyprus: only 2017 data available

Source: World Bank 2019b

2.2 Organisation of the health care system

Health care systems are usually classified as either ➲ Social Health Insurance (SHI) or ➲ National Health Service (NHS).

Figure 2.2:
Key figures – Organisation of the health care system in PPRI network member countries, 2018



NHS = National Health Service, SHI = Social Health Insurance
NHS: Canada, Kazakhstan, South Africa; SHI: Israel, Republic of Korea; mixed NHS/SHI: Kyrgyzstan
Countries were classified according to the predominant features of health care system organisation and funding

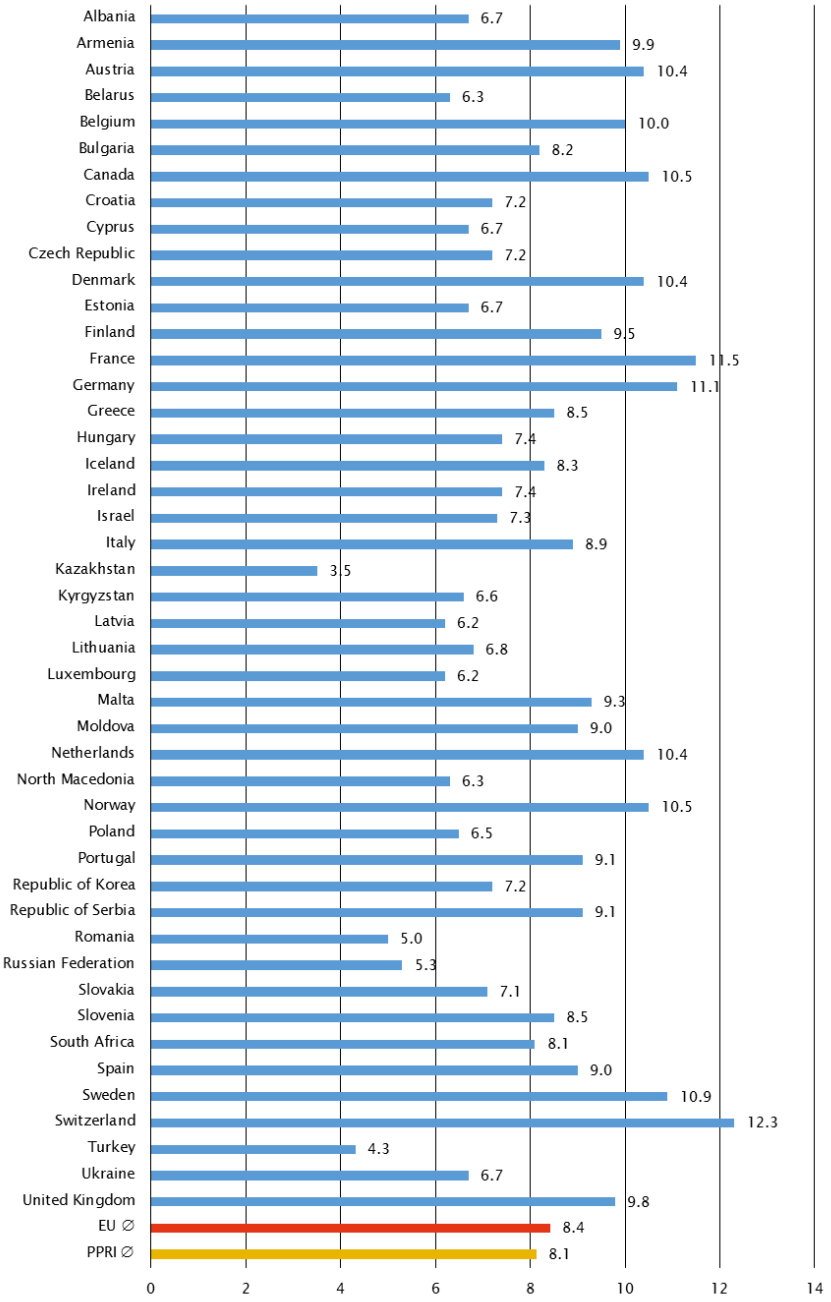
Source: PPRI secretariat based on information of OECD and national country reports

Out of 47 PPRI countries, the majority (~57%, 27 countries) have a health care system that mainly relies on contributions from employers and employees (social health insurance). Some countries, however, tend to present features of both systems.

2.3 Health expenditure

Health expenditure per capita in PPRI countries varied from 240 USD PPP in Kyrgyzstan to 7,867 USD PPP in Switzerland in 2016 (for details see Annex 2).

Figure 2.3:
Key figures – Current health expenditure in % of GDP in PPRI network member countries, 2016

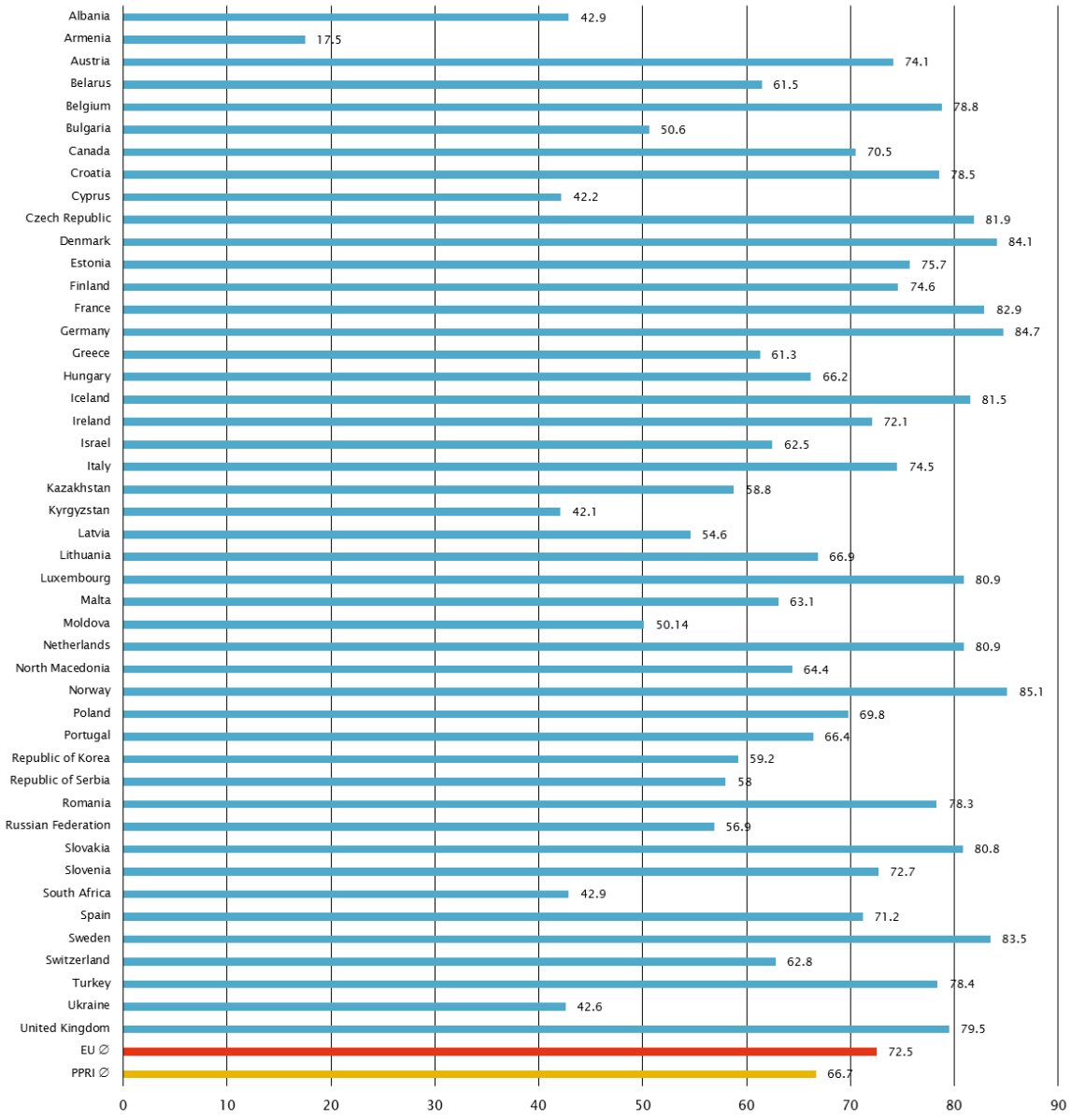


No data available: Kosovo

Source: World Bank 2019c based on World Health Organization Global Health Expenditure database

In 2016, PPRI member countries spent on average 8.1% of their GDP on health. The shares ranged from 12.3 % in Switzerland to 3.5 % in Kazakhstan.

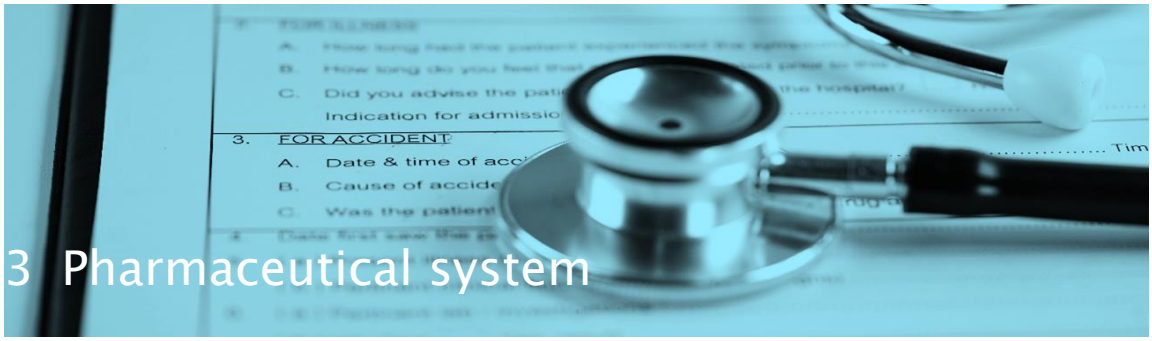
Figure 2.4:
Key figures – Public expenditure in % of current health expenditure in PPRI network member countries, 2016



No data available: Kosovo

Source: World Bank 2019c based on World Health Organization Global Health Expenditure database

In 40 of 46 PPRI countries more than 50% of the health expenditure is covered by public payers.



3 Pharmaceutical system

3.1 Organisation of the pharmaceutical system

The life-cycle of a medicine spans from the research and development phase to its marketing and post-marketing. For the different stages in the life-cycle, governments can apply different regulations and policies. This report focuses on policies related to the ➲ pricing and ➲ reimbursement of medicines which falls in the time after marketing of the medicines. Pricing and reimbursement are classified as ➲ peri-launch activities, and they add to ➲ pre-launch activities (such as ➲ horizon scanning) or ➲ post-launch activities (e.g. monitoring of prescription behaviour).

In PPRI countries, government authorities responsible for the pricing of medicines are usually Ministries of Health, in some countries also the Ministry of Social Affairs (e.g. Belgium) or, recently less common, the Ministry of Economy (e.g. Luxembourg). Depending on the organisation of the health care systems (cf. chapter 2.2), bodies and agencies that form part of the social health insurance or the NHS oversee reimbursement. In some PPRI countries (e.g. Italy), medicines agencies that are typically in charge of ➲ marketing authorisation are also government entities responsible for pricing and/or reimbursement. In France, while health care is funded through a statutory health insurance, the pricing decision is made by a committee composed of several Ministries representatives (Health, Social Security and Economy) as well as the statutory and the private health insurances. The scope of medicines that are price regulated and/or included in reimbursement varies between the countries (cf. also chapters 4.1 and 5.2).

Table 3.1:
Pharmaceutical system – Government authorities responsible for pharmaceutical pricing and reimbursement in PPRI network member countries, 2018

Countries	Pricing	Reimbursement
Czech Republic, Italy, Norway, Portugal	Medicines Agency	Medicines Agency
Slovenia	Medicines Agency	MoH
Turkey	Medicines Agency (MoH)	SHI
Republic of Serbia	MoH/SHI	SHI
Belarus, Cyprus, Greece, Kazakhstan, Lithuania, Malta, Netherlands, Republic of Korea, Russian Federation, Slovakia, Spain, Switzerland, Ukraine, United Kingdom	MoH	MoH
Austria, North Macedonia	MoH	SHI
Albania, Hungary, Moldova, Poland, Romania	MoH	SHI/MoH
Luxembourg	Ministry of Economy	SHI
Croatia, Estonia	SHI	SHI
Latvia, Ireland	NHS	NHS
Belgium[1], Finland[2]	A Ministry that is not MoH	A Ministry that is not MoH
Armenia, Kyrgyzstan	No price regulation	MoH
Denmark	No price regulation in the out-patient sector	Medicines Agency
Kosovo	No price regulation	No reimbursement/funding in the outpatient sector
Bulgaria	National Council on Prices and Reimbursement of Medicinal Products	National Council on Prices and Reimbursement of Medicinal Products
Canada	PMPRB / Provincial and territorial governments via the pan-Canadian pharmaceutical Alliance	Provincial and territorial governments / private plans / federal government
France	Health Care Products Pricing Committee (composed of Ministries and health insurances)	SHI
Germany	SHI	Federal Joint Committee
Iceland, Sweden	Pricing and Reimbursement Agency	Pricing and Reimbursement Agency
Israel	MoH	HMO
South Africa[3]	MoH	National Essential Medicines List Committee

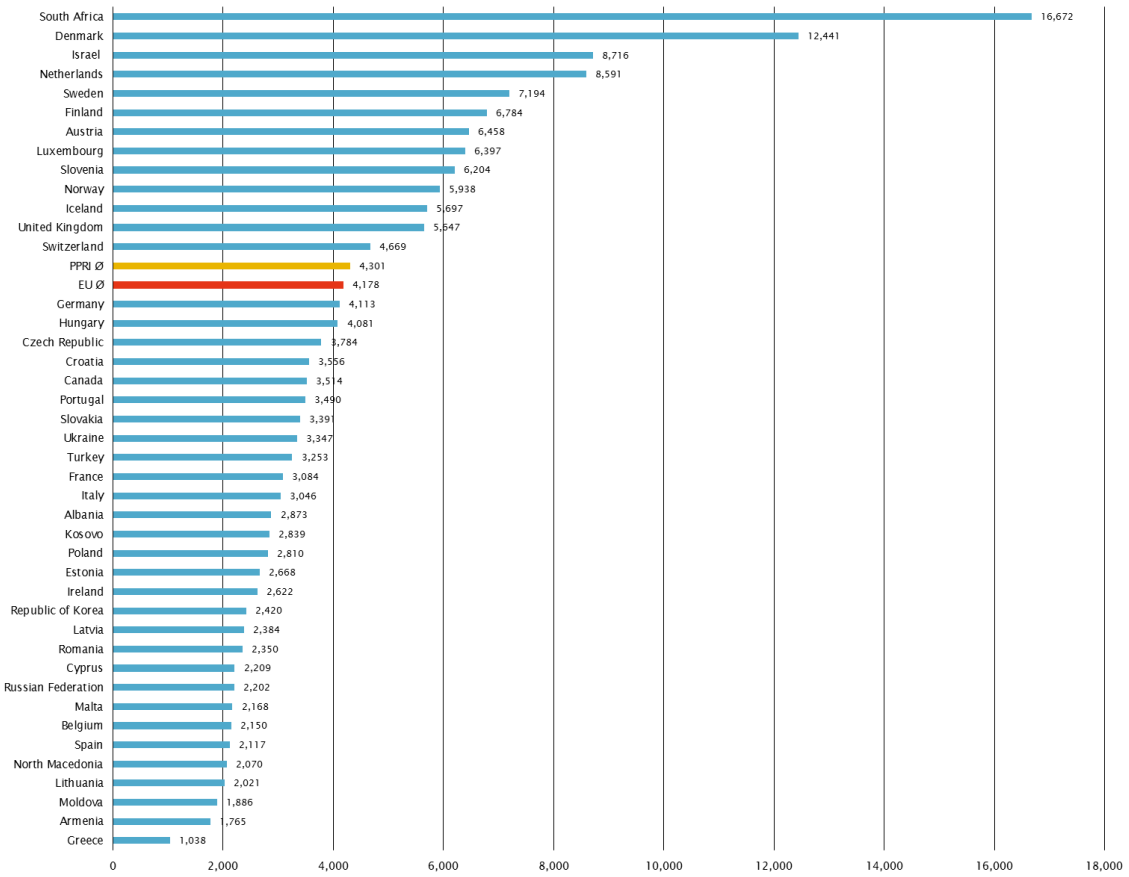
HMO = Health maintenance organization, MoH = Ministry of Health, NHS = National Health Service, PMPRB = Patented Medicine Prices Review Board (Canada), SHI = Social Health Insurance
[1] Belgium: authority responsible for pricing: Ministry of Economy; authority for reimbursement: Ministry of Social Affairs
[2] Finland: authority responsible for pricing and reimbursement: Ministry of Social Affairs and Health, Pharmaceutical Pricing Board
[3] Introduction of a national health insurance is planned

Source: PPRI network members; data compilation by PPRI secretariat

3.2 Dispensing of medicines for outpatients

Throughout Europe, ➲ prescription-only medicines (POM) are mainly dispensed to outpatients in ➲ community pharmacies. The pharmacy density (inhabitants per community pharmacy) for some PPRI countries is presented in Figure 3.1. On average (data for 42 PPRI member countries available), one community pharmacy serves 4,301 inhabitants, but there is a wide range in the pharmacy density across the countries. With one community pharmacy serving on average 16,672 inhabitants, South Africa has the highest number of people served by one pharmacy followed by Denmark (12,441 inhabitants), whereas Greece shows the highest density of often small-sized pharmacies per inhabitant (1,038 inhabitants/pharmacy).

Figure 3.1:
Pharmaceutical system – Inhabitants per community pharmacy in PPRI network member countries, 2018



No data available for: Belarus, Bulgaria, Kazakhstan, Kyrgyzstan, Republic of Serbia
Estimate of number of community pharmacies: Kosovo. United Kingdom data only refer to England.
Data for 2017: Albania, Armenia, Cyprus, Czech Republic, Finland, France, Netherlands, Portugal, Republic of Korea, South Africa, Sweden, Turkey, Ukraine, United Kingdom; 2016: Croatia, Germany, Greece, Romania, Slovenia; 2015: Belgium, Switzerland; 2014: Slovakia; 2011: Iceland, Israel, Lithuania; 2009: Moldova

Source: data collected by the PPRI secretariat from websites of pharmacy associations validated by PPRI network members

Apart from community pharmacies, other ➲ POM dispensaries serving outpatients include ➲ dispensing doctors and hospital pharmacies. For instance, the number of hospital pharmacies serving outpatients amounts to 117 in Hungary and 32 in Norway. Dispensing by dispensing doctors has lost importance in many countries over the years but is still common practice in Austria and Switzerland. In Denmark, there are around 300 sites attached to community pharmacies where patients can pick up their prescription-only medicines after having ordered them from the pharmacy.

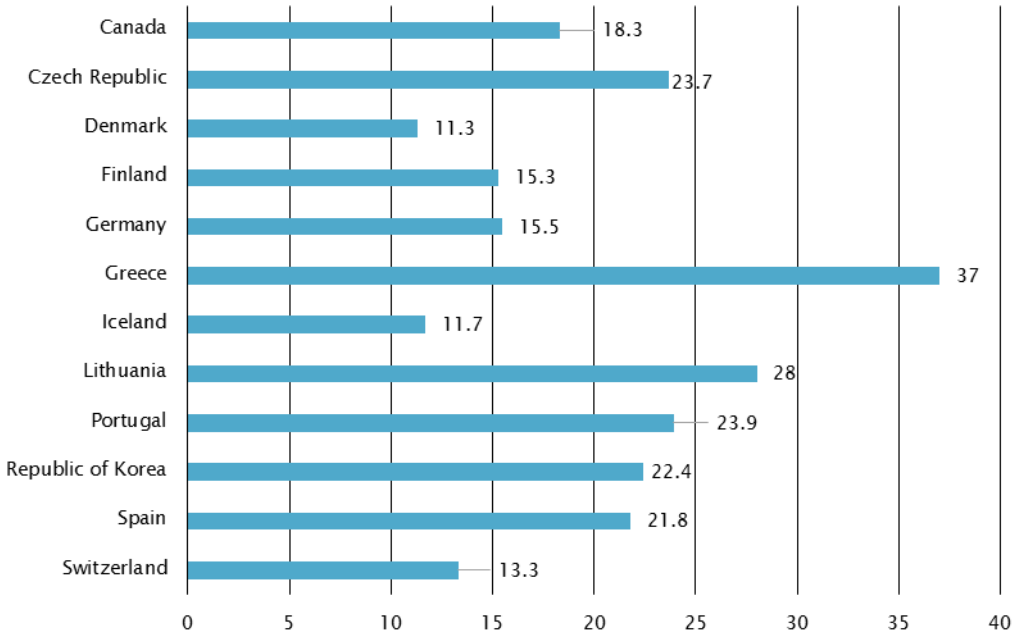
While POM are usually dispensed in community pharmacies, ➲ non-prescription medicines (NPM) may also be sold in retail shops other than pharmacies, depending on national legislation. Distribution channels for NPM, or for some categories of NPM, have been liberalised in several EU Member States, including the Czech Republic, Denmark, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Sweden and the United Kingdom. The extent of liberalisation in the distribution channels (e.g. range of NPM allowed to be sold outside pharmacies, obligations for non-pharmacies) differs among the countries. For instance, in Italy, all NPM are allowed to be sold outside pharmacies (e.g. supermarkets, para-pharmacies) under the condition that a pharmacist is employed and present at all times. In Poland, any retail shop has been allowed to sell NPM since 1991. In Sweden, the sale of a selected number of NPM outside pharmacies has been permitted since 2009.

In addition, a significant increase in the number of online pharmacies in the PPRI countries has been observed over the past decade. Since 1 July 2015, websites of pharmacies and authorised retailers in EU / European Economic Area (EEA) countries legally selling medicines to the public over the internet are obliged to display a new logo, which helps customers to verify legally operating websites.

3.3 Pharmaceutical expenditure

Comprehensive statistics of ➲ total pharmaceutical expenditure that cover both the in- and outpatient sectors exist for only few countries.

Figure 3.2:
Pharmaceutical system – Total pharmaceutical expenditure in % of current health expenditure in PPRI network member countries, 2017



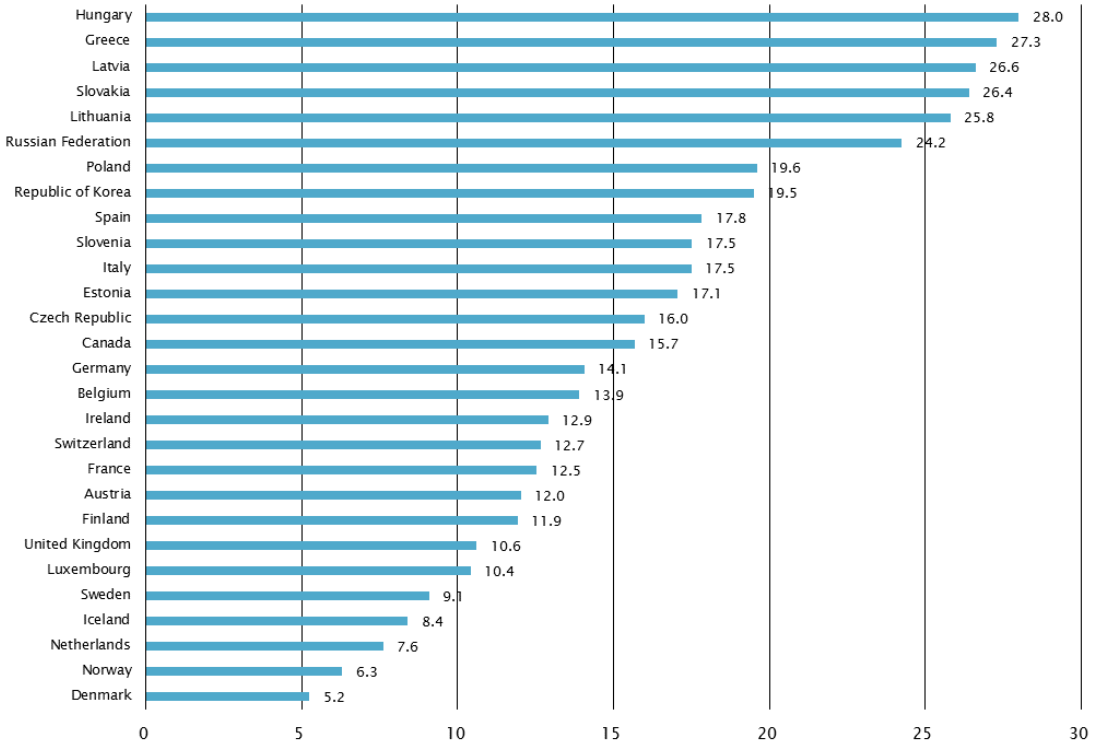
No data available for the other PPRI member countries

Source: OECD Health Statistics 2019a

Pharmaceutical expenditure can account for a substantial share of the health expenditure, ranging from nearly 40% of the health expenditure in Greece to approximately 11% in Denmark. However, international comparability of the expenditure data is limited by inaccuracies in the data documentation or by a different interpretation of the overall market (i.e. inclusion of medical devices). For the outpatient sector, pharmaceutical expenditure data of more countries is available in international databases. According to OECD Health Statistics 2019a[5] on average 16% of the current health expenditure was spent on pharmaceuticals in the outpatient sector (usually POM and NPM) in PPRI countries (considering data of only 28 countries) in 2017. The shares ranged from 5.2% (Denmark) to 28% (Hungary).

5
In health expenditure statistics according to the OECD System of Health Accounts (SHA) classification, pharmaceutical spending covers expenditure on prescription-only medicines and non-prescription medicines. In some countries also expenditure on other medical non-durable goods (i.e. adhesive and non-adhesive bandages, hypodermic syringes, first-aid kits, hot-water bottles and ice bags, medical hosiery items such as elastic stockings and knee supports, etc.), are included. Expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax.

Figure 3.3:
Pharmaceutical system – Outpatient pharmaceutical expenditure in % of current health expenditure in PPRI network member countries, 2017

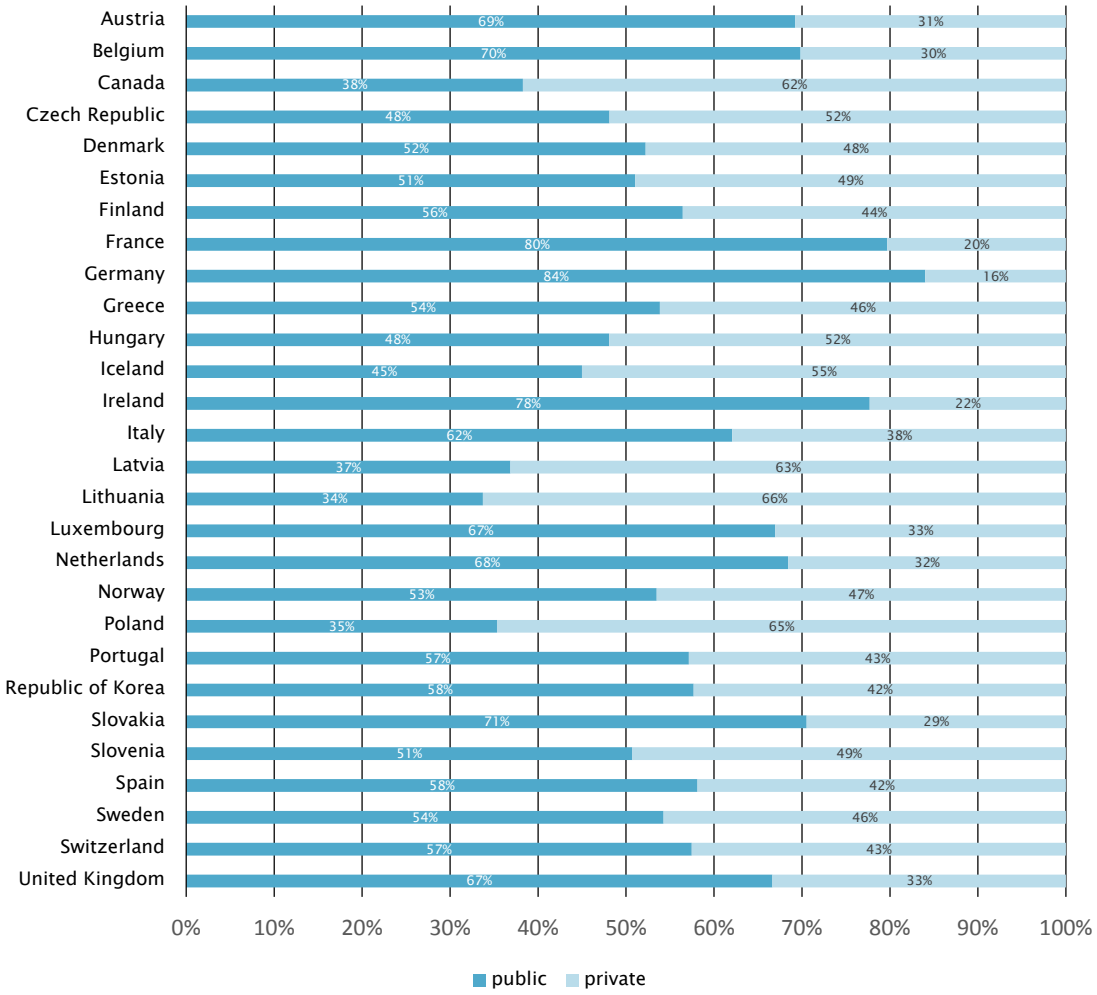


For definitions see OECD Health Statistics
Expenditure data cover both prescription-only medicines and non-prescription medicines
Data include expenditure on other medical non-durables: Greece, Ireland, Italy, Lithuania, the Netherlands, Portugal
No data available for the other PPRI network member countries

Source: OECD Health Statistics 2019a

In the majority of the PPRI countries a large share of pharmaceutical expenditure (in 2017, on average 57% for 28 PPRI member countries), at least for POM, is covered by public payers (i.e. government budget, social health insurance etc.); with shares ranging from 84% in Germany to 34% in Lithuania.

Figure 3.4:
Pharmaceutical system – Public and private outpatient pharmaceutical expenditure in PPRI network member countries, 2017

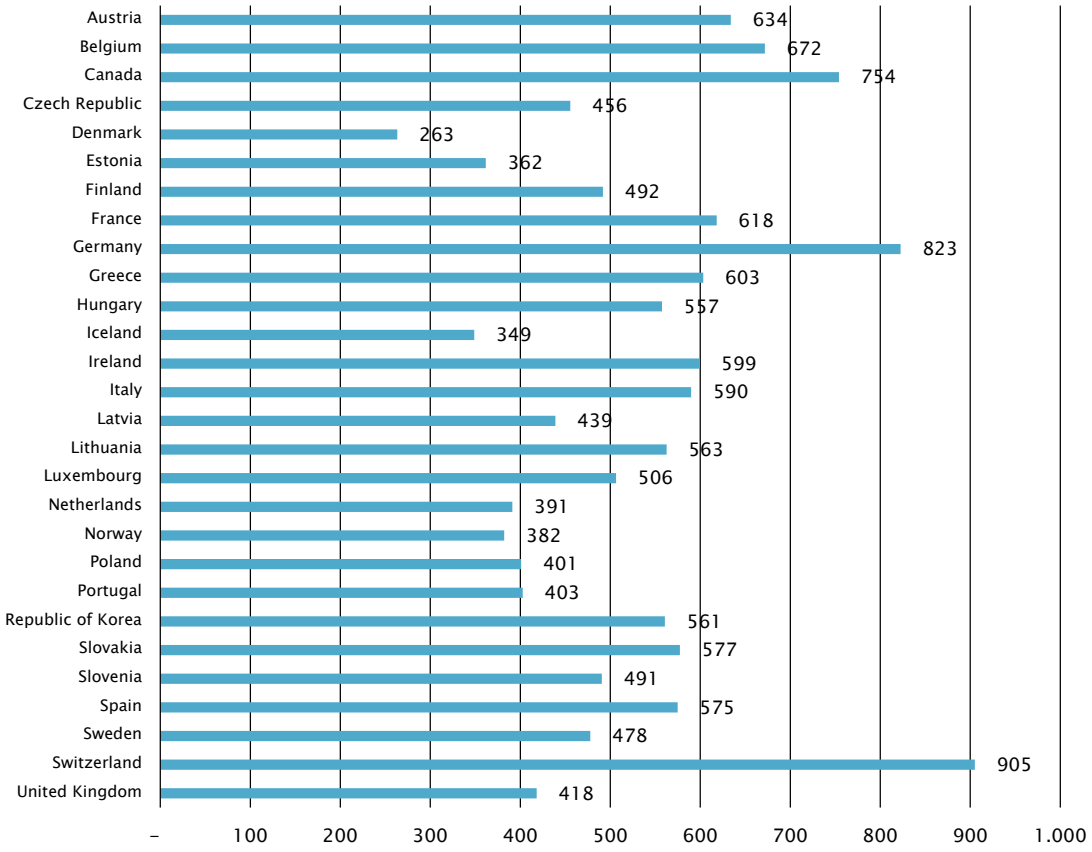


Expenditure data cover both prescription-only medicines and non-prescription medicines
Public = government/compulsory schemes; private = voluntary schemes/household out-of-pocket payments
Data include expenditure on other medical non-durables: France, Greece, Ireland, Italy, Lithuania, Netherlands, Portugal
No data available for the other PPRI network member countries

Source: OECD Health Statistics 2019a

Figure 3.5 shows per capita expenditure expressed in USD PPP for pharmaceuticals (prescribed and non-prescribed medicines) in the outpatient sector in PPRI countries in 2017. Switzerland, Germany and Canada had the highest pharmaceutical expenditure per capita.

Figure 3.5:
Pharmaceutical system – Current expenditure on pharmaceuticals, per capita, USD PPP (current prices, current PPP) in PPRI network member countries, 2017



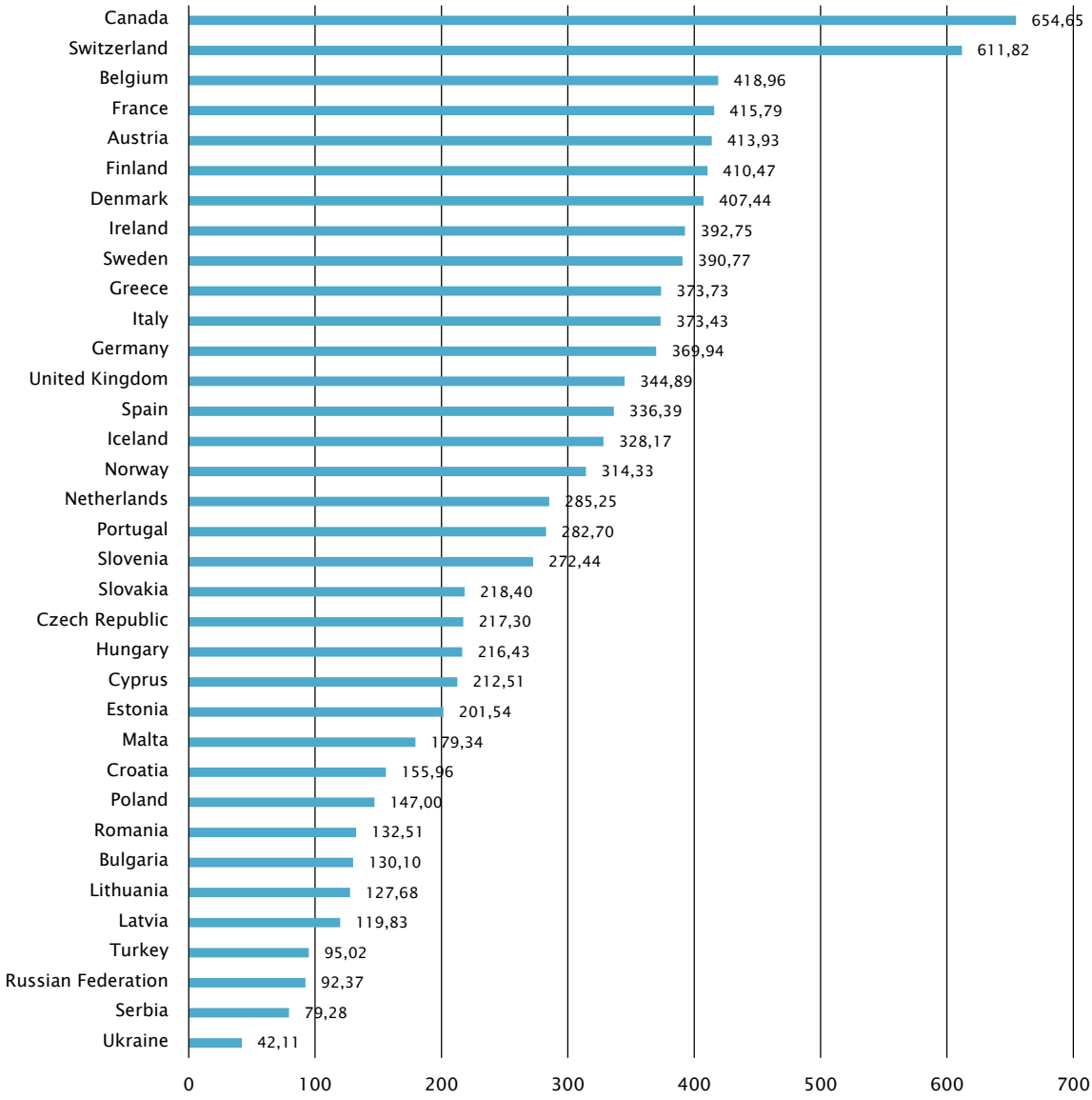
PPP = Purchasing Power Parities, USD = United States dollars
Expenditure data cover both prescription-only medicines and non-prescription medicines
Data include expenditure on other medical non-durables: France, Greece, Ireland, Italy, Lithuania, Netherlands, Portugal
No data available for the other PPRI network member countries

Source: OECD Health Statistics 2019a

3.4 Pharmaceutical markets

Figure 3.6 illustrates the sales of medicines in almost all PPRI countries: there are important differences of Canada and Western and North European countries compared to Eastern European countries and the Russian Federation. The median value at ex-factory price level for all PPRI countries (where data available) equaled 282.70 Euros per inhabitant in 2015.

Figure 3.6:
Pharmaceutical system – Pharmaceutical market value at ex-factory price level in Euros per inhabitant in PPRI network member countries, 2015



No data available for Albania, Armenia, Belarus, Israel, Kazakhstan, Kosovo, Kyrgyzstan, Luxembourg, Moldova, North Macedonia, Republic of Korea, South Africa
Pharmaceutical market value at pharmacy purchasing prices: Cyprus, Denmark, Finland, Iceland, Lithuania, Latvia, Norway, Russian Federation, Sweden, Slovenia
Pharmaceutical market value at consumer price level and data from 2016: Canada, Ukraine
Iceland: data from 2013, Republic of Serbia: data from 2011, Malta: data from 2007
Estimate: Belgium, France, Germany, Ireland, Italy, Malta, Norway, Spain, United Kingdom
Data taken from secondary sources (see below); it should be noted that some countries do not set medicine prices at ex-factory prices (cf. chapter 4.1).

Source: EFPIA 2019 (all PPRI network member countries presented except Canada and Ukraine), AESGP 2019 (Canada, Ukraine), calculations by the PPRI secretariat based on World Bank population data

3.5 Generic market

Table 3.2 and Table 3.3 present ➲ generic market shares in value and in volume, respectively, in the PPRI countries.

Table 3.2:
Pharmaceutical system – Generic market shares in value in PPRI network member countries, 2018

Country	Share in value (%)	Year	Notes	Source
Austria	48.4	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Belarus	48.5	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Belgium	15.1	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Bulgaria	39.0	2018	Share of generics in total pharmaceutical market sales	Data provided by PPRI network member, based on BGPharmA data
Canada	27.0	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Croatia	42.0	2016	Share of generics in pharmacy market sales	EFPIA 2018
Cyprus	45.7	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Czech Republic	28.1	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Denmark	18.7	2015	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Estonia	16.1	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Finland	18.0	2015	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
France	19.6	2016	Share of generics in reimbursable pharmacy market sales	EFPIA 2018
Germany	34.1	2016	Share of generics in reimbursable pharmaceutical market sales.	OECD Health Statistics 2019b
Greece	22.6	2015	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Hungary	37.6	2016	Share of generics in pharmacy market sales	EFPIA 2018
Iceland	22.0	2013	Share of generics in total pharmaceutical market sales	PPRI Network Query 2014 (unpublished)
Ireland	15.6	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Israel	22.4	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Italy	18.8	2017	Share of generics in community pharmacy market sales	OECD Health Statistics 2019b
Kazakhstan	85.0	2016	–	WHO Europe 2019

Country	Share in value (%)	Year	Notes	Source
Latvia	43.0	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Lithuania	32.2	2016	Share of generics in total pharmaceutical market sales	EFPIA 2018
Luxembourg	5.6	2017	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Moldova	59	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Netherlands	20.0	2018	Share of generics in outpatient reimbursable medicines dispensed	SFK 2019
Norway	17.7	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Poland	69.0	2017	Share of generics in total pharmaceutical market sales	Ministry of Health based on data provided by the Polish Pharmaceutical Association
Portugal	19.8	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Republic of Korea	47.1	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Republic of Serbia	61.9	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Romania	28.1	2016	Share of generics in total pharmaceutical market sales	EFPIA 2018
Russian Federation	57.0	2016	Share of generics in total pharmaceutical market sales	EFPIA 2018
Slovakia	27,0	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Slovenia	22.8	2016	Share of generics in community pharmaceutical market sales	OECD Health Statistics 2019b
South Africa	32.4	2014	Share of generics in total pharmaceutical market sales	IFPMA 2017
Spain	22.3	2017	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Sweden	19.0 / 21.0	2016	Share of generics in total outpatient market / in outpatient reimbursement market	PPRI Pharma Profile 2017 based on data of the Swedish eHealth Agency and TLV
Switzerland	17.9	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Turkey	31.0	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Ukraine	89.0	2017	-	WHO Europe 2019
United Kingdom	37.6	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b

EFPIA = European Federation of Pharmaceutical Industries and Associations, IFPMA = International Federation of Pharmaceutical Manufacturers and Associations, OECD = Organisation for Economic Co-operation and Development, PPRI = Pharmaceutical Pricing and Reimbursement Information, SFK = Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics (the Netherlands), TLV = Tandvårds- & läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency (Sweden), WHO = World Health Organization
No data available for Albania, Armenia, Kosovo, Kyrgyzstan, Malta, North Macedonia, Republic of Serbia and Republic of Korea

Sources: indicated in the table

Across the PPRI network member countries, generic market shares amount to an average of approximately 31% in value and nearly 50% in volume. However, the generic shares relate to different sub-markets, and different calculation methods might be applied in the data sources, as presented in the tables. This limits the comparability of national generic market shares. High generic market shares in volume and low shares in value indicate high generic uptake, at comparably low generic prices (including possible discounts).

Table 3.3:
Pharmaceutical system – Generic market shares in volume in PPRI network member countries, 2018

Country	Share in volume (%)	Year	Notes	Source
Armenia	70.0	2018	Share of registered medicines	WHO Europe 2019
Austria	53.1	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Belarus	80.0	2017	Share of registered medicines	WHO Europe 2019
Belgium	33.3	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Bulgaria	72,0	2017	Share of generics in total pharmaceutical market in volume	Data provided by PPRI network member, based on BGPharmA data
Canada	76.0	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Cyprus	49.5 (public sector)/ 16.1 (private sector)	2013	Generic market share in percent of the total outpatient market	PPRI Network Query 2016 (unpublished)
Czech Republic	63.6	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Denmark	60.8	2015	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Estonia	35.7	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Finland	42.0	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
France	27.6	2016	Number of packages	OECD data, 20 July 2018
Germany	81.2	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Greece	23.9	2015	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Hungary	65.0	2013	Share of generics measured as the rate of competitive markets in the outpatient reimbursement market (at gross retail price level)	PPRI Network Query 2016 (unpublished)
Ireland	40.3	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Italy	29.3	2017	Share of generics in community pharmacy market sales	OECD Health Statistics 2019b
Kazakhstan	90.0	2016	–	WHO Europe 2019
Kyrgyzstan	82.0	2017	–	WHO Europe 2019

Country	Share in volume (%)	Year	Notes	Source
Latvia	75.0	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Lithuania	50.0	2013	Reimbursed pharmaceutical market for outpatient market data	PPRI Network Query 2016 (unpublished)
Luxembourg	11.4	2017	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Moldova	84.0	2017	-	WHO Europe 2019
Netherlands	77.7	2018	Share of generics in outpatient reimbursable medicines dispensed	SFK 2019
Norway	49.1	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Poland	75.0	2012	Total outpatient market	PPRI Network Query 2016 (unpublished)
Portugal	46.4	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Russian Federation	78.0	2011	Total outpatient market	PPRI Network Query 2016 (unpublished)
Slovakia	64.0	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Slovenia	50.7	2016	Share of generics in community pharmaceutical market sales	OECD Health Statistics 2019b
Spain	46.4	2017	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b
Sweden	49.0 / 52.0	2016	Share of generics in total outpatient market / in outpatient reimbursement market	PPRI Pharma Profile 2017 based on data of The Swedish eHealth Agency and TLV
Switzerland	22.8	2017	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Turkey	57.0	2016	Share of generics in total pharmaceutical market sales	OECD Health Statistics 2019b
Ukraine	98.0	2017	-	WHO Europe 2019
United Kingdom	85.2	2016	Share of generics in reimbursable pharmaceutical market sales	OECD Health Statistics 2019b

OECD = Organisation for Economic Co-operation and Development, PPRI = Pharmaceutical Pricing and Reimbursement Information, SFK = Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics (the Netherlands), TLV = Tandvårds- & läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency (Sweden), WHO = World Health Organization
No data available for Albania, Croatia, Iceland, Israel, Kosovo, Malta, North Macedonia, Republic of Korea, Republic of Serbia, Romania and South Africa

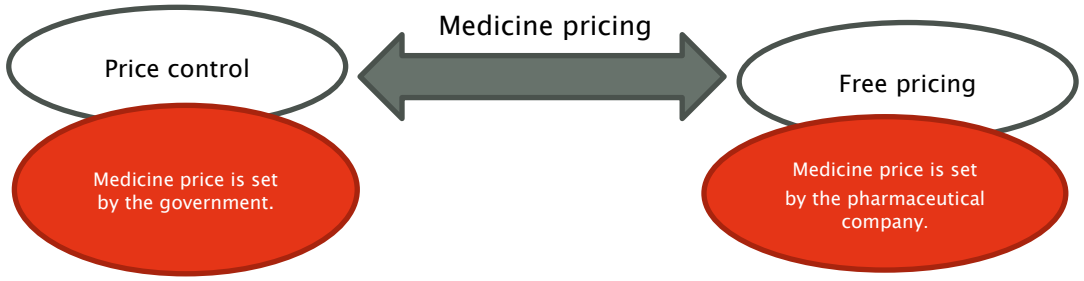
Sources: indicated in the table

4 Pricing policies

4.1 Price regulation framework

The setting of a medicine price is either an action taken by the pharmaceutical company (➲ free pricing) or is the competence of government authorities (i.e. pricing authority, public payer) that implement ➲ price control (Figure 4.1).

Figure 4.1:
Pricing policies – Actors involved in setting a medicine price



Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2018

Different ➲ pricing policies may be applied for different ➲ price types (i.e. prices at different stages). Common price types are the ➲ ex-factory price (manufacturer price), ➲ pharmacy purchasing price (wholesale price) and ➲ pharmacy retail price (consumer price). The latter usually includes distribution remuneration (e.g. ➲ mark-ups, ➲ fee-for-service), whose extent and design can be regulated by government authorities (cf. chapter 4.3.1), and taxes such as ➲ value-added tax (cf. chapter 4.3.2).

Almost all PPRI countries have mechanisms in place to set medicine prices at the ex-factory price level[6]. The scope of medicines that are subject to price regulation can differ. In most PPRI countries, price regulation is targeted at ➲ reimbursable medicines (i.e. medicines eligible for public funding) or prescription-only medicines (most of which are reimbursable); for details see Table 4.1. This highlights the close linkage between pricing and reimbursement. The amount covered by the third party payer (public payer) is referred to as reimbursement price. In a few lower-income PPRI member countries, mainly in Central Asia, ex-factory prices are not regulated.

6
In some countries, prices are not set at the ex-factory price but at the wholesale price level since ex-factory prices and wholesale remuneration are not regulated (cf. chapter 4.3.1).

Table 4.1:
Pricing policies – Scope of price control for medicines at ex-factory (or wholesale) price levels in PPRI network member countries, 2018

Countries	State / authority	Pharmaceutical company
Albania, Belgium, Cyprus, Israel, Lithuania, Luxembourg, Malta, Moldova, Netherlands, North Macedonia, Republic of Serbia, Turkey	All medicines	–
Croatia, Czech Republic, Estonia, Finland, France[1], Germany, Hungary, Ireland, Italy, Kazakhstan, Latvia, Poland, Republic of Korea, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, United Kingdom[1], Ukraine	Reimbursable medicines[2]	Non-reimbursable medicines
Austria	Reimbursable outpatient medicines	Non-reimbursable medicines and inpatient medicines
Canada	On-patent medicines and off-patent reimbursable medicines	Off-patent non-reimbursable medicines
Bulgaria, Greece, Iceland, Norway, Portugal, Romania	Prescription-only medicines	Non-prescription medicines
Armenia[3], Belarus[3], Denmark[4], Kosovo, Kyrgyzstan[3]	–	All medicines

Most countries set the ex-factory prices except for Croatia, Cyprus, Denmark, Finland, Iceland, Malta (public sector), Netherlands, North Macedonia, Norway, Sweden and United Kingdom (cf. chapter 4.3.1).
[1] Indirect price control: In 2018, the UK had indirect cost control mechanisms in the form of the Pharmaceutical Price Regulation Scheme (PPRS), which was in place from 1 January 2014 to 31 December 2018 and the statutory scheme for branded medicines pricing, set out in legislation. The PPRS capped growth on sales of branded medicines to the NHS, with any sales above that rate being subject to payments to the Department of Health and Social Care. In addition, some direct price control was in place, with the Department setting maximum NHS list prices, although companies under the PPRS had freedom of list pricing for new active substances at the time of launch. For generic medicines, prices are not controlled. Instead, the Department relies on competition to drive prices down.
France has also an indirect price control via the so-called 'M amount' that limits the total annual growth of the pharmaceutical market. However, in France the indirect price control adds to direct price regulation.
[2] The term 'reimbursable medicines' relates to medicines that are (fully or partially) subsidized by the state. In some countries (e.g. Central Asian countries, South Africa), the term 'public sector' is used instead. The scope of medicines included into reimbursement varies importantly between countries (e.g. some dozens International Non-proprietary Names (INN) in some Central Asian countries to a few thousands medicines in Western European countries).
[3] Armenia, Belarus and Kyrgyzstan have free pricing but wholesale prices for centralised state-purchased and reimbursed medicines are subject to tender mechanisms.
[4] Denmark has free pricing but reimbursement limits (reimbursement prices) are regulated in the outpatient sector and tendered and EPR-based prices are applied in the inpatient sector.

Source: PPRI network members; data compilation by PPRI secretariat

4.2 Pricing policies for ex-factory prices

Pricing authorities can use different criteria on which to base their pricing (and reimbursement) decision. This results in different pricing policies (cf. Table 4.2). The use of key pricing policies in the PPRI countries will be described in the sub-chapters to follow.

Table 4.2:
Pricing policies – Pricing policies in PPRI network member countries and their underlying criteria, 2018

Criteria	Pricing policy	Reference to chapter
Medicine price in other countries	➲ External price referencing	Chapter 4.2.1
Medicine price in the same country	➲ Internal price referencing	Chapter 4.2.2 For RPS, a related reimbursement policy, cf. chapter 5.3
'Value' (e.g. (added) therapeutic value)	➲ Value based pricing	Chapter 4.2.3 For HTA cf. chapter 6.1.2
Defined conditions (either health outcomes or related to procurement processes e.g. minimum purchases)	➲ Conditional pricing	Chapter 4.2.4 For MEA cf. chapter 6.1.3
'Best offer' (based on price, but also product and procurement specifics) in comparison to other bids	➲ Tendering	Chapter 4.2.5
Costs (e.g. production costs, R+D costs)	➲ Cost-plus pricing	Chapter 4.2.6

HTA = Health Technology Assessment, MEA = managed-entry agreement(s), R+D = research and development, RPS = reference price system

Source: Classification provided by the authors, based on Vogler 2019

The pricing policies do not always address all medicines but

» can be focused on specific groups of medicines (e.g. on-patent or off-patent medicines, prescription-only or non-prescription medicines),
» can be targeted at a specific sector or setting (e.g. hospital or outpatient, public / reimbursement or private sector) and
» may be applied as sole, dominant or supplementary policy for defined medicines.

As a result, countries may and do use several pricing policies in parallel.

Even in EU Member States pricing (and reimbursement) policies are a national competence. Still, there are some collaborative approaches in pricing (and reimbursement), which will be presented in chapter 4.2.7.

4.2.1 External price referencing

➲ External price referencing (EPR) is a commonly applied pricing policy in the PPRI countries. This pricing policy relates to the price of the same medicine in other countries.

The practice of EPR varies across from country to country with respect to:

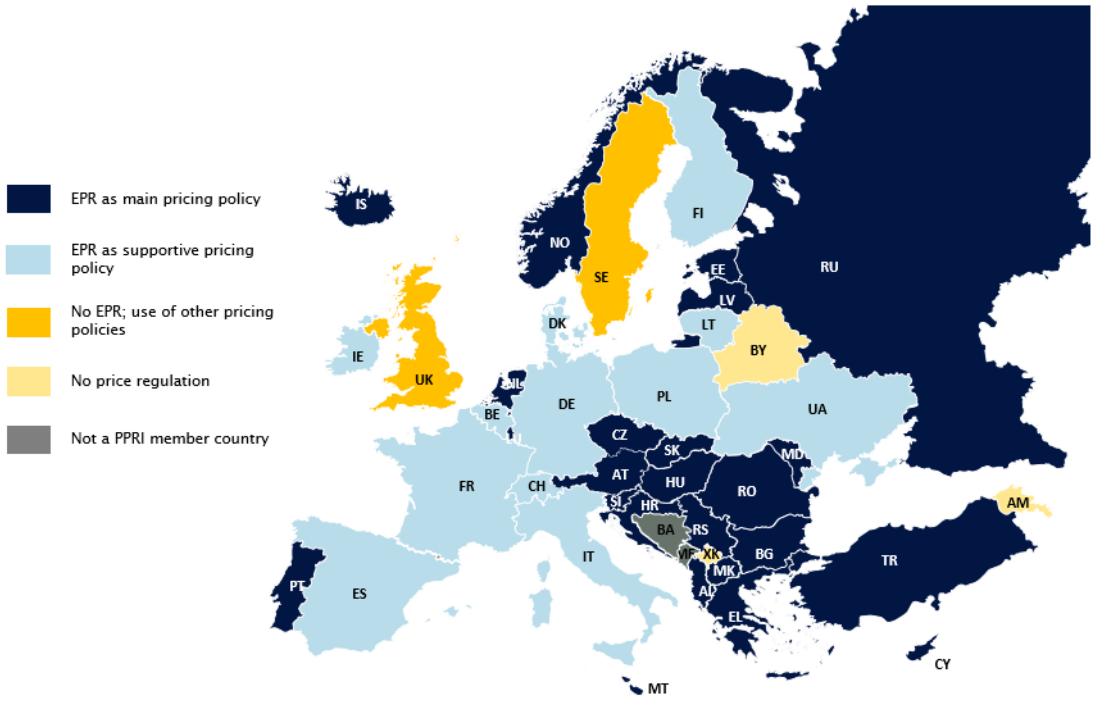
» the methodology to derive the benchmark price (cf. chapter 4.2.1.2),
» the reference countries considered (cf. chapter 4.2.1.3),
» the scope of medicines covered (e.g. originator / on-patent medicines, prescription-only medicines, new innovative medicines, medicines in the outpatient sector, medicines in the public sector),

» the price type considered for calculations (e.g. ex-factory price, wholesale price, list price),
» the frequency of price revisions (at regular and irregular intervals),
» the data sources of price information considered (e.g. information provided by the marketing authorisation holders, national or European databases),
» the approaches of how to deal with missing information and
» the choice of exchange rates applied for foreign currencies.

4.2.1.1 Application of EPR

41 of the PPRI countries apply EPR to derive a benchmark for setting national medicine prices, at least for some of the medicines. Non-EPR-applying countries either have other pricing policies in place (Sweden, UK), or have no price regulation at all (4 countries: Armenia, Belarus, Kosovo and Kyrgyzstan). However, the latter are in the process of implementing ➲ price control, and they aim to base it on EPR. 27 of countries that apply EPR use it as a main pricing policy, and 14 as a supplementary policy (cf. Figure 4.2).

Figure 4.2:
Pricing policies – Overview of the use of external price referencing in PPRI network member countries, 2018



EPR as main pricing policy: Canada, Israel, Kazakhstan
EPR as supportive pricing policy: Republic of Korea, South Africa
No price regulation: Kyrgyzstan
Austria: While EPR is the main pricing policy, it is a supplementary policy in the reimbursement process

Source: PPRI network members; data compilation by PPRI secretariat

EPR tends to be applied for outpatient medicines, but some countries also apply it for inpatient medicines. As of 2018, Denmark only uses it for medicines in the inpatient sector. Usually, medicines that fall under EPR are on-patent medicines subject to medical prescription.

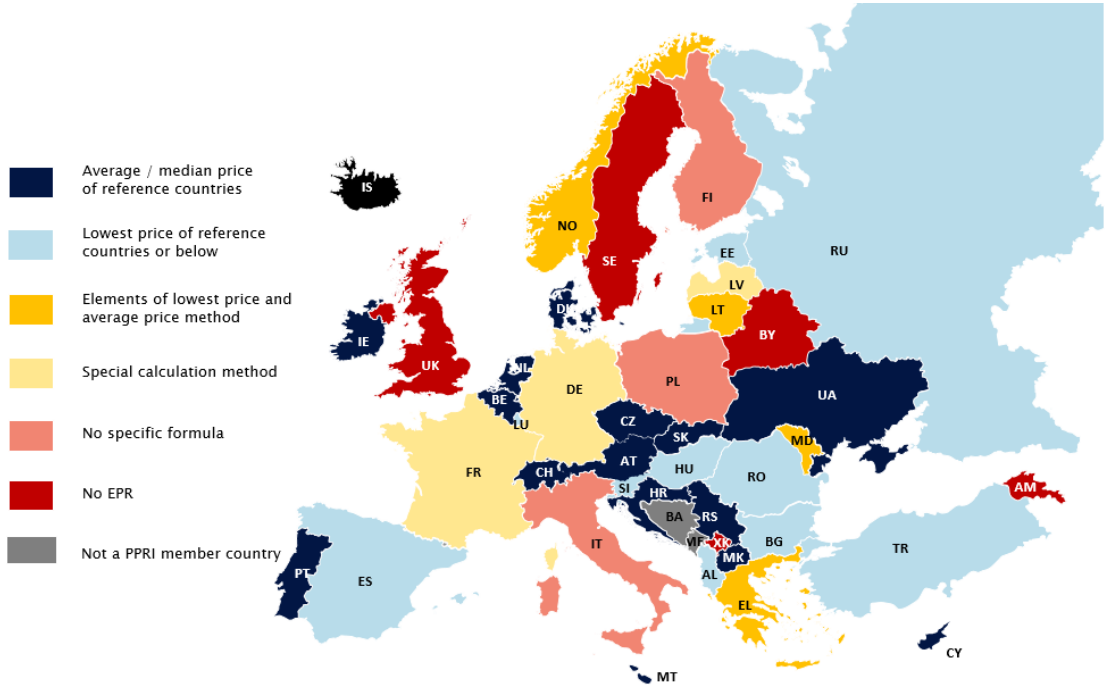
Differences between countries exist with respect to the scope of medicines covered by EPR, e.g. originator, prescription-only or new innovative medicines.

4.2.1.2 Calculation of the EPR benchmark

Different methodological approaches are applied to calculate the benchmark price. 18 countries apply an average / median price, and 9 countries determine their price as being equal to or lower than the lowest price of the reference countries. 6 countries use a combination of average and lowest price (e.g. average of the three of lowest prices in Lithuania and Moldova). In Ukraine, the

median of the prices in defined reference countries is taken for the price regulation of medicines under the 'Affordable Medicine Programme', which are 23 INN for cardio-vascular diseases, bronchial asthma and diabetes type 2, whereas for insulins the average of the prices of a larger group of reference countries is considered (cf. Figure 4.3).

Figure 4.3:
Pricing policies – Methodology to determine the reference price under EPR in PPRI network member countries, 2018



Average / median of reference countries: Canada
Average price of reference countries: Israel, Republic of Korea
Elements of lowest price and average price method: Kazakhstan
No EPR: Kyrgyzstan
No information available: South Africa

Source: PPRI network members; data compilation by PPRI secretariat

Table 4.3:
Pricing policies - Countries in baskets for EPR in PPRI network member countries, 2018

C	AL	AM	AT	BY	BE	BG	CA	HR	CY	CZ	DK	EE	FI	FR	DE	EL	HU	IS	IE	IL	IT	KZ	XK	KG	LV	LT	LU	MT	MD	NL	MK	NO	PL	PT	RS	KR	RO	RU	SK	SI	ZA	ES	SE	CH	TR	UA	UK	Other	
AL																																																	5
AM	not applicable																																																0
AT																																																	26
BY	not applicable																																																0
BE																																																	27
BG																																																	17
CA																																																US	6
HR																																																	5
CY																																																	9
CZ																																																	18
DK																																																	9
EE																																																	3
FI																																																LI	30
FR																																																	4
DE																																																	15
EL																																																	27
HU																																																	30
IS																																																	4
IE																																																	14
IL																																																	7
IT																																																	25
KZ																																																AU, CL, JP, NZ, US	39
XK	not applicable																																																0
KG	not applicable																																																0
LV																																																	7
LT																																																	27
LU	reference to the country of origin																																																0
MT																																																	12
MD																																																	9
NL																																																	4
MK																																																	12
NO																																																	9
PL																																																	30
PT																																																	3
RS	no information																																																0
KR																																																JP, US	7
RO																																																	12
RU																																																	12
SK																																																	27
SI																																																	3
ZA	no information																																																0
ES																																																		14
SE	not applicable																																																	0
CH																																																		9
TR																																																		5
UA																																																		5
UK	not applicable																																																	0
	0	1	19	1	22	12	1	12	10	19	20	13	17	26	24	19	18	5	15	1	25	0	0	1	14	16	10	8	0	19	1	8	16	18	3	1	13	1	20	16	0	22	20	5	2	1	24		

Country abbreviations indicated horizontally inform about the reference countries of the EPR-applying PPRI network member countries (listed vertically).
Austria: consideration of Croatia as reference country from July 2020 on; Denmark: EPR only used in the hospital sector; Germany: EPR is provided for in law but rarely used in practice; North Macedonia: 12 reference countries for pricing and 4 (Bulgaria, Croatia, Republic of Serbia, Slovenia) plus lowest Macedonian registered price for reimbursement; Ukraine: information on reference countries refers to price regulation for medicines under the 'Affordable Medicine Programme', which are 23 INN for cardio-vascular diseases, bronchial asthma and diabetes type 2. For insulins, Bulgaria, Moldova and Republic of Serbia are additionally considered (a total of 8 reference countries).

Source: PPRI network members; data compilation by PPRI secretariat

4.2.1.3 Country baskets

In 2018, the number of countries included in the country baskets ranges from 1 (Luxembourg) to 39 countries (Kazakhstan). 20 countries have fewer than 10 reference countries, and 5 countries (Austria, Belgium, Greece, Lithuania and Slovakia) reference to all or nearly all other 27 EU Member States. France and Italy are the countries most referenced to, followed by Germany and UK (Table 4.3).

One challenge in this respect is the non-availability of data in the reference countries. Some countries use solely the data that are available whereas others have some defined rules such as the use of prices of the country of origin, specific algorithms or re-evaluations (Vogler et al. 2016).

4.2.2 Internal price referencing: price link policies for generic and biosimilar medicines

A prerequisite for the ➲ internal price referencing policy (i.e. referencing to the prices of identical or similar medicines in the same country) is the availability of comparable medicines (usually off-patent medicines). Internal price referencing can have different variants; the main common ones include a price link for ➲ generic and ➲ biosimilar medicines or a reference price system. The latter is described in chapter 5.3 as it is rather a reimbursement policy than a pricing policy.

4.2.2.1 Generic price link

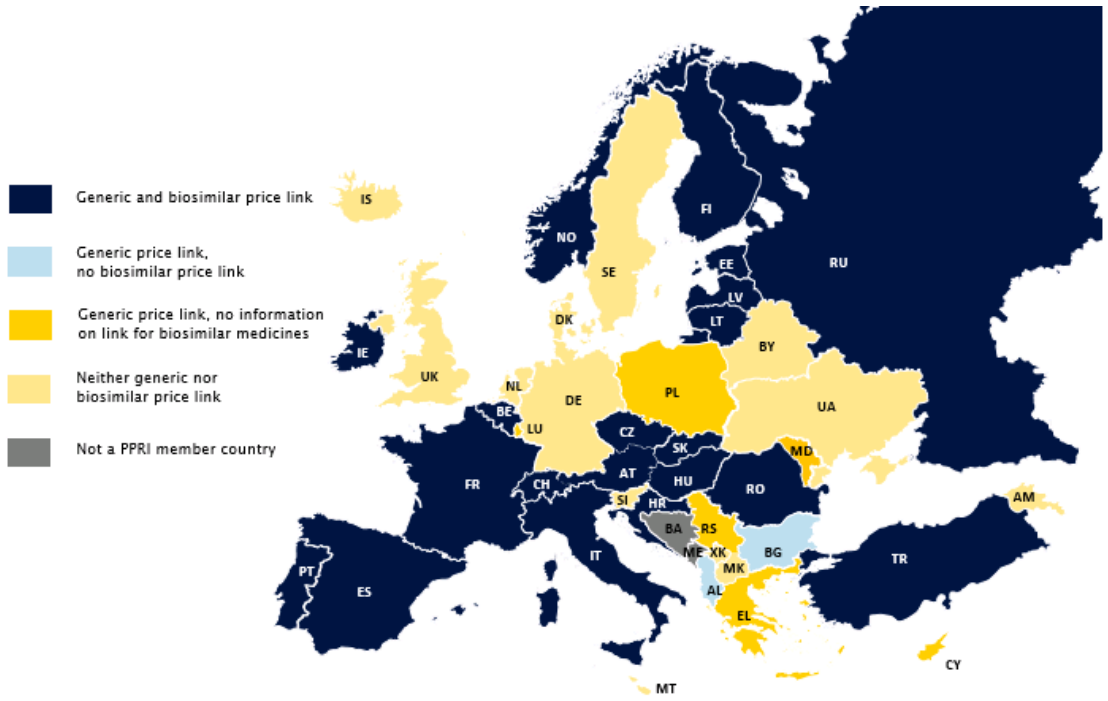
The ➲ generic price link policy relates to a commonly applied pricing policy that links the prices of generic medicines to the originator price. It is in place in 32 PPRI member countries (Figure 4.4). Typically, the first generic coming on the market, or requesting reimbursement (reimbursable generic), is required to be priced lower than the originator medicine, and the second generic must be lower than the first one, with additional price reductions for subsequent generics. Price reductions for the first generics tend to be between 20% and 50% but may also be up to 80%; subsequent price reductions for further generics are usually smaller. In some countries (e.g. Norway, some provinces of Canada) the sales volume of the active ingredient before patent expiry determines the percentage rate. A generic price link policy may also provide for mandatory price reductions for originator medicines at patent expiry or at a defined period afterwards (in at least seven PPRI member countries, for example Austria, France, Republic of Korea).

4.2.2.2 Biosimilar price link

The price link policy is also applied for biosimilar medicines (➲ biosimilar price link) but less frequently: 23 of the 32 PPRI member countries with a 'generic price link' also set the price of

(reimbursable) biosimilar medicines in relation to the reference medicine (Figure 4.4), and two countries (Albania, Bulgaria) reported on applying a generic price link but no linkage policy for biosimilar medicines (no information or no specific regulation related to biosimilar medicines for 7 countries). Usually, biosimilar medicines are granted higher prices than generics, i.e. the required price difference between a biosimilar and the biological reference medicine is lower than the corresponding reduction for a generic medicine. The required price difference is usually less than 50%, and rates of 15%–20% are in place in some countries. Only three countries (Italy, Kazakhstan and Latvia) apply the same rates for generic and biosimilar medicines in their price link policies.

Figure 4.4:
Pricing policies – Application of a price link policy related to generic or biosimilar medicines in PPRI network member countries, 2018



Generic and biosimilar price link: Kazakhstan, Republic of Korea, South Africa
Generic price link, no information on link for biosimilar medicines: Canada
Neither generic nor biosimilar price link: Israel, Kyrgyzstan

Source: PPRI network members; data compilation by PPRI secretariat

15 PPRI countries have no price link policies (neither for generics nor for biosimilar medicines). These countries might have no price regulation (e.g. Armenia, Kosovo), set generic and biosimilar

medicines based on other pricing policies (e.g. external price referencing)[7] or tend to have competition for identical or similar medicines, sometimes supported by competitive procurement methods (e.g. tendering, cf. chapter 4.2.5).

4.2.3 Value based pricing

Though commonly used, there is no clear definition for ➲ value based pricing (VBP). In a full-fledged VBP, the pricing and ➲ reimbursement systems are integrated. Among the PPRI member countries, Sweden is the only country with a full-fledged VBP system. In several other PPRI countries, health technology assessments (HTA) and pharmacoeconomic instruments (e.g. cost-effectiveness analyses) are used to support mainly reimbursement decisions (reimbursement prices) of new medicines (cf. chapter 6.1.2).

4.2.4 Conditional pricing

➲ Conditional pricing is particularly applied for new medicines with uncertainty concerning their value, and thus real-world data about their effectiveness in clinical practice need to be collected. Besides health outcomes ('success' of the medicine in treating a disease), further conditions could also be procurement-relevant aspects such as a minimum number of units purchased or a capping on price or utilisation. In the PPRI member countries of the EU, the commonly applied term related to conditional pricing (and reimbursement) is managed-entry agreement (MEA). Its use in the PPRI member countries will be presented in chapter 6.1.3 in the section on high-priced medicines.

4.2.5 Tendering

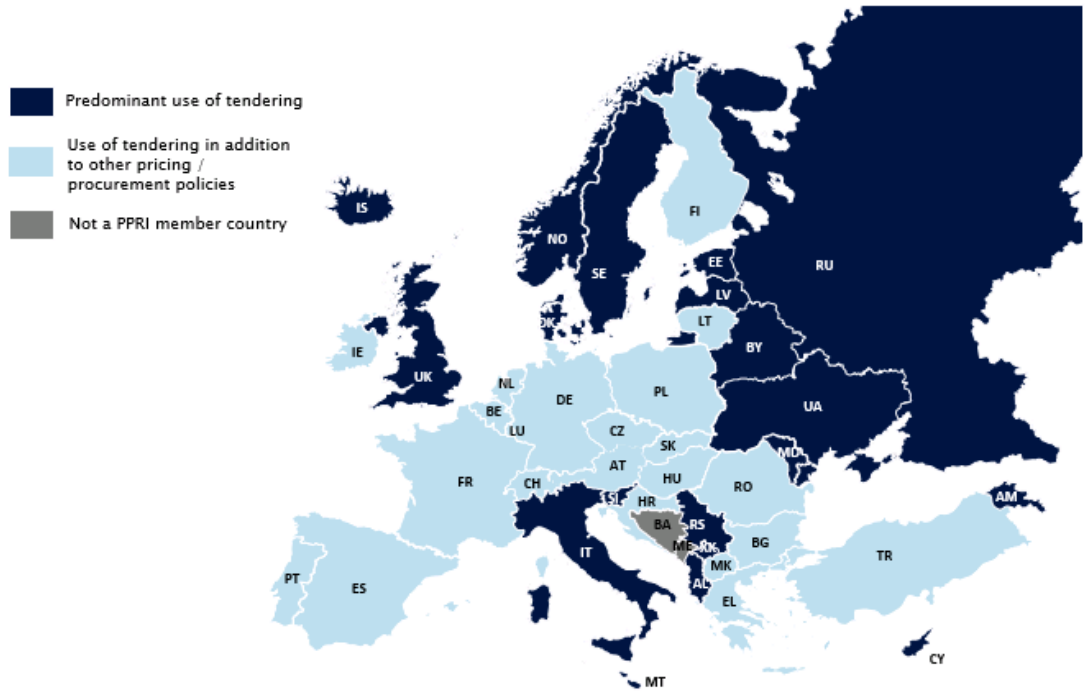
4.2.5.1 Tendering in the hospital sector

46 of the 47 PPRI member countries reported using ➲ tendering of medicines as ➲ procurement policy in the hospital sector. Whereas 23 PPRI member countries apply a tender process in addition to other pricing or procurement strategies, tendering is in predominant procurement policy for medicines used in hospitals in 23 countries. The use of tendering is particularly in place in smaller countries and in countries in the Balkans and Central Asia (cf. Figure 4.5).

---

7 Some countries use a mix of internal as well as external price referencing for generic and biosimilar medicines (e.g. EPR serves as first indication and then a generic / biosimilar price link is applied).

Figure 4.5:
Pricing policies – Tendering for medicines in the inpatient sector in PPRI network member countries, 2018



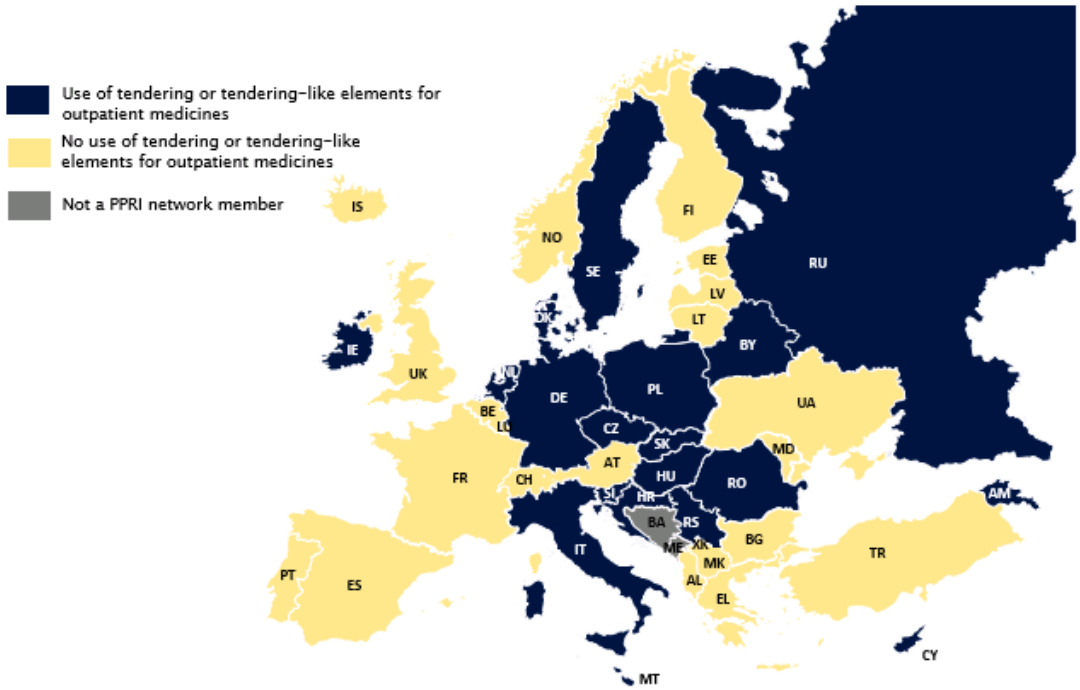
Predominant use of tendering: Kazakhstan, Kyrgyzstan, Republic of Korea, South Africa
Use of tendering in addition to other pricing / procurement policies: Canada
No use of tendering: Israel

Source: PPRI network members; data compilation by PPRI secretariat

4.2.5.2 Tendering in the outpatient sector

In the outpatient sector, however, there is a different pattern. Tendering, or procurement policies with tendering, or auction elements, are not applied in the majority of the PPRI member countries (29 out of 47 PPRI member countries). Still, 18 PPRI member countries use tendering, or tender-like procedures or auction elements, for parts of outpatient medicines (Figure 4.6). This concerns mainly medicines with competitor products, thus medicines in the generic or biosimilar sector. For instance, in Italy tendering in the outpatient sector is applied in case of the direct and 'per conto' distribution when medicines are purchased by public health facilities either dispensed directly by them (for instance the first cycle of treatment after hospital discharge – so-called direct distribution) or dispensed by community pharmacies through specific agreements between the pharmacists' association and local health unit (so-called 'per conto' distribution).

Figure 4.6:
Pricing policies – Tendering and policies with tendering elements for medicines in the outpatient sector in PPRI network member countries, 2018



No use of tendering or tendering-like elements for outpatient medicines: Canada, Israel, Kazakhstan, Kyrgyzstan, Republic of Korea, South Africa

Source: PPRI network members; data compilation by PPRI secretariat

4.2.6 Cost-plus pricing

➲ Cost-plus pricing used to be a major pricing policy but an increasing number of countries discontinued this policy. While two decades ago some PPRI member countries (e.g. Cyprus – for locally produced generics, France, Greece, Spain, Slovakia, Turkey) used cost-plus in their pricing decisions, none of them now uses cost-plus pricing policy. Still, pricing authorities consider data on production cost and other costs as additional information for the price negotiations (e.g. Spain).

4.2.7 Collaborative pricing

In addition to these pricing policies, some PPRI member countries have been involved in ➲ collaborative pricing approaches with other countries (cross-country collaborations). These may result

in ➲ joint procurement and/or joint pricing (and reimbursement) negotiations for specific medicines (in addition to collaborations in other areas such as information sharing, HTA or horizon scanning, Vogler et al. 2018), but, overall, pricing (and reimbursement) continues to be a national competence also for countries that are involved in pricing and reimbursement collaborations. The most widely-recognized cross-country collaborations in which PPRI network members are involved include the Beneluxa initiative of Belgium, the Netherlands, Luxembourg, Austria and Ireland (Beneluxa initiative 2019), the Valletta Declaration that involves Mediterranean and Central Eastern countries (Valletta Declaration 2018) and 'Fair and Affordable Pricing' (FAAP) (Ministerstwo Zdrowia 2019; for an overview of these and further collaborations see also European Commission 2018).

Discussion about the possible introduction of ➲ differential pricing as a pricing policy (i.e. based on principles and mechanisms of collaborations determined by the governments, in full transparency) has been ongoing for some years. Legal issues and the existence of parallel trade have been identified as major challenges in Europe, and such a country-driven collaborative approach would require strong political will (Vogler et al. 2016).

4.3 Pricing in the supply chain

The final price of a medicine is the result of different price components, including the ➲ distribution remuneration for ➲ wholesale companies and ➲ community pharmacies, and sales taxes.

4.3.1 Remuneration for wholesalers and pharmacies

In the majority of the 47 PPRI member countries (32 countries), the remuneration for wholesalers is regulated; so the ➲ mark-up and ➲ margin that wholesale companies are allowed to charge is limited. In several countries, the wholesale remuneration regulation addresses all medicines (a few countries, e.g. Austria, have different schemes for different medicine groups), but in some countries its scope is limited (usually to reimbursable medicines, e.g. in Switzerland).

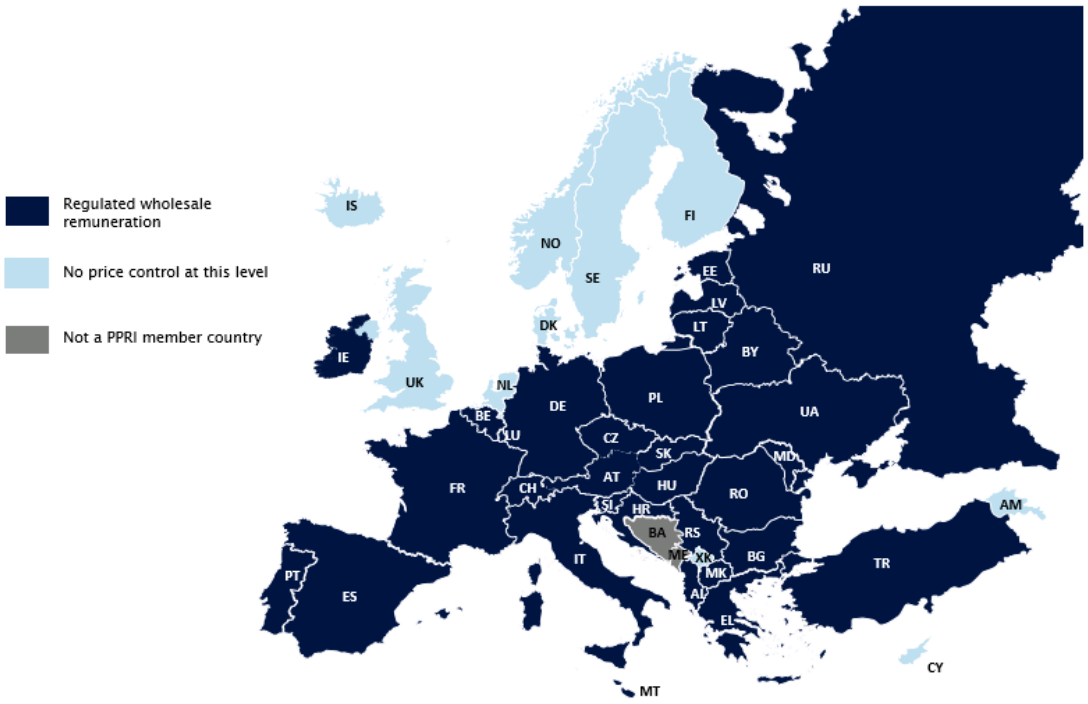
PPRI member countries which regulate wholesale remuneration usually apply a ➲ regressive mark-up or margin scheme whereas a ➲ linear mark-up or margin (e.g. Italy) is much less commonly used. Solely ➲ price-oriented remuneration regulation is in place.

11 PPRI network member countries have no regulated wholesale remuneration because they set medicine prices at the level of the pharmacy purchasing price, and the ex-factory prices and wholesale remuneration remain at the discretion of the manufacturer and wholesaler. In addition, four countries (e.g. Armenia, Kosovo) have no price control at any price type at all, and thus they do not regulate wholesale remuneration (Figure 4.7).

Remuneration of pharmacies is regulated in most PPRI network member countries (all but Kosovo and three Central Asian countries that have no price regulation at all). The scope of medicines

covered in regulated countries is nearly always the same as for the wholesale remuneration (either all or reimbursed medicines).

Figure 4.7:
Pricing policies – Regulation of wholesale remuneration in PPRI network member countries, 2018



Regulated wholesale remuneration: Canada
No price control at this level: Israel, Kazakhstan, Kyrgyzstan, Republic of Korea, South Africa:

Source: PPRI network members; data compilation by PPRI secretariat

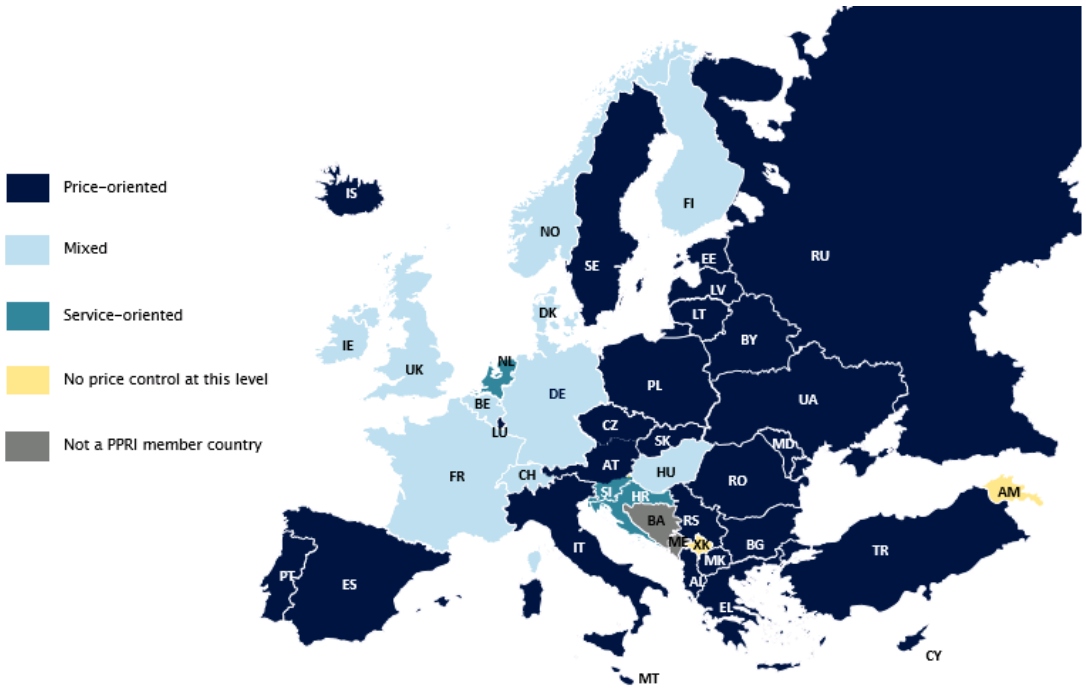
Pharmacy remuneration is regulated in a price-oriented form (29 countries) and is thus usually designed as regressive mark-up or margin schemes with defined percentage rates.[8] In recent years, some PPRI countries introduced a price-independent remuneration element, e.g. a ➲ dispensing fee. However, in these cases, ➲ fee-for-service pharmacy remuneration usually adds to

8

In the UK, the medicine margin is the difference between what pharmacy contractors pay when they purchase a product to be dispensed and the amount they are reimbursed by the NHS for that product. The cheaper an individual pharmacy sources a product at, the more medicine margin they individually retain. The Department of Health assesses the medicine margin achieved by pharmacy contractors through an annual medicine margin survey. The difference between the medicine margin found in the survey and the medicine margin set as part of the Community Pharmacy Contractual Framework determines whether there needs to be any adjustments to payments. If too much margin is being delivered then downwards adjustments are needed, if not enough margin is being delivered upwards adjustments are made. Usually these adjustments are made through reimbursement prices of most commonly prescribed generic medicines.

the price-oriented remuneration (9 countries), and only five countries have a fee-for-service pharmacy remuneration as a sole remuneration for pharmacies (Figure 4.8). The extent of pharmacy remuneration can also be impacted (reduced or increased) by discounts (e.g. in Italy, there is a mandatory discount of pharmacies to the NHS, whose amounts depends on the geopgraphic location and the turnover of the pharmacy, and in France, wholesale companies may grant a discount of up to 40% for generics in the outpatient sector to the community pharmacy).

Figure 4.8:
Pricing policies – Regulation of pharmacy remuneration in PPRI network member countries, 2018



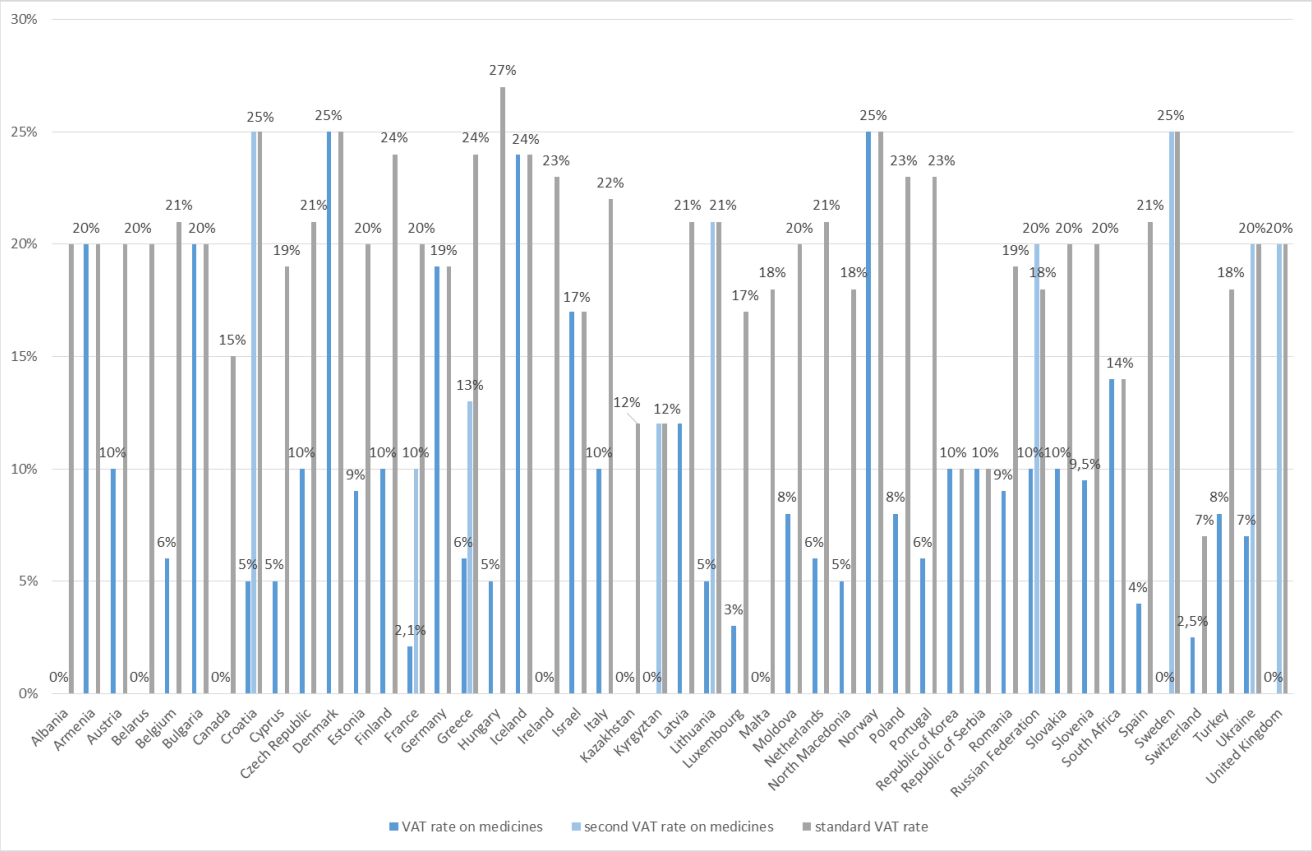
Price-oriented: Canada, Israel
Service-oriented: Republic of Korea, South Africa
No price control at this level: Kazakhstan, Kyrgyzstan

Source: PPRI network members; data compilation by PPRI secretariat

4.3.2 Taxes

Another important element that defines the final price (➲ pharmacy retail price, consumer price) is duties, tariffs and taxes. In the PPRI member countries, the relevant tax is the ➲ value-added tax (VAT) which is usually applied on the (pharmacy retail price). With the exception of a few countries (e.g. Denmark, Norway), the VAT on medicines is lower than the standard VAT rate. A few countries exempt all medicines (e.g. Belarus, Malta) or defined medicines (e.g. Kyrgyzstan, Sweden, UK) from the VAT. A few countries (e.g. France, Lithuania) have defined VAT rates for different types of medicines (cf. Figure 4.9). A few PPRI member countries apply additional taxes that impact the final prices of a medicine (e.g. a 'tax' for the benefit of the Medicines Agency INFARMED in Portugal).

Figure 4.9:
Pricing policies – Value-added tax on medicines in PPRI network member countries, 2018



Differentiated rates for reimbursable and non-reimbursable medicines in Croatia, France and Lithuania; for prescription-only medicines (POM) and non-prescription medicines (NPM) in Kosovo, Sweden and UK; for medicines in general (POM and NPM) and for specific groups (standard categories: heparins, blood products, other muscle relaxants, peripherally acting agents, antidiarrheal microorganisms, enzyme preparations) in Greece; and for authorised and non-authorised medicines in Ukraine. All VAT rates in Ireland are variable depending on service / product (0–23%) including medicines. Oral medicines in Ireland attract a 0% rate. In addition to a reduced VAT (8%) for POM in Kosovo, some medicines are exempt from VAT (antianemics and other medicines for treatment of blood diseases; antidiabetics / insulin; cytostatic (cytotoxic) medicines; haemodialysis and peritoneal dialysis; fluid and electrolyte substituents). Source: PPRI network members; data compilation by PPRI secretariat

5 Reimbursement policies

Governments in PPRI network member countries apply a range of reimbursement policies in the outpatient and inpatient sectors. As for pricing policies, the same policies may differ in design between the countries. As shown in previous chapters (particularly chapter 3.1), there is linkage between pricing and reimbursement.

5.1 Reimbursement process

5.1.1 Reimbursement decision

The ➲ reimbursement process may vary between countries depending on the authorities and stakeholders involved, however, some common characteristics can be observed: In the majority of PPRI network member countries the competent authority for pricing and/or reimbursement or the public payer requires the marketing authorisation holder to submit an application dossier if the latter intends their medicine to be considered for reimbursement. After submission of the application dossier, scientific evidence on the medicine's benefit is commonly appraised by an independent expert committee tasked to advise decision-makers on reimbursement.

The final decision on pharmaceutical reimbursement is usually in the competence of social health insurance (e.g. Austria, France, Hungary, and Republic of Serbia) or the Ministry of Health / Social Affairs (even in countries with a SHI system, such as Greece, Netherlands, Slovakia). In France the reimbursement decision is taken by the Ministry of Social Affairs, however, the social health insurance decides on the reimbursement rate. In some countries (e.g. Denmark, Italy), medicines agencies are mandated to take reimbursement decisions, while in others, specific institutions are responsible for reimbursement (e.g. Bulgaria – National Council on Prices and Reimbursement of Medicinal Products, Iceland – pricing and reimbursement agency, Sweden – the Dental and Pharmaceutical Benefits Agency TLV). Institutions responsible for the pricing of medicines may also oversee reimbursement (e.g. Bulgaria, Iceland, Sweden), see also chapter 3.1 (particularly Table 3.1).

In several PPRI network member countries, the same authority is in charge of reimbursement decisions for both outpatient and inpatient medicines (e.g. Cyprus, Germany, Portugal). In addition, decisions on reimbursement of inpatient medicines and the inclusion of inpatient medicines in a ➲ hospital pharmaceutical formulary may also be taken at the hospital level; in some PPRI network member countries (e.g. Austria, Finland), hospitals have their own positive list with centralized decision-making only applying to the outpatient sector (cf. chapter 5.3.3).

In some countries with a NHS (including Italy and Spain), decisions for pharmaceutical reimbursement are taken at the federal (national) level, whereas individual regions purchase medicines and may negotiate specific arrangements, for instance ➲ managed entry agreements (MEA).

5.1.2 Reimbursement criteria

Most PPRI member countries apply a limited set of different criteria, which may overlap, to guide decision-making on pharmaceutical reimbursement. In addition to the (added) therapeutic benefit of a medicine and medical need, financial considerations such as budget impact and cost-effectiveness are key criteria to inform the decision about the inclusion of a medicine into reimbursement (Table 5.1).

Table 5.1:
Reimbursement policies – Criteria for inclusion in reimbursement in PPRI network member countries, 2018

Country	(Added) therapeutic benefit	Budget impact	Cost-effectiveness	Medical need / priority	Safety	Others
Albania	no information available					
Armenia	√			√	√	
Austria	√		√		√	
Belarus			√			
Belgium	√	√[1]				
Bulgaria	√	√	√		√	
Canada[2]	√	√	√	√		
Croatia	√					
Cyprus	no information available					
Czech Republic	√	√	√	√	√	√[3]
Denmark	√				√	
Estonia	√	√	√	√	√	
Finland	√	√	√			√[4]
France	√[4]					√[5]
Germany[6]						
Greece	√	√	√	√	√	√[7]
Hungary	√	√	√	√		
Iceland	√	√	√	√	√	
Ireland	√	√	√	√	√	√
Israel	√	√		√	√	
Italy	√	√	√		√	
Kazakhstan	√		√	√		
Kosovo[8]	√	√		√		
Kyrgyzstan				√		√
Latvia	√	√	√			
Lithuania	√	√	√ (partially)		√	
Luxembourg	no information available					
Malta	√	√	√	√	√	
Moldova	√	√		√	√	
Netherlands	√	√	√			
North Macedonia	√	√	√			
Norway	√	√	√	√	√	

Country	(Added) therapeutic benefit	Budget impact	Cost-effec-tiveness	Medical need / priority	Safety	Others
Poland	√	√	√	√	√	
Portugal	√	√	√		√	
Republic of Korea			√			
Republic of Serbia	√					
Romania	√	√	√	√		
Russian Federation	√				√	√[9]
Slovakia	√	√	√		√	
Slovenia	√	√	√	√	√	
South Africa	no information available					
Spain	√	√	√	√		
Sweden			√			√[10]
Switzerland	√	√	√	√	√	
Turkey		√	√	√		
Ukraine	√			√		
United King-dom	√		√	√		

[1] The budget impact criterion in Belgium only relevant for medicines with added value (not applicable for generics, me-too products and orphan medicines)
[2] Safety is a prerequisite for marketing authorisation in Canada. HTA bodies review the therapeutic benefit and cost-effectiveness; in addition public plans can also take budget impact and medical priority / need into account; the latter especially for rare diseases and oncology.
[3] 'Others' include in the Czech Republic 'public interest', which is defined as 'interest on ensuring the quality and availability of reimbursed services, the functioning of the health care system and its stability within the financial possibilities of the public health insurance system' and 'guidelines of medical expert societies' as well as 'necessary duration of treatment' or 'usual dosage'
[4] 'Others' may include prices of comparable medicines in Finland and the price of the medicine in question in the reference countries (other EEA countries)
[5] In France, the criterion is therapeutic benefit but not added therapeutic benefit. The therapeutic benefit which guides the reimbursement decision is based on five criteria: Disease severity, efficacy / tolerance balance, preventive / curative / symptomatic use, therapeutic strategy position and public health interest.
[6] In Germany, none of the listed criteria is of relevance since a medicine is considered reimbursable as soon as it is launched
[7] In Greece, as an additional criterion new active substances must be on the market in at least 9 countries and reimbursed in 6 countries (thereof three include Austria, Belgium, Finland, France, Netherlands, Portugal, Spain, Sweden and United Kingdom). There are some exemptions.
[8] Indicated criteria are applied to the National Essential Medicines List (NEML) that comprises inpatient medicines, since Kosovo has no outpatient reimbursement list.
[9] In the Russian Federation, cost minimization is taken into account. Other methods of clinical and economic analyses can be used as additional, but are not decisive criteria.
[10] Other criteria in Sweden are the 'human value principle' and the 'need and solidarity principle'.
No data are available for Albania, Cyprus, Luxembourg and South Africa

Source: PPRI network members; data compilation by PPRI secretariat

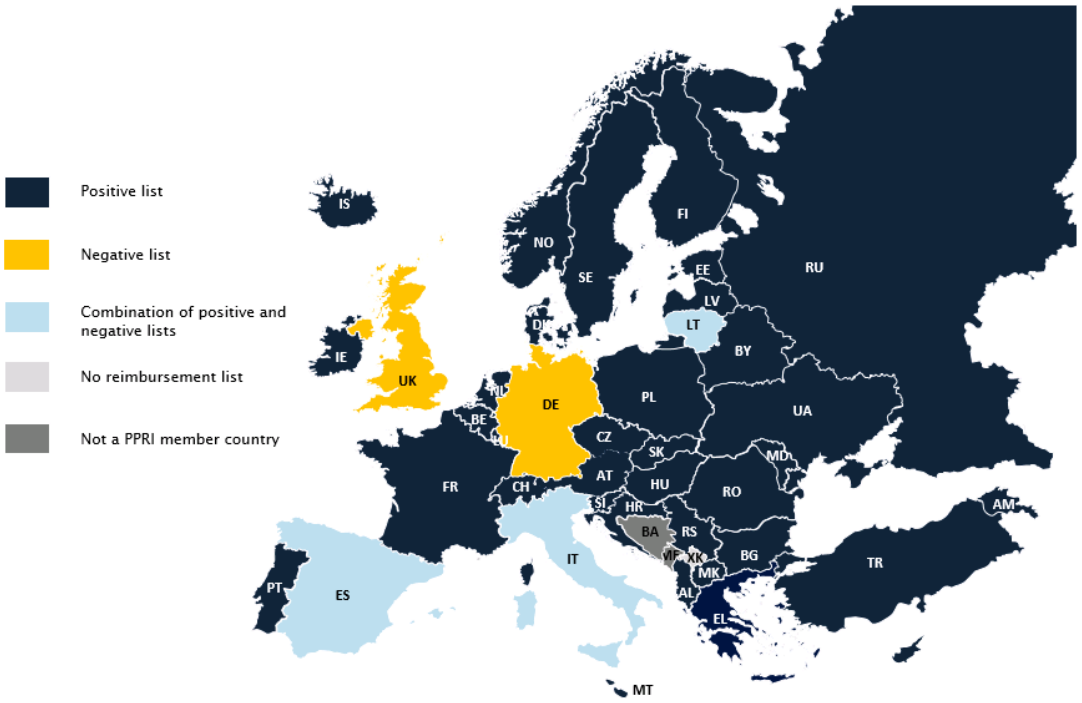
5.2 Reimbursement lists and rates

Medicines that are considered as eligible for reimbursement are included in ➲ reimbursement lists (formularies). The number of medicines included into reimbursement may vary considerably.

5.2.1 Reimbursement lists in the outpatient sector

46 PPRI network member countries have one or more reimbursement lists for outpatient medicines. Kosovo is the only country without any outpatient reimbursement list. 41 of the 46 countries apply solely ➲ positive lists. Germany and UK have a ➲ negative list, whereas Italy, Lithuania and Spain apply both a positive and a negative list. Some countries have adopted more than one positive list or more than one negative list (e.g. Lithuania, United Kingdom with a 'grey list' and a 'black list'). Another form of implementation is having different categories (Austria) within the lists.

Figure 5.1:
Reimbursement policies - Reimbursement lists in the outpatient sector in PPRI network member countries, 2018



Positive list: Canada (at the province / territorial level), Israel, Kazakhstan, Kyrgyzstan, Republic of Korea, South Africa

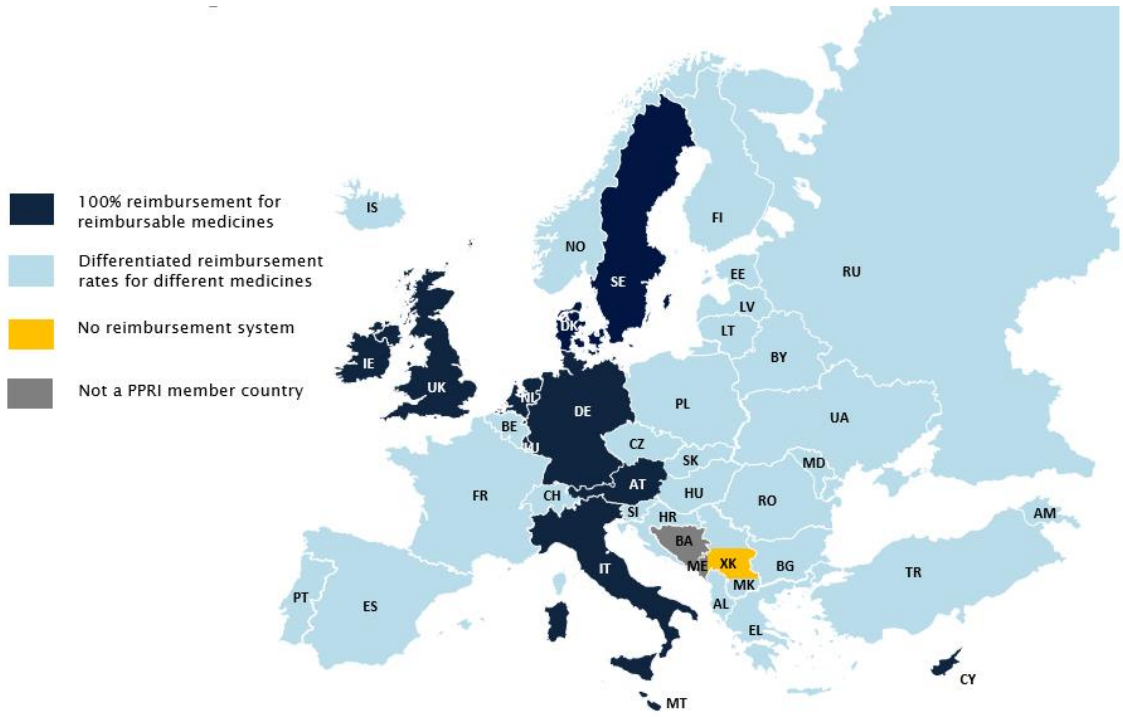
Source: PPRI network members; data compilation by PPRI secretariat

5.2.2 Reimbursement rates in the outpatient sector

Expenditure on reimbursable medicines may be fully or partially covered by third party payers.

In 35 of the 46 PPRI network member countries which have a reimbursement system for outpatient medicines (all but Kosovo), differentiated percentage ➲ reimbursement rates are applied. In the 32 of these countries (all but Canada), some of the medicines included in the outpatient reimbursement system (i.e. benefits package scheme) such as essential medicines usually have 100% reimbursement, whereas other medicines have lower reimbursement rates. In eleven countries (e.g. Austria, Germany, Italy), all reimbursable medicines have a 100% reimbursement rate, however other co-payments such as prescription fees, deductibles (cf. chapter 5.4.1) and/or co-payments due to a reference price system (cf. chapter 5.3) may still apply. In addition, the scope of medicines eligible for reimbursement and included in the public sector may vary considerably across these countries.

Figure 5.2:
Reimbursement policies - Reimbursement rates of outpatient reimbursable medicines in PPRI network member countries, 2018



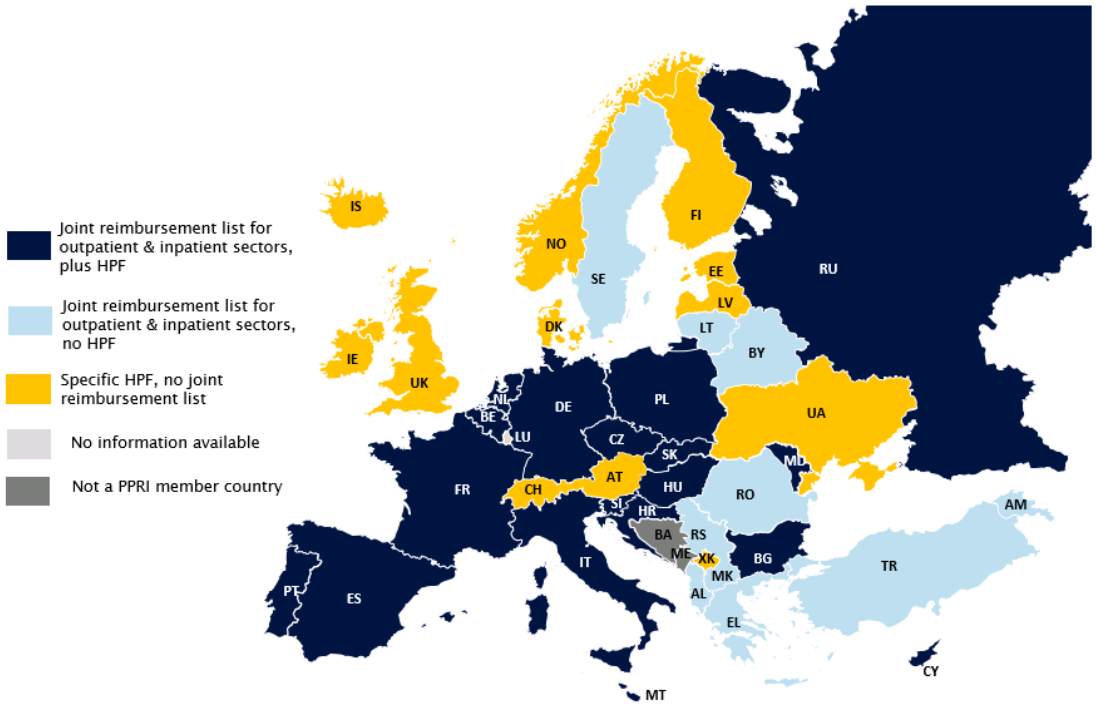
100% reimbursement rate for all reimbursable medicines: Kazakhstan
Differentiated reimbursement rates for different medicines: Israel, Kyrgyzstan, Republic of Korea, South Africa; Canada has differentiated rates for different provincial plans, each having their specific design and reimbursement rates.

Source: PPRI network members; data compilation by PPRI secretariat

5.2.3 Reimbursement lists in the inpatient sector

In the inpatient sector, reimbursement lists for medicines are commonly called ➲ hospital pharmaceutical formularies (HPF). In the majority of PPRI network member countries hospitals have their own HPF which are used as basis for the eligibility of a medicine to be administered and funded in the hospital sector. In addition to HPF at the level of individual hospitals, HPF at national level (e.g. in Portugal) or at regional level (Denmark, Norway) may also be in place.

Figure 5.3:
Reimbursement policies – Reimbursement lists (hospital pharmaceutical formularies, HPF) in the inpatient sector in PPRI network member countries, 2018



Joint reimbursement list for outpatient and inpatient sectors, plus HPF: Canada, Israel, Republic of Korea, South Africa
Joint reimbursement list for outpatient and inpatient sectors, no HPF: Kazakhstan, Kyrgyzstan

Source: PPRI network members; data compilation by PPRI secretariat

Reimbursement may be organised in a way that the reimbursement decision is taken for both outpatient and inpatient medicines, resulting in a joint reimbursement list (positive list) that is applicable for outpatient and inpatient sectors (the list may be divided into different sections or categories, which relate to outpatient and inpatient medicines respectively). Joint reimbursement lists are in place in 31 of the 46 PPRI network member countries (missing information for Luxembourg). Out of these countries, 20 countries (e.g. Belgium, Bulgaria, Republic of Korea, Slovakia, Slovenia) have one or more HPF in place, whereas in 11 countries (e.g. Lithuania, Republic of Serbia, Turkey) there is no specific HPF (other than the national reimbursement list). In contrast, in

15 PPRI network member countries (e.g. Austria, Denmark, Estonia, Norway) reimbursement processes between the outpatient and inpatient sectors are separated. The positive list for the outpatient sector is not applicable for the inpatient sector, in which separate formularies (at the level of individual hospitals, but also at national or regional levels, see above) are in place (Figure 5.3). The decision about the inclusion of medicines into a HPF is taken by Pharmaceutical and Therapeutic Committees.

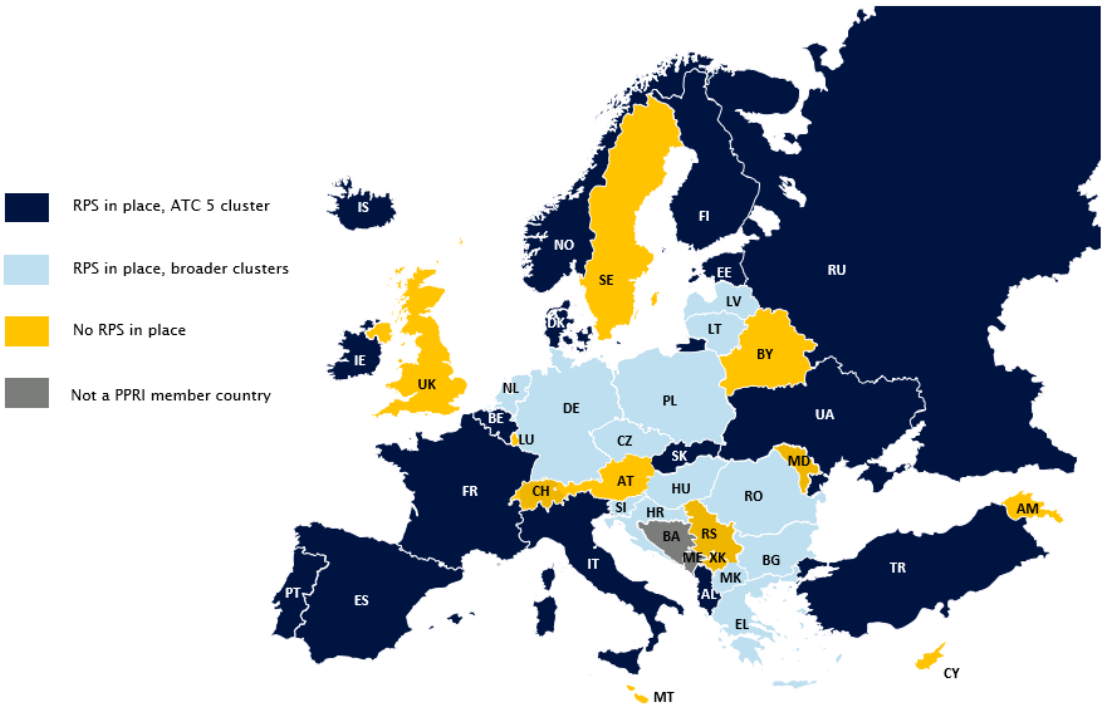
5.3 Reference price system

Several PPRI member countries (32 out of the total of 47; however in Canada it is only applied in one province) apply a reimbursement policy for outpatient medicines in which the third party payer covers the same reimbursement amount for all identical or similar medicines clustered into a ➲ reference group. If the price of a medicine is above this reimbursement amount (➲ reference price), the patient has to pay the difference between the reference price and the pharmacy retail price. This policy is called ➲ reference price system and makes use of the efficiency gains of substitutable lower-priced medicines, such as generics. Typically, a reference group includes the off-patent originator medicine and its generic alternatives. Some countries, such as Germany and Slovenia, consider copy products and me-too products when establishing reference groups.

The broader the reference groups are defined in terms of included substitutable medicines, the more savings countries may achieve. At the time of the introduction of a reference price system, usually medicines of the same active ingredient (clusters at level 5 of the Anatomical Therapeutic Chemical / ATC classification) are clustered in a reference group, and in the course of time, the reference groups become broader. As of 2018, 18 PPRI network member countries had reference groups at ATC 5 level, and 14 countries at ATC 4 level or some other broader interpretation (Figure 5.4). Further differences in the methodology and organisation of a reference price system may apply. In the majority of countries with a reference price system (at least 16 countries), the lowest price of the medicines in a reference group is taken as the reference price.

Since a reference price system is a policy linked to off-patent medicines, it is usually accompanied by ➲ demand-side measures that aim to enhance the uptake of generics and lower-priced medicines (such as ➲ prescribing by INN, cf. chapter 6.2.1 and ➲ pharmaceutical substitution, cf. chapter 6.2.2).

Figure 5.4:
Reimbursement policies – Reference price system in PPRI network member countries, 2018



RPS in place, ATC 5 cluster: Israel, Kyrgyzstan (kind of RPS)
RPS in place, broader clusters: Canada (only in one province: British Columbia)
No RPS in place: Kazakhstan, Republic of Korea, South Africa

Source: PPRI network members; data compilation by PPRI secretariat

5.4 Patient payments for medicines

Patient payments for health services, including pharmaceuticals, may either be formal or informal – the latter describe contributions in cash or in kind provided by patients or their carers to health care professionals outside the official remuneration schemes of a third party payer. Formal patient payments might either be full ➲ out-of-pocket (OOP) payments for health services, including medicines, that are not covered by funding of a third party payer or patients' contributions towards the expenses of a health service, including a medicine, that is covered by a third party payer (so-called ➲ co-payments).

5.4.1 Co-payments for outpatient medicines

For medicines in the outpatient sector, (direct) co-payments are applied in at least 43 PPRI network member countries (information available for 46 PPRI network member countries, missing information on South Africa). Four countries (Canada, Italy, UK) apply co-payments in some provinces / regions and not in others, and in one country (Ireland) the existence and type of co-payments vary between so-called drug schemes (relating to different population groups and medicines). Kazakhstan and Malta do not apply any co-payment for reimbursable medicines included in the outpatient benefits package scheme but these schemes are rather limited compared to other countries. In Kosovo there is no outpatient reimbursement system, thus no co-payment (patients have to pay fully out-of pocket for outpatient medicines).

Co-payments for outpatient medicines are of three different types:

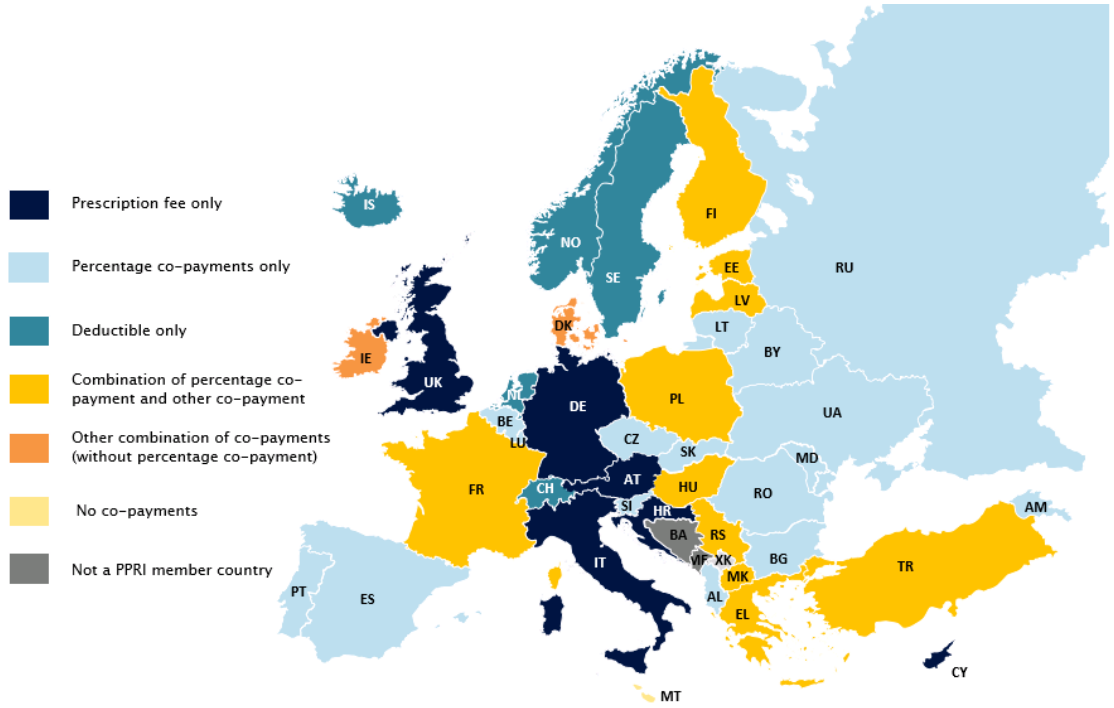
» A ➲ prescription fee is charged on reimbursable medicines in 20 PPRI member countries (including Canada, Italy and UK with a variation per province / region / country and including the Republic of Korea with an application of the prescription fee as sole co-payment for elderly people instead of a percentage co-payment). Among those, it is the sole direct co-payment in six countries (Austria, Croatia, Cyprus, Germany, Italy, UK).
» The most commonly used form is ➲ percentage co-payment that is applied in 30 PPRI member countries. In 18 countries it is the sole form of co-payment for outpatient medicines.
» A ➲ deductible is in place in 9 PPRI countries (Denmark, Finland, Iceland, Netherlands, Norway, Sweden, Switzerland, in some provinces in Canada and in a drug scheme in Ireland), in five of these it is the sole co-payment policy.[9]

Concerning a combination of different types of co-payments for outpatient medicines, the mix of percentage co-payments and a prescription fee is the most commonly applied one (in 12 countries, such as Estonia, France, Greece and Turkey). A combination of a deductible with other co-payment is only in place in some provinces in Canada and in Finland which employs all three types of co-payments. Figure 5.5 provides an overview of the different types of co-payments for outpatient medicines and their specifications in the PPRI network member countries.

In addition, several countries (e.g. Italy) employ an indirect co-payment policy as they have a reference price system in place in which patients have to co-pay the difference between the reimbursed amount (reference price) and the actual pharmacy retail price if they insist on a higher-priced medicine from the cluster (cf. chapter 5.3).

9
Even if the deductible has percentage elements, it is not considered as percentage co-payment.

Figure 5.5:
Reimbursement policies – Co-payments in the outpatient sector in PPRI network member countries, 2018



Percentage co-payment only: Israel, Kyrgyzstan, Republic of Korea (standard co-payment; however, only a prescription fee instead of percentage co-payments is charged for elderly people)
No co-payments: Kazakhstan
No information available: South Africa
Application of co-payments depending on the province: Canada, Italy and United Kingdom (prescription fee only in England; no prescription charge or other co-payment in Wales, Scotland and Northern Ireland); depending on the drug scheme: Ireland. In this report, they are counted as countries with co-payments for outpatient medicines.
Percentage co-payment but no defined percentage rates: Czech Republic, Republic of Serbia, Slovakia
Combination of prescription fee and percentage co-payment: Estonia, France, Greece, Hungary, Latvia, North Macedonia, Poland, Republic of Serbia, Turkey
Combination of prescription fee and deductible: Denmark, Ireland (however, different co-payments apply in different schemes)
Combination of prescription fee, percentage co-payments and deductible: Canada (some territories), Finland
Prescription fee containing a percentage rate element: Germany
Deductible based on percentage rates: Denmark, Iceland, Norway, Sweden, Switzerland
Deductible relates to all health expenditure: Netherlands

Source: PPRI network members; data compilation by PPRI secretariat

Table 5.2:
Reimbursement policies - Reasons for exemptions or reductions in co-payments for outpatient medicines in PPRI network member countries, 2018

Country	Illness / condition		Income / social disadvantage		Age		Disability		Pensioners		War veterans		Pregnant women		Others	
	E	R	E	R	E	R	E	R	E	R	E	R	E	R	E	R
Albania	√	√	√	√	√	√	√	–	√	√	√	√	–	√	–	–
Armenia	√	–	√	√	–	–	–	–	–	–	–	–	–	–	–	–
Austria	√	√	√	√	–	–	–	–	–	–	–	–	–	–	–	–
Belarus	√	–	–	–	–	–	–	√	–	–	√	–	–	–	–	–
Belgium	–	√	–	√	–	–	–	√	–	√	–	√	–	–	–	–
Bulgaria	√	√	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Canada	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]
Croatia	√	–	√	–	√	–	–	–	–	–	√	–	√	–	–	–
Cyprus	√	–	√	–	–	–	–	–	–	–	–	–	–	–	–	–
Czech Republic	–	–	–	–	–	√	–	–	–	–	–	–	–	–	–	–
Denmark	√	–	–	√	–	√	–	√	–	–	–	–	–	–	–	–
Estonia	√	√	–	√	√	√	–	√	–	√	–	–	–	–	–	–
Finland	–	√	–	–	√	–	–	–	–	–	–	√	–	–	–	–
France	√	–	√	–	√	–	–	–	–	–	–	–	√	–	–	–
Germany	–	√	–	√	√	–	–	–	–	–	–	–	–	–	√[2]	–
Greece	√	√	√	√	–	–	(√)[3]	–	–	√[3]	–	–	√[3]	–	–	–
Hungary	√[4]	–	√[4]	–	(√)[4]	–	√[4]	–	(√)[4]	–	–	–	–	–	–	–
Iceland	–	–	–	–	–	√	–	√	–	√	–	–	–	–	–	–
Ireland	√	–	–	–	–	–	–	–	–	–	–	–	–	–	√[5]	–
Israel	–	√	–	–	–	√	–	–	–	√	–	√	–	–	–	–
Italy	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	(√)[1]	–	(√)[1,6]	(√)[1,6]
Kazakhstan	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Kosovo	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Kyrgyzstan	√	√	–	–	–	–	–	–	–	–	–	–	–	–	–	–

Country	Illness / condition		Income / social disadvantage		Age		Disability		Pensioners		War veterans		Pregnant women		Others	
	E	R	E	R	E	R	E	R	E	R	E	R	E	R	E	R
Latvia	√	√	√	–	√	–	–	√	–	–	–	–	–	–	–	–
Lithuania	√	√	–	√	√	–	–	√	–	√	–	–	–	–	–	–
Luxembourg	√	√	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Malta	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Moldova	√	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Netherlands	–	–	–	–	√	–	–	–	–	–	–	–	–	–	–	–
North Macedonia	(√)[7]	–	–	–	–	–	√[7]	–	–	–	–	–	–	–	–	–
Norway	√	–	(√)[8]	–	√	–	–	–	(√)[8]	–	–	–	–	–	–	–
Poland	√	–	–	√	√	–	–	–	√	–	√	–	–	–	–	–
Portugal	√	–	–	(√)[8]	–	–	–	–	–	(√)[8]	–	–	–	–	–	–
Republic of Korea	–	√	–	–	–	√	–	–	–	√	–	–	–	–	–	–
Republic of Serbia	–	–	–	–	√	√	–	–	–	–	–	–	√	√	–	–
Romania	√	–	–	√	–	√	–	–	–	(√)[8]	–	√	–	√	–	–
Russian Federat.	√	√	–	–	–	–	√[9]	–	–	√	–	√	–	–	–	–
Slovakia	–	–	–	–	–	√	√[10]	√	–	√	–	–	–	–	–	–
Slovenia	√	–	√[11]	–	–	–	√	–	–	–	–	–	√	–	–	–
South Africa	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Spain	–	√	√[8]	√	–	–	–	–	√[8]	√	–	–	–	–	–	–
Sweden	√	–	–	–	√	–	–	–	–	–	–	–	–	–	–	–
Switzerland	–	–	–	–	–	–	–	–	–	–	–	–	√	–	–	√[12]

Country	Illness / condition		Income / social disadvantage		Age		Disability		Pensioners		War veterans		Pregnant women		Others	
	E	R	E	R	E	R	E	R	E	R	E	R	E	R	E	R
Turkey	√	–	–	–	–	–	–	–	–	√	–	–	–	–	–	–
Ukraine	√[13]	–	–	–	√	√	√	√	√	–	√	–	√[13]	–	√[14]	√[15]
United Kingdom	√	–	√	–	√[16]	–	√	–	√	–	√	–	√	–	–	–

E = exemption, Federat. = Federation, n.a. = no information available, n.app. = not applicable (since there are no co-payments in place), R = reduction (e.g. lower co-payment or social protection through thresholds of co-payments)

[1] Co-payment regulation, including exemptions and reductions, varies between provinces (Canada) or regions (Italy)
[2] Germany: exempt if the price of a medicine is 30% below the reference price
[3] Greece: exemption for patients with paraplegia and tetraplegia (but not for other disabled people), reduction for pensioners on low income and exemption for women during pregnancy and lactation
[4] Hungary: all exemptions relate to a defined amount of annual / monthly spending; exemption only for children in social care and for those pensioners who receive retirement benefits due to disabilities or accidents
[5] Ireland: exemption for children in care or foster care or refugees living in emergency reception or an orientation centre
[6] Italy: others relate to victims of organised crime (exempt in some regions of Italy) and conscientious objectors (one region in Italy), for instance
[7] North Macedonia: only for patients with organ transplantation and for disabled children and youth up to 26 years
[8] Norway, Portugal, Romania and Spain: pensioners on low incomes
[9] Russian Federation: disabled children under 18 years
[10] Slovakia: disabled children under 6 years
[11] Slovenia: through coverage of the voluntary health insurance by the state
[12] Switzerland: lower co-payment for generic medicines compared to originator medicines
[13] Ukraine: insulin (human insulin / analogue insulin) for children aged below 18 years and pregnant women
[14] Ukraine: Chernobyl veterans
[15] Ukraine: honorary donors (i.e. frequent blood donors)
[16] United Kingdom: children under 16, 16-18 year olds in full time education, and for people over 60 years

Source: PPRI network members; data compilation by PPRI secretariat

5.4.2 Exemptions and reductions of co-payments for outpatient medicines

All PPRI countries included in this analysis (43 countries, no co-payments in three countries and missing data for one country, cf. chapter 5.4.1) have mechanisms in place to exempt and charge lower co-payments for some medicines and defined population groups. Common reasons for exemption / reduction mechanisms are specific illnesses / conditions (37 countries that have either an exemption or a reduction or both, exemption in 31 countries and reduction in 18 countries), age, usually children and youth below 18 years (25 countries, exemption in 18 countries and reduction in 13 countries), income and social disadvantage (23 countries, exemption in 16 countries and reduction in 15 countries), retirement status (29 countries, exemption in 9 countries and reduction in 16 countries), disability (24 countries, exemption in 10 countries and reduction in 11 countries), status as war veteran (13 countries, exemption in 8 countries and reduction in 8 countries) and pregnancy (11 countries, exemption in 9 countries and reduction in 4 countries). In some countries, eligibility for social protection is specific (e.g. pensioners on low incomes, children in social care). Table 5.6 informs about exemptions or reductions in co-payments for outpatient medicines applied in PPRI member countries.

5.4.3 Co-payments for inpatient medicines

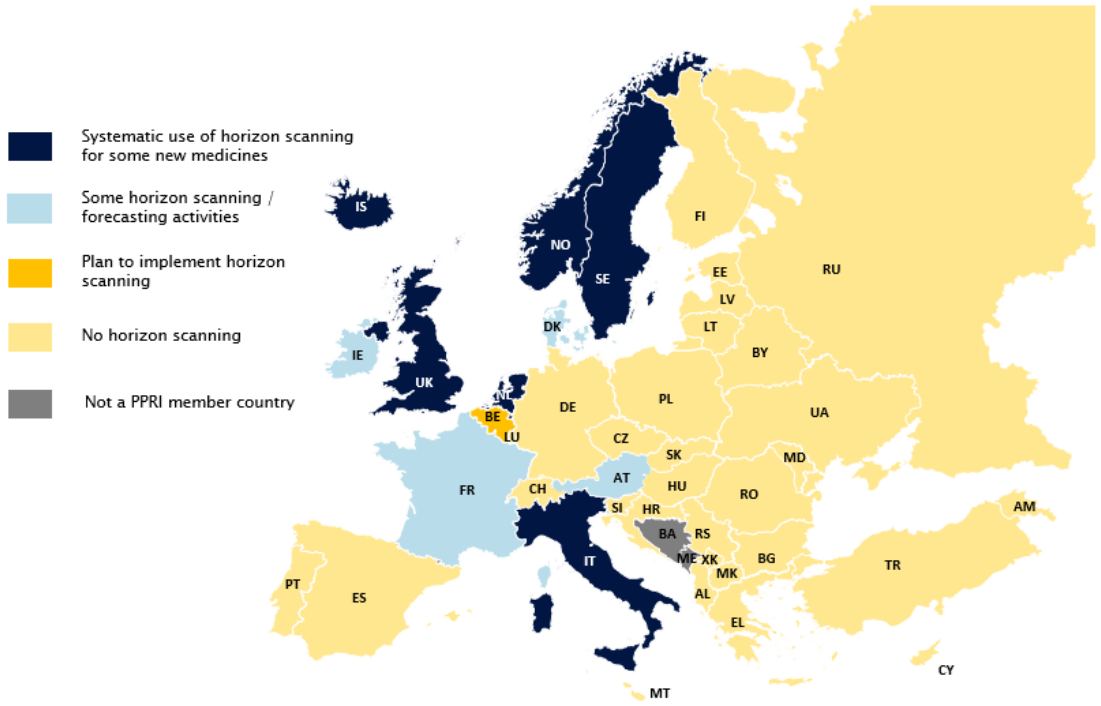
The majority of PPRI member countries (41 countries out of a total of 46 countries for which information is available; no information on South Africa) do not charge any co-payments for medicines administered in the inpatient sector. Co-payments for inpatient medicines are, however, applied in Armenia, Belgium, North Macedonia and the Republic of Korea. Belgium, for instance, charges a fee of 0.62 Euros per patient and hospital day for reimbursed medicines. In North Macedonia patients co-pay for medicines included in the Diagnosis Related Groups (DRG) system as well as those outside the system (usually high-priced medicines); exemptions were provided for low-income pensioners, pregnant women, patients with defined diseases (e.g. cancer, AIDS/HIV, having been subject to transplantation), and reductions for low-income families. The co-payment is staged depending on the medicine price. In the Republic of Korea, patients pay 20% of total costs for inpatient medicines (a reduced rate of 10% for beneficiaries of social welfare), whereas the co-payment rate for outpatient prescriptions amounts to 30%.

6 Policies for specific medicines

6.1 Policies for high-priced medicines

In a WHO report published in 2015, countries in the WHO European region reported that ➲ health technology assessments (HTA) and ➲ managed-entry agreements (MEA) were commonly used policies to manage the entry of new premium-priced medicines (i.e. balancing access for patients and long-term financial sustainability). In addition, governments were working on tools to be better prepared (WHO Europe 2015).

Figure 6.1:
Policies for specific medicines – Use of horizon scanning in PPRI network member countries, 2018



Systematic use of horizon scanning for some new medicines: Canada
No horizon scanning: Israel, Kazakhstan, Kyrgyzstan, South Africa
No information available: Republic of Korea
Systematic use of horizon scanning for some new medicines in the inpatient sector and some horizon scanning activities in the outpatient sector in Sweden

Source: PPRI network members; data compilation by PPRI secretariat

6.1.1 Horizon scanning

➲ Horizon scanning is not a pharmaceutical pricing and reimbursement policy per se, but it helps countries to be prepared for the launch of new medicines with high price tags which will likely strongly impact the pharmaceutical budget.

Horizon scanning is a rather new activity related to medicines. As of 2018, it is systematically used in only a few PPRI member countries: seven countries (e.g. Canada, Netherlands, Norway) reported using it systematically for new medicines, and four countries (e.g. Austria, France, Ireland) have some horizon scanning and forecasting activities for some medicines in place (cf. Figure 6.1). In addition, horizon scanning is one working area of cross-country collaborations (cf. chapter 4.2.7).

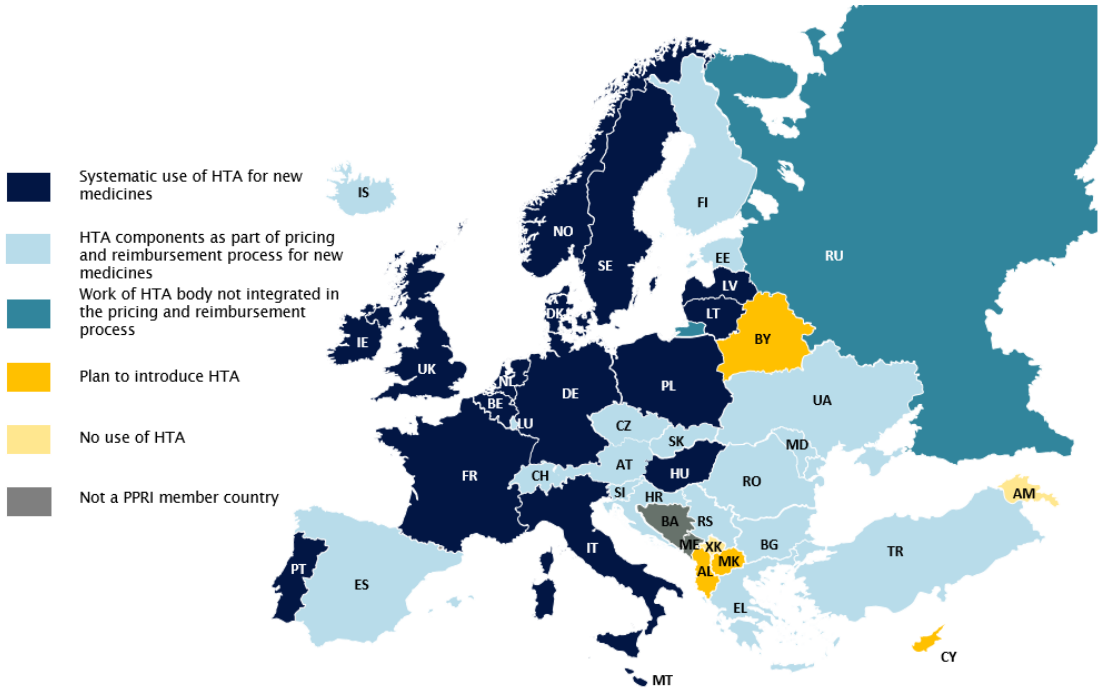
6.1.2 Health technology assessment

PPRI network member countries increasingly use methods and principles of ➲ health technology assessment (HTA) to guide their reimbursement decisions, as well as for pricing decisions (Figure 6.2). 37 of the 46 PPRI member countries with available information apply HTA, or elements of HTA, in their pricing and/or reimbursement decisions, thereof 18 countries (e.g. Germany, France, Norway, UK) in a systematic way (with assessment and appraisal processes having been implemented). A few further countries have HTA entities in place; however, HTA is not yet embedded in pricing and reimbursement processes (e.g. Kazakhstan, Russian Federation). Some of the countries, mainly countries in Eastern Europe and Central Asia, that do not yet use HTA, are considering introducing it.

The extent to which pricing and reimbursement decisions are based on HTA differs between countries. A number of countries employ HTA to inform decision-making regarding reimbursement and funding for all new medicines, whereas others apply HTA only if there is cause for concern due to, for instance, the high price of the medicine or uncertainty about its effectiveness.

At EU level, there has been joint work on HTA within the European network for health technology assessment (EUnetHTA). EUnetHTA further developed HTA tools and aimed to strengthen their practical application to cross-border HTA collaboration (EUnetHTA 2019).

Figure 6.2:
Policies for specific medicines – Use of HTA in PPRI network member countries, 2018



Systematic use of HTA for some new medicines: Canada, Republic of Korea
HTA components as part of pricing and reimbursement process for new medicines: Israel
Work of HTA body not integrated in pricing and reimbursement process: Kazakhstan
Plan to introduce HTA: South Africa
No use of HTA: Kyrgyzstan

Source: PPRI network members; data compilation by PPRI secretariat

6.1.3 Managed-entry agreements

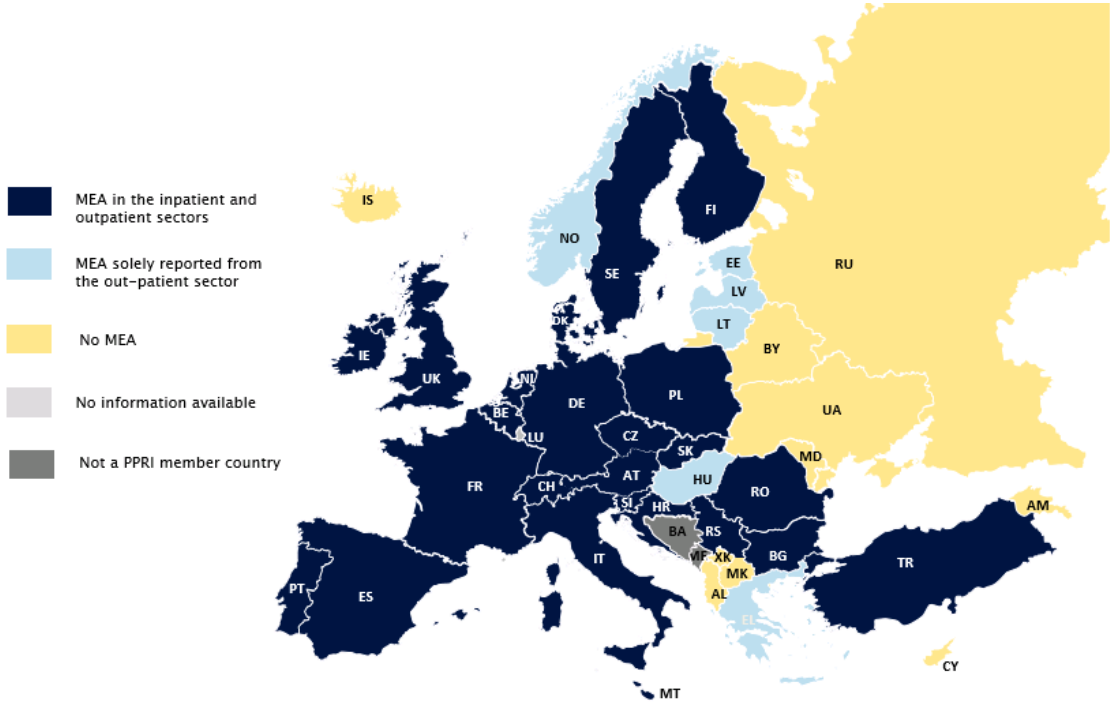
An increasing number of PPRI network member countries have been applying so-called ➲ managed-entry agreements (MEA) for new high-priced medicines. As of 2018, the majority of PPRI member countries (33 out of 45 PPRI network member countries for which information is available) use these arrangements; a few PPRI countries (12 countries), mainly in Eastern Europe and Central Asia, which have pricing and reimbursement regulation for a very limited range of medicines or not at all, do not apply MEA (but three of them, e.g. Kazakhstan and Ukraine, are considering introducing it).

Some countries (e.g. Hungary, Poland, Spain) manage several hundred of MEA whereas the number of MEA is lower in other countries (e.g. fewer than 100 in Bulgaria and Romania, less than 20 in Finland and fewer than ten in Greece and Norway). The differences in the number of MEA between countries is due to the fact that legal requirements to implement an MEA have been introduced at

different points in time (for instance, in Norway and in the outpatient sector in Finland, MEA have only been in place since 2017).

Most countries apply MEA both in the outpatient and inpatient sectors (26 countries reported to do so); for a few countries (7 countries) MEA were only reported from the outpatient sector (Figure 6.3).

Figure 6.3:
Policies for specific medicines – Use of MEA in the inpatient and outpatient sectors in PPRI network member countries, 2018



MEA in the inpatient and outpatient sectors: Canada, Republic of Korea
MEA solely reported from the outpatient sector: Israel
No MEA: Kazakhstan, Kyrgyzstan
No information available: South Africa

Source: Adamski et al. 2010, Ferrario and Kanavos 2013, Ferrario et al. 2017, Panteli et al. 2017, Pauwels et al. 2017, PPRI network members; data compilation by PPRI secretariat

MEA are typically distinguished into two categories:

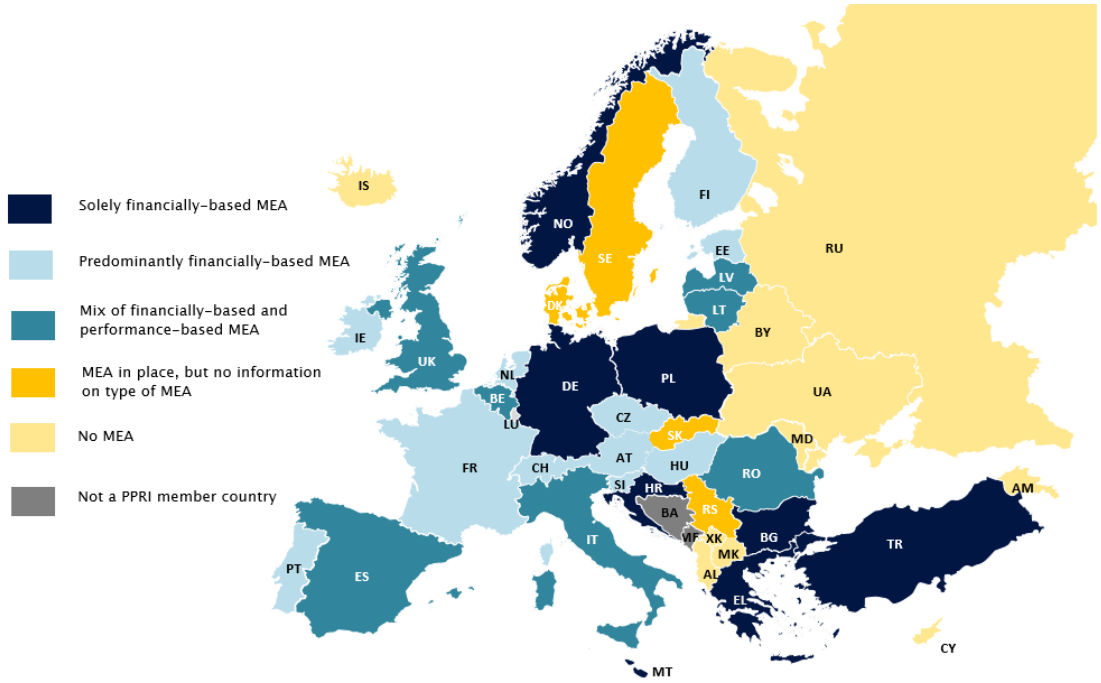
» financially-based (or non-health outcome-based) schemes, e.g. (price or dose dependent) discounts, price or utilisation capping or price-volume agreements

» performance-based (or health outcome-based) schemes, e.g. outcome guarantees (i.e. an agreement where the manufacturer provides rebates, refunds, or price adjustments if the product fails to meet the agreed outcome target), coverage with evidence development (i.e. reimbursement where additional data gathered in the context of clinical care would further

clarify the impact of the medicine, and patient eligibility linked to patient registries to measure post-marketing clinical outcomes).

Previous studies (Adamski et al. 2010, Ferrario and Kanavos 2013, Ferrario et al. 2017, Garrison et al. 2013, Pauwels et al. 2017) showed the predominant use of financially-based MEA though performance-based MEA have also increasingly been applied in recent times: as a result, while both financially- and performance-based MEA were reported from 21 countries (including 11 countries that predominantly use financially-based MEA), financially-based MEA appear to be still more common (Figure 6.4).

Figure 6.4:
Policies for specific medicines – Type of MEA in PPRI network member countries, 2018



Mix of financially-based and performance-based MEA: Canada, Israel, Republic of Korea
No MEA: Kazakhstan, Kyrgyzstan
No information available: South Africa

Source: Adamski et al. 2010, Ferrario and Kanavos 2013, Ferrario et al. 2017, Panteli et al. 2017, Pauwels et al. 2017, PPRI network members; data compilation by PPRI secretariat

Major indications for which MEA are concluded include oncology (e.g. Austria, Belgium, Bulgaria, Czech Republic, Hungary, Latvia, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovenia), rheumatology (e.g. Belgium, Bulgaria, Czech Republic, Latvia, Portugal, Romania, Slovenia), hepatitis (e.g. Belgium, Bulgaria, the Netherlands, Portugal, Romania, Switzerland) and diabetes (e.g. Belgium, Hungary, Portugal).

6.2 Policies for off-patent medicines

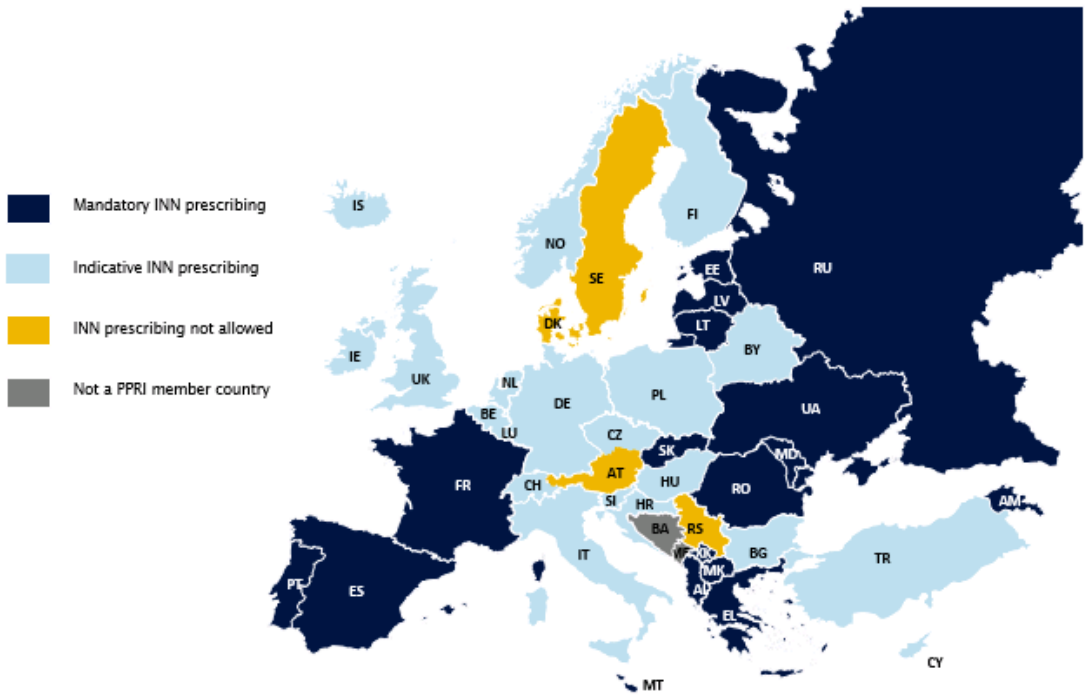
Off-patent medicines are pharmaceuticals that are not covered by patent protection: they include ➲ generic medicines, ➲ biosimilar medicines as well as ➲ originator medicines whose patent(s) have expired. Given lower prices resulting from competition, these medicines can contribute to cost-containment.

In this context, demand-side measures, which mainly address health professionals and patients, play an important role since they help increase the uptake of off-patent medicines. As such, they add to ➲ supply-side measures in this area (as described in previous chapters on pricing and reimbursement, such as the generic and biosimilar price links, cf. chapter 4.2.2, and a reference price system, cf. chapter 5.3).

6.2.1 Prescribing by INN

A key demand-side measure to enhance the uptake of off-patent medicines is ➲ prescribing by International Non-proprietary Name (INN). This practice has been implemented in 43 of the PPRI network member countries (on a voluntary basis in 25 countries, and 18 countries oblige doctors to prescribe the INN instead of the brand name). In four countries (Austria, Denmark, Republic of Serbia and Sweden) INN prescribing is not allowed (Figure 6.5).

Figure 6.5:
Policies for specific medicines – Prescribing by International Non-proprietary Name (INN) in PPRI network member countries, 2018



Mandatory INN prescribing: Kyrgyzstan, South Africa
Indicative INN prescribing: Canada, Kazakhstan, Israel, Republic of Korea
Latvia: mandatory INN prescribing for newly diagnosed patients and indicative for patients who have already received reimbursable medicines

Source: PPRI network members; data compilation by PPRI secretariat

6.2.2 Pharmaceutical substitution

➲ Pharmaceutical substitution refers to the action of a pharmacist who dispenses a medicine that is considered substitutable (usually of the same active ingredient) instead of the prescribed medicine, which normally has a higher price. The term ➲ generic substitution is more commonly used; however, dispensed medicines upon a substitution may also be copy products, me-too products or biosimilar medicines (➲ biosimilar substitution), depending on legislation.

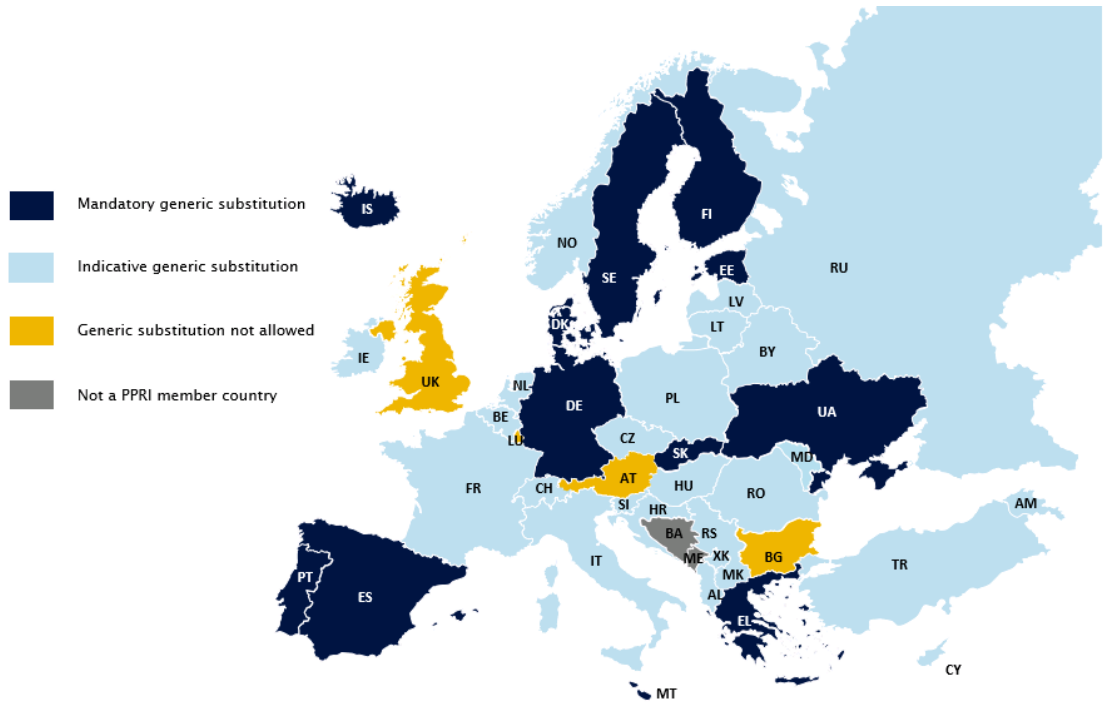
6.2.2.1 Generic substitution

Similar to the practice of INN prescribing, generic substitution is applied in a large number of the PPRI network member countries (43 countries). Again, implementation on a voluntary basis (29

countries, e.g. Hungary, Moldova, Switzerland, Turkey) is more common than obligatory generic substitution (13 countries, e.g. Denmark, Germany, South Africa, Sweden). In Canada, the obligation varies from province to province but overall there is mandatory generic substitution across Canadian public payers, and many private payers also have this policy in place (Figure 6.6). In a few countries (e.g. Denmark, Germany) pharmacists are also allowed to substitute the originator medicine with a parallel-imported medicine. Only four PPRI member countries (Austria, Bulgaria, Luxembourg, UK) do not have generic substitution in place.

Most PPRI member countries have both INN prescribing (cf. chapter 6.2.1) and generic substitution in place; a few of them employ only one of these tools. Austria is the only country in which INN prescribing and generic substitution are not allowed.

Figure 6.6:
Policies for specific medicines – Generic substitution in PPRI network member countries, 2018



Mandatory generic substitution: South Africa
Indicative generic substitution: Israel, Kazakhstan, Kyrgyzstan, Republic of Korea
In Canada, generic substitution is mandatory in some provinces and indicative in other provinces

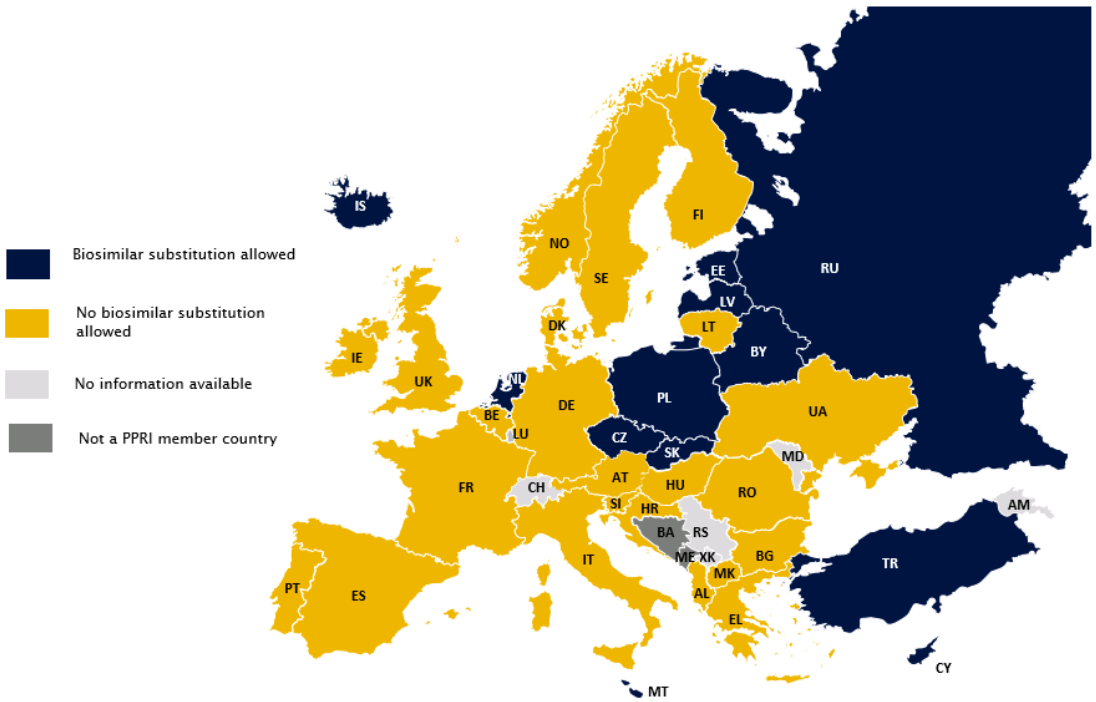
Source: PPRI network members; data compilation by PPRI secretariat

6.2.2.2 Biosimilar substitution

While substitution of an originator medicine with a generic is commonly used in the PPRI member countries (cf. chapter 6.2.2.1), this practice has been implemented less often for biological medicines (Figure 6.7). Only 15 PPRI member countries (all of them also have generic substitution) allow biosimilar substitution (thereof mandatory in at least two countries: Estonia and Slovakia). In 24 PPRI member countries substitution of a biological reference medicine with a biosimilar is not allowed, though 21 of them have generic substitution in place (information missing for 8 countries). In Germany biosimilar substitution is planned to enter in force in 2022. France is waiting for a decree to allow its implementation.

While pharmaceutical substitution relates to the action of a (community) pharmacist, medicines can also be changed at the level of the prescribing doctor (➲ switch). Some countries (e.g. Norway, United Kingdom) that do not allow biosimilar substitution have policies of supporting switches (e.g. from a biological reference medicine to a biosimilar, or between biosimilar medicines) in order to enhance the uptake of biosimilar medicines. Other PPRI member countries (e.g. France) encourage the use of biosimilar medicines for treatment-naïve patients (i.e. those who have never received a treatment of this specific indication before) but do not allow switches.

Figure 6.7:
Policies for specific medicines – Biosimilar substitution in PPRI network member countries, 2018



No information available: Republic of Korea, South Africa

Source: PPRI network members; data compilation by PPRI secretariat

7 Conclusions

The PPRI network comprises public authorities responsible for pharmaceutical pricing and reimbursement in 47 countries. These countries, which include a total of more than 1 billion people, are predominantly allocated in the WHO European region but they vary in terms of population (Russian Federation having 425 times the number of inhabitants of Iceland) and of economic situation (Luxembourg's per capita GDP expressed in USD PPP 28 times that of Kyrgyzstan). Differences are also reflected in investments in health care, including medicines. While per capita spending in health care and in pharmaceuticals tends to be lower in countries with lower per capita GDP, the shares of pharmaceutical expenditure in health expenditure are higher in these countries, and patients pay more out-of-pocket (higher shares of private health and pharmaceutical expenditure).

Most PPRI network member countries have advanced universal health coverage and/or have made great progress: they have a social health insurance or national health service in place, apply coverage policies for essential and further cost-effective medicines, and employ exemption mechanisms for co-payments. However, there are still a few countries (mainly in Central Asia) whose benefit package schemes for (outpatient) medicines are limited to a very narrow scope of medicines and/or indications.

High medicine prices constitute a barrier to affordable access to medicines, and price regulation has been recommended by WHO (WHO 2013). Most PPRI network member countries have price control policies for medicines in place, at least for those whose costs are covered by a public payer (i.e. reimbursable medicines), and a few PPRI countries without price regulation plan to introduce price control. There appears to be a tendency towards price regulation.

PPRI network member countries use similar pricing and reimbursement policies, such as external price referencing, regressive mark-up schemes to regulate the remuneration for wholesalers and pharmacies, positive lists to include medicines eligible for reimbursement, percentage co-payments, co-payment exemptions linked to diseases and generic policies to make use of efficiency gains of off-patent medicines. Specific policies are applied for some groups of medicines (e.g. managed-entry agreements for high-priced medicines). However, there are differences with regard to the design of these policies among countries.

Changes in policies, and their design, can be observed over time. For instance, an increasing number of countries have included a price-independent component (e.g. a dispensing fee) in their remuneration system for pharmacies, have been applying a broader definition for clustering medicines in a reference price system and have been using HTA for pricing and reimbursement decisions of new, possibly high-priced medicines. In addition, countries have been observed to constantly search for optimising their 'tool box' of policies to ensure affordable, equitable and sustainable access to cost-effective medicines. Their efforts also include exploring new pathways such as measures outside the classical pricing and reimbursement policy arena (e.g. horizon scanning as a peri-launch measure) and collaborative approaches between countries.

The effectiveness of these new policies is yet to be seen as some of these measures have only been introduced recently. It is recommended that the introduction of new policies be accompanied by an evaluation to learn whether, or not, the intended objectives have been achieved and if untended effects occurred.

For the well-established pricing and reimbursement policies, findings from impact assessments are available. They have not been presented in this report since the presentation of policy analyses was not in the scope of this mapping exercise. The aim of this report was to describe a comparative cross-country overview of existing and possible upcoming policies in the 47 PPRI member countries. This knowledge serves as the basis for further studies to perform assessments of effects of these measures and to foster debate between countries. PPRI aims to contribute to an exchange between its members of information and of cross-country learning, and this updated report provides one contribution to achieve this objective.

8 References

Adamski J, Godman B, Ofierska-Sujkowska G, Osinska B, Herholz H, Wendykowska K, et al. (2010): Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC health services research 10:153

AESGP (2019): AESGP Med Data Bank. Brussels, Association of the European Self-Medication Industry. Available from: https://med.aesgp.eu/ (accessed 25 September 2019)

Beneluxa initiative (2019): Beneluxa Initiative on Pharmaceutical Policy. Available from: http://www.beneluxa.org (accessed 14 May 2019)

EFPIA (2018): The Pharmaceutical Industry in Figures. Key Data 2018. Brussels, European Federation of Pharmaceutical Industries and Associations. Available from: https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf (accessed 3 May 2019)

EFPIA (2019): The Pharmaceutical Industry in Figures. Brussels, European Federation of Pharmaceutical Industries and Associations. Available from: https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-economy/market-value/ (accessed 25 September 2019)

EUnetHTA (2019): European network for health technology assessment. Available from: https://www.eunethta.eu/about-eunethta/history-of-eunethta (accessed 10 October 2019)

European Commission, DG SANTE (2018): Health Technology Assessment and Regional Cooperations – Sharing Experiences from the Regional Cooperations. High-Level Summary. Brussels. Available from: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_regional_hta_reportsum_en.pdf (accessed 10 October 2019)

Ferrario A, Arāja D, Bochenek T, Čatić T, Dankó D, Dimitrova M, et al. (2017): The Implementation of Managed Entry Agreements in Central and Eastern Europe: Findings and Implications. PharmacoEconomics. 35(12):1271-85

Ferrario A, Kanavos P (2013): Managed entry agreements for pharmaceuticals: The European experience. EMINet

Garrison LP, Towse A, Briggs A, de Pouvourville G, Grueger J, Mohr PE, et al. (2013): Performance-based risk-sharing arrangements—good practices for design, implementation, and evaluation: report of the ISPOR good practices for performance-based risk-sharing arrangements task force. Value in Health 16(5):703-19

IFPMA (2017): The Pharmaceutical Industry and Global Health: Facts and Figures. Geneva; International Federation of Pharmaceutical Manufacturers and Associations. Available from:

https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf (accessed 30 April 2019)

Ministerstwo Zdrowia (2019): Projekt FaAP (Fair and Affordable Pricing). Warsaw. Available from: https://www.gov.pl/web/zdrowie/faap (accessed 10 October 2019)

OECD Health Statistics (2019a): Pharmaceutical expenditure. Available from: https://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (accessed 26 September 2019)

OECD Health Statistics (2019b): Pharmaceutical Market: Generic market. Available from: https://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (accessed 17 April 2019)

Panteli D, Arickx F, Cleemput I, Dedet G, Eckhardt H, Fogarty E, et al. (2016): Pharmaceutical regulation in 15 European countries. Review. Health Systems in Transition 18(5):1–118

Pauwels K, Huys I, Vogler S, Casteels M, Simoens S. (2017): Managed Entry Agreements for oncology drugs: lessons from the European experience to inform the future. Frontiers in Pharmacology 8:171

SFK (2019): Data en feiten 2019. Het jaar 2018 in cijfers. Stichting Farmaceutische Kengetallen. Available from: https://www.sfk.nl/publicaties/data-en-feiten/data-en-feiten-2019 (accessed 30 September 2019)

Ukraine's central statistical office (2019): Чисельність населення (за оцінкою) на 1 січня 2019 року та середня чисельність у 2018 році [Population size (per unit) per year 2019 and average number in 2018]. Available from: http://www.ukrstat.gov.ua/operativ/operativ2018/ds/kn/kn_u/kn1218_u.html (accessed 6 September 2019)

United Nations (2019): Sustainable Development Goals (SDG). Available from: https://unstats.un.org/sdgs/ (accessed 2 October 2019)

Valletta Declaration (2018): Information on the Valletta Declaration, 7 June 2018

Vogler S (2019): Pharmaceutical pricing policies. In: Babar ZUB (2019): Encyclopaedia of Pharmacy Practice and Clinical Pharmacy. Academic Press

Vogler S, Espin J, Habl C (2009): Pharmaceutical Pricing and Reimbursement Information (PPRI) – New PPRI analysis including Spain. Pharmaceuticals Policy and Law 11(3):213–34

Vogler S, Habl C, Leopold C, Rosian-Schikuta I, de Joncheere K, Lyager Thomsen T (2008): PPRI Report. Vienna: Pharmaceutical Pricing and Reimbursement Information. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Report_final_3.pdf (accessed 26 April 2019)

Vogler S, Leopold C, Zimmermann N, Habl C, de Joncheere K (2014): The Pharmaceutical Pricing and Reimbursement Information (PPRI) initiative-experiences from engaging with pharmaceutical policy makers. Health Policy and Technology 3(2):139-48

Vogler S, Lepuschütz L, Schneider P, Stühlinger V (2016): Study on enhanced cross-country coordination in the area of pharmaceutical product pricing. Gesundheit Österreich Forschungs- und Planungs GmbH, University for Health Sciences, Medical Informatics and Technology (UMIT) and SOGETI. Funded by the Health Programme of the European Union, Vienna

Vogler S, Paris V, Panteli D (2018): Policy Brief: Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? European Observatory on Health Systems and Policies of the WHO Regional Office for Europe. Available from: http://www.euro.who.int/__data/assets/pdf_file/0009/379710/PolicyBrief_AUSTRIA_PB30_web_13082018.pdf (accessed 26 April 2019)

WHO (2013): WHO Guideline on Country Pharmaceutical Pricing Policies. World Health Organization, Geneva. Available from: http://apps.who.int/medicine-docs/documents/s21016en/s21016en.pdf (accessed 20 October 2019)

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2019): Glossary of pharmaceutical terms. Vienna. Available from: https://ppri.goeg.at/ppri-glossary (accessed 29 September 2019)

WHO Europe (2015): Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. Copenhagen; WHO Regional Office for Europe. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/WHO_AccessNewMedicines_Report_FINAL2015_1.pdf (accessed 26 April 2019)

WHO Europe (2019): Pharmaceutical pricing and reimbursement systems in Eastern Europe and Central Asia. Report of the Pharmaceutical Pricing and Reimbursement Information network for countries of in Eastern Europe and Central Asia, 2018 (in print)

World Bank (2019a): World Development Indicators - Population, total. Available from: https://databank.worldbank.org/source/world-development-indicators (accessed 26 September 2019)

World Bank (2019b): World Development Indicators - GDP per capita, PPP (current international $). Available from: https://databank.worldbank.org/source/world-development-indicators (accessed 26 September 2019)

World Bank (2019c): World Development Indicators - Current health expenditure in % of GDP, public, private and per capita, PPP (current international $). Available from: https://databank.worldbank.org/source/world-development-indicators (accessed 26 September 2019)

Annex

Annex 1: Glossary

Terminology is based on the Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2019).

Authority	Government entity responsible for designing the regulatory framework and implementing policies (e.g. ministry, public agency). In the European context the term 'competent authority' is frequently used.
Biosimilar medicine	A biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). Biosimilar medicines can only be marketed following the patent expiry of the reference medicine. Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines. The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Like the reference medicine, the biosimilar has a degree of natural variability. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety or effectiveness. An authorised biosimilar is generally used at the same dose to treat the same conditions. If there are specific precautions to be considered when taking the reference medicine, the same will generally apply to the biosimilar. Biosimilars can only be authorised for use once the period of data exclusivity on the original 'reference' biological medicine has expired. In general, this means that the biological reference medicine must have been authorised for at least 10 years before a similar biological medicine can be made available by another company.
Biosimilar price link	Practice of setting the price of a biosimilar medicine, in relationship to the reference medicine price, usually at a certain percentage lower than the reference medicine price. The design of the price link policy may vary, with different percentages for the different following biosimilar products (first follower coming to the market, second follower, etc.), and in some cases the prices of reference medicines might also be part of the policy, i.e. that they will also be required to decrease.
Biosimilar substitution	Practice of dispensing a biosimilar medicine instead of another equivalent and interchangeable biosimilar or biotechnological originator medicine at the pharmacy level without consulting the prescriber.
Collaborative pricing	Practice of cooperation between countries in the area of pharmaceutical pricing (including joint procurement, joint price negotiations).

Community pharmacy	Health care facility dispensing medicines (prescription-only medicines and non-prescription medicines, reimbursable and non-reimbursable medicines) to outpatients. Pharmacies are subject to pharmacy legislation (e.g. national legislation regarding establishment and ownership of pharmacies). In many countries, community pharmacies are private facilities, but public pharmacies (i.e. in public ownership) also exist. Pharmaceutical provision for inpatients is provided for by hospital pharmacies or pharmaceutical depots; in some cases hospital pharmacies also act as community pharmacies.
Conditional pricing	Pricing policy that links the price of a medicine to specific criteria (e.g. health outcomes, minimum purchases). Conditional pricing falls under a variety of terms and taxonomies (e.g. managed-entry agreements, risk-sharing, pay-for-performance).
Co-payment	Insured patient's contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
Cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered 'reasonable'.
Deductible	Initial expense up to a fixed amount which must be paid out-of pocket for a service or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a third party payer.
Demand-side measures	Policies that are directed at stakeholders who prescribe (doctors), dispense (pharmacies) or ask for medicines (patients).
Differential pricing	Cross-country approach of setting the price of medicine in accordance with the ability-to-pay, and/or the economic situation of the involved countries. The pricing decision would be taken in a collaborative approach by the governments of the involved countries or an international organisation. There is a difference to 'price discrimination' ('market discrimination', 'Ramsey pricing') that describes a business strategy of economic actors to segment the market according to the observed demand-elasticity of consumers.
Dispensing doctors	Physicians who have been granted the right to dispense medicines to their patients.
Dispensing fee	Remuneration that pharmacies are allowed to charge per prescription or prescribed item. It is a variant of a fee-for-service remuneration and not linked to the price of a medicine.
Distribution remuneration	Reward for distribution actors (e.g. wholesalers, community pharmacies) to pay them for their services rendered. Distribution remuneration can take the form of linear or regressive mark-ups (add-ons) or margins that constitute part of the final pharmacy retail price, and of a fee / fees (fee-for-service) not linked to the price.
Essential medicines	Those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts,

	in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility. The concept of essential medicines is forward-looking. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs; the need to ensure medicine quality; and the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns.
Ex-factory price (manufacturer price)	The price at the level of industry, charged by a pharmaceutical manufacturer; official ex-factory prices can be lowered by discounts or other arrangements offered by manufacturers (actual price).
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Fee-for-service	Payments to a provider (for example a general practitioner) for each act or service rendered.
Free pricing	Pricing policy, where in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
Generic market share	The proportion of generic medicines in relation to the total pharmaceutical market. It can either be described in value (share of sales) or in volume (share of consumption/packages). If data is not available for the total pharmaceutical market, the generic share may refer to a sub-market (e.g. off-patent market, outpatient reimbursement market).
Generic medicine	A medicine which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies. Generics can be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company).
Generic price link	Practice of setting the price of a generic in relationship to the original product / originator medicine, usually at a certain percentage lower than the original medicine / originator price. The design of this the generic price link policy may vary, with different percentages for the different generics (first generic coming to the market, second generic, etc.), and in some cases the prices of original originator medicines might also be part of the policy, i.e. that they will also be required to decrease.
Generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s). Generic substitution may be allowed (indicative generic substitution) or required (mandatory/obligatory generic substitution).

Health technology assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
Horizon scanning	The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society.
Hospital pharmaceutical formulary (HPF)	A list of medicines that may be prescribed and applied by physicians in a hospital.
INN prescribing (prescribing by International Non-proprietary Name)	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its International Non-proprietary Name (INN), i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).
Internal price referencing	Practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.
Joint procurement	The procurement of certain products or services is done by a single purchasing body for several healthcare providers (e.g. hospitals, regions, countries).
Linear mark-up or margin	A defined amount (expressed in a fixed amount or a percentage) that is added to the product to create profit (mark-up) or that is profit (mark-up).
Managed-entry agreement (MEA)	An arrangement between a manufacturer and payer / provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.
Margin	The percentage of the selling price that is profit.
Marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
Mark-up	Percentage of the purchasing price added on to get the selling price. A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit.
Me-too product	A medicine that is approved after a pioneering product and is defined as comparable or similar but not clinically superior product.
National Health Service (NHS)	The system of social security and health services arising out of the Beveridge report (1943) in England and Wales, and set in place in 1948. A NHS system is financed through general taxation (central or regional) usually covering all inhabitants / residents. The scope of services rendered is identical for every person covered and most services are offered by public institutions. In some countries people may opt

	for a complementary voluntary health insurance for services, which are not covered through the NHS.
Negative list	List of medicines that cannot be prescribed at the expense of a third party payer.
Non-prescription medicine(s) (NPM)	Pharmaceutical(s) which may be dispensed without a prescription.
Originator medicine (original product)	The first version of a medicine, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product for a defined period of time.
Out-of-pocket payments	The expenses of a person for medical care or medicines that are not covered by reimbursement of a third party payer – often for a defined period (e.g. a year). It includes: - Expenses for non-reimbursable medicines - Any form of co-payment, e.g. prescription fee, percentage co-payment, deductible
Percentage co-payment	One type of co-payment asking patients to cost-share in the form of a set proportion of the cost of a service or product. The patient pays a defined share of the cost of a service or product, with the third party payer paying the remainder.
Peri-launch activity	Policies undertaken around the launch of a medicine on the market. Related to the entry of new medicines, they might be specific arrangements (e.g. managed-entry agreements, HTA) during the pricing and reimbursement decision process. Peri-launch activities address, among other things, issues of access and affordability.
Pharmaceutical substitution	Action of a pharmacist who dispenses a medicine that is considered substitutable (usually of the same active ingredient) instead of the prescribed medicine, which normally has a higher price. The term generic substitution is more commonly used; however, dispensed medicines upon a substitution may also be copy products, me-too products or biosimilar medicines (biosimilar substitution), depending on legislation.
Pharmacy purchasing price (pharmacy purchase price)	The price charged by wholesalers to the retailers (usually community pharmacies). It is based on the ex-factory price and additionally includes any remuneration for pharmaceutical wholesale (e.g. in the form of a wholesale mark-up or wholesale margin).
Pharmacy retail price (consumer price)	The price charged by community pharmacies to the general public. It is based on the pharmacy purchasing price and additionally includes any pharmacy remuneration such a pharmacy mark-up, pharmacy margin or dispensing fee. It can be a gross pharmacy retail price (including value-added tax/VAT) or a net pharmacy retail price (excluding VAT).
POM dispensaries	Facilities that are allowed to dispense prescription-only medicines POM to outpatients, e.g. community pharmacies, dispensing doctors.
Positive list	List of medicines that may be prescribed at the expense of a third party payer. It is one form of a reimbursement list.

Post-launch activity	Policies undertaken after the launch of a medicine on the market. Related to the entry of new medicines, post-launch activities include monitoring the effectiveness and safety of new medicines in clinical practice and ensuring that patients with the greatest clinical need and those most likely to benefit from treatment can access the medicine, and include systematic detailed analysis of medicine usage data.
Pre-launch activity	Policies undertaken before the launch of a medicine on the market. This includes the review of the potential specific clinical and treatment outcomes and health system impact (in terms of cost and benefit to patients). Pre-launch activities also anticipate the budget impact and include horizon scanning and demand forecasting.
Prescription fee	A fixed amount for each prescription item dispensed on the expense of a third party payer to be payable by the patient, i.e. a form of fixed co-payment.
Prescription-only medicine(s) (POM)	Pharmaceutical(s) that can be dispensed only on a health professional prescription.
Price control (price regulation)	Action by a government authority to set the price of a medicine and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it. Criteria that governments apply to set prices include prices in the same country or other countries, (added) therapeutic benefit, (production) costs and return on investment.
Price type	The level (i.e. stage in the supply chain) at which the price of a medicine is set. Common price types include: ex-factory price, pharmacy purchasing price and pharmacy retail price.
Price-oriented remuneration	Remuneration that is linked to the price of a medicine, e.g. through a linear mark-up or margin or a regressive scheme.
Pricing (price setting)	Act of setting the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a competent authority (price control).
Pricing policies	Regulations and actions taken by government authorities to set the price of a medicine as part of exercising price control. Strategies by private sector actors (e.g. pharmaceutical industry and supply chain actors) to determine and set a medicine price are not subsumed under the term 'policy'.
Procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Reference group	A group of medicines of the same active ingredient (ATC 5), in a given therapeutic class (ATC 4) or clustered based on a broader definition but still considered interchangeable. These clusters of medicines form the basis for establishing a reference price system.
Reference price	Price that is set in a reference price system, where the third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in

	addition to any further co-payments (e.g. prescription fees, or percentage co-payment rates).
Reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group).
Regressive mark-up or margin scheme	A staggered system in which remuneration is negatively associated with the underlying price.
Reimbursable medicines	Medicines which are eligible for reimbursement. Costs of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
Reimbursement	Coverage of the expenditure by a third party payer (e.g. Social Health Insurance / National Health Service).
Reimbursement list	A list that contains medicines with regard to their reimbursement status. They may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list). Reimbursement lists may target either the outpatient sector (usually positive lists or negative lists) or the inpatient sector (typically called hospital pharmaceutical formulary), or both.
Reimbursement process	The reimbursement process is a decision-making process on the reimbursement status, reimbursement price, reimbursement rate of medicines that involves the roles and the composition of the responsible bodies and committees, the application process, the decision-making itself, the information process around the decision and the arbitration process after the decision. The outcome of the process is the decision whether or not the medicine will be included in reimbursement lists, and at which cost.
Reimbursement rate	The percentage share of the price of a medicine or medical service, which is reimbursed / subsidised by a third party payer. The difference to the full price of the medicine or medicinal service is paid by the patients.
Social Health Insurance (SHI)	Social health insurance is a type of health care provision, often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) persons whose income does not exceed a certain amount/limit (= insurance obligation) in place. Social health insurance is often organised in different sickness funds - in some countries allowing the patient to select a sickness fund (Germany) whereas in others the membership is determined mandatory, e.g. depending on the type of occupation (e.g. Poland, Austria).
Supply-side measure	Policies that are applied by governments (e.g. public authorities and public payers in the health care system) to control prices and/or profit, manage access and/or determine coverage.
Switch	Reclassification of a prescription-only medicine (POM) to a non-prescription medicine (NPM). Since in many countries the positive lists only include POM but no NPM medicines, a switch might also change the reimbursement status and might be considered as a 'hidden' de-listing measure. In In the context of biosimilars a switch is a decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment.

Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender / offer is the most advantageous.
Total pharmaceutical expenditure	It is defined as total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. Other medical nondurables comprise wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices. Pharmaceutical expenditure can be separated in: - Public expenditure: pharmaceutical expenditure incurred by public funds (state, regional and local government bodies and social security schemes). - Private expenditure: privately funded part of total pharmaceutical expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care. Pharmaceutical expenditure data reported in the OECD System of Health Accounts encompass expenditure by both private and public sectors. Pharmaceutical expenditure may or may not include the value of pharmaceuticals dispensed in hospitals, depending on the country.
Value based pricing (VBP)	Through this policy authorities set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
Value-added tax	A sales tax on products collected in stages by enterprises.
Wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Annex 2: Health expenditure data

Table 8.1:
Annex – Health expenditure in PPRI network member countries, 2016

Country	Current HE % of GDP	Public HE % of current HE	OOP in % of current HE	Per capita HE in USD	Per capita HE in current USD PPP
Albania	6.7	42.9	58.0	271.4	759.7
Armenia	9.9	17.5	80.6	358.8	876.6
Austria	10.4	74.1	18.9	4688.3	5295.2
Belarus	6.3	61.5	35.8	317.8	1151.4
Belgium	10.0	78.8	15.9	4149.4	4667.9
Bulgaria	8.2	50.6	47.9	612.5	1577.9
Canada	10.5	70.5	14.6	4458.2	4718.3
Croatia	7.2	78.5	15.4	884.5	1705.2
Cyprus	6.9	42.2	44.9	1634.3	2270.8
Czech Republic	7.1	81.9	15.0	1321.6	2484.6
Denmark	10.4	84.1	13.7	5565.6	5093
Estonia	6.7	75.7	22.7	1185.3	1987.7
Finland	9.5	74.6	20.4	4117.3	4112.1
France	11.5	82.9	9.8	4263.4	4782.3
Germany	11.2	84.7	12.4	4714.3	5463.3
Greece	8.5	61.3	34.3	1510.7	2261.2
Hungary	7.4	66.2	29.7	942.6	1963.2
Iceland	8.3	81.5	16.8	5063.6	4245.1
Ireland	7.4	72.1	13.0	4758.6	5299.7
Israel	8.1	62.5	23.0	2837.1	2843.0
Italy	8.9	74.5	23.1	2738.7	3427.3
Kazakhstan	3.5	58.8	35.5	262.0	858.8
Kosovo	n.a	n.a	n.a	n.a	n.a
Kyrgyzstan	6.6	42.1	57.6	72.9	240.2
Latvia	6.2	54.6	44.6	874.2	1589.7
Lithuania	6.7	66.9	32.3	987.9	1978.3
Luxembourg	6.2	80.9	11.2	6271.4	6374.2
Malta	9.3	63.1	34.8	2327.8	3511.1
Moldova	9	50.2	46.3	171.2	480.4
Netherlands	10.4	80.9	11.2	4742.0	5251.2
North Macedonia	6.3	64.4	35.4	327.8	934.6
Norway	10.5	85.1	14.5	7477.9	6203.5
Poland	6.5	69.8	23.0	809.0	1784.4
Portugal	9.1	66.4	27.8	1800.9	2778.4
Republic of Korea	7.3	59.2	33.3	2043.9	2711.7
Republic of Serbia	9.1	58.0	40.5	494.2	1322.6

Country	Current HE % of GDP	Public HE % of current HE	OOP in % of current HE	Per capita HE in USD	Per capita HE in current USD PPP
Romania	5.0	78.3	20.8	476.4	1152.2
Russian Federation	5.3	56.9	40.5	469.1	1329.3
Slovakia	7.1	80.8	17.8	1178.7	2172.2
Slovenia	8.5	72.7	12.0	1834.2	2772.2
South Africa	8.1	42.9	7.8	428.2	1071.4
Spain	8.9	71.2	23.8	2389.9	3259.8
Sweden	10.9	83.5	15.2	5710.6	5386.8
Switzerland	12.3	62.8	29.6	9836.0	7867.4
Turkey	4.3	78.4	16.5	468.6	1089.3
Ukraine	6.7	42.6	54.3	141.2	534.2
United Kingdom	9.8	79.5	15.1	3958	4177.8
PPRI countries	8.1	66.7	27.6	2433.7	2909.1
EU28	8.4	72.5	22.4	2730.3	3377.8

EU = European Union, GDP = Gross Domestic Product, HE = Health expenditure; n.a. = not available; OOP = out-of-pocket payments, PPP = Purchasing Power Parities, USD = United States dollars
[1] average of 46 PPRI member countries (excl. Kosovo)

Source: The World Bank 2019c