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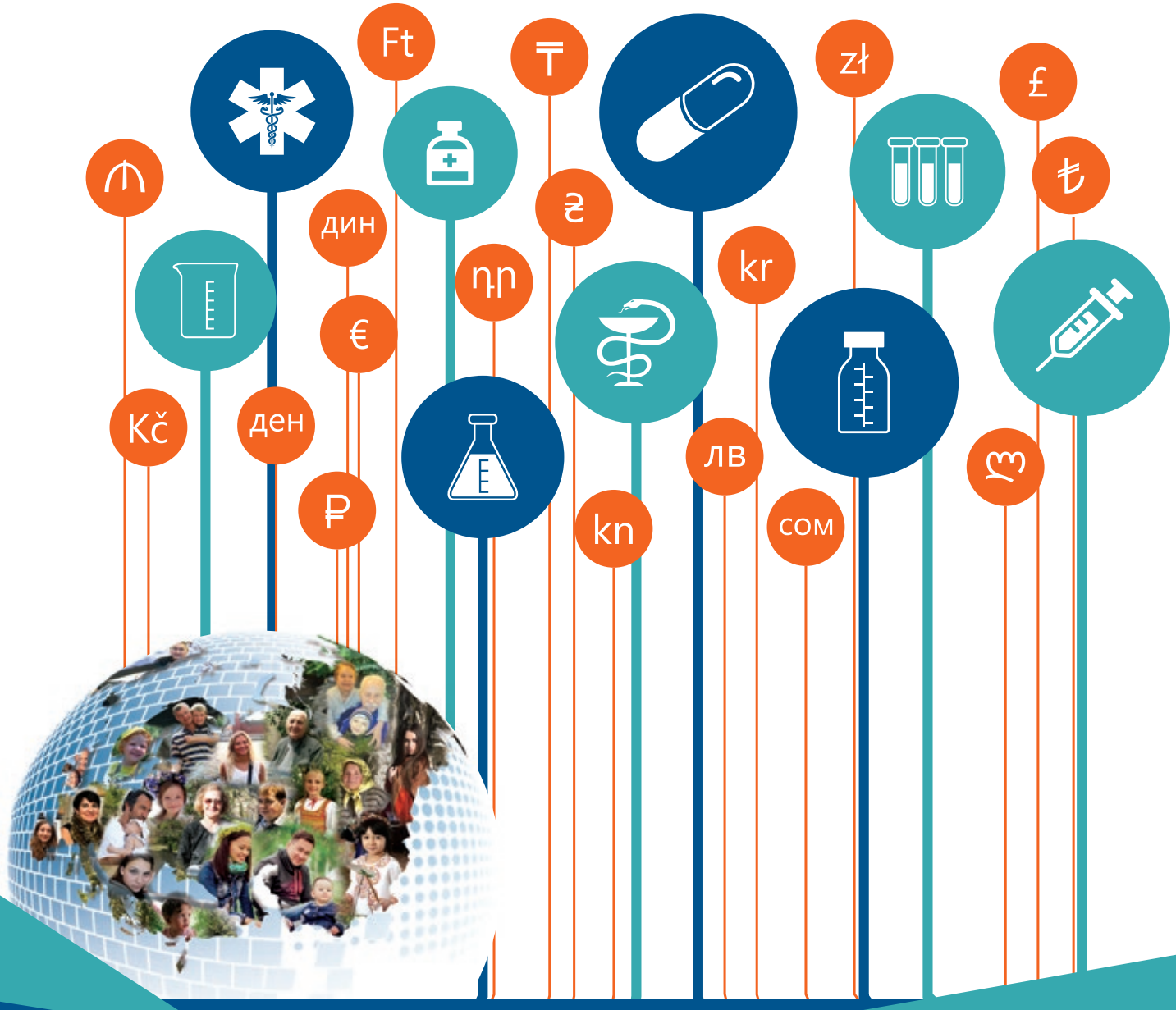
MEDICINES REIMBURSEMENT POLICIES IN EUROPE



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Abstract

This report reviews and analyses different reimbursement policies for medicines applied by countries in the WHO European region. The study used a mixed methods approach including primary data collection through a questionnaire addressing the competent authorities included in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, a literature review, qualitative interviews with authorities and researchers in selected case study countries, and a cross-country analysis of the actual financial burden for patients. The study found that while almost all countries provide full coverage for medicines in the inpatient sector, patients can be asked to co-pay for reimbursable medicines in the outpatient sector. As a commonly applied co-payment patients pay a defined share of the price of a medicine; in addition, prescription fees and/or deductibles are also in place in some countries. In the countries of the WHO European region, mechanisms have been established to protect defined population groups from excessive co-payments for medicines; key reasons for reductions of and exemptions from co-payments include low income, defined diseases or disabilities and age. The analysis of the actual financial burden suggested that co-payments may pose a substantial financial burden for patients, particularly in lower-income countries. The report identified several principles aiming to improve affordable access to medicines and protect people from excessive out-of-pocket co-payments. These include clear priority-setting processes, evidence-based decision-making, transparent processes, consideration of vulnerable population groups, making use of the efficiency of lower-priced medicines, regular evaluations and strategic design of policy measures.

Keywords

PHARMACEUTICAL POLICY
INSURANCE, HEALTH, REIMBRUSEMENT
ACCESS TO MEDICINES
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Abbreviations

ADP	Additional Drug Package [of Kyrgyzstan]
ATC	Anatomical Therapeutic Chemical [WHO Classification]
CIS	Commonwealth of Independent States
COPD	Chronic Obstructive Pulmonary Disease
DDD	Defined Daily Dose
DKK	Danish Kroner
EML	Essential Medicines List
EOPYY	National Organization For Healthcare Service Provision [Greece]
EU	European Union
FJC	Federal Joint Committee
GDP	Gross Domestic Product
HMO	Health Maintenance Organization
HPF	Hospital Pharmaceutical Formulary
HTA	Health Technology Assessment
INN	International Nonproprietary Name
MA	Marketing Authorization
MAH	Marketing Authorization Holder
MEA	Managed Entry Agreement
NHIC	National Health Insurance Company [of The Republic Of Moldova]
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OOP	Out-of-Pocket Payment
PPP	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information [Network]
RPS	Reference Price System
SDG	Sustainable Development Goal
SGBP	State-Guaranteed Benefit Package [of Kyrgyzstan]
SHI	Social Health Insurance
TB	Tuberculosis
UHC	Universal Health Coverage
USD	United States Dollar

Abbreviations of country names used in some figures

ALB	Albania
AND	Andorra
ARM	Armenia
AUT	Austria
AZE	Azerbaijan
BEL	Belgium
BGR	Bulgaria
BIH	Bosnia and Herzegovina
BLR	Belarus
CHE	Switzerland
CYP	Cyprus
CZE	Czechia
DEU	Germany
DNK	Denmark
ESP	Spain
EST	Estonia
FIN	Finland
FRA	France
GBR	United Kingdom of Great Britain and Northern Ireland
GEO	Georgia
GRC	Greece
HRV	Croatia
HUN	Hungary
IRL	Ireland
ISL	Iceland
ISR	Israel
ITA	Italy
KAZ	Kazakhstan
KGZ	Kyrgyzstan
LTU	Lithuania
LUX	Luxembourg
LVA	Latvia
MCO	Monaco
MDA	Republic of Moldova
MKD	The former Yugoslav Republic of Macedonia[1]
MLT	Malta
MNE	Montenegro
NLD	Netherlands
NOR	Norway
POL	Poland
PRT	Portugal
ROM	Romania
RUS	Russian Federation
SMR	San Marino
SRB	Serbia
SVK	Slovakia
SVN	Slovenia
SWE	Sweden
TJK	Tajikistan
TKM	Turkmenistan
TUR	Turkey
UKR	Ukraine
UZB	Uzbekistan

1 The abbreviation MKD is by the International Organization for Standardization (ISO).

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Executive summary

Aim and methods

Policy-makers face important challenges when implementing pharmaceutical policies that aim to achieve affordable, equitable and, at the same time, sustainable access to medicines. High out-of-pocket payments (OOPs), including co-payments for funded medicines, create a risk of lower consumption of needed medicines.

Evidence on which reimbursement policies could be considered best-practice models to ensure access to medicines is lacking. This study therefore aims to provide a comparative review and analysis of the different reimbursement policies for medicines applied by countries in the WHO European Region and to identify practices that best protect vulnerable groups from excessive OOPs.

The review covers the 53 countries in the Region. Primary data were collected through a questionnaire that surveyed the pharmaceutical reimbursement situation in members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. Respondents included competent authorities for pharmaceutical pricing and reimbursement from 46 countries, including 43 of the countries in the WHO European Region. The survey and previous PPRI queries collected information from 37 countries in the Region, including all 28 European Union Member States, Russian Federation and Ukraine. In addition, some data pertaining to the Commonwealth of Independent States (CIS) were collected via the newly established CIS PPRI network through brief country profiles. Information was provided by eight of the 12 CIS countries (two CIS countries had already responded to the first survey). As a result, information was available from 45 of the 53 countries in the WHO European Region.

Nine countries, including three CIS countries, were investigated in further detail in case studies. Via data collection through literature reviews and qualitative interviews with policy-makers and researchers, the case studies aim to analyse selected reimbursement policies related to their impact on affordable access to medicines. In addition, a literature review was performed to identify analyses of the impact of reimbursement policies. To exemplify the relevance and potential of reimbursement policies, the actual financial burden that co-payments pose to various patient groups for selected medicines was assessed.

European mapping

Variations in expenditure and system organization

Wide differences in pharmaceutical expenditure per capita exist across the WHO European Region, ranging from US$ 1056 purchasing power parity (PPP) in Switzerland to US$ 310 PPP in the Russian Federation (2015 data). Lower-income countries tend to have a higher share of pharmaceutical expenditure as a proportion of current health expenditure; for example, the level is more than 26% in some countries, including Hungary, Latvia and Slovakia, compared to less than 8% in Denmark, the Netherlands and Norway (2015 data). A similar pattern is seen for funding sources: higher-income countries usually – but not always – have a higher proportion of public pharmaceutical expenditure, ranging from more than 80% in Germany and Luxemburg to only 16% in the Russian Federation (2015 data). Nevertheless, health care – including pharmaceutical – coverage is high in many European countries compared to other regions of the world.

Public pharmaceutical spending and policies are embedded in organizational settings that aim to achieve universal health coverage. The two main types in Europe are a social health insurance (SHI) system –

found, for instance, in France, Germany and several eastern European countries – and a national health service (NHS) – found in Italy, Spain and the United Kingdom. The main difference concerns the basis for entitlement to services: in SHI systems it is often linked to payment of contributions, while in NHS systems there is no link between payment of taxes and entitlement to services.

Reimbursement policies for medicines should not be seen in isolation. In particular, there is a strong link between pharmaceutical pricing and reimbursement. This is, for instance, reflected in the way pricing and reimbursement processes are completed concurrently in some countries (e.g. Sweden) and are the responsibility of the same competent authority in others (e.g. Italy). Countries can apply different policy options to regulate medicine prices. A common policy applied by several countries in the Region is the practice of external price referencing, which considers prices of the same medicine in other countries as a basis for pricing – and sometimes also reimbursement – decisions; this is frequently supplemented by price regulation targeted at supply chain actors (including pharmaceutical wholesalers and community pharmacies).

Linking reimbursement to different criteria

Reimbursement schemes in countries in the WHO European Region differ considerably between the outpatient and inpatient sectors. Almost all countries have full coverage for medicines in the inpatient sector, meaning that patients do not have to co-pay for medicines in hospitals (formally; informal payments were observed in some CIS countries, for instance).

The report thus looks in particular at reimbursement policies for the outpatient sector, in which patients can be asked to co-pay for reimbursable medicines. For example, a medicine may be considered reimbursable, but this does not necessarily mean that it is 100% funded by a third-party payer (which is in most cases a public entity). In some countries, some medicines with high added therapeutic benefit are fully reimbursed in terms of full coverage of the medicine price (although other co-payments such as a prescription fee may apply), while patients have to co-pay a share of the price for other medicines with lower added therapeutic benefit. Such differentiation per medicine (product-specific reimbursement eligibility) is a frequently used scheme to define eligibility in European countries. The Baltic countries are among a small group of countries using a disease-specific eligibility scheme, meaning that the same medicine may require different co-payments depending on the disease it is used to treat. Denmark and Sweden operate consumption-based reimbursement schemes, in which patients have to pay out-of-pocket for medicines up to a specific threshold of expenses, after which they share payments with the public payer. Over the course of a year the co-payments decrease, depending on patients' spending on medicines. Another type of reimbursement eligibility is the population group-specific scheme that grants higher reimbursement to defined groups of people. In several European countries more than one reimbursement eligibility criterion is applied, although the product-specific eligibility scheme is usually the dominant scheme, supplemented by specific rules for defined population groups.

Competent authorities for reimbursement and/or public payers decide on reimbursement of a medicine, on receipt of a submission from a marketing authorization holder. Decision-making is often supported by expert committees (reimbursement committees) that may or may not include representatives of other public authorities and stakeholders. The decision usually concerns both the reimbursement status and its extent (the reimbursement price) – i.e. whether or not a medicine is considered reimbursable, and to what extent it will be funded by the state. Key criteria used in countries in the Region to determine reimbursement status and extent include the therapeutic value of a medicine (also in comparison to existing alternatives), medical necessity/priority, safety, cost–effectiveness and budget impact. An increasing number of countries have applied health technology assessment to inform reimbursement decisions.

Approaches to protect against vulnerability

A key reimbursement instrument to ensure affordable patient access to medicines is a reimbursement list that specifies medicines selected for coverage (positive list) or explicitly lists those excluded from reimbursement (negative list). All countries in the WHO European Region surveyed have at least one reimbursement list, usually in the form of a positive list.

Only in a few countries (e.g. Austria, Croatia, Cyprus – public sector, Germany, Ireland, Italy, Malta – public sector, the Netherlands and the United Kingdom) is the price of reimbursable medicines or medicines in the public sector fully covered by the public payer (with no percentage reimbursement/co-payment applied), but other co-payments may apply. In addition to percentage co-payment rates that are widespread in the Region, fixed co-payments are also common in several countries (e.g. Estonia, France, Poland). These usually take the form of a prescription fee. Less common is a deductible that requires the patient to pay fully out-of-pocket initially up to a fixed amount; these are found, for instance, in Denmark, Finland and Switzerland. In addition, payments from patients can also be required if they refuse the lowest-priced medicine equivalent to the medicine in the reference price system. The different types of co-payment do not necessarily allow conclusions to be drawn on the extent of payments to be made by the patient, as this also depends on the number of medicines in the outpatient positive list or in the public sector.

In the countries surveyed, mechanisms have been established to protect defined population groups from excessive co-payments on medicines. The most commonly applied mechanisms include a 100% reimbursement rate, a higher than standard reimbursement rate, reductions of or exemptions from the prescription fee and/or lower deductibles. Key reasons for reductions of or exemptions from co-payments include low income, defined diseases or disabilities and age.

Policies for high-priced medicines

An increasing number of countries in the WHO European Region have concluded managed entry agreement (MEAs). These are contractual arrangements between a pharmaceutical company and a public payer that enable reimbursement of a medicine, subject to specified conditions. A variety of different types of MEAs exist, which can be classified, in principle, as either finance-based (such as simple discounts or price–volume agreements) or performance-based (linked to health outcomes); the former are applied more frequently. Common indications covered by an MEA are oncology, rheumatology, hepatitis C and diabetes. In general, MEAs tend to be confidential – at least those aspects relating to the prices and discount arrangements.

Managing the uptake of lower-priced medicines

Tools to promote the use of generics are the demand-side measures of prescribing by international nonproprietary name (INN) and generic substitution. In most European countries doctors are asked to prescribe by INN, usually on a voluntary basis, and some countries have also implemented mandatory INN prescribing. Generic substitution is the practice of substituting a medicine, whether marketed under a trade or generic name (branded or unbranded generic), with a lower-priced alternative medicine (branded or unbranded generic). This practice is in place in the majority of European countries, predominantly on an indicative basis. In recent years an increasing number of countries have moved to make INN prescribing and generic substitution obligatory.

A reimbursement policy that can be used in markets with therapeutic alternatives (e.g. generics) is the reference price system (RPS) (internal price referencing): medicines that are considered interchangeable

(e.g. medicines with the same active ingredient or of the same chemical subgroup) are clustered into one reference group, and the public payer covers the same reimbursement amount for all medicines in that cluster. Most countries set the reference price at the level of the pharmacy retail price of the lowest-priced medicine of the reference group. Patients wishing to get a higher-priced medicine (e.g. an originator brand) have to pay the difference between the reference price and the pharmacy retail price. An RPS benefits from the availability of generics and other lower-priced equivalent medicines on the market, and at the same time contributes to enhancing the uptake of these medicines. Under an RPS, patients are financially incentivized to use generics in order to avoid co-payments.

Case studies

More detailed findings were gained from nine country case studies on specific reimbursement policies or progress towards universal health coverage and access to medicines.

Three case studies relate to CIS countries (Azerbaijan, Kyrgyzstan and the Republic of Moldova); they highlight the countries' struggles to reduce high OOPs in the outpatient sector. In these countries patients are required to purchase most outpatient medicines for chronic use fully out-of-pocket or with a high co-payment. This entails the risk that patients may not purchase medicines they need. Coverage through an SHI or NHS is shown to provide a supportive framework, but the mere existence of a mandatory health insurance fund does not automatically ensure financial protection for patients.

The case studies on the CIS countries and another on Turkey confirm the need to apply different policies, including price regulation. In Azerbaijan and Turkey price control has been effective in bringing medicine prices down, which is beneficial to both public payers and patients. The case of Finland adds to this good-practice example by showcasing the role of policies to manage generic uptake: mandatory generic substitution in combination with an RPS helped to reduce prices in Finland, making medicines accessible to patients through reduced expenditure. The Finnish experience also stresses the importance of a strategic "design" in order to optimize desired impacts and avoid unintended effects.

The case studies on Greece and Spain relate to European countries hit hard by the global financial crisis with a need to implement several cost-containment measures, some of which (e.g. increased co-payments) also address patients. Both countries saw reductions in public pharmaceutical expenditure and in medicine consumption. It remains to be seen whether patients decided to forego needed medication or whether high consumption before the crisis was also attributable to some inefficiencies. The Dutch case study suggests the effectiveness of a reimbursement restriction, not only in terms of cost-containment but also – and in particular – as an improvement in the quality of prescribing.

While most countries in the WHO European Region are confronted by fragmentation of the outpatient and inpatient pharmaceutical sectors, the Scottish case study presents an approach to improve cross-sectoral coordination through joint reimbursement lists and guidelines.

Findings from the literature

Published evidence on evaluations of pharmaceutical reimbursement policies in Europe is limited. Peer-reviewed literature tends to focus on a few western European or Mediterranean countries with large pharmaceutical markets. The literature review identified few studies that assessed the impact of pharmaceutical reimbursement policies. Most focused on an analysis of the introduction of – or an increase in – co-payments for medicines, and of demand-side measures to improve the uptake of generics. While the former increases the financial burden for patients, with a potential risk of excluding

vulnerable populations from access, the latter can create both savings for public payers and higher affordability for patients due to the lower prices of generics. The findings of the literature review also suggest that, in some cases, interventions labelled as cost-containment measures have not always had a negative impact on accessibility and affordability – in particular when they were able to address inefficiencies in the system. The few pieces of research that could be identified in the literature review, however, all pointed to the importance of design of the policy intervention: this tends to be a decisive factor in the effectiveness and success of a policy measure.

Financial burden of co-payments

The financial burden different patient groups encounter for reimbursed medicines was surveyed and assessed for an illustrative sample of medicines in nine selected countries (Albania, Austria, France, Germany, Greece, Kyrgyzstan, Sweden and the United Kingdom). The analysis confirmed significant cross-country differences.

The results showed that the financial burden was eased in some countries for defined patient groups. People on low income were exempt from any co-payment in five of the nine countries surveyed; patients with high medication needs – defined in terms of medicine expenses above a threshold – also benefited from lower co-payments or exemptions in five of the nine countries studied. These factors reflect the preoccupation of some countries with the protection of vulnerable populations.

The study illustrated the impact of medicine prices on the extent of co-payments born by patients: high-income countries had the highest co-payments in some cases, particularly for originator medicines. For the cardiovascular medicine amlodipine, for instance, co-payments ranged from US$ 26.90 PPP to US$ 3.72 PPP for the originator and from US$ 12.25 PPP to US$ 0.35 PPP for the lowest-priced generic in the countries studied. A similarly large variation was found for the respiratory medicine salbutamol (from US$ 12.25 PPP to US$ 0.67 PPP for the originator and from US$ 12.25 PPP and US$ 1.19 PPP for the lowest-priced generic). In another analysis, the same price of the medicines was assumed for all countries to limit the effect of medicine prices in the estimation of co-payments. Under this assumption the picture changed, and particularly high co-payments were seen in lower-income economies.

The analysis also confirmed that co-payments can pose a substantial financial burden for patients. While for most of the selected medicines and countries co-payments in terms of monthly needs or quantities to treat one episode represented less than 1% of the minimum monthly wage, these were higher in Albania and Kyrgyzstan (in particular, up to 9% for a one-month pack of generic amlodipine in Kyrgyzstan, for instance). In this respect, the results also confirmed that patients who used a generic instead of the originator tended to have lower co-payments.

Conclusions

The study describes reimbursement policies in countries in the WHO European Region. While there is no "one size fits all" model, some principles were identified that could be supportive to improve affordable access to medicines and protect people from excessive OOPs. These include clear prioritization, evidence-based decision-making, real-world data generation, transparent and smooth processes, making use of the efficiency of lower-priced medicines, patient involvement in decision-making, systematic and regular evaluations and strategic design of policy measures. Price regulation is a valuable policy to add to the mix of reimbursement policies, and consideration of specific socioeconomic groups (e.g. people on low income) that should be protected from high OOPs can be built into reimbursement policies.

1. Introduction

Policy-makers have to ensure that a balanced mix of pharmaceutical policy options is implemented to meet the goal of affordable, equitable and sustainable access to medicines. WHO has proposed several tools and strategies to support policy-makers in developing appropriate policies, including the concept of the essential medicine list *(1)* and the universal health coverage (UHC) approach (see section 3.1).

European countries with advanced UHC and social protection systems have developed pharmaceutical pricing and particularly reimbursement systems that aim to offer a range of essential medicines to their citizens at no or reduced cost, and sometimes with a particular focus on access for vulnerable groups. Reimbursement systems include a mix of supply-side and demand-side measures targeting different stakeholders (such as the pharmaceutical industry, doctors, pharmacists and patients) with the purpose of reducing or containing medicine prices and ensuring responsible use *(2-5)*.

The last global financial crisis of 2008-2012 saw a decline in pharmaceutical expenditure growth rates and even negative growth rates across European countries *(6)*. This was particularly true for public pharmaceutical expenditure *(7)*. During this period, an intensification of cost-containment measures was observed, particularly in countries that were hit hard by the crisis *(8-10)*. Between 2010 and 2015, changes in co-payments were the second most commonly applied policy measure in European countries, with higher implementation rates in "crisis countries" *(10)*.

High out-of-pocket payments (OOPs) for medicines, including co-payments, create a risk of lower treatment adherence and lower medicine consumption; this may have a negative impact on health *(11)*. During the financial crisis medicine consumption fell in Portugal and Greece – two countries strongly hit by the crisis but with a high level of medicine consumption before it *(8)*. Nonetheless, co-payments policy schemes, if designed properly, may improve efficiency without lowering equity, in particular in the off-patent market *(11)*.

The lack of robust evidence from Europe makes it a challenge to identify which reimbursement systems and policies could be taken as best-practice models to ensure equitable and efficient access to needed medicines. While overviews on reimbursement policies used in European countries exist, up-to-date and more in-depth information, including an impact assessment, about national pharmaceutical reimbursement frameworks has not been published for a large number of countries in the WHO European Region *(12)*.

The objective of this report is therefore to provide a comparative review and analysis of the different medicine reimbursement policies applied by the countries in the WHO European Region. It also aims to identify practices that best protect vulnerable groups from excessive OOPs on medicines. This introduction is followed by seven chapters.

- Chapter 2 presents different methodological approaches developed for primary data collection for the report through a survey of competent authorities, qualitative interviews for the case studies, a literature review and a quantitative analysis to assess the financial burden for patients.
- Chapter 3 provides an overview of the global and European policy context and framework by outlining key approaches to achieve UHC, and highlights the links between policies. It also presents data on pharmaceutical expenditure and consumption.
- Chapter 4 gives a descriptive overview of the reimbursement models, systems and policies from 45 European countries in both the outpatient and inpatient sectors. It also includes information on the market segment for generics.
- Chapter 5 provides an assessment of identified reimbursement models in various countries presented as case studies.
- Chapter 6 presents the key findings of the literature review on assessment of reimbursement models to discuss possible best practices and policies that are able to achieve affordable and equitable access to medicines.
- Chapter 7 outlines the findings of a quantitative analysis of the financial burden of co-payments for the concrete examples of a few medicines for selected patient groups in a few countries.
- Chapter 8 sets out the report's conclusions.

In addition, the report contains a comprehensive set of annexes. Annex 1 offers brief background information from the literature about the countries in the WHO European Region covered by neither the questionnaire survey nor the case studies; Annex 2, Annex 3 and Annex 4 present the methodological tools used for the survey and the case study interviews (see sections 2.3 and 2.4); Annex 5 gives more detailed information on the various pricing and reimbursement policies presented in the core of the report; Annex 6 provides a more detailed description of the results of the literature review; and Annex 7 offers background information and detailed findings from the cross-country analysis of the financial burden for patients presented in Chapter 7. Annex 8 consists of a glossary of the technical terms used throughout the report.

2. Methods

2.1 Mixed methods

The report is based on a mixed methods approach to address a range of study objectives:

- primary data collection from competent authorities to survey information of pharmaceutical reimbursement policies in countries in the WHO European Region (section 2.3);
- qualitative interviews to explore experiences with specific policy measures (section 2.4);
- a literature review to supplement the data collection and in particular to investigate what evidence exists on reimbursement policy objectives (section 2.5);
- a quantitative analysis of the financial burden of co-payments for selected countries, based on price data (section 2.6).

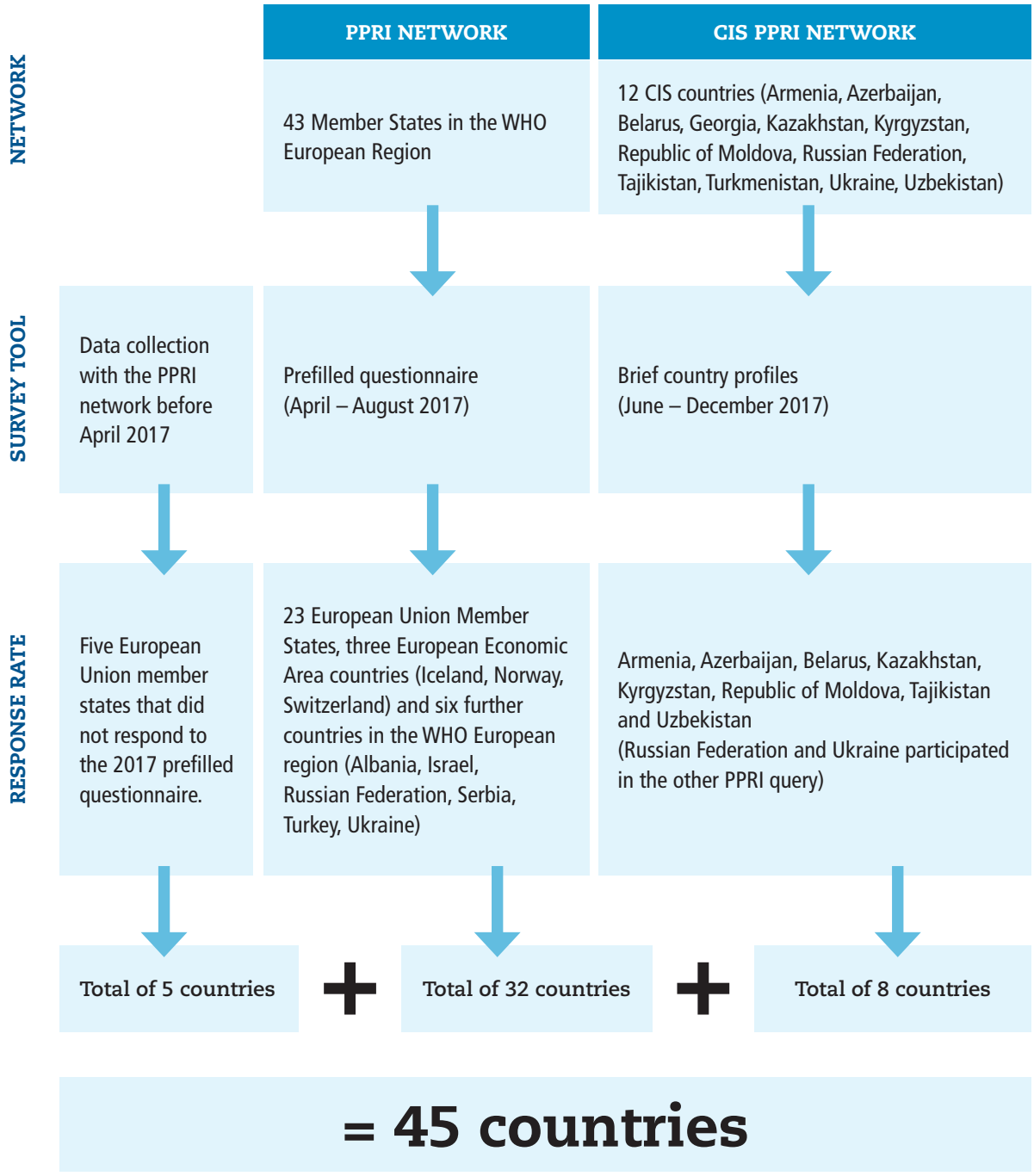
This review relates to the 53 countries in the WHO European Region *(13).* Data were collected from countries that are members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network[1] and that responded to a questionnaire from the network, and from the eight CIS countries[2] that provided data in brief country profiles (see section 2.3). Figure 2.1 represents the different sources of information used in this report.

The review covers both outpatient and inpatient pharmaceutical sectors, with additional analyses of generic markets (mainly outpatient). Although it focuses on reimbursement models, the strong link between pricing and reimbursement policies is acknowledged by highlighting the relevance of the policy mix and presenting key relevant information on pricing in section 3.2. Unless specified, all information about the reimbursement models surveyed (through the PPRI questionnaire and qualitative interviews) relates to 2017.

1 PPRI is a networking and information-sharing initiative on pharmaceutical policies for and with national policy-makers. As of June 2017, the PPRI network consisted of around 90 institutions, mainly medicines agencies, ministries of health, and social insurance institutions from 46 countries including all 28 EU Member States, 15 further countries in the WHO European Region and three non-European countries (Canada, South Africa and South Korea), as well as European and international organizations (European Commission services and agencies, OECD, WHO and the World Bank).

2 In this report, the term "CIS countries" is used to refer to the following countries: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan.

Figure 2.1 | Flowchart of information sources



This study collected primary data on reimbursement policies from 45 of the 53 countries in the WHO European Region (see Table 2.1). For the eight countries in the Region not covered by primary data collection (Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia, Turkmenistan) general information was retrieved through the literature review; this is summarized in Annex 1.

2.2 Terminology

The terminology used in this review is based on the *Glossary of pharmaceutical terms* created by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in Vienna,

Austria *(14)*. Survey respondents were encouraged to refer to this glossary when completing the PPRI questionnaire or the brief country profiles.

The characteristics used to describe the reimbursement systems are based on the standard terminology and literature to define reimbursement policies *(15, 16)*.

2.3 Survey of competent authorities

The study offers detailed information on the reimbursement policies of 45 of the 53 countries in the WHO European Region. These data were collected through two surveys. First, the most up-to-date information on the current status and design of reimbursement policies was collected through a comprehensive questionnaire that addressed a range of pharmaceutical reimbursement policies in the outpatient and inpatient sectors (see Annex 2). This was sent to competent public authorities responsible for pharmaceutical pricing and reimbursement represented in the PPRI network. In April 2017, the 46 countries (of which 43 are in the WHO European Region) that are members of the PPRI network were asked to participate in the survey. A substantial part of the questionnaire was pre-filled for several countries, based on existing evidence in literature, previous PPRI network queries and biannual monitoring of key measures by PPRI. PPRI network members were instructed to update and/or validate information on reimbursement mechanisms in their countries. Returned questionnaires were reviewed and respondents were asked to provide additional information or clarification where applicable. In May and June 2017 reminders were sent to non-respondent countries to submit survey responses. On 22 June 2017 all submitted responses were consolidated and shared with the PPRI network. In August 2017 the survey results were updated on the arrival of a late questionnaire.

In total, 33 of 46 PPRI member countries responded to the questionnaire, including 23 EU Member States, three European Economic Area countries (Iceland, Norway and Switzerland), six other countries in the WHO European Region (Albania, Israel, Russian Federation, Serbia, Turkey, Ukraine) and Canada (excluded from the study as it is outside its scope).

Since the PPRI secretariat has regularly collected information and data from PPRI network members *(17)*, the decision was taken to include information from the five PPRI network members that are in the EU but did not respond to the survey (France, Ireland, Italy, Luxembourg and Slovakia). Ireland and France validated the data and information presented in the report during a review of the final draft report. It is acknowledged that data from Italy, Luxembourg and Slovakia are not validated as of 2017.

As a second step, in June 2017 CIS countries were asked to provide an overview of their pharmaceutical pricing and reimbursement system by filling a brief country profile (see the template in Annex 3). Eight of the 12 CIS countries addressed did so, and two further CIS countries (Russian Federation and Ukraine) had already participated in the PPRI survey. As a result, coverage of 10 of the 12 CIS countries was achieved.

Table 2.1 | Surveyed countries and institutions in the WHO European Region

Albania	Department of Drug Prices and Reimbursement, Compulsory Health Insurance Fund
Armenia	The Scientific Center of Drug and Medical Technologies Expertise, Ministry of Health
Austria	Federal Ministry of Health and Women's Affairs Main Association of Social Security Institutions
Azerbaijan	Secretariat of Tariff (price) Council of the Republic of Azerbaijan
Belarus	Department of Pharmaceutical Inspections and Medicine Provision, Ministry of Health
Belgium	National Institute for Health and Disability Insurance
Bulgaria	National Council on Prices and Reimbursement of Medicinal Products

Table 2.1 | Continued

Croatia	Croatian Health Insurance Fund
Cyprus	Pharmaceutical Services, Ministry of Health Health Insurance Organization
Czechia	State Institute for Drug Control
Denmark	Ministry of Health
Estonia	Medicines Department, Ministry of Social Affairs
Finland	Pharmaceuticals Pricing Board, Ministry of Social Affairs and Health
France	Ministry of Social Affairs and Health
Germany	Federal Ministry of Health
Greece	Division of Pharmaceuticals, National Organization for Healthcare Service Provision
Hungary	National Institute of Health Insurance Fund Management
Iceland	Icelandic Medicine Pricing and Reimbursement Committee
Ireland	Department of Health Health Service Executive
Israel	Ministry of Health
Italy	Italian Medicines Agency
Kazakhstan	National Center for Expertise of Medicines, Medical Devices and Medical Equipment
Kyrgyzstan	Department of Health Care Services Organization and Drug Policy, Ministry of Health
Latvia	Division of Economic Evaluation of Pharmaceuticals, Department of Pharmaceuticals and Medical Devices, National Health Service
Lithuania	Department of Pharmacy, Ministry of Health
Luxembourg	Ministry of Health
Malta	Department for Policy in Health, Directorate of Pharmaceutical Affairs, Ministry of Health
Netherlands	Pharmaceuticals and Medical Technology Department, Ministry of Health, Welfare and Sports
Norway	Norwegian Medicines Agency
Poland	Department of Drug Policy and Pharmacy, Ministry of Health
Portugal	Health Technology Assessment Department, National Authority of Medicines and Health Products
Republic of Moldova	Ministry of Health
Romania	Pharmaceutical and Medical Devices Policy Department, Ministry of Health
Russian Federation	National Research Institute of Public Health
Serbia	Department for Drugs and Pharmacoeconomy, National Health Insurance Fund
Slovakia	Ministry of Health
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
Spain	Directorate General for National Health Service Basic Services Portfolio and Pharmacy, Ministry of Health, Social Services and Equality
Sweden	Dental and Pharmaceutical Benefits Agency
Switzerland	Federal Office of Public Health
Tajikistan	Department of Pharmaceuticals and Medical Goods of the Ministry of Health and Social Protection of Population
Turkey	Department of Economic Assessments and Medicines Supply Management Unit of Health Technology Assessments, Turkish Medicines and Medical Devices Agency, Ministry of Health
Ukraine	Department of Rational Pharmacotherapy, State Expert Centre of the Ministry of Health of Ukraine
United Kingdom	Medicines Pricing, Medicines and Pharmacy Directorate, Department of Health
Uzbekistan	Center for Pharmaceutical and Medical Devices Policy

Note: No 2017 data were received from France, Ireland, Italy, Luxembourg and Slovakia but survey data provided by the institutions listed in Table 2.1 in previous years were considered. France and Ireland validated the information. Information provided on the United Kingdom in this report refers solely to England, apart from the case study on Scotland in section 5.7.

2.4 Qualitative interviews

Qualitative interviews were conducted with the aims of:

- collecting further, more detailed information on selected reimbursement models and policies and exploring its particularities and possible impacts on outcomes; and
- gathering information and data on countries in the WHO European Region that were not part of the PPRI network but whose progress on reimbursement and UHC could be of interest for other countries working on UHC for medicines.

Country selection was based on evidence identified in the literature review and during WHO country work. Interview partners were experts in the field: they either worked in competent authorities responsible for pharmaceutical pricing and reimbursement or were researchers who had published on relevant aspects in this field.

The interviews were based on a guide adjusted for each country to account for the specific focus of the interview (see Annex 4), which was shared in advance. The interviews were held between July and September 2017. Interviews with representatives of Azerbaijan, Kyrgyzstan and the Republic of Moldova were held in Russian, with the support of an interpreter; the other interviews were in English. The minutes of the interviews were shared with the interviewees for validation; they were also offered the opportunity to review the completed case studies for their countries.

2.5 Literature review

A literature review was conducted to:

- review existing data on reimbursement models used in the WHO European Region (in particular, data relevant to those countries that were not part of the primary data collection); and
- search for any evidence (analytical information) on specific reimbursement models, systems and practices that best protect vulnerable groups from excessive OOPs on medicines.

The literature review was based on the following search strategy. A search was conducted in PubMed and Google Scholar based on the following terms (no medical subject headings terms were used):

- "reimbursement", "expenditure", "payment", "co-payment", "Out-of-Pocket Payment", "accessibility", "affordability", "equity", "cost-containment";
- solely and in combination with "medicinal product(s)", "medicine(s)", "drug(s)", "generic(s)", "pharmaceutical";
- solely and in combination with "policy", "policies", "measure(s)";
- solely and in combination with "Europe", "European" and the names of individual European countries.

In addition, searches were conducted in the following data sources to identify grey literature (including in local languages) that might not have been captured in peer-reviewed literature:

- the websites of the WHO Regional Office for Europe, Organisation for Economic Co-operation and Development (OECD) and WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (to identify Health in Transition and Health System Review reports, PPRI or Pharmaceutical Health Information System profiles and PPRI posters, including the 2015 PPRI Conference poster book *(18)*);
- known literature in the field through a list of references in key articles and reports;
- further articles by authors that had been found to have published on the topic;

- recommendations of experts (PPRI network members and interview partners asked to provide information about literature); and
- findings of previous reviews, including:
  - relevant Cochrane reviews *(19, 20)*;
  - a bibliographic review on reimbursement policies in EU Member States as of 2013 *(4);*
  - the 2015 WHO review on access to new medicines in Europe *(15)*.

When working on these data sources, a snowballing approach was also applied, using the following inclusion and exclusion criteria:

- inclusion criteria:
  - both peer-reviewed and grey literature;
  - in any language used in the WHO European Region (sourced with support from country experts and Google Translate);
  - in the geographical scope of the 53 countries in the WHO European Region;
  - published between 2000 and June 2017;
- exclusion criterion:
  - not relating to medicines.

2.6 Quantitative analysis of financial burden

For selected medicines in defined countries, the financial burden resulting from co-payments in various patient groups was assessed.

2.6.1 Selection of medicines

Five medicines commonly used in the outpatient sector were selected. The focus was on the outpatient sector as almost no co-payments are applied for inpatient medicines. A mixture of medicines for acute and chronic care were chosen:

- amlodipine 5 mg, 30 tablets (cardiovascular)
- amoxicillin/clavulanic acid 875 mg/125 mg, 21 tablets (infectious disease)
- ibuprofen 600 mg, 30 tablets (pain/inflammation)
- salbutamol 100 µg, 200 inhalation solution/pressurized inhalation (asthma)
- metformin 500 mg, 100 tablets (diabetes).

2.6.2 Selection of countries

Countries were selected to represent a mix of different income levels, health care systems (national health service (NHS) versus social health insurance (SHI); level of progress in UHC) and different reimbursement/co-payment regulations.

The countries selected were:

- Albania
- Austria
- France
- Germany

- Greece
- Hungary
- Kyrgyzstan
- Sweden
- United Kingdom

2.6.3 Specification of price data and co-payments

Price information was surveyed in national currency units for both the originator and the lowest-priced generic as of September 2017. Pharmacy gross retail prices and (where available) reimbursement prices were retrieved from national official price sources, accessed through the Pharma Price Information service of the Austrian Public Health Institute for EU Member States and through direct contacts for selected non-EU countries.

The amount of co-payments for the selected medicines for defined population groups in the countries surveyed was determined, based on the various co-payment systems described in this report (see Chapter 4 on percentage co-payment rates, prescription fees and deductibles as well as payments due to the reference price system) and on exemptions from or reductions of co-payments for specific population groups or for other reasons (such as having reached a threshold).

2.6.4 Definition of population groups

The financial burden was surveyed in the following population groups for all medicines of the survey:

- people with no specific indication related to a condition/disease, age or income/social condition ("base case");
- children – although because of the dosage of the selected medicines it was only possible to assess this category for salbutamol;
- people on low income according to national definitions (which vary);
- retired people;
- unemployed people;
- people with pharmaceutical expenses within a defined period above a specified threshold (which varies).

By including medicines to treat asthma, diabetes and cardiovascular conditions in the survey, the burden for patients with a specific chronic condition was also investigated.

2.6.5 Comparative analysis

The co-payment amount for the medicines expressed in national currency units for the defined population groups was made comparable using the following indicators:

- expressed in purchasing power parity (PPP) (shown in US dollars, using a 2016 conversion rate);
- expressed as a percentage of the gross pharmacy retail price;
- expressed as a percentage of the minimum wage (official data on the minimum wage published by Eurostat, the statistical office of the EU, were used where available; for Austria and Sweden that do not have official minimum wage data, a subsidy called "minimum security" and survey data were used; in Kyrgyzstan published data confirmed by the Ministry of Finance were used).

In addition, analyses were run based on the assumption that all countries were charged the same price for all medicines.

3. General policy context

3.1 The global development context

A fundamental part of every person's human right to health is the right to access essential, quality-assured health technologies, including medicines *(21)*. Essential medicines satisfy the priority health care needs of the population. Within the context of functioning health systems, essential medicines are intended to be available at all times, in adequate amounts, in the appropriate dosage forms and with assured quality at a price both the individual and the community can afford *(22)*.

The importance of essential medicines is also recognized in the Sustainable Development Goals (SDGs). SDG 3.8 mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of UHC *(23)*, which is a key tenet of the health-related SDGs. All United Nations Member States have agreed to meet the SDG health targets by 2030 with the aim of achieving UHC.

UHC means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, high-quality health services, from health promotion and prevention to treatment, rehabilitation and palliative care *(24)*. UHC is an integrated approach to improve health outcomes, but it does not mean (free) coverage for all possible health interventions, irrespective of cost, since not all interventions are effective or cost-effective. Instead, it is about ensuring a basic package of health services and progressively expanding coverage of health services and financial protection as more resources become available.

The three dimensions of UHC to consider are: who is covered; what services are covered; and to what extent (Fig. 3.1). Moving towards UHC requires strengthening of health systems – a goal that every country can work towards.

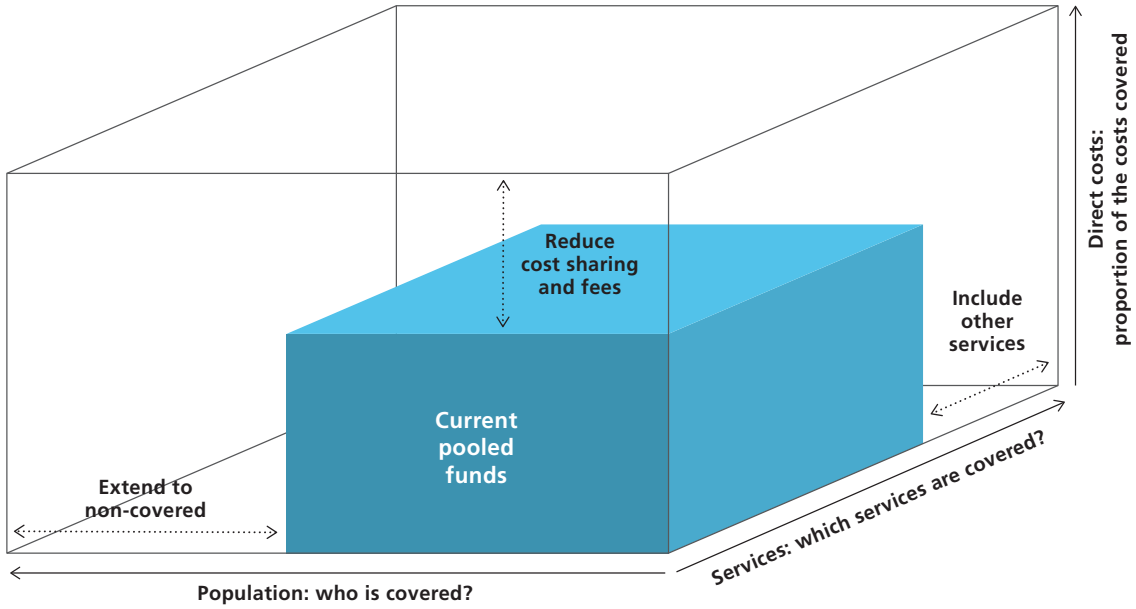
WHO has proposed several approaches and tools to support public decision-making in developing appropriate policies that ensure access to medicines. One approach is the concept of essential medicines, which is complemented by WHO's Model Lists of Essential Medicines, revised every two years *(26)*. A cornerstone of the development of these model lists is the careful selection of essential medicines for public supply and reimbursement based on a systematic review of comparative efficacy, safety and value for money. These principles are relevant for low-, middle- and high-income countries

(27). Based on these principles, some medicines to treat cancer and hepatitis C have been classified as essential medicines, despite their very high prices *(28)*.

WHO has also formulated a four-part framework to guide and coordinate collective action on access to essential medicines (Fig. 3.2).

In practice, there is room for improvement in implementation of the framework. The 2010 World Health Report on health systems financing *(30)* estimated that 20–40% of health spending was wasted, and medicines account for three of the 10 leading sources of inefficiency: underuse of generics and unnecessary high prices for medicines; the use of substandard and falsified medicines; and inappropriate and ineffective use of medicines *(30)*. Ensuring access to medicines is considered a key health system strengthening activity and WHO's UHC strategy puts strong emphasis on this topic *(31)*. Furthermore, there are issues in certain parts of the WHO European Region regarding governance, regulation and quality assurance of medicines, leading to loss of confidence in medicines and ineffective spending.

Fig. 3.1 | Dimensions to consider when moving to UHC



Source: WHO *(25)*.

Fig. 3.2 | Framework for collective action

Source: WHO *(29)*.

3.2 The situation in the WHO European Region

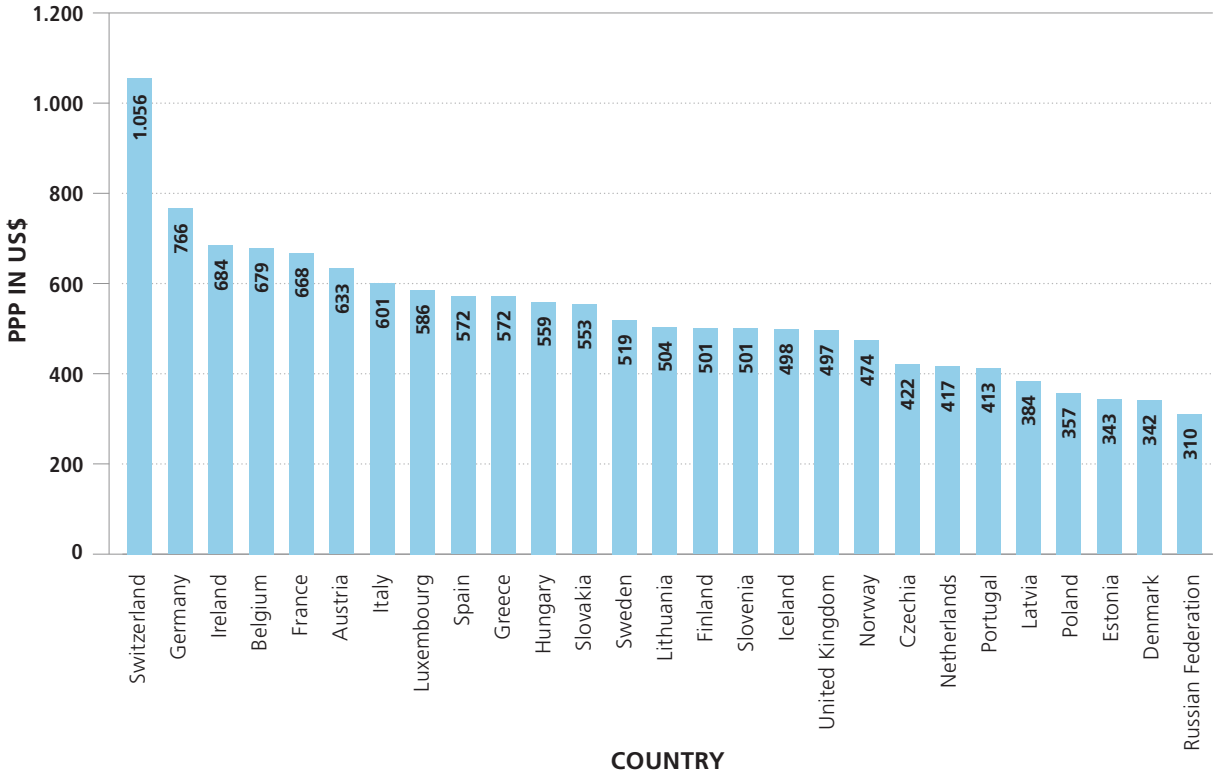
3.2.1 Pharmaceutical expenditure and utilization

Fig. 3.3 and Fig. 3.4 illustrate the variations in pharmaceutical expenditure across countries in the Region.

Fig. 3.5 illustrates public pharmaceutical expenditure as a proportion of total pharmaceutical expenditure. Among selected countries in the Region (for which data are available through OECD Health Statistics *(7)*), public pharmaceutical expenditure in 2015 was on average 55.9% (median 55.5%) of total pharmaceutical expenditure, with figures ranging from 15.7% (Russian Federation) to 83.9% (Germany).

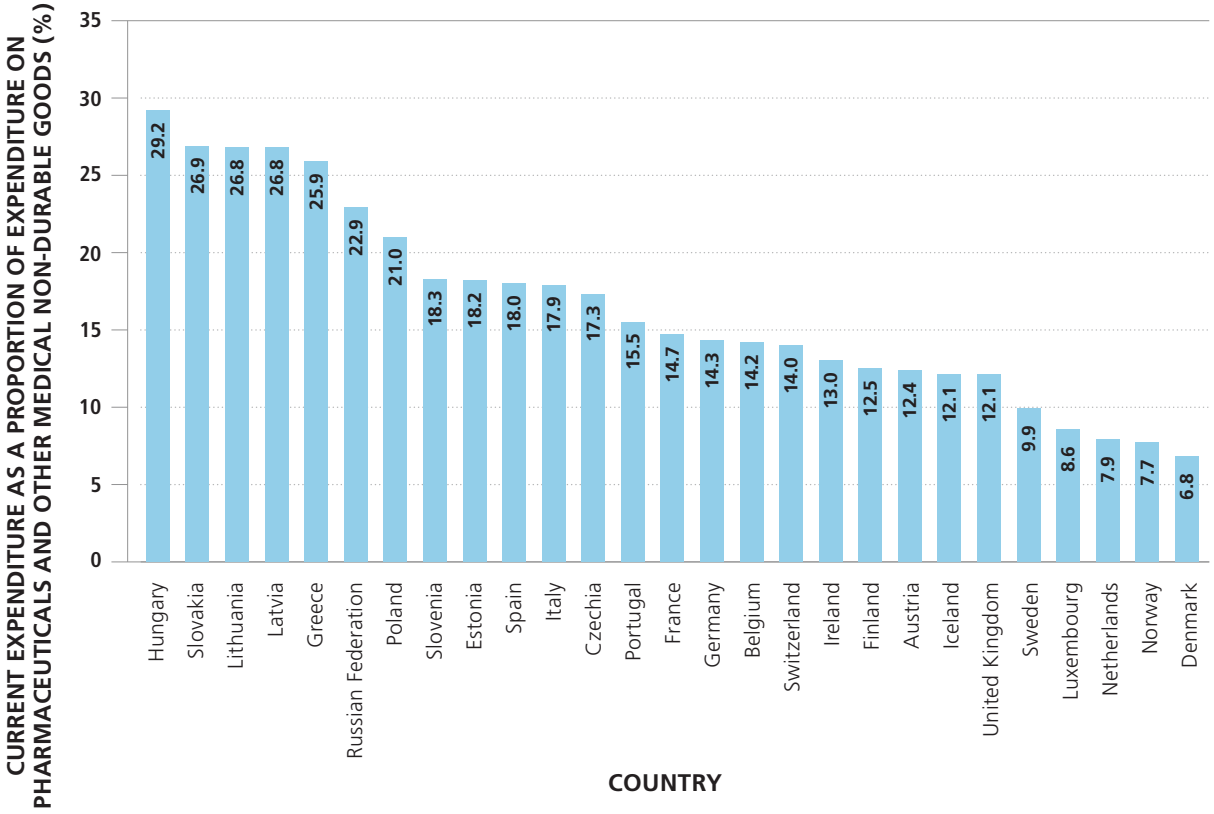
Medicine utilization varies across countries in the Region *(32-34)* owing to several factors including market entry of competitor medicines *(35)*, changes in clinical guidelines and adherence to these, different cultural attitudes and beliefs towards medicines, and pharmaceutical policies.

Fig. 3.3 | Expenditure per capita on pharmaceuticals and other medical non-durable goods in countries in the WHO European Region, 2015



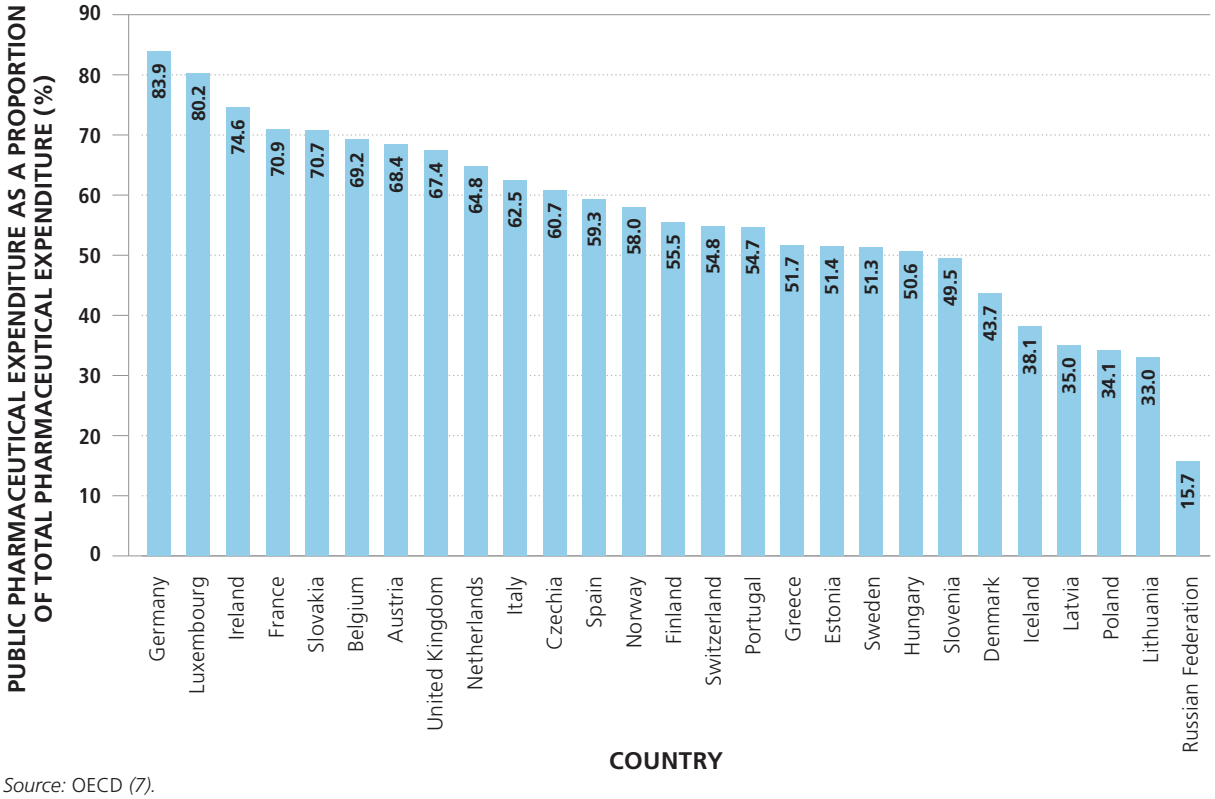
Source: OECD *(7)*.

Fig. 3.4 | Expenditure on pharmaceuticals and other medical non-durable goods as a share of current expenditure on health in countries in the WHO European Region, 2015



Source: OECD *(7)*.

Fig. 3.5 | Public pharmaceutical expenditure as a proportion of total pharmaceutical expenditure in countries in the WHO European Region, 2015



Source: OECD *(7)*.

3.2.2 Health system financing in the Region

Compared to other regions, health care coverage is high in many countries in the WHO European Region *(36)*.

Some western European countries (such as Austria, Belgium, France and Germany) have an SHI system ("Bismarck system") to provide social protection. In the 1990s SHI was also introduced in several countries of central and eastern Europe and the CIS. SHI is a system of financing health care often funded through insurance contributions made by employers, employees and state subsidies. Many countries using the SHI approach have mandatory schemes for (employed) people whose income does not exceed a certain threshold (insurance obligation). SHI is delivered through different health insurers (such as health insurance institutions and sickness funds[3]). In some countries patients have choices when selecting a sickness fund (as in Germany), while in others patients are assigned to a specific sickness fund based on, for example, their occupation (as in Poland).

NHS systems are financed through general taxation (central or regional), usually covering all residents. The scope of services rendered is identical for every person covered, and services are often offered by public institutions. Besides the United Kingdom, some Mediterranean countries (including Italy, Spain and Portugal) and some Nordic countries (including Denmark and Sweden) operate an NHS-based health care system.

Voluntary health insurance may play a role in any health system.

Table 3.1 provides information about the implementation and design of NHS and SHI systems in European countries and of the share of the population covered.

3.2.3 Organization of the pharmaceutical sector

A range of different regulations and policies are required to ensure affordable access to safe medicines. Public investment in research and development of medicines is key: it provides the basis and sets the agenda for access to new medicines. Major stages along the lifecycle of a medicine concern marketing authorization, pricing and reimbursement.

3.2.3.1 Marketing authorization

Marketing authorization (MA) ensures that medicines coming onto the market are safe, effective and quality assured. However, in recent years there has been a move towards bringing new medicines to the market more swiftly. Conditional MAs are used when data on efficacy are limited. Pharmacovigilance functions focus on the post-marketing phase to monitor the safety of medicines and to take action to reduce risks and adverse effects.

3 A sickness fund is a single SHI institution. Several sickness funds may operate in one country (as in Austria) and even compete with each other (as in Germany). Some sickness funds operate on a regional basis, whereas others are limited to specific professional groups such as farmers or self-employed people.

Table 3.1 | Health care coverage in countries in the WHO European Region, 2017

Country	NHS/SHI	Single (S) or multipayer (M)	Competitive SHI	Proportion of population covered by public health insurance
Albania	SHI	S	n/a	n/a
Armenia	Mixed NHS/SHI	M	Yes	n/a
Austria	SHI	M	No	99.9%
Azerbaijan	NHS	S	Not applicable	100%
Belarus	NHS	S	Not applicable	100% [a]
Belgium	SHI	M	Yes	99%
Bulgaria	SHI	S	No	88.2% (2013)
Croatia	SHI	S	No	100%
Cyprus	NHS	S	Not applicable	83% (2013)
Czechia	SHI	M	Yes	100%
Denmark	NHS	S	Not applicable	100%
Estonia	SHI	S	No	93.9%
Finland	NHS	S	Not applicable	100%
France	SHI	M	No	99.9%
Germany	SHI	M	Yes	88.9% (public) 10.9% (private)
Greece	Mixed SHI/NHS	S	No	86% (2015)
Hungary	SHI	S	n/a	95%
Iceland	NHS	S	Not applicable	99.8% (public) 0.2% (private)
Ireland	NHS	S	Not applicable	100%
Israel	SHI	M	Yes	100% (2015)
Italy	NHS	S	Not applicable	100%
Kazakhstan	NHS	S	Not applicable	100%
Kyrgyzstan	NHS[b]	S	Not applicable	100%
Latvia	NHS	S	Not applicable	100%
Lithuania	SHI	S	No	100%
Luxembourg	SHI	M	No	95.9%
Malta	NHS	S	Not applicable	100%
Netherlands	SHI	M	Yes	99.8%
Norway	NHS	S	Not applicable	100%
Poland	SHI	S	No	91.3%
Portugal	NHS	S	Not applicable	100%
Republic of Moldova	SHI	S	n/a	87%
Romania	SHI	S	No	86%
Russian Federation	NHS	S	Not applicable	98.2%
Serbia	SHI	S	No	100%
Slovakia	SHI	M	Yes	94.2%
Slovenia	SHI	S	No	100%
Spain	NHS	S	Not applicable	99.1% (public) 0.8% (private)[c]
Sweden	NHS	S	Not applicable	100%
Switzerland	SHI	M	Yes	100%
Tajikistan	NHS	S	Not applicable	100%[d]
Turkey	SHI	S	No	98.4%
Ukraine	NHS	S	Not applicable	n/a
United Kingdom	NHS	S	Not applicable	100%
Uzbekistan	NHS	S	Not applicable	100%

Notes: n/a = information not available. Health insurance coverage is provided for a core set of services for 2014 (or nearest year). Information on coverage always refers to public coverage unless otherwise indicated.

a In Belarus, access to care and general health service is universal but eligibility for reimbursement of medicines is not.

b Kyrgyzstan's health system presents features of both an NHS and an SHI but it is classified here as an NHS since access to a basic benefit package is not linked to those who contribute financially to the system.

c Some citizens have access to both public and private systems. Civil servants may choose between public and private systems. Data on the private sector might be underestimated.

d In Tajikistan the entire population is covered for a limited set of services under the state-guaranteed package.

Sources: OECD *(36)*; Rosen, Waitzberg & Merkur *(37)*.

The MA process is harmonized for EU Member States and European Economic Area countries: for defined medicines (e.g. medicines developed by specific biotechnological processes, orphan medicinal products) a centralized MA procedure is completed by the European Medicines Agency; for other medicines national regulatory agencies complete the process in a coordinated way (Directive 2004/27/EC). For non-EU countries in the WHO European Region MA varies by country, with ongoing reform efforts influenced by international guidance, including from WHO. For instance, since the establishment of the Eurasian Economic Union in 2016, efforts are under way to harmonize the MA process among these countries and in line with international standards.

3.2.3.2 Pricing and reimbursement

Pricing policies are defined as "regulations and processes used by government authorities to set the price of medicines to exercise price control" *(14)*. They are closely linked to reimbursement policies where a public payer such as an SHI institution or NHS covers the cost of the medicine.

Several countries discussed in this report have established a strong link between pricing and reimbursement processes. For example, pricing and reimbursement of medicines in Finland and Sweden are taken concurrently. In other countries (such as Italy and Portugal) the same institution is in charge of both pricing and reimbursement (see section 4.2.1.1).

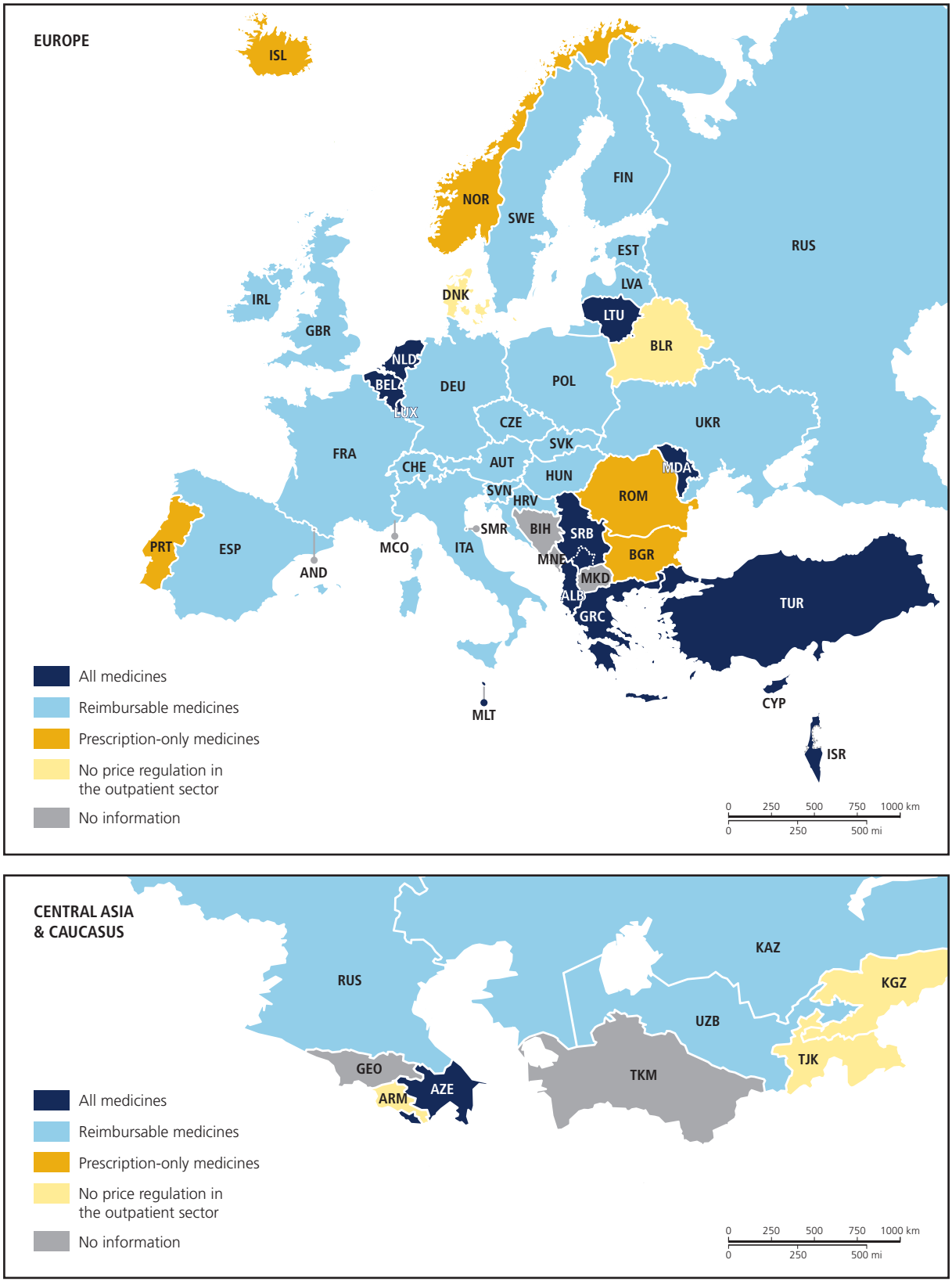
Although the MA process is harmonized for EU Member States, pricing and reimbursement decisions for medicines remain a national competence (subsidiarity principle). Nevertheless, EU Member States are required to comply with the EU Transparency Directive (Directive 89/105/EEC). The Directive's provisions stipulate that decisions on pricing or reimbursement of medicines have to be taken within 90 days after each dossier submission (or within 180 days for joint pricing and reimbursement). Furthermore, they require competent authorities to follow transparent processes in pricing and reimbursement decisions. The national decision has to contain a statement of reasons based on objective and verifiable criteria that will be published appropriately. The Transparency Directive grants manufacturers the possibility of an appeal to an independent body against a pricing and/or reimbursement decision.

Most countries discussed in this report have price controls in place for reimbursable medicines (those whose costs are, at least partially, covered by a public payer) (see Fig. 3.6). In some countries (including Albania, Belgium and Lithuania) prices are regulated for all medicines, including non-reimbursable medicines; in others (including Bulgaria, Iceland and Romania) the scope of price regulation refers to prescription-only medicines. Price regulation refers not only to setting medicine prices at the ex-factory price level but also to remuneration of wholesalers, pharmacists and further distributors and dispensers, as well as taxes (such as value-added tax), duties and other mark-ups *(38)*.

External reference pricing is a key pricing policy often applied in the outpatient sector. It is the practice of using the price(s) of a medicine in several countries to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product in a given country. Several countries (including Austria, Belgium, Estonia and Romania) apply external price referencing as a starting-point to set the list price for some medicines (typically new on-patent medicines) (see Fig. 3.7). A second step involves negotiations between the public payer and the pharmaceutical manufacturer on the specific reimbursement price and conditions (such as managed entry agreements for high-priced medicines; see section 4.2.6).

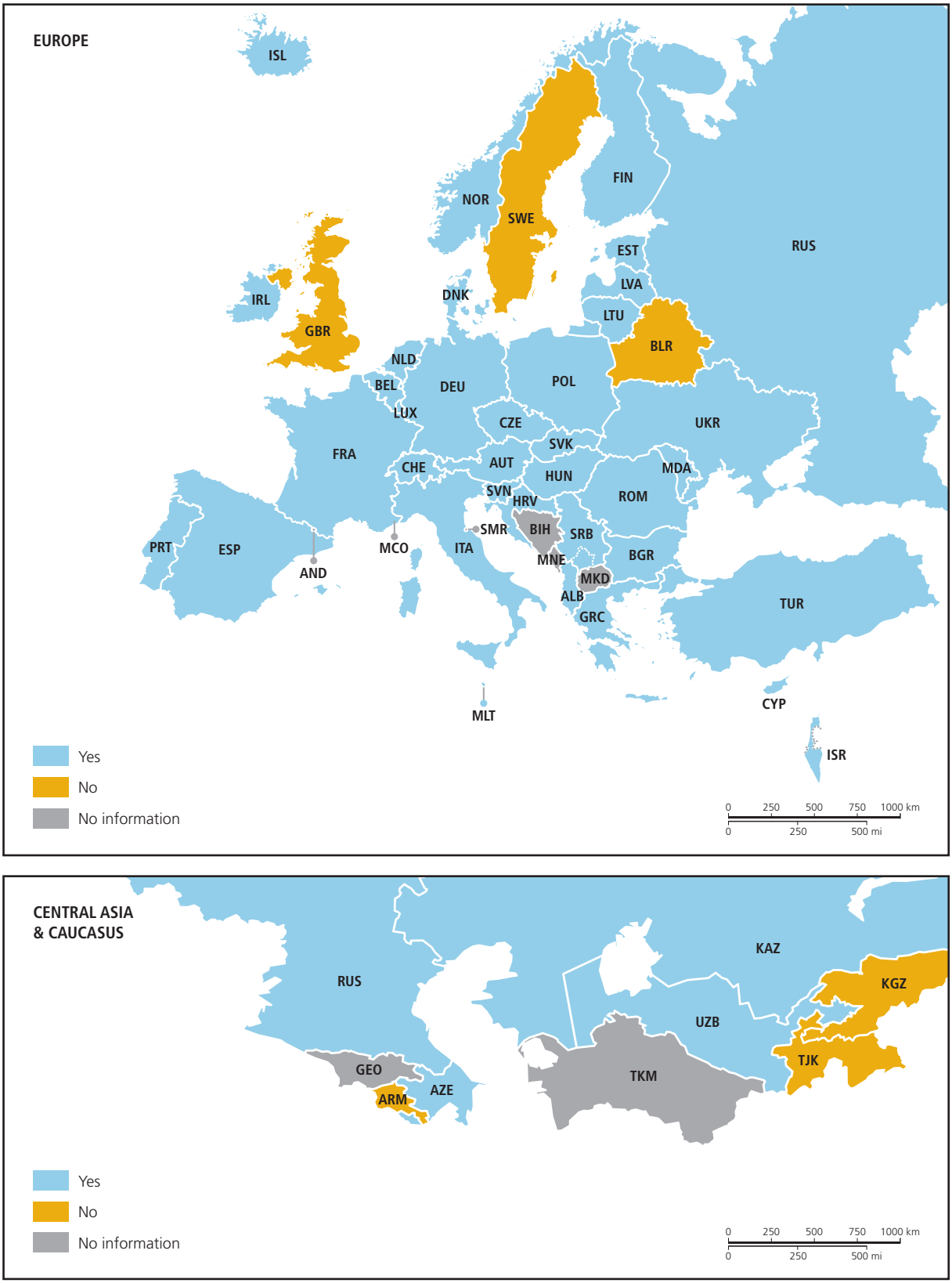
In the inpatient sector medicines are usually procured by tendering through a centralized procedure or by individual hospitals. In recent time, hospitals have increasingly been moving to more joint procedures – involving regional or central procurement – particularly in the light of new high-priced medicines (see section 4.2.5.1).

Fig. 3.6 | Scope of price regulation in the outpatient sector in countries in the WHO European Region, 2017

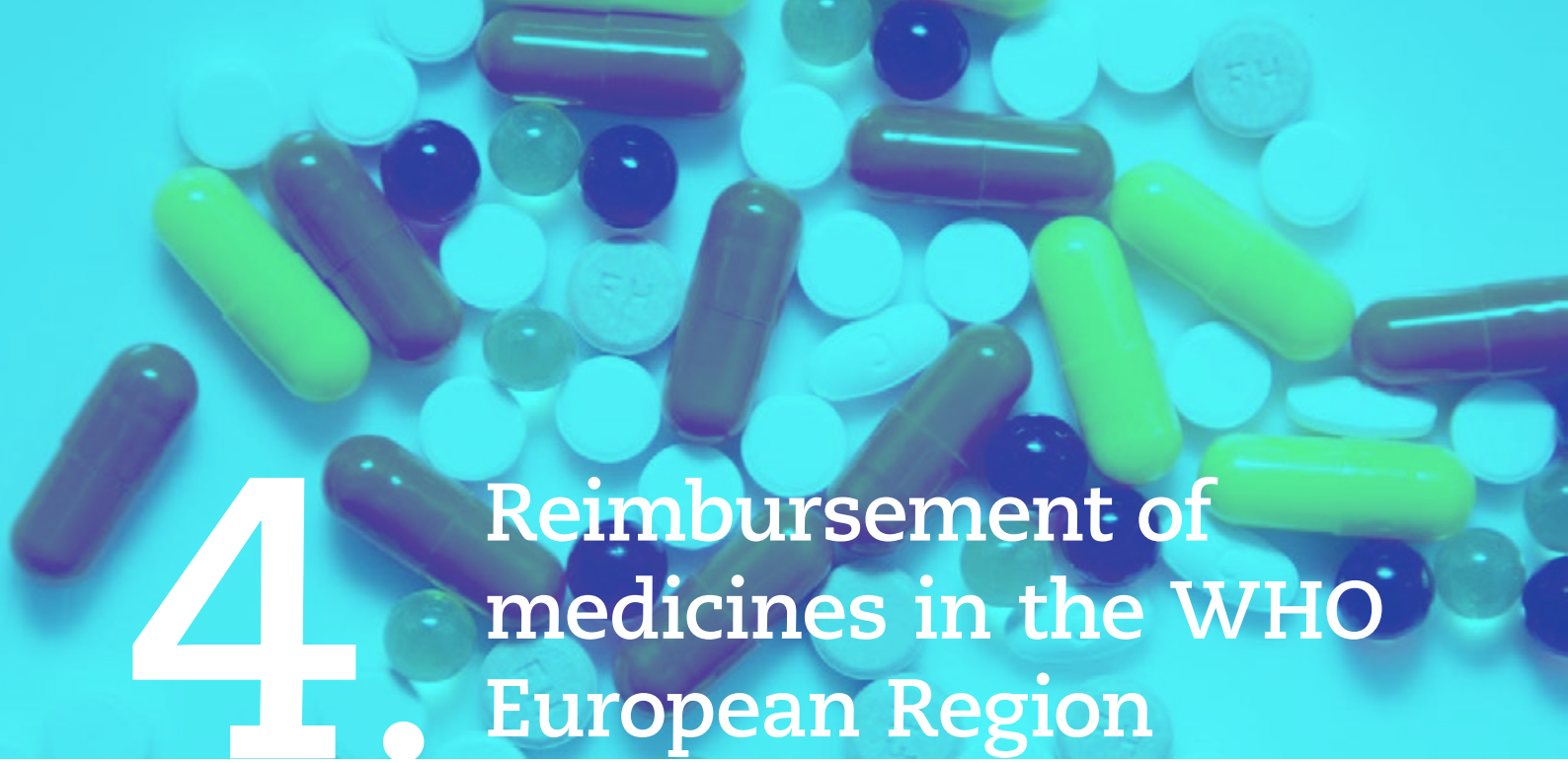


Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health. ©WHO 2018. All rights reserved.
Notes: Unless specified, price regulation is understood to be applied at the ex-factory level. **BLR:** there is a formal price declaration system but it does not lead to medicines price control in practice. **DNK:** no price regulation in the outpatient sector, but mechanisms for setting a reimbursement 'price' (i.e. amount that is reimbursed). **CYP, DNK, FIN, GBR, HRV, ISL, MLT, NLD, NOR, SRB, SWE:** regulation at wholesaler price level. **KAZ:** medicines reimbursed are part of the "Guaranteed Free Healthcare Package". **MLT:** medicines in the public sector. **UZB:** medicines reimbursed are part of the "list of socially important medicines"

Fig. 3.7 | Practice of external price referencing in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health.
Notes: Countries stating that they apply external price referencing do not necessarily use this tool for all medicines.
ARM, BEL, KGZ, TJK: no use for ERP as prices are not formally regulated. **DNK:** ERP used only in the inpatient sector. **DEU:** present in the legislation, rarely used in practice. **UKR:** used in a pilot project only.



4. Reimbursement of medicines in the WHO European Region

This chapter provides an overview of different reimbursement policies, instruments and models in the outpatient and inpatient sectors in countries in the Region. Following an outline of the key eligibility schemes in study countries (section 4.1), section 4.2 contains key elements of pharmaceutical reimbursement (framework, process and tools). Section 4.3 addresses patient co-payments for medicines, with a focus on vulnerable populations, and section 4.4 addresses policies for the off-patent market.

The description provided covers 45 countries; these include all 28 EU Member States and 17 other countries in the WHO European Region (Albania, Armenia, Azerbaijan, Belarus, Iceland, Israel, Kazakhstan, Kyrgyzstan, Norway, Republic of Moldova, Russian Federation, Serbia, Switzerland, Tajikistan, Turkey, Ukraine and Uzbekistan). Of these, 32 countries responded to the PPRI network questionnaire or – as in the case of five EU Member States – to previous PPRI surveys (see section 2.3). In addition, information was collected from the PPRI network for a further eight CIS countries (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan).

4.1 Eligibility for reimbursement coverage

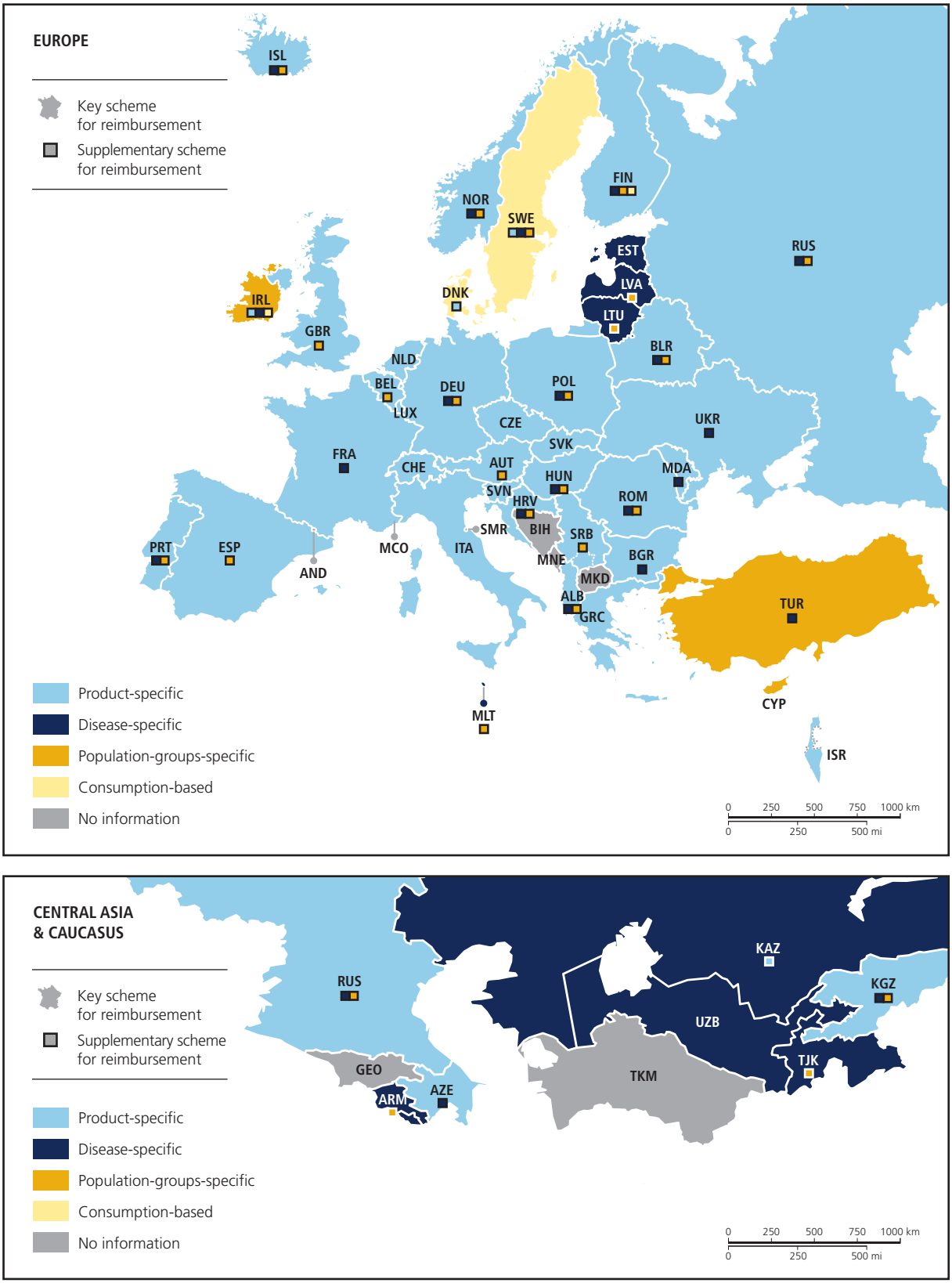
Eligibility for reimbursement coverage may depend on the medicine (product-specific) or the disease the medicine aims to treat (disease-specific); reimbursement eligibility may also be linked to a specific population group in need of medicines (population groups-specific) or the total medicine expenditure of a patient within a certain period of time (consumption-based). While a country may apply more than one reimbursement eligibility criterion, there is typically one dominant reimbursement scheme.

Fig. 4.1 provides an overview of the application of reimbursement schemes in the countries surveyed. More in-depth information can be found in Table A5.1 in Annex 5.

4.1.1 Product-specific eligibility

Under this scheme, reimbursement eligibility depends on the medicine in question: a medicine is considered either reimbursable (its expenses are fully or partially paid for by a public payer) or non-reimbursable.

Fig. 4.1 | Reimbursement eligibility schemes for outpatient medicines in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health.
Definitions: **Product-specific reimbursement:** Eligibility for reimbursement depends on the medicine in question (either a medicine is considered as reimbursable or as non-reimbursable). **Disease-specific reimbursement:** Eligibility for reimbursement is linked to the underlying disease that shall be treated. The disease-specific reimbursement targets the reimbursement status and the reimbursement rate. A medicine may be reimbursed at different reimbursement rates for the treatment of different diseases. Specific programmes for some indications also fall under disease-specific reimbursement. **Population-groups-specific reimbursement:** Specific population groups (e.g. children, old-age pensioners) are eligible for free medicines, or medicines at higher reimbursement rates, while others are not. **Consumption-based reimbursement:** The level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption).

The competent authority for pharmaceutical pricing and reimbursement or a public payer determines the reimbursement status of a medicine, typically based on an evaluation of different criteria (such as therapeutic benefit, added therapeutic value compared to alternative products, cost–effectiveness and budget impact; for further details see section 4.2.2). The evaluation of these criteria also influences the reimbursement rate of the product, which may vary depending on the proven benefits of the medicine or the therapeutic indication of the treatment. In a few of the 45 countries surveyed, all reimbursable medicines are 100% reimbursed (no percentage co-payment); however, other co-payments such as prescription fees or payments due to a reference price system may still apply (see sections 4.2.4 and 4.3.1). In the other countries different percentage co-payment rates are in place for different medicines.

Product-specific eligibility is the main reimbursement scheme for outpatient medicines in 32 of the 45 countries surveyed. Ireland and Kazakhstan apply this approach as a supplementary scheme: Ireland applies a population groups-specific approach and Kazakhstan a disease-specific approach as the main scheme.

4.1.2 Disease-specific eligibility

In this approach, the reimbursement status and the reimbursement rate are linked to the disease to be treated. The same medicine may be reimbursed at different rates depending on the patient's disease.

Disease-specific reimbursement for outpatient medicines is the main scheme in the three Baltic States – Estonia, Latvia and Lithuania – as well as in Malta and several CIS countries, namely Armenia, Kazakhstan, Tajikistan and Uzbekistan. In several countries in the WHO European Region disease-specific reimbursement is employed as supplementary scheme (including Azerbaijan, Bulgaria, France, Ireland, Kyrgyzstan and Portugal). Countries with disease-specific reimbursement eligibility schemes employ a list of specified reimbursable diseases for which pharmaceutical treatment is reimbursed (whereas the reimbursement list in a product-specific scheme specifies the selected medicines).

4.1.3 Population groups-specific eligibility

Under this scheme, specific population groups are eligible for pharmaceutical reimbursement (at a higher rate than the standard reimbursement rate or at 100% reimbursement rate). Eligible population groups may include individuals who require special financial protection in order to ensure access to treatment owing to their condition (e.g. chronic or infectious diseases, disability, pregnancy), age (e.g. children, elderly people), status (e.g. pensioner, war veteran) or means (e.g. people on low income, unemployed).

Population group-specific reimbursement is a key scheme in Cyprus, Ireland and Turkey in the outpatient sector. In Turkey, different population groups access reimbursable medicines at different rates. A 90% reimbursement rate of the total amount of prescription applies to retired people and their dependants, while active workers and their dependants are eligible for 80% reimbursement. Medicines for patients with chronic diseases certified by a medical report are 100% reimbursed.

Many countries in the WHO European Region have adopted elements of the population groups-specific eligibility approach to complement another key scheme (product-, disease- or consumption-based reimbursement) by offering higher or full coverage for vulnerable patients and other specific population groups. Patients with specific conditions (including severe chronic diseases such as diabetes or cancer) may qualify for reductions or exemptions in several countries, including Albania, Finland, Hungary,

Latvia, Lithuania, Poland, Portugal, Romania and the United Kingdom. Patients with low income may be exempted from co-payments (as in Austria, Germany and the United Kingdom). In Malta, population group-specific reimbursement is a subscheme in the outpatient sector for means-tested patients who are not eligible for disease-specific reimbursement.

4.1.4 Consumption-based eligibility

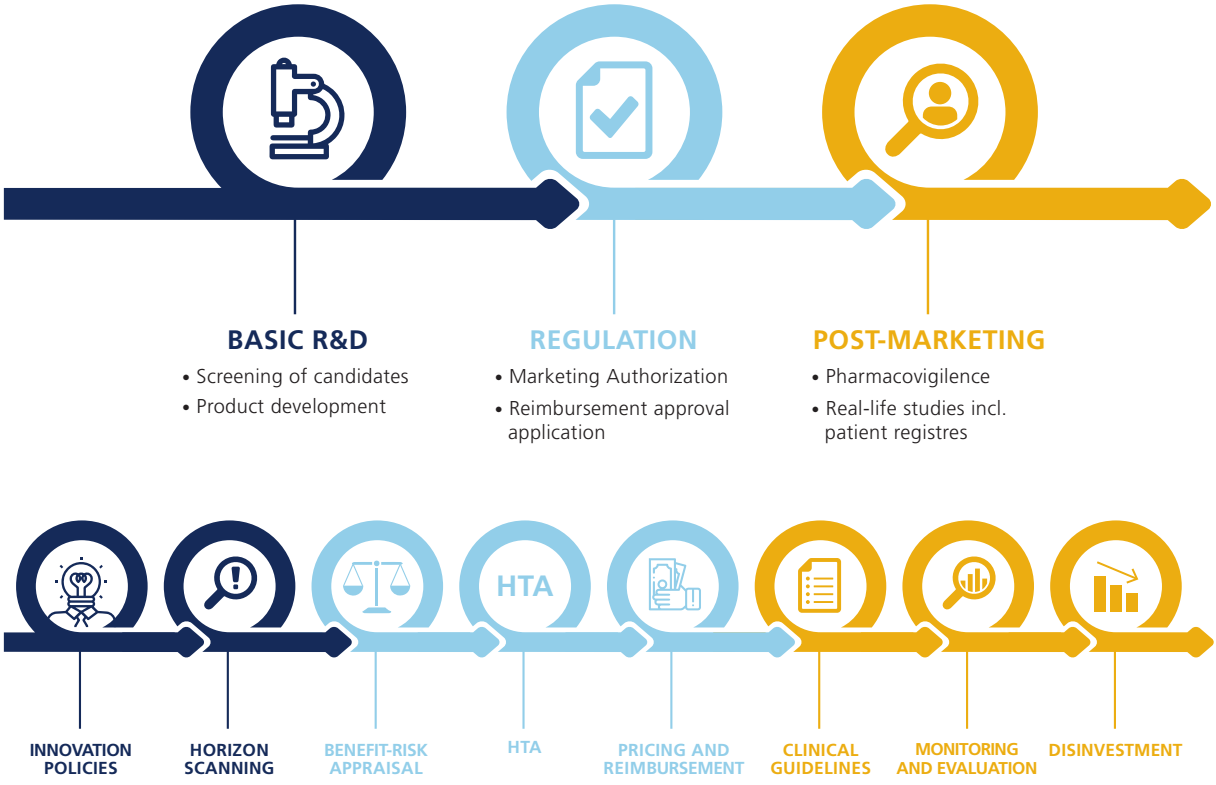
With this approach, reimbursement coverage increases with rising pharmaceutical consumption (measured through a patient's gross pharmaceutical expenditure) of an insured patient within a specified time period (usually a year). Once a patient has reached a defined threshold of OOPs (the so-called "deductible"), the public payer fully or partially covers any additional pharmaceutical expenses incurred by the patient within the remaining time period. Consumption-based eligibility schemes favour patients that require more pharmaceutical care (such as the chronically ill).

Consumption-based reimbursement in the outpatient sector is the predominant scheme in Denmark (see Box 4.1) and Sweden.

4.2 Reimbursement framework

As outlined in section 3.2.3, there is a strong link between pricing and reimbursement processes and further pharmaceutical policies (see also Fig. 4.2). As such, this section will also address pricing-related issues and information related to MA.

Fig. 4.2 | Flowchart of the pharmaceutical system



Box 4.1

Consumption-based reimbursement in Denmark

Before a patient is entitled to reimbursement through a public payer, he/she must pay the full cost of his/her reimbursable medication up to a threshold of 950 Danish kroner (DKK) (€128) within a period of one year (the reimbursement period). After passing this first threshold, the reimbursement rate increases as expenses for reimbursable medicines increase. The amount of reimbursement differs between patients younger or older than 18 years at the start of the period (see table below). The one-year reimbursement period begins when reimbursable medicines are bought for the first time after the end of the preceding period.

Annual personal expenses on reimbursable medicine	Reimbursement for adults (>18 years)	Reimbursement for children and adolescents (<18 years)
Annual expenses <DKK 950	0%	60%
Between DKK 950 and DKK 1565	50%	60%
Between DKK 1565 and DKK 3390	75%	75%
>DKK 3390	85%	85%
For adults: >DKK 18 331	100% (equivalent to a total annual co-payment of DKK 3995)	-
For children and adolescents (<18 years): >DKK 22 541	-	100% (equivalent to a total annual co-payment of DKK 3995)

For annual personal expenses on reimbursable medicines, only the cost of the cheapest generic medicine is considered. For children and adolescents under the age of 18 years, the threshold to be eligible for 100% reimbursement is the fixed annual maximum co-payment for adults (DKK 3995 or €537).

If the patient requires a more expensive generic medicine than its lower-priced marketed alternative, the doctor may apply for increased reimbursement. In this case, the funding is based on the pharmacy retail price instead of the reimbursement price.

In special cases, a patient can be reimbursed for a particular medicine that does not have general reimbursement. This requires an application, including justification, for single reimbursement by the doctor to the Danish Medicines Agency.

For terminally ill people, all medicine expenses are covered if prescribed by a doctor.

With these three types of individual reimbursement, as well as the reimbursement for those aged less than 18 years, the Danish system also includes elements of a population group-specific reimbursement scheme.

Note: At currency exchange rates checked on 30 October 2017, DKK 1 = €0.134. In 2018, the maximum patient co-payment was DKK 4030 per year.
Source: Danish Medicines Agency *(39)*.

4.2.1 Reimbursement process

4.2.1.1 Institutions

Table 4.1 provides an overview of national authorities in charge of MA, pricing and reimbursement in the WHO European Region. Decisions on pharmaceutical reimbursement in the outpatient sector are commonly carried out by the SHI fund, the ministry of health or ministry of social affairs. In the inpatient sector, funding decisions are sometimes taken at a more decentralized level (see section 4.2.5.1).

In some countries (such as Czechia, Denmark, Italy and Norway), reimbursement decisions are taken by medicines agencies, while in others specific institutions are in charge of reimbursement (as in Bulgaria, Finland, Iceland, Sweden and Uzbekistan). Institutions in charge of pricing may also be responsible for reimbursement (as in Bulgaria, Iceland, Italy and Norway). In several countries in the Region, inpatient and outpatient reimbursement decisions are within the competence of the same authority, but practical decisions such as which medicines to procure and to put on the hospital formulary (see section 4.2.5.2) might be taken at the hospital level (such as Greece, Lithuania and Norway). Among the few examples of cross-sectoral policies aiming to bridge the outpatient and inpatient sectors is the collaboration related to the list of recommended medicines in Swedish regions (see the model example of the "Wise List" of Stockholm County Council, Box 4.2).

Table 4.1 | National competent authorities responsible for marketing authorization decisions, pricing and reimbursement of medicines and institutions in charge of reimbursement/funding of medicines in countries in the WHO European Region, 2017

Country	Competent authority for				Public payers for medicines	
	MA	Product pricing	Reimbursement (outpatient)	Reimbursement (inpatient)	Outpatient	Inpatient[a]
Albania	Medicines Agency	Ministry of Health	Ministry of Health/ Obligatory Health Care Insurance Fund	Ministry of Health/Obligatory Health Care Insurance Fund	n/a	Hospitals
Armenia	Scientific Centre of Drug and Medical Technology Expertise	No price regulation	Ministry of Health	Ministry of Health	State Health Agency	State Health Agency
Austria	Medicines Agency	Ministry of Health	SHI	Hospitals and hospital owners (regions)	SHI (sickness funds, mainly at regional level)	Hospitals and hospital owners (mostly regions)
Azerbaijan	Ministry of Health	Tariff Council (Ministry of Health)	Ministry of Health	Ministry of Health	NHS	NHS
Belarus	Ministry of Health	Ministry of Health[b]	Ministry of Health	Ministry of Health	NHS	NHS
Belgium	Ministry of Health	Ministry of Economy/ Economics	Ministry of Social Affairs	Ministry of Social Affairs	SHI	SHI
Bulgaria	Medicines Agency	National Council on Prices and Reimbursement of Medicinal Products	National Council on Prices and Reimbursement of Medicinal Products	National Council on Prices and Reimbursement of Medicinal Products	National Health Insurance Fund and Ministry of Health	National Health Insurance Fund, hospitals and Ministry of Health
Croatia	Medicines Agency	SHI	SHI	SHI	SHI	SHI
Cyprus	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	n/a	n/a
Czechia	Medicines Agency	Medicines Agency	Medicines Agency	Health insurance funds/Ministry of Health	SHI	SHI

Table 4.1 | Continued

Country	Competent authority for				Public payers for medicines	
	MA	Product pricing	Reimbursement (outpatient)	Reimbursement (inpatient)	Outpatient	Inpatient[a]
Denmark	Medicines Agency	No price regulation	Medicines Agency	Regions	Regions	Regions through a purchasing agency
Estonia	Medicines Agency	Ministry of Social Affairs[c]	Ministry of Social Affairs[c]	SHI	SHI	SHI
Finland	Medicines Agency	Ministry of Social Affairs and Health, Pharmaceutical Pricing Board	Ministry of Social Affairs and Health, Pharmaceutical Pricing Board	Hospitals	SHI	Hospital owners (municipalities)
France	Medicines Agency	Health Care Products Pricing Committee	SHI	SHI	SHI	Hospitals via their donation from the SHI and the SHI directly for expensive innovative medicines
Germany	Medicines Agency	Federal Joint Committee/SHI in negotiations with pharmaceutical company	Federal Joint Committee	Federal Joint Committee	SHI	SHI
Greece	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	SHI	Hospital budget for public hospitals
Hungary	Medicines Agency	Ministry of Health/SHI	SHI/Ministry of Health	SHI/Ministry of Health	SHI	hospitals
Iceland	Medicines Agency	Pricing and reimbursement agencies	Pricing and reimbursement agencies	Pricing and reimbursement agencies	NHS	University hospital, reimbursed by Icelandic Health Insurance (NHS)
Ireland	Medicines Agency	Health Service Executive (competent authority for pricing and reimbursement decisions)	NHS	NHS	NHS	Hospitals via own budget/ NHS for medicines covered under national drug management programmes
Israel	Ministry of Health	Ministry of Health	Health maintenance organization (HMO)	Ministry of Health/HMO	Ministry of Health/HMO	Ministry of Health/HMO
Italy	Medicines Agency	Medicines Agency	Medicines Agency	Medicines Agency	Regions	Regions

Table 4.1 | Continued

Country	Competent authority for				Public payers for medicines	
	MA	Product pricing	Reimbursement (outpatient)	Reimbursement (inpatient)	Outpatient	Inpatient[a]
Kazakhstan	Medicines Agency	Medicines Agency and Ministry of Health	Ministry of Health	Ministry of Health	NHS	NHS
Kyrgyzstan	Medicines Agency	No price regulation	Ministry of Health and mandatory health insurance fund	Ministry of Health	Mandatory health insurance fund	Hospitals via the donation received from the mandatory health insurance fund
Latvia	Medicines Agency	NHS	NHS	NHS	NHS	NHS
Lithuania	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	National health insurance fund (SHI)	SHI, hospitals
Luxembourg	Ministry of Health	Ministry of Economy	SHI	SHI	SHI	SHI
Malta	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health
Netherlands	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	SHI (health insurers)	SHI (health Insurers)
Norway	Medicines Agency	Medicines Agency	Medicines Agency	Medicines Agency	National insurance scheme (SHI)	Regional health authorities (hospitals)
Poland	Medicines Agency	Ministry of Health	Ministry of Health/SHI	Ministry of Health/SHI	SHI	SHI
Portugal	Medicines Agency	Medicines Agency	Ministry of Health and Medicines Agency	Ministry of Health and Medicines Agency	NHS	NHS
Republic of Moldova	Medicines Agency	Medicines Agency	Ministry of Health	Ministry of Health	Mandatory health insurance fund	Mandatory health insurance fund
Romania	Medicines Agency	Ministry of Health	Medicines Agency/Ministry of Health/SHI	Medicines Agency/Ministry of Health/SHI	Ministry of Health/SHI	Ministry of Health/SHI
Russian Federation	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health	n/a	n/a
Serbia	Medicines Agency	Ministry of Health/SHI	SHI	SHI	SHI	SHI
Slovakia	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	SHI	SHI
Slovenia	Medicines Agency	Medicines Agency	SHI	SHI	SHI	SHI (only "expensive" medicines)
Spain	Medicines Agency	Ministry of Health/ Interministerial Committee for Pricing	Ministry of Health	Ministry of Health	Autonomous Community budgets	Autonomous Community budgets

Table 4.1 | Continued

Country	Competent authority for				Public payers for medicines	
	MA	Product pricing	Reimbursement (outpatient)	Reimbursement (inpatient)	Outpatient	Inpatient[a]
Sweden	Medicines Agency	Pricing and reimbursement agency	Pricing and reimbursement agency	Not defined	County councils (regions)	County councils (regions)
Switzerland	Medicines Agency	Ministry of Health	Ministry of Health	Ministry of Health	SHI	SHI
Tajikistan	Service for State Vigilance of Pharmaceutical Activities	No price regulation	Ministry of Health	Service for State Vigilance of Pharmaceutical Activities	Primary care facilities via their own budget	Hospitals via their own budget
Turkey	Medicines Agency	Medicines Agency/SHI	SHI	SHI	SHI	SHI
Ukraine	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health
United Kingdom[d]	Medicines Agency	Department of Health[e]	Department of Healthe	NHS England	NHS	NHS
Uzbekistan	Medicines Agency	State committee for supporting private enterprises	Ministry of Health and Ministry of Finance	Ministry of Health and Ministry of Finance	Ministry of Health	Hospitals via their own budget (Ministry of Health also procures hospital medicines centrally)

Notes: n/a = not available. SHI might be a single payer institution or different health insurers. Competences for pricing only refer to those medicines under price control – usually reimbursable medicines (see section 3.2.3.2).

a Public payers for inpatient medicines are, at first glance, the hospitals that procure, but they receive funding from other institutions (e.g. their owners). For some countries, details of allocation of funding for inpatient medicines could not be collected.

b In Belarus there is a formal price declaration system at the point of registration but in fact the country remains a price taker only since there is little oom to contest declarations from MA holders, this is why the country is referenced as having no price regulation in figure 3.6.

c In 2018 the Ministry of Social Affairs was renamed the Health Insurance Fund.

d Information refers to England only.

e In 2018 the Department of Health was renamed the Department of Health and Social Care.

As shown in Table 4.1, payers and purchasers may be different from competent authorities that are responsible for decision-making. In countries with SHI-based systems (see section 3.2.2), the umbrella organization of the SHI institutions takes reimbursement decisions for the country, whereas individual health insurers pay for medicines (as in Austria, France and the Netherlands).

In some NHS countries (including Italy and Spain), reimbursement decisions are taken at the federal (national) level, but regions pay, and may also negotiate specific arrangements such as managed entry agreements (see section 4.2.6).

Box 4.2

Cooperation to develop the "Wise List" in Stockholm (Sweden)

Sweden has an autonomous regional structure where reimbursement decisions are taken at a national level through the Dental and Pharmaceutical Benefits Agency; however, regions (county councils) work on lists of medicines that are recommended for prescribing.

The "Wise List" (*Kloka Listan* in Swedish) concept has been developed and expanded since 2000 as a means to communicate independent medicine recommendations to improve the quality of medicine prescribing and use throughout the Stockholm metropolitan region. The concept was launched to provide only one set of medicine recommendations for the entire region. The recommendations are jointly developed by evidence-informed medicine experts to improve responsible use of medicines. The first edition of the Wise List, launched in 2001, only addressed the outpatient sector; in 2006 it was expanded to cover medicines used in hospitals in addition. It is thus one example of an "interface management" policy bridging both outpatient and inpatient sectors.

The Wise List is the result of a joint effort: a panel of 21 experts (consisting of trusted physicians, clinical pharmacologists and pharmacists) assists Stockholm County Council in reviewing and evaluating the scientific evidence within their respective fields. The experts propose medicines to be recommended based on an agreed guideline for evaluating efficacy and safety, pharmaceutical appropriateness, cost–effectiveness and environmental factors. All experts are required to comply with a strict policy for potential conflicts of interest, declared annually.

The suggestions of the expert panels are presented to the drug and therapeutics committee, which is an independent and multidisciplinary medical steering committee for medicine use and policy within Stockholm County Council. After careful review, a decision on the suggested medicines recommended by the expert panels is made. Recommendations are reviewed annually or as needed.

The Wise List recommends 200 medicines for treating common diseases in primary and hospital care and an additional 100 medicines for specialized care. It is issued by the regional drug and therapeutics committee as a pocket-sized booklet and is also available in a web version.

Sources: Janusinfo (40); Gustafsson et al. (41).

4.2.1.2 Decision-making processes

The processes applied to make reimbursement decisions may vary between countries according to the institutions and stakeholders involved, but some common characteristics can be identified in many of the countries surveyed. In most countries MA holders are required to submit an application dossier to the competent authority for pricing and/or reimbursement or to the public payer if they want their medicine to be considered for inclusion in the positive list of reimbursed medicines.

Upon application for reimbursement by the MAH, scientific evidence on the medicine's therapeutic benefit is compiled and assessed by a technical department, and a summary report prepared. The evidence is usually appraised by an independent expert committee responsible for providing advice on reimbursement to the final decision-makers (such as the ministry of health or health insurance institution). In most countries (including Austria, Czechia, Hungary, Romania and Serbia) the national competent authority decides on inclusion of the medicines in the (outpatient) positive list.

In the Netherlands the final decision on the reimbursement status of medicines is taken by the Minister of Health, while in Germany, the reimbursement and pricing process involves a number of stakeholders (see Box 4.3). In Norway, the MAH for a medicine can apply for pre-approved reimbursement so that physicians can prescribe the reimbursed medicine directly to the patient.

The application is assessed and the decision is made by the Norwegian Medicines Agency. If the budgetary implication is expected to exceed 5 million Norwegian krone (€526 691)[4] in the fifth year after marketing, the decision is made by parliament on the advice of the Ministry of Health and Care Services. Under certain conditions reimbursement can be granted on the basis of individual patient applications for medications not included in the reimbursement list. In such cases, applications are sent by the physician to the Norwegian Health Economics Administration (a governmental institution, under the Norwegian Directorate for Health and Social Affairs).

Box 4.3

The German Reform of the Market for Medical Products Act

In Germany, all prescription-only medicines with MA (either from the national authorization body or the European Medicines Agency) are in principle reimbursable through statutory health insurance. The Federal Joint Committee (FJC) may limit or exclude the prescription-only medicines on behalf of public payers due their inappropriateness or the availability of more cost-efficient options with the same therapeutic value. Non-reimbursable medicines include non-prescription and lifestyle medicines. The FJC may list a non-prescription medicine as reimbursable if it is considered the standard of care for a more severe disease.

In December 2010, the Reform of the Market for Medical Products Act was passed with the aim of limiting the increasing cost of pharmaceuticals. The Act obliges pharmaceutical companies to subject their new medicines containing new active substances or new combinations of active substances to an early assessment of additional benefit by the FJC after entering the German market. The company is required to submit a dossier providing data to prove an additional benefit of the medicines over the appropriate comparator specified by the FJC. The FJC's assessment is also the basis for the pricing of reimbursable medicines.

If no additional benefit to the comparator therapy can be proven, the medicine is allocated to a reference price group of comparable active substances with an existing fixed-rate arrangement. The fixed rate is the maximum refund up to which a specific product is reimbursed. If no reference price group is in place, the statutory health insurance institution negotiates a refund rate with the pharmaceutical company; this must not lead to higher annual therapy costs than the comparator.

If an additional benefit is proven, the statutory health insurance institution negotiates the price with the pharmaceutical company, using the price of the comparative therapy as a starting-point. The negotiated price applies from the first day of the thirteenth month after market launch (before that, the product is priced freely by the MAH), for patients with statutory and private insurance. Further, individual contracts between individual health insurance institutions and pharmaceutical companies can be created on specific medicines; however, the negotiated price remains the upper price ceiling for such contracts.

If no price agreement is reached between the negotiating parties within six months of the FJC resolution, the proceeding goes into arbitration. Following an arbitral award, both sides may apply to the FJC for a cost–benefit valuation. An arbitral award can be challenged in the competent social court.

Until completion of the Act's procedures 12 months after market launch, the price set by the pharmaceutical company applies to the new medicine and is reimbursed by the statutory health insurance institution. Under specific circumstances, the FJC may also evaluate the additional benefits of medicines already on the German market prior to 1 January 2011.

Medicines of little economic impact (below €1 million turnover per year with statutory health insurance) and medicines for hospital use only are excluded from early assessment of additional benefit.

4 At currency exchange rates checked on 30 October 2017, 1 Norwegian krone = €0.105.

In several countries (such as Croatia, Denmark and Lithuania), national reimbursement committees are involved as advisory bodies, assessing the value of the medicine using specified criteria and formulating recommendations on reimbursement eligibility before a final decision is made. The recommendations of the reimbursement committee are usually not binding for the competent authority, however.

These committees may vary in composition, with different stakeholders. In Austria the committee consists of members from academia, sickness funds (health insurers), as well as physicians, pharmacists and consumers. Committees in Sweden and France put the emphasis on academic and scientific experts *(42)*. Estonia's expert committee is composed of representatives from the Ministry of Social Affairs, Medicines Agency, SHI, two societies of doctors, two societies of patients and the University of Tartu.

4.2.1.3 Timelines and duration of reimbursement decisions

All EU Member States surveyed reported making a decision on reimbursement status within 90 days (or 180 days if a decision on price is also made) after an application submission by the MAH. This is in line with the requirements of the EU Transparency Directive (see section 3.2.3.2). If further information on behalf of the MAH or further negotiation on managed entry agreements (see section 4.2.6) are needed, however, the public payer and the MAH can agree on a "clock-stop" during the price and reimbursement negotiations. For generic medicines, faster access is ensured, as some country examples show (Box 4.4).

Box 4.4

Duration of the reimbursement decision process – examples from several countries in the WHO European Region

In Austria the Main Association of Social Security Institutions decides on inclusion of medicines in the outpatient positive list of reimbursed medicines, upon application for reimbursement by the MAH. A decision about reimbursement status is taken within 90 days (or 180 days if also a decision on price is taken) of the application. During this time, a medicine is temporarily included in the so-called "red box" of the reimbursement code.

In Belgium the Commission for Reimbursement of Medicines has 150 days to transmit its advice to the Ministry of Social Affairs, which has to decide within an additional 30 days. Thus, reimbursement decisions are taken within 180 days of submission of the request by the company.

In Bulgaria the recommendation for inclusion of medicines with a new international nonproprietary name (INN) in the positive list is issued by the Health Technology Assessment Committee within 90 days. With a positive decision, the National Council on Prices and Reimbursement of Medicinal Products announces its final reimbursement decision within 90 days. For generic products with a new concentration of the active substance or dosage form, a reimbursement decision is taken within 60 days; for other generic products a decision is announced within 30 days.

In Czechia a decision on reimbursement status is taken within 30 days if a similar medicine is already reimbursed; otherwise, the maximum time allotted for pricing or reimbursement decisions is 75 days, or 165 days for a joint pricing and reimbursement decision.

In Estonia the Ministry of Social Affairs (as of 2017) decides on inclusion of medicines in the outpatient positive list on receipt of a full application from an MAH for an originator medicine. A preliminary evaluation is made by the Ministry within 15 days; this is sent to the Medicines Agency and SHI for their expert opinions (subsequently in a further 30 days per institution). Further advice on the reimbursement

Box 4.4 | Continued

of medicines is requested from the drug and therapeutics committee (which includes representatives from the Ministry of Social Affairs, Medicines Agency, SHI, two societies of doctors, two societies of patients and University of Tartu). The Ministry has to announce a decision within 180 days of application submission. A simplified application for generic medicines is presented, assessed and decided by the Ministry of Social Affairs within 90 days of the date of submission.

In Finland the Pharmaceuticals Pricing Board confirms reimbursement and a reasonable wholesale price of medicines, clinical nutritional preparations and basic ointments that are reimbursable under the Health Insurance Act. The Board may consult the social insurance institution and/or expert group during the process. Patient organizations may also express their opinions. The evaluation takes 90 or 180 days depending on the type of application. Medications for which a reasonable price has not been confirmed are not reimbursed.

In Hungary a reimbursement decision for new active substances or combinations of new indications is taken within 90 days.

In Latvia in order to apply for reimbursement of a pharmaceutical the MAH has to submit a written application to the NHS. The decision on inclusion in the reimbursement system and on pricing has to be made within 180 days of application, whereas a decision on a price change of a medicine already reimbursed is taken within 90 days.

In Portugal the National Authority of Medicines and Health Products, delegated by the Ministry of Health, decides on inclusion of medicines in the outpatient positive list, upon web application for reimbursement by the MAH. A decision on reimbursement status is taken within 75 days for non-generics and 30 days for generics.

In Romania the National Agency for Medicines and Medical Devices decides on inclusion of medicines in the positive list (outpatient and inpatient) upon application for reimbursement by the MAH. The decision about reimbursement status is taken within 90 days. A positive decision can be conditional (depending on the cost-volume outcome) or unconditional. Decisions issued by the Agency are subject to approval by the government.

In Serbia the Central Commission for Medicines makes the final decision on inclusion of medicines in the outpatient positive list upon application for reimbursement by the MAH. A decision on reimbursement status is taken within 90 days (or 180 days for new INN) of the application. Other committees involved are expert committees in various fields and a pharmacoeconomics committee.

Future reimbursement policies need to be more agile to address regulatory approaches that use conditional licencing and adaptive pathways. When evidence on a new medicine's efficacy is limited at the time it enters the market, countries could consider reviewing the reimbursement decision only when more evidence and data on efficacy are available, or could reassess a reimbursement decision once such data become available.

4.2.2 Criteria for reimbursement

The majority of countries surveyed apply a limited set of decision-making criteria for pharmaceutical reimbursement. Commonly assessed criteria include the following (Table 4.2).

Table 4.2 | Criteria for reimbursement in countries in the WHO European Region, 2017

Key criteria for reimbursement	Countries
Therapeutic benefit of a medicine and/ or relative therapeutic benefit (added value compared to existing alternatives)	Armenia, Austria, Belgium, Bulgaria, Czechia, Croatia, Denmark, Estonia, Finland, Kazakhstan, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Republic of Moldova, Serbia, Slovenia, Spain, Ukraine
Medical necessity/priority	Armenia, Estonia, Finland, Kazakhstan, Netherlands, Norway, Poland, Republic of Moldova, Turkey, Ukraine
Safety	Armenia, Bulgaria, Denmark, Estonia, Iceland, Malta, Netherlands, Poland, Republic of Moldova, Russian Federation
Cost–effectiveness	Belarus, Czechia, Estonia, Finland, Kazakhstan, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Turkey, United Kingdom
Budget impact	Belgium, Bulgaria, Czechia, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland, Republic of Moldova, Slovenia, Turkey

Note: No data are available for: Albania, Azerbaijan, Cyprus, France, Greece, Hungary, Ireland, Israel, Italy, Kyrgyzstan, Luxembourg, Romania, Slovakia, Sweden, Switzerland, Tajikistan, Uzbekistan.

Country-specific criteria for decision-making are shown in Table A5.2 in Annex 5.

4.2.2.1 Role of health technology assessment

Health technology assessment (HTA) is a multidisciplinary process that systematically assesses information not only on the clinical benefits but also on the social, ethical and economic aspects related to use of health technologies and interventions. HTA aims to inform policy- and decision-making in health care, with a focus on how best to allocate limited resources to health technologies and interventions. In particular, its objective is to determine the relative value for money provided by a new medicine compared to existing treatment options in order to prioritize the use of efficient and effective health technologies.

Many countries have established HTA systems to inform decision-making in the reimbursement of medicines, but the extent to which HTA is used for coverage decisions may vary (see Box 4.5). While some countries systematically apply HTA for all new medicines (such as Denmark, France and Poland), others only assess those causing certain concerns due to, for instance, uncertain effectiveness, high prices or high budget impact (such as United Kingdom). Of the 45 countries surveyed, 34 have at least one HTA agency in place, primarily in the public sector. The remaining 11 (Albania, Armenia, Azerbaijan, Belarus, Cyprus, Greece, Kyrgyzstan, Republic of Moldova, Slovakia, Tajikistan and Uzbekistan) have no independent public sector HTA entity; however, an HTA strategy is currently in development in Albania, Belarus, Cyprus, Greece and Slovakia *(15)*. Turkey has an HTA department as part of the Medicines and Medical Devices Agency but there is no mandatory HTA evaluation on a product basis yet.

Information required for HTA is usually taken from the reimbursement application dossier submitted by the MAH. Appraisal of the evidence aims to advise decision-makers on the recommended reimbursement status of the technology. Various criteria are employed, of which relative therapeutic value and cost–effectiveness are among those most reported in the countries using HTA to inform reimbursement decision-making (see Table A5.2 in Annex 5).

To foster collaboration on HTA across European countries, the EUnetHTA project was initiated. This established a sustainable network of HTA agencies, research institutions and ministries of health across European countries, in order to enable an effective exchange of information and to support policy decisions. Strategic objectives of the EUnetHTA collaboration include a reduction of overlaps and

duplications of efforts, an increase of HTA input into decision-making – and hence of the impact of HTA – and an improved link between HTA and health care policy-making. The EUnetHTA collaboration started in 2007, with the financial support of the European Commission, and has grown to a network of 78 organizations from 29 countries in the form of a joint action (a cooperation between government authorities and researchers, co-funded by the Commission). Key deliverables are the so-called "core models" that provide practical guidance for the performance of core and rapid HTAs. With EUnetHTA Joint Action 3 ending in 2020, the future of the HTA collaboration among European Union Member States is yet to be decided. In January 2018, the European Commission published a proposal for regulation of HTA.

Box 4.5

HTA – examples from Malta, Norway and Poland

Malta reported that HTA for a medicine is performed after the MAH or lead consultant working within the public sector has submitted a reimbursement application for a new medicine, a new formulation or a medicine already included in the government formulary but with a new indication. The HTA is then presented to the Government Formulary List Advisory Committee for technical appraisal. Subsequently, the Advisory Committee of Health Care Benefits appraises the HTA from the financial perspective. Both committees give their recommendations to the Minister of Health, who ultimately has the final decision on the product's reimbursement status.

Norway uses three HTA formats: a mini HTA, a single technology appraisal and a full HTA. The mini-HTAs are limited assessments performed by clinicians and supporting units within hospitals. The single technology appraisals focus on a single method of health technology related to a comparator and are performed by either the Norwegian Medicines Agency (for medicines) or the Norwegian Institute of Public Health (for all other technologies). Full HTAs are broad assessments performed at the national level by the Norwegian Institute of Public Health and may be, for instance, used to compare various technologies that have been used in clinical practice. When performing an assessment, the appropriate agency works in close dialogue with clinicians who, among others, have been recruited by the four regional health authorities. To optimize the process for introduction of new medicines, it was decided to conduct single technology appraisals on all new medicines and indications from 1 January 2018. In this way, the system achieved improved predictability and efficiency in completing timely reports for MA.

In Poland an HTA evaluation for new molecules is led by the Agency for Health Technology Assessment and Tariff System, which consults and advises the Minister of Health. A recommendation, given by the President of the Agency, is issued within 60 days of the date the Agency obtains an HTA report. Although used as a basis for the National Economic Commission's negotiations, the recommendation is not binding for the Minister of Health (although it is unlikely that the Minister would make a reimbursement decision contrary to the recommendation).

4.2.2.2 Reimbursement lists

A reimbursement list, in which new medicines are added for reimbursement if they comply with predefined criteria, is the main instrument used by countries to manage their benefit packages.

Reimbursement lists are in place in all the countries surveyed (see Table 4.3 and Fig. 4.3). The majority (44 of 45 countries) apply a positive list (also called a formulary); all medicines included in the list may be prescribed at the expense of a public payer. Germany applies only a negative list, which specifies all medicines explicitly excluded from reimbursement. Thus, all pharmaceuticals are fundamentally

covered unless they are on a negative list. Spain and the United Kingdom apply both a positive and a negative list.

Some countries employ more than one positive list (including Croatia, which has a basic and a supplementary list, and Slovenia). Other countries have one positive list which is divided into different parts according to the different reimbursement and/or prescribing rules that apply.

Positive lists are important tools to prioritize medicines for reimbursement in line with the principles of an essential medicines list (see section 3.1). The term "essential medicines list" is only used in some – mainly Balkan and CIS – countries, however; western European countries do not use this term. The number of medicines included in the reimbursement lists of European countries is often higher than the number included in the WHO Model Lists of Essential Medicines *(26)*.

Table 4.3 | Reimbursement lists in the outpatient sector in countries in the WHO European Region, 2017

Type of reimbursement list	Countries
Positive	Armenia, Albania, Austria, Azerbaijan, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Greece (positive list, non-prescription medicines list), Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, Serbia, Slovenia, Slovakia, Sweden, Switzerland, Tajikistan, Turkey, Ukraine, Uzbekistan
Negative	Germany (negative list for prescription-only medicines; non-prescription medicines can be reimbursed in exceptional cases)
Both	Spain, United Kingdom

Note: in some countries the list (positive/negative) consists of two or more positive/negative lists (e.g. Slovenia, United Kingdom) or categories (Austria) within the lists.

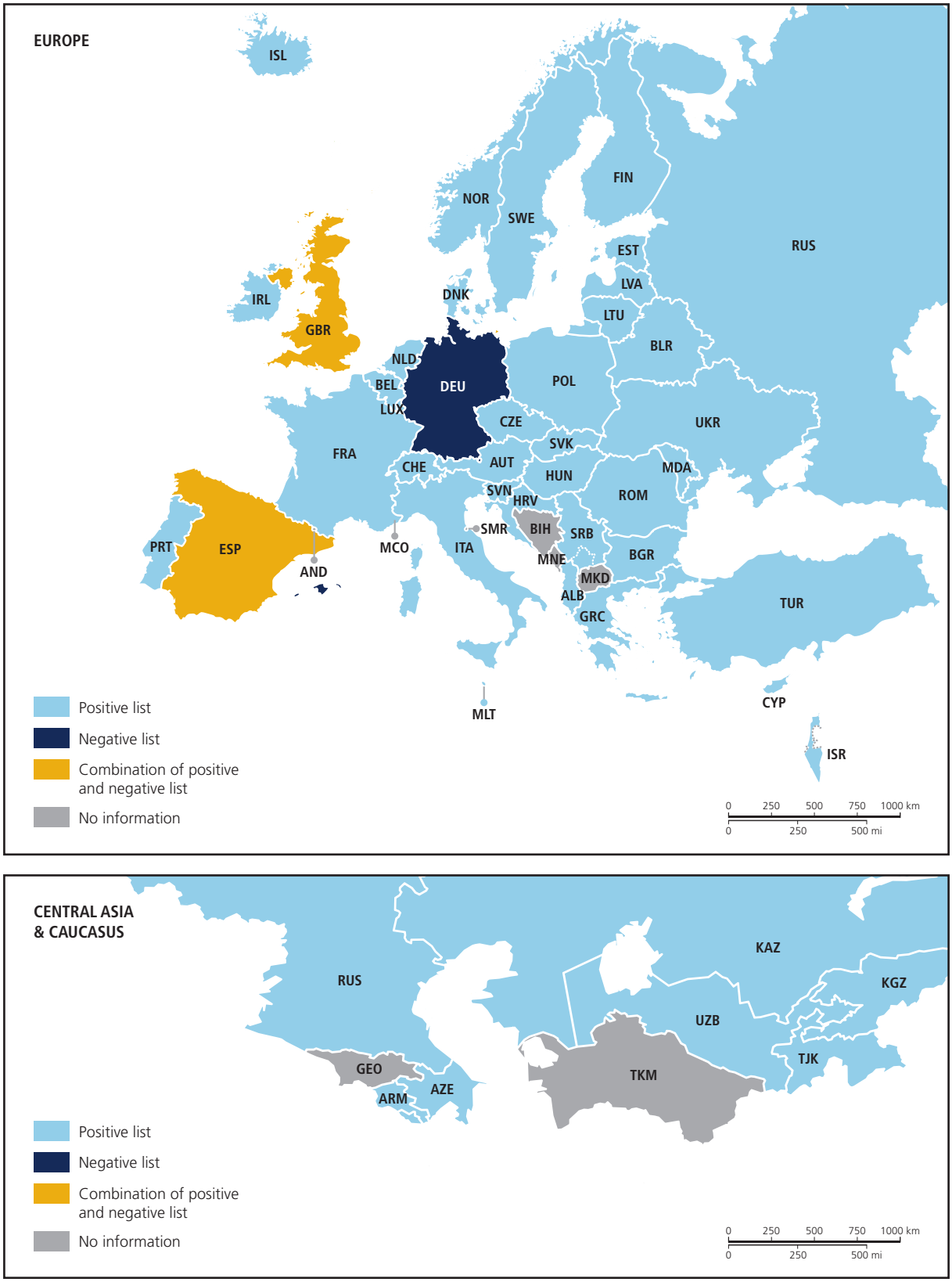
Most European countries regularly review and update their reimbursement lists. For instance, Belgium, Finland and Ireland review their positive lists every month.

Countries with disease-specific reimbursement schemes commonly use a list of reimbursable diseases as basis for which medicines are covered. In addition, some countries have established an individual reimbursement scheme, under which medicines not on the positive list may be prescribed and reimbursed in specific cases after individual application, usually by a doctor. In Austria, for instance, medicines categorized in the so-called "yellow box" require an ex-ante or ex-post approval for reimbursement by the sickness fund before they can be prescribed at the expense of the SHI.

4.2.2.3 Reimbursement rates

The inclusion of a medicine in an outpatient positive list does not automatically guarantee full cost coverage by a public payer. Medicines included in a positive list may also be partially reimbursed (up to a specific percentage rate). In fact, only a few countries surveyed – Austria, Croatia, Cyprus (in the public sector only), Germany, Ireland, Italy, Malta (in the public sector only), the Netherlands and the United Kingdom, as well as a few CIS countries with a more limited public sector – provide 100% reimbursement of the price of all publicly subsidized medicines (reimbursable medicines or outpatient medicines in the public sector). However, other co-payments such as prescription charges, deductibles and/or fees due to a reference price system may still apply (see section 4.3). It should also be noted that that the scope of medicines eligible for reimbursement and included in the public sector can vary considerably.

Fig. 4.3 | Reimbursement lists in the outpatient sector in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health. ©WHO 2018. All rights reserved.
Notes: **TJK:** not formally a positive list but a National Essential Medicines List which includes the medicines reimbursed via the vertical programs.

Of the 45 countries surveyed, 32 have differentiated reimbursement rates (see Table 4.4 and Table A5.3 in Annex 5). All of these provide 100% reimbursement for a certain number of medicines, whereas other reimbursable medicines are covered only at defined rates (i.e. a percentage of the medicine price). In Czechia and Slovakia the price of some medicines is partially reimbursed, but the reimbursement rate is not set at defined rates. Several countries provide 100% reimbursement for specific essential medicines for life-threatening or severe diseases, while other non-essential or less cost-effective reimbursable medicines have lower defined rates (see Box 4.6).

Table 4.4 | Reimbursement rates of outpatient reimbursable medicines in countries in the WHO European Region, 2017

Country	No percentage reimbursement rate for publicly subsidized medicines	Reimbursement rates
Albania		100%, 95%, 85%, 75%, 65%, 55%, 50%[a]
Armenia		100%, 50%, 30%
Austria	✓	No percentage reimbursement rates applied
Azerbaijan	✓	No percentage reimbursement rates applied for medicines listed on the positive list
Belarus		100%, 90%, 50%
Belgium		100%, 75%, 50%, 40%[a]
Bulgaria		100%, 75%, <50%[a]
Croatia	✓	No percentage reimbursement rates applied. Full coverage of the price of all reimbursable outpatient medicines included in the basic list of medicines[a,b]
Cyprus	✓	No percentage reimbursement rates applied (public sector)[c]
Czechia		100% and partial reimbursement (no fixed reimbursement rates for partially reimbursed medicines)[a]
Denmark		100%, 85%, 75%, 50%[a]
Estonia		100%, 75% (or 90% for vulnerable groups), 50%[a,d]
Finland		100%, 65%, 40% (basic rate for reimbursement)[a]
France		100%, 65%, 30%, 15%[a]
Germany	✓	No percentage reimbursement rates are applied[a]
Greece		100%, 90%, 75%[a]
Hungary		100%, 90%, 80%, 70%, 55%, 50%, 25%[a]
Iceland		100%, 92.5%, 85%, 0%; 65-70% on average for medicines with general reimbursement status[a]
Ireland	✓	No percentage reimbursement rates applied[a,e]
Israel		85-90% (for all medicines in the positive list)[a]
Italy	✓	No percentage reimbursement rates applied[a]
Kazakhstan	✓	No percentage reimbursement rates applied for medicines under the guaranteed free health care package
Kyrgyzstan		50% of a calculated tariff for medicines part of the additional drug package scheme
Latvia		100%, 75%, 50%[a,f]
Lithuania		100%, 90%, 80%, 50%[a,g]
Luxembourg		100%, 80%, 40%
Malta	✓	No percentage reimbursement rates applied (public sector)[h]
Netherlands	✓	No percentage reimbursement rates applied[a]
Norway		100%, 61%[a]
Poland		100%, 70%, 50%[a]
Portugal		100%, 90%, 69%, 37%, 15%[a,i]

Table 4.4 | Continued

Country	No percentage reimbursement rate for publicly subsidized medicines	Reimbursement rates
Republic of Moldova		100%, 70%, 50%, 30%
Romania		100%, 90%, 50%, 20%[a]
Russian Federation		100%, 87%[a,j]
Serbia		10-90% (depending on medicine price)
Slovakia		100% and partial reimbursement (no fixed reimbursement rates for partially reimbursed medicines)[a]
Slovenia		100%, 70%, 10%[a]
Spain		100%, 90%, 40-60% (standard rate linked to income)[a,k]
Sweden		100%, 90%, 75%, 50%[l]
Switzerland		90% and 80% (upon reaching deductible)
Tajikistan	✓	No percentage reimbursement rates applied for medicines under the state-guaranteed package
Turkey		100%, 90%, 80%[a]
Ukraine		100%, 50% (for defined population groups)[a]
United Kingdom	✓	No percentage reimbursement rates applied
Uzbekistan	✓	No percentage reimbursement rates applied for "socially important medicines"

Note: The table provides information about the different reimbursement rates in place but does not allow conclusions to be drawn on the extent of payments for patients. Countries may have 100% reimbursement for medicines in the public sector but only a few medicines may be included.

a Additional co-payments are possible due to a reference price system (see section 4.2.4). While in this case patients are also asked to provide a contribution, this policy is not discussed under the heading of contributions since patients have an option not to be charged this co-payment.

b All outpatient reimbursable medicines included in the basic list (one part of the positive list) are 100% funded. However, patients have to pay co-payments between the pharmacy retail price and reference price for outpatient reimbursable medicines included in the supplementary list if a higher-priced medicine compared to the generic or other clinically substitutable medicine included in the basic list is dispensed.

c Cyprus has no reimbursement system. There is a public sector (around 80% of the population are covered if the family income is below a certain percentage). Access to medicines in the public sector is free apart from a service fee of €0.50 per item on the prescription (up to the ceiling of 10 Euro). Patients not eligible to use the public sector have to access medicines in the private sector. They have to pay fully out-of-pocket or through private insurances (paying a service fee of 1 Euro per prescription +VAT). Availability of medicines in the private sector is higher than in the public sector. There is a so-called "co-payment scheme" that allows patients eligible to use the public sector to access medicines in the private sector: these patients have access to interchangeable medicines (e.g. originators) not procured in the public sector by presenting a prescription issued in the public sector to a private pharmacy. Patients eligible pay a service fee of 1 Euro per prescription +VAT, as for prescriptions in the private sector. Medicines eligible for this co-payment scheme are on a list – their pharmacy retail price and a co-payment rate is indicated. Private pharmacies can claim for reimbursement.

d Estonia has a higher reimbursement rate (90% instead of 75% for the general population) for medicines for disabled or retired pensioners, children between 4 and 16 years old and people aged 63 years and above.

e Ireland has 100% reimbursement of all reimbursable medicines in its different drug schemes. There is 100% reimbursement without any conditions for a specific group of population (with certain long-term conditions); all others have 100% reimbursement of medicines only after a deductible is paid in advance.

f In Latvia children up to 18 years of age and people on low income are fully reimbursed for all medicines included in the positive list, unless the more expensive product (instead of the cheapest reference product) is dispensed, in which case the patient pays the difference between the reference price and the actual price. In addition, prescription-only medicines not included in the Latvian positive list are reimbursed for children up to 24 months of age (reimbursement rate 50%) and for pregnant women and women within 42 days of the postnatal period (reimbursement rate 25%).

g In Lithuania treatment for children under the age of 18 years and severely disabled people is reimbursed at 100%, with co-payment capped at €1.50.

h In Malta medicines on the formulary are 100% free of charge for eligible patients. Medicines in the private sector have to be paid entirely out-of-pocket.

i Portugal has higher reimbursement rates for pensioners on low income (95%; 84%, 52% and 30% instead of 90%, 69%, 37% and 15%).

j In the Russian Federation defined vulnerable groups such as disabled children aged less than 18 years, patients with oncological diseases and patients having undergone organ transplantation are eligible for 100% reimbursement.

k Spain provides 100% reimbursement rates for unemployed people without benefits, people with the lowest social pension and people suffering from occupational diseases.

l In Sweden insulins, medicines prescribed for children younger than 18 years, medicines for treatment of communicable diseases such as HIV and hepatitis, contraceptives for young adults (under 21 years) and medicines for individuals lacking perception of their own state of illness are reimbursed at 100% without further co-payment for the patient.

Box 4.6

Reimbursement regulations in Hungary

The National Institute of Health Insurance Fund Management is in charge of the administration of Hungary's health insurance and public reimbursement. Patients are required to make co-payments on most prescribed medicines. Reimbursement rates mainly depend on the therapeutic value of the medicine, the severity and duration of the disease and the price. In general, a higher reimbursement rate is granted if the disease is considered more severe or longer lasting or the medicine is more effective.

There are two major reimbursement categories in the outpatient sector: indication-linked reimbursement and normative reimbursement.

- Indication-linked reimbursement restricts prescribing to medical specialists and grants reimbursement only for a subset of confirmed indications. Reimbursement rates in this category are 50%, 70%, 90% (for less severe chronic conditions) or 100% (for more severe, life-threatening diseases). For medicines that are 100% reimbursed in this category, a fixed co-payment (prescription fee) of 300 Hungarian forints (approximately €1)[5] per package must be paid by the patient.
- Normative reimbursement applies to medicines that can be prescribed by all physicians authorized to prescribe. It may be used for all authorized indications of a medicine included in the positive list. Depending on the therapeutic value of the medicine, and the severity of the disease, the reimbursement rates for this category are 25%, 55% and 80%. The reimbursement rate for substances of the pharmacopoeia and magistral products (prepared in the pharmacies) is 50%, resulting in a 50% co-payment. In addition to the reimbursement categories listed above, Hungary also applies internal reference pricing for off-patent medicines (generics and biosimilar medicines), whereby the patient pays the difference between reference price and actual pharmacy retail price if the chosen product is priced above the reference price. There are no co-payments for medicines applied in the inpatient sector as they are fully covered through the hospital financing system (i.e. within diagnosis-related groups).

Exemptions

Hungary has a special scheme of co-payment exemptions up to a certain monthly budget for socially disadvantaged people and/or people with serious chronic disease. Eligibility includes:

- People with serious disabilities (such as blindness, schizophrenia, physical and mental disabilities);
- People eligible for defined social cash benefits;
- Pensioners who receive retirement benefits due to disabilities or accidents;
- Children in social care for various reasons (illness, economic conditions of the family, orphans); and
- People with low household incomes and high pharmaceutical expenditure.

Individuals eligible for co-payment exemptions are entitled to a monthly personal budget of up to 12 000 Hungarian forints (approximately €40) transferred to a dedicated account to cover co-payments for their prescribed medicines (calculated based on the lowest-priced available product). An additional budget of 6000 Hungarian forints (approximately €20) per year for medicines treating acute diseases is also provided. No restrictions apply with regard to the range of eligible medicines; however, charges exceeding the budget ceiling must be paid out-of-pocket.

5 At currency exchange rates checked on 30 October 2017, 1 Hungarian forint = €0.003209.

Three of the countries surveyed (Cyprus, Ireland, and Turkey) adopted population group-specific reimbursement as the predominant scheme. Cyprus and Ireland (which has a so-called "general medical services scheme" for patients on low income and their dependents) grant 100% reimbursement for all eligible populations, whereas Turkey provides different reimbursement rates for different population groups (e.g. 100% for chronic patients, 90% reimbursement for retired medicines and 80% for active workers). In Denmark and Sweden reimbursement rates depend on the extent of a patient's annual expenditure on reimbursable medicines (consumption-based reimbursement), with reimbursement rates ranging from 0% to 100% in both countries. In Ireland the Drug Payment Scheme is consumption-based reimbursement with a range of 0% (below threshold) to 100% (above a threshold of €144/ month) in 2017.

4.2.3 Appeals against reimbursement decisions

In accordance with stipulations in the Transparency Directive, the legal right of an MAH to appeal a reimbursement decision is available in all EU Member States. For example, in the case of a negative decision related to reimbursement or a delisting in Austria, the manufacturer may appeal to the Federal Administrative Court. In Czechia the manufacturer can appeal to the Ministry of Health, followed by a court decision. The situation is similar in Latvia, where the MAH has the right to appeal to the Ministry of Health against a decision of the NHS within one month of the date from which the decision is in force. In Estonia applicants and/or other interested parties have the option to appeal in court, whereas in Lithuania an applicant may appeal to the Appeal Committee.

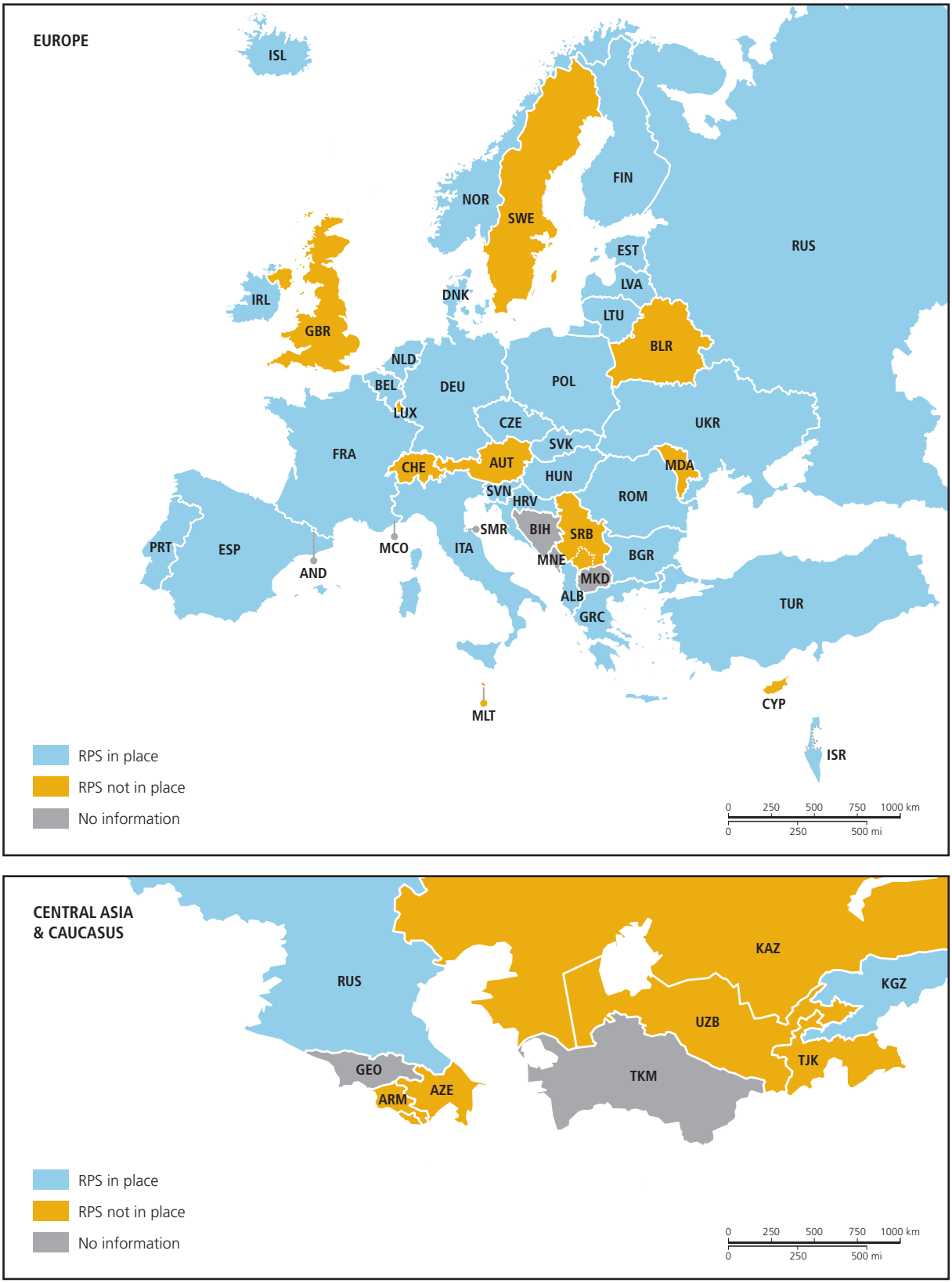
4.2.4 Reference price systems

A reference price system (RPS) is a reimbursement policy in which interchangeable medicines are clustered into a reference group, often by the same active substance (Anatomic Therapeutic Chemical (ATC) classification level 5) or chemically related subgroup (ATC level 4). The public payer determines a price (called the "reference price") to be reimbursed for all medicines included in the group. If the pharmacy retail price of the medicine exceeds its reference price, the patient must pay the difference, in addition to any other co-payments that may be applicable (such as prescription fees or percentage co-payments). The rationale of setting reimbursement amounts is to generate savings for the public payer without compromising access to medicines. In addition, an RPS may also promote generic uptake and stimulate competition in pharmaceutical markets.

As of 2017, an RPS is in place in 30 of the 45 countries surveyed (see Fig. 4.4 and Table 4.5). The system of reference pricing was pioneered in Europe in 1989, when Germany introduced the "Festbetragssystem". A few years later, the Netherlands (1991), Sweden and Denmark (1993) also adopted an RPS, followed by countries in central and eastern Europe (Czechia, Hungary, Poland and Slovakia), which implemented the scheme throughout the second half of the 1990s, and several countries in western and southern Europe (such as Belgium, France, Lithuania and Portugal) in the early 2000s. Countries that have recently adopted an RPS are Ukraine (2012) and Ireland (2013).

In contrast, Sweden abandoned its RPS in 2002 after nine years, as it was administratively complex and the expected cost savings did not materialize. Instead, Sweden uses the concept of the "preferred product of the month" and established a system of mandatory substitution for the lowest-priced generic alternative for reimbursement (regardless of what the doctor has indicated on the prescription). The French RPS (tariff forfaitaire de responsibilité) does not build reference groups for all therapeutic classes where it would be possible. Austria failed to introduce an RPS in 2008, as due to an anticipated parliamentary election in September 2008 the reforms were annulled. The United Kingdom, while having a high generic market share, has never introduced an RPS.

Fig. 4.4 | RPSs (internal reference pricing) in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health.
Notes: **KGZ:** elements of RPS in place. **NOR:** the 'step-price' system is a kind of RPS for off-patent products. **SWE:** a RPS was introduced in 1993 but was then abolished in 2002. Within the system for generic substitution, substitutable medicines are still grouped together.

The organization of an RPS varies across the countries surveyed. There are different approaches to composing the reference groups, the kind of medicines included in an RPS, and the calculation of a common reimbursement level (see Table 4.5).

Of the 30 countries with an RPS, 18 cluster medicines based on the active substance (ATC level 5); this means that only medicines with the same active substance are considered alternatives to be included in the same reference group of an RPS. The other 12 countries apply a broader understanding of how to build a cluster. Croatia, Czechia, Poland and Romania define reference groups on a mix of ATC levels 3, 4 and 5; this means that medicines of the same pharmacological subgroup can be considered substitutable. For the Netherlands, the grouping of medicines into clusters is done for medicines that are considered "interchangeable" (no application of ATC classification in this respect).

Table 4.5 | RPSs in countries in the WHO European Region, 2017

Country	RPS in place	Year of introduction	Grouping
Albania	Yes	2001	ATC 5
Armenia	No	Not applicable	Not applicable
Austria	No	Not applicable	Not applicable
Azerbaijan	No	Not applicable	Not applicable
Belarus	No	Not applicable	Not applicable
Belgium	Yes	2001	ATC 5
Bulgaria	Yes	2004	ATC 5 and ATC 4 (in exceptional cases)
Croatia	Yes	2006	ATC 5, 4 and 3
Cyprus	No	Not applicable	Not applicable
Czechia	Yes	1995	ATC 5, 4 and 3
Denmark	Yes	1993	ATC 5
Estonia	Yes	2003	ATC 5
Finland	Yes	2009	ATC 5
France	Yes	2003	ATC 5
Germany	Yes	1989	ATC 5 and 4
Greece	Yes	2006	ATC 5 and ATC 4 (for some products)
Hungary	Yes	1991	ATC 5 and ATC 4 (for some products)
Iceland	Yes	n/a	ATC 5
Ireland	Yes	2013	ATC 5
Israel	Yes	n/a	ATC 5
Italy	Yes	2001	ATC 5
Kazakhstan	No	Not applicable	Not applicable
Kyrgyzstan	Yes[a]	2001	ATC 5
Latvia	Yes	2005	ATC 5 and 4
Lithuania	Yes	2003	ATC 5 and 4
Luxembourg	No	Not applicable	Not applicable
Malta	No	Not applicable	Not applicable

Table 4.5 | Continued

Country	RPS in place	Year of introduction	Grouping
Netherlands	Yes	1991	ATC classification is not used in the RPS; clusters of "interchangeable products"
Norway	Yes	2003	ATC 5
Poland	Yes	1998	ATC 5, 4 and 3
Portugal	Yes	2003	ATC 5
Republic of Moldova	No	Not applicable	Not applicable
Romania	Yes	1997	ATC 5, 4 and 3
Russian Federation	Yes	n/a	ATC 5
Serbia	No	Not applicable	Not applicable
Slovakia	Yes	1995	ATC 5
Slovenia	Yes	2003	ATC 5 and (since 2013) ATC 4
Spain	Yes	2000	ATC 5
Sweden	No	1993-2002	Not applicable
Switzerland	No	Not applicable	Not applicable
Tajikistan	No	Not applicable	Not applicable
Turkey	Yes	2004	ATC 5
Ukraine	Yes	2012 (pilots)	ATC 5
United Kingdom	No	Not applicable	Not applicable
Uzbekistan	No	Not applicable	Not applicable

Note: n/a = no information available.
a In Kyrgyzstan, the additional drug package scheme defines a reimbursement tariff for medicines, so elements of an RPS are present.

Reference groups usually contain the originator medicine that has gone off patent and its generic substitutes. Several countries (such as Germany and Slovenia) also include copy and me-too products. In addition, Germany includes on-patent brands when forming reference groups.

Most countries (including Bulgaria, Iceland, Italy, Latvia, Lithuania, Russian Federation, Slovakia and Spain) set the reference price at the lowest-priced medicine within the reference group. A few (such as Croatia and Hungary) require that the lowest-priced product has a defined minimum market share over a fixed period. In Greece the reference price is the weighted average generic price with the lowest-priced daily dose (the generics taken into account need to represent 20% of the total sales volume in the last six months of the given cluster). In Germany the reference price of each cluster is based on the average price, package size and dose (for ATC level 5 clusters), or alternatively, the division of dose and defined daily dose (DDD) (for ATC level 4) of all medicines in the cluster. Portugal bases its reference price on the average of the five lowest prices in each reference group, whereas Estonia sets the reference price at the second-to-lowest price of medicines in the reference group. It should be noted that in Portugal and Greece, for example, the percentage co-payment is based on the reference price.

As patents expire and generic alternatives become available in the market, frequent revisions of RPSs are common in most countries surveyed. The frequency of revising reference groups and prices varies from every two weeks (Denmark) to quarterly (Finland) to every five years (France). Quarterly updates of reference groups and prices occur in Estonia, Germany, Hungary, Portugal and Slovakia. Slovenia conducts price revisions every six months, whereas Italy conducts a more frequent monthly update. Greece conducts price revisions twice a year.

4.2.5 Inpatient reimbursement

4.2.5.1 Medicine procurement for the inpatient sector

In some countries strategic procurement and tendering is centralized at national level for the inpatient sector (as in Denmark and Norway). In many countries (such as Austria, Czechia, Finland, Iceland, Romania, Switzerland and Turkey) procurement of medicines in the inpatient sector is decentralized, with decisions taken by individual hospitals or hospital owner organizations (for example, through purchasing bodies). Nevertheless, procurement of certain inpatient medicines (such as those for HIV or oncology) in these countries may be centralized (as in Romania and the United Kingdom). In Serbia a large number of medicines in the inpatient sector are centrally procured, with decisions taken by the health insurance fund. In Sweden the public procurement of medicines used in hospitals is carried out by the county councils (regions), which have lists of preferred medicines (see Box 4.2).

In several countries (including Czechia, Iceland, Romania and Turkey), tendering is common for most inpatient medicines and is the responsibility of hospitals. In Denmark a tendering process is undertaken for most of the medicines used in hospitals, with tenders carried out by the hospital purchasing agency, which is owned by the regions (i.e. the owners of public hospitals in Denmark). In Slovenia a central public tendering process is currently being put in place for all medicines (with approved MA, availability and price) for all hospitals in the country, carried out in cooperation with the Ministry for Public Administration and Ministry of Health. In Austria and Germany tendering is less common, but is on the rise.

In several countries surveyed (Austria, Finland, Germany, Iceland, Switzerland and Turkey) hospitals may be in direct contact with the manufacturers/pharmaceutical companies and negotiate individual prices (see Box 4.7). In Czechia hospitals are in direct contact with insurance funds to discuss procurement agreements and negotiate prices.

Box 4.7

Inpatient sector processes in Iceland

The University Hospital of Iceland is in charge of purchasing medicines for inpatient use. The purchasing department is in direct contact with the manufacturers and negotiates the prices. Tendering is common.

The hospital is reimbursed by the Icelandic Health Insurance. Hospital-designated medicines are assigned two categories: A for low-priced and B for specialty care high-priced medicines.

- For category A products the hospital is restricted by a special annual budget for hospital medicines, overseen by the Icelandic Health Insurance.
- For category B products the Icelandic Medicine Pricing and Reimbursement Committee processes applications for reimbursement status. If approval is granted, the expenses are covered by the special annual budget of the Icelandic Health Insurance. If no approval is given, the Icelandic Health Insurance does not reimburse the hospital if it uses the medicine.

Clinical and economical evaluations for high-priced medicines are done in cooperation between the University Hospital and Icelandic Health Insurance. Iceland has recently made legislative changes to facilitate access to medicines via international procurement.

In several countries (such as Austria, Germany and Slovakia) the decision-making body related to the inclusion of medicines in the hospital pharmaceutical formulary is the drug and therapeutics committee. In Austria each hospital can have its own committee, but joint hospital commissions per

owner organization are also common. In Denmark, where the health system is regionalized, the Danish Medicines Council was established in 2017 to ensure fast and homogeneous use of new and existing medicines across hospitals and regions and to enhance the basis for price negotiations and calls for tenders to the public hospital procurement agency Amgros.

In several European countries (including Austria, Germany and Switzerland) medicines are integrated into the lump sums that can be generated for reimbursement of the procedure and diagnosis-related groups in hospitals. In Austria approximately 50 defined single medical procedures exist within the system for which the dispensing of a specific oncology medicine is explicitly reimbursed.

4.2.5.2 Reimbursement lists in the inpatient sector

In several countries in the WHO European Region the basis for eligibility of a medicine to be used and funded in the inpatient sector is the hospital positive list. In some countries (such as Hungary and Italy) positive lists are relevant not only for the outpatient but also for the inpatient sector, while in others (including Denmark, Estonia, Finland and Norway) the national positive list is only applied in the outpatient sector. In some countries (such as the Netherlands and Poland) the (outpatient) positive list is apparently used as basis for discussion during the procurement process for the inpatient sector.

In the hospital sector, reimbursement lists for medicines are usually called hospital pharmaceutical formularies (HPFs). Of the 45 countries surveyed, information on inpatient reimbursement lists was available for 37 countries, of which 18 use an HPF. In Austria only medicines included in the HPF are funded by hospital owners and there is no national positive list of medicines used in hospitals. HPFs in Austria include approximately 1500-2500 medicines. In Finland, all medicines used in hospital settings are funded by hospitals.

In Turkey hospitals are responsible for creating their own HPF, on the understanding that only reimbursed medicines can be used in the inpatient sector, with Turkey's Social Security Institution restricting and defining conditions and the use of medicines in hospitals. In Latvia two lists of medicines are used in health care institutions: the basic HPF (defined by the NHS in cooperation with medical practitioners and representatives from the professional associations of doctors) and an additional HPF (developed by the hospitals' drug and therapeutics committees). The basic HPF is used in all hospitals financed from the state budget, while the additional HPF is aligned with the medicine needs of each individual hospital.

In several countries (including Austria and Denmark), the decision-making body in charge of the inclusion of medicines in the HPF is the drug and therapeutics committee. The hospital pharmacies take care of administration and preparation of the HPFs, which are updated once a year when the processes for new tenders are finished and new prices become available. Inclusion in the HPF depends on an assessment of effectiveness, side-effects and price. In Portugal the reimbursement process for medicines to be used at hospitals follows the same route as in the outpatient sector: a national hospital-specific drug and therapeutics committee decides on inclusion in the national HPF. In general, public hospitals are supposed only to use medicines included in this formulary.

4.2.6 Managed entry agreements

Uncertainty regarding the clinical evidence, cost–effectiveness or budget impact of a medicine may prevent health care payers from reaching conclusions on coverage decisions, thus affecting patient access *(43)*. A managed entry agreement (MEA) is a contractual arrangement between a manufacturer and health care payer/provider that enables access to (or reimbursement of) a health technology,

subject to specified conditions. These arrangements employ a variety of mechanisms to address uncertainty about a medicine's performance or adoption to maximize its effective use, or manage the risk of its budget impact.

Various types of MEAs exist (such as access with evidence development, conditional coverage, conditional treatment continuation, only in research, only with research, outcome guarantees, pattern or process care, price–volume agreements and risk-sharing schemes) under different names (for example, "patient access schemes" in the United Kingdom). The objective of an MEA is to share the cost of uncertainty between the manufacturer and the payer. MEAs are classified as finance-based (such as price–volume agreements) or performance-based (based on health outcomes).

Of the 45 countries surveyed, information was available for 38. Of these, 24 countries reported having an MEA in place: 24 used MEAs in the outpatient sector and 17 in the inpatient sector (see Table 4.6). Six countries reported use of MEAs only in the outpatient sector (Estonia, Hungary, Israel, Latvia, Norway and Romania). In four countries (Greece, Iceland, Russian Federation and Ukraine) no MEAs were in place (in the outpatient or inpatient sectors), although the Russian Federation announced that implementation of an MEA is in development. In Finland MEAs may be used in the outpatient sector (since January 2017) and seven were signed during 2017. Table A5.4 in Annex 5 provides country-specific information on the numbers and types of MEA, degree of confidentiality and the indications for which MEAs are used. Overall, financial-based MEAs appear to be used more frequently, and key indications of medicines subject to an MEA are oncology, rheumatology, hepatitis C and diabetes. MEAs may be fully confidential or a list of MEAs may be publicly accessible (as in Hungary), although the negotiated prices and discounts are confidential. There is large variation between the number of MEAs applied in countries: Norway, for instance, agreed on two MEAs in May 2017, whereas in Poland nearly 500 MEAs are managed (Table A5.4 in Annex 5).

Table 4.6 | Reported MEAs in countries in the WHO European Region

MEAs in place in the outpatient sector	MEAs in the inpatient sector
Austria, Belgium, Bulgaria, Croatia, Czechia, Estonia, Finland, Hungary, Israel, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	Austria, Belgium, Bulgaria, Croatia, Finland, Lithuania, Malta, Netherlands, Poland, Portugal, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom

Note: No MEAs were reported from Germany; however, discount agreements between health care funds and industry that have the features of MEAs are in place.

4.3 Co-payments

4.3.1 Co-payments in the outpatient sector

In the outpatient sector, reimbursement eligibility does not equal 100% coverage of reimbursable medicines through public financing. Instead, patients are often required to pay a share of the medicine's price out-of-pocket and/or some further non-price-dependent co-payments. Co-payments represent an insured patient's contribution towards the cost of a medicine or medical service covered by a public payer. While patient cost-sharing may be used to reduce unnecessary use of medical care and to contain costs, financial barriers to care, especially for vulnerable groups, could also increase.

Three main types of co-payments in the outpatient sector are used in the countries surveyed: fixed co-payments (typically in the form of prescription fees), percentage co-payments and deductibles (see Fig. 4.5). More details are provided in Table A5.5 in Annex 5.

With a fixed co-payment policy, a public payer requires the insured patient to pay a fixed amount per medicine or prescription. Fixed co-payments are in place in 17 of the 45 countries surveyed in the Region. In several of these, a fee per prescription (as in Croatia, Greece, and Serbia) or per item on the prescription (as in Austria, Germany and England, United Kingdom) is charged for reimbursable medicines.

In Turkey, the prescription fee is fixed for up to three packages of medicines, after which an additional fixed fee per package is charged. Finland applies a prescription fee of €4.50 each time a medicine that is in the 100% reimbursement category (higher special rate of reimbursement) is dispensed (up to a three-month supply). In the other reimbursement categories the patient is charged a prescription fee of €2.50 once the patient reaches the maximum annual limit on medicines expenditure (€605.13 in 2017; see Box 4.8). Estonia applies different prescription fees for different (disease-specific) reimbursement categories.

Box 4.8

Co-payment scheme in Finland

In Finland all permanent residents are covered under the national health insurance scheme, which provides partial reimbursement on the expenses of reimbursable prescription-only medicines. Patients become eligible for reimbursement once they pay an initial €50 deductible on reimbursed medicines within a calendar year, although children aged 0-18 years are exempt from this. Products are assigned to three reimbursement categories. Patients have a universal right to basic reimbursement and can apply for a higher rate of reimbursement given eligibility conditions.

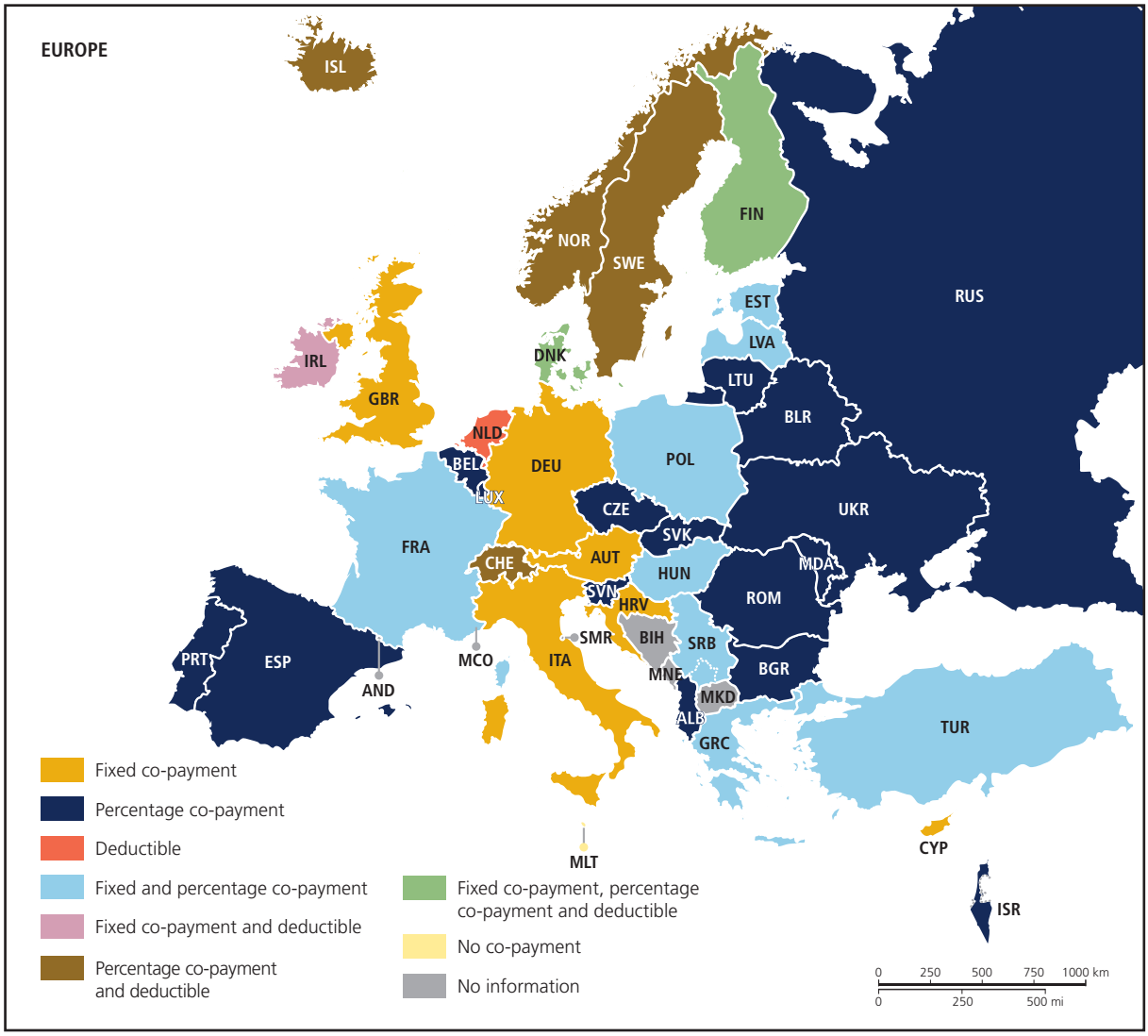
- The basic rate of reimbursement is 40% of the pharmacy retail price. This is the minimum rate that everyone is eligible to receive. In the same way, all reimbursable products can be reimbursed at 40%.
- The lower special rate of reimbursement is 65% of the pharmacy retail price for defined diseases (12 diseases including cardiac insufficiency, hypertension, coronary heart disease, asthma and rheumatoid arthritis) or groups of diseases.
- The higher special rate of reimbursement is 100%. This is provided for a list of severe and life-threatening diseases (including cancer, diabetes (insulin), multiple sclerosis, Parkinson's disease, epilepsy and severe mental disorders). Patients eligible for full reimbursement pay a fixed co-payment of €4.50 each time a medicine is dispensed up to a maximum of a three-month supply.

Reimbursement categories are not mutually exclusive: for example, a patient with chronic hypertension and diabetes may receive 65% reimbursement for medicines for hypertension and 100% for medicines for diabetes.

In principle, a patient may be entitled to any of these reimbursed rates and the product may also be reimbursed at any of these rates, but the patient must have the specific condition in question to qualify to receive a higher reimbursement rate. Thus, both the product and the patient need to meet the eligibility criteria, since one medicine can be used for several diseases. For example, corticosteroids for cancer are reimbursed at 100%, whereas corticosteroids for asthma or allergies are reimbursed at 65% or 40%. In this case, it depends on the patient's eligibility.

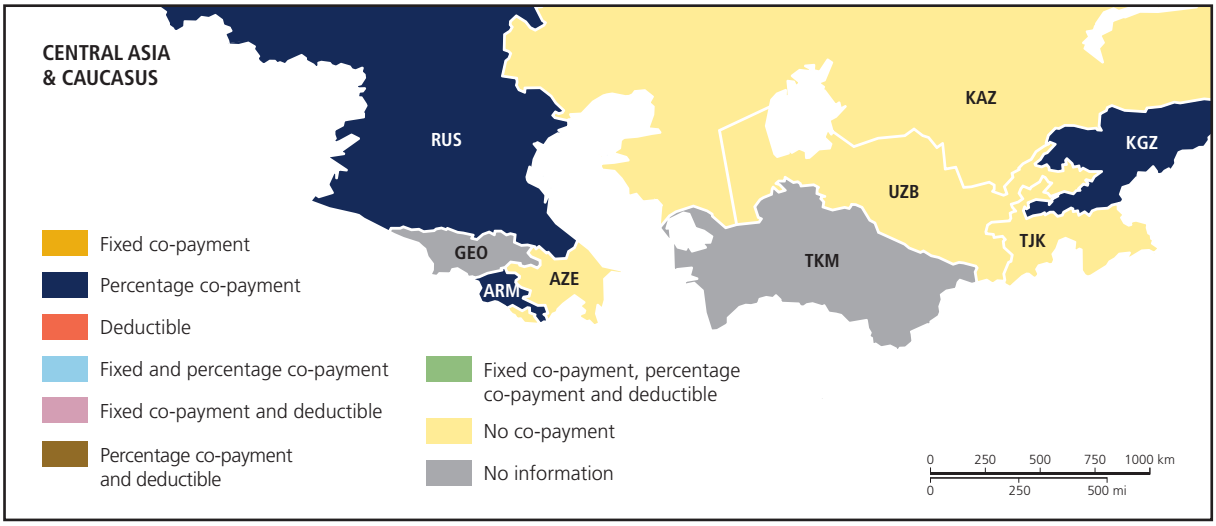
Irrespective of the reimbursement category, once OOPs for reimbursable medicines reach the maximum amount (€605.13, as of 2017) within a calendar year, any additional expenditure on reimbursable medicines is covered by the national health insurance scheme for the rest of the year. In this case, patients pay a reduced fixed co-payment of €2.50 for each medicine dispensed up to a three-month supply.

Fig. 4.5 | Co-payments for publicly subsidized outpatient medicines in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health.
Notes: Further co-payments due to an RPS can apply. **BLR:** percentage co-payment applies only for patients eligible to the State Budget Based Reimbursement Scheme, the rest of the population pays fully OOP (appart for some diseases for which full coverage is provided to the entire population). **CHE:** after reaching the deductible, patient normally pays 10% of the medicine price (up to a maximum of 700 francs). **CYP:** no percentage co-payment in the public sector; patients eligible for the public sector can access medicines in the private sector, which has a higher availability of medicines, by paying a defined share of the pharmacy retail price. **CZE:** no defined percentage rates; co-payment equals the difference between reimbursement amount and pharmacy retail price. **DEU:** 10% of medicine's price - min €5, max €10; medicines priced 30% below the reference price are exempt from co-payment. **HRV:** co-payment due to the RPS (supplementary list) if a higher-priced medicine compared to the generic or other clinically substitutable medicine included in the basic list is dispensed. **HUN:** prescription fee only applies in cases of medicines 100% reimbursed under the "indication-linked reimbursement scheme". **ISL:** After reaching the deductible and before reaching the ceiling, co-payment rates of 15% and 7.5% are applied, depending on the patient's pharmaceutical expenditure within a year. **ITA:** fixed co-payments only in some regions. **LVA:** a fixed co-payment is applied for 100% reimbursed medicines only. **MLT:** no co-payment for medicines dispensed in the public sector. **SVK:** no defined percentage rates; co-payment equals the difference between reimbursement amount and pharmacy retail price.

Fig. 4.5 | Continued



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health. ©WHO 2018. All rights reserved.
Notes: **ARM:** percentage co-payments for population-groups-specific reimbrusement scheme; no co-payments for the disease-specific schemes. **AZE:** no co-payments for medicines listed in the positive list. **KAZ:** no co-payment for medicines part of the "Guaranteed Free Healthcare Package". **KGZ:** percentage co-payments only for medicines provided through the "Additional Drug Package"; no co-payments for medicines part of the "State Guaranteed Benefit Package". **TJK:** no co-payments for a limited number of medicines as part of the State Guaranteed Package. **UZB:** no co-payments for "Socially Important Medicines".

With a percentage co-payment policy, the insured person pays a fixed share of the pharmacy retail price or the reference price of a medicine (the so-called "percentage co-payment"), while the public payer covers the remaining cost/percentage share (which is the reimbursement rate; see section 4.2.2.3). Percentage co-payment is the most common form of co-payment in the WHO European Region as most countries (32 of the 45 surveyed) apply different reimbursement rates for reimbursable medicines. Of the 32 countries with a percentage co-payment, 30 have defined rates (resulting from the fixed percentage reimbursement rates). Only Czechia and Slovakia have no defined co-payment rates; their co-payment share of the pharmacy retail price results from the difference between the reimbursement amount and the pharmacy retail price. In Poland the percentage co-payment depends on the disease indication and treatment duration. In general, percentage co-payments may vary depending on the severity of disease or condition (such as if it is chronic or a disability), the patient's age or income status.

A deductible is the initial expense up to a fixed amount which the patient has to pay out-of-pocket for a defined period of time before the expenses of a medicine (or some medical service) is fully or partially covered by a public payer. A deductible is in place in eight of the 45 countries surveyed (Denmark, Finland, Iceland, Ireland (Drug Payment Scheme), the Netherlands, Norway, Sweden and Switzerland use a consumption-based reimbursement scheme).

In addition, patients might also be asked for a financial contribution if they insist on being dispensed the originator medicine or another high-priced medicine under an internal price referencing system (see section 4.2.4). However, this co-payment is avoidable for a patient. Internal price referencing is often used as a measure to support generic competition and uptake.

4.3.2 Exemptions and reductions

In all countries surveyed mechanisms have been established to protect vulnerable groups (including people on low income, specific age groups and people with chronic diseases or disabilities) from excessive OOPs on health. The most commonly applied mechanisms include a 100% reimbursement rate, a higher than standard reimbursement rate, exemptions from fixed co-payments and/or lower deductibles. For detailed information see Table 4.7 and Table A5.5 in Annex 5.

Table 4.7 | Reasons for exemptions or reductions in co-payments for outpatient medicines in countries in the WHO European Region, 2017

Reason	Exemptions of usual co-payments	Reductions of usual co-payments
Specific illness/ condition	Armenia, Albania, Belarus (no co-payment for two disease programmes: tuberculosis (TB) and HIV/AIDS), Belgium (exemption after annual threshold and co-payment ceiling per prescription), Bulgaria, Croatia (exempt from fixed co-payments per prescription for all reimbursable medicines), Denmark (exemption after deductible, no co-payment and no deductible for terminal illness and other special cases), Estonia, France, Germany (co-payment ceiling of 1% of annual income for chronically ill patients), Greece, Hungary (no co-payment up to a limit), Iceland (co-payment ceiling), Ireland, Israel, Kyrgyzstan (the state-guaranteed benefit package provides medicines that are in theory free of charge for a subset of diseases), Latvia, Luxembourg, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, Spain, Sweden, Slovenia, Tajikistan, Turkey, United Kingdom	Albania, Belgium, Bulgaria, Estonia (people with chronic diseases), Finland, Greece, Latvia, Luxembourg, Portugal, Russian Federation, Slovenia, Spain
Income/social disadvantage	Albania, Austria (co-payment ceiling of 2% net annual income or defined monthly income), Belgium (once annual co-payment ceiling is reached), Croatia (exempt from fixed co-payments per prescription for all reimbursable medicines), France, Germany (co-payment ceiling of 2% of income), Hungary (no co-payment up to a limit), Iceland (co-payment ceiling), Latvia, Norway (pensioners on low income), Slovenia, Spain (long-term unemployed people without social benefits), United Kingdom	Albania, Belgium, Denmark, Greece (pensioners on low income), Portugal (pensioners on low income), Romania (pensioners on low income), Slovenia, Spain
Age	Albania (<18 years, old age pensioners), Belgium (children <19 years), Croatia (<18 years exempt from fixed co-payment per prescription for all reimbursable medicines), Czechia (co-payment ceiling <18 and >65 years), Estonia (<4 years), France (no fixed co-payment for <18 years), Germany (<18 years), Hungary (children in social care exempted up to a limit), Latvia (<18 years), Lithuania (<18 years), Norway (<16 years), Poland (>75 years), Romania (students <26 years), Slovenia, Sweden (<18 years, contraceptives for <21 years), Ukraine (<3 years; insulin for <18 years), United Kingdom (<16 and >60 years, students 16-18 years)	Albania (1-18 years), Denmark (<18 years), Estonia (<16 and >63 years), Finland (<18 years are exempt from annual deductible but co-payment still applies), Iceland (reduced deductible for <22 years and elderly people), Israel (>72 years), Latvia (prescription-only medicines not included in positive list are reimbursed at 50% for children <2 years), Romania (children and students <26 years), Serbia, Slovakia (<6 years, co-payment limit), Slovenia, Ukraine (3-6 years)
Disability	Albania, Belgium (annual threshold and co-payment ceiling per prescription), Hungary (no co-payment up to a limit), Lithuania, Russian Federation (disabled children <18 years), Slovakia (disabled children <6 years), Tajikistan, Ukraine (disabled children <16 years), United Kingdom	Belgium, Denmark, Estonia, Iceland (reduced deductible), Latvia, Slovakia (co-payment limit), Ukraine

Table 4.7 | Continued

Reason	Exemptions of usual co-payments	Reductions of usual co-payments
Pensioners/ retirees/war veterans	Albania, Croatia (exempt from fixed co-payments per prescription for all reimbursable medicines), Poland (soldiers), Spain, Tajikistan, Ukraine, United Kingdom	Albania (soldiers), Belgium, Denmark, Estonia, Finland (war veterans are eligible for 10% discount from the price of products reimbursed at basic reimbursement rate), Israel, Romania, Russian Federation, Slovakia (co-payment ceiling), Slovenia, Spain, Turkey
Pregnant women	Croatia (exempt from fixed co-payments per prescription for all reimbursable medicines), France, Romania, Slovenia, Ukraine (insulins), United Kingdom	Albania, Latvia (prescription-only medicines not included in positive list reimbursed at 25%), Romania, Serbia
Other	Germany (if price of medicine is 30% below reference price), Israel (Holocaust survivors)	Estonia (reduction after reaching annual co-payment ceiling), Finland (reduction after reaching annual co-payment ceiling)

4.3.3 Co-payments in the inpatient sector

Among all countries surveyed, Belgium is the only one with inpatient co-payments for medicines in public hospitals. For reimbursed medicines a fee of €0.62 is charged per patient per hospital day. In addition, medicines dispensed by the hospital pharmacist for outpatients in the hospital setting (such as in a one-day clinic) have different percentage reimbursement rates than those applied in community pharmacies (depending on the reimbursement category).

4.4 Managing uptake for off-patent medicines

Policies to manage and improve the uptake of off-patent medicines (originators whose patent has expired, generic and biosimilar medicines) facilitate efficiency gains without disadvantaging patients. They are often integrated with general reimbursement policies. This section covers demand-side measures to enhance the off-patent market.

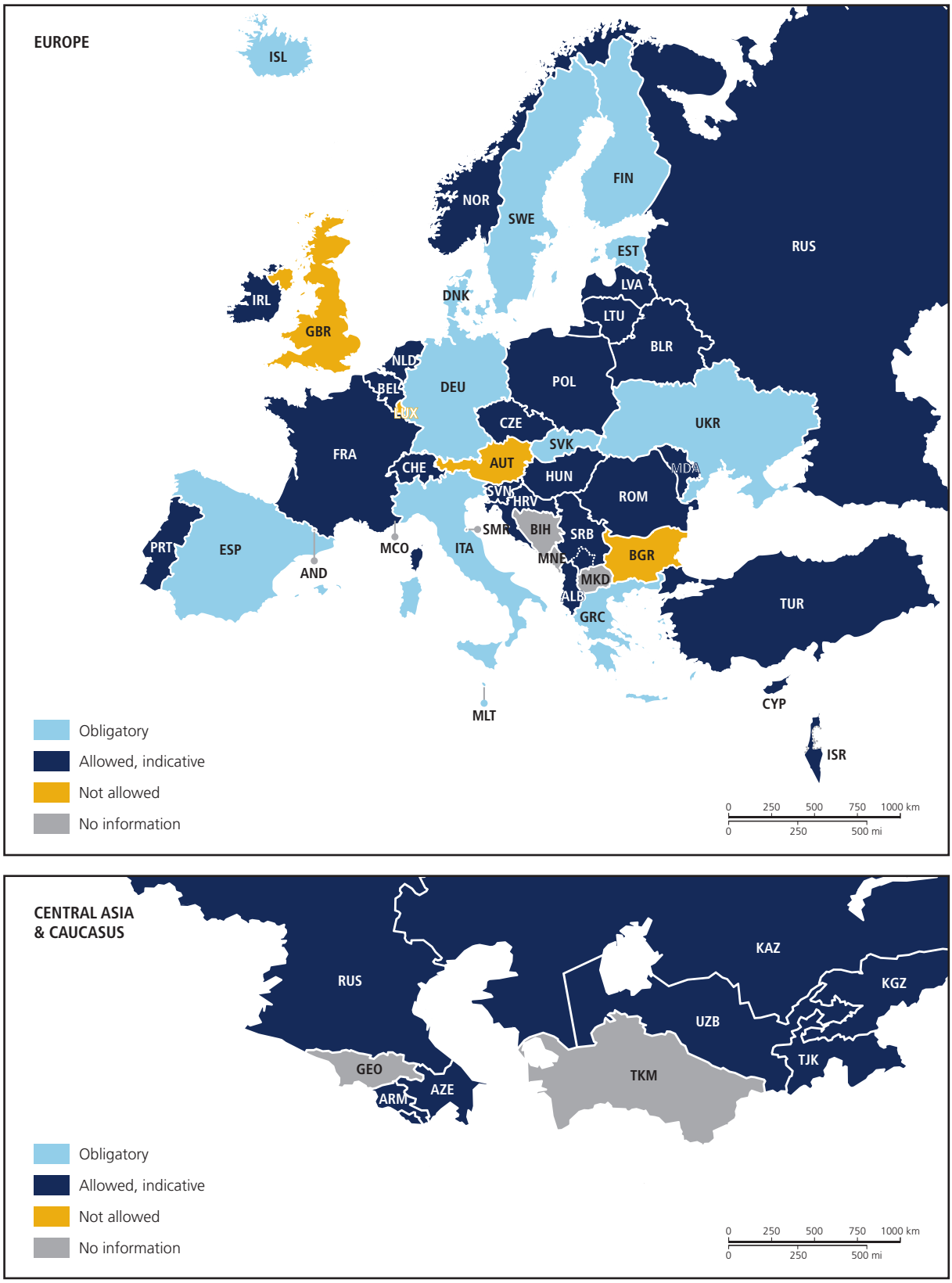
4.4.1 Generic substitution and INN prescription

Generic substitution is the practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (branded or unbranded generic), often containing the same active ingredient(s) at the community pharmacy level. Generic substitution is practised in most of the countries surveyed, except Austria, Bulgaria, Luxembourg and the United Kingdom. Generic substitution is allowed (indicative generic substitution) in 29 of the countries surveyed and required (obligatory/mandatory generic substitution) in 12 (see Table 4.8 and Fig. 4.6).

In Belgium generic substitution is in principle indicative but it is obligatory for antibiotics and antimycotics (in acute care). In Switzerland pharmacists receive a fee for generic substitution, while France incentivizes generic substitution and prescription through an equivalent mark-up for pharmacists dispensing generics and through a voluntary pay-for-performance remuneration scheme for physicians. In the Netherlands generic substitution is obligatory if the medicine falls under the scope of the preferential pricing policy (exemption applies if the prescriber indicates a medical need to prescribe other products).

Even if generic substitution is obligatory, the prescribing doctor normally has the option to exclude the medicine from generic substitution – for example, by writing a brand name on the prescription.

Fig. 4.6 | Generic substitution in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health.
Notes: **BEL:** generic substitution is in general indicative, but mandatory for antibiotics /antimycotics (for acute diseases). **ROM:** generic substitution is not allowed in case of transplant rejection medication.

Normally, this has to be justified (in writing). Without a doctor's justification, a patient can also choose the more expensive product, but he or she usually needs to cover the price difference between the two medicines. In France, patients refusing generic substitution have to pay for their medicines in advance before being reimbursed the difference, while in Greece a patient receives an additional charge if the more expensive medicine is requested. In several countries pharmacists are required to notify patients if cheaper alternatives are available.

Table 4.8 | INN prescribing and generic substitution in countries in the WHO European Region, 2017

Country	INN prescribing	Generic substitution
Albania	Obligatory	Allowed, indicative
Armenia	Obligatory	Allowed, indicative
Austria	Not allowed	Not allowed
Azerbaijan	Obligatory	Allowed, indicative
Belarus	Allowed, indicative	Allowed, indicative
Belgium	Allowed, indicative	Allowed, indicative, and obligatory in the case of antibiotics/ antimycotics (for acute diseases)
Bulgaria	Allowed, indicative	Not allowed
Croatia	Allowed, indicative	Allowed, indicative
Cyprus	Allowed, indicative	Allowed, indicative (public sector)
Czechia	Allowed, indicative	Allowed, indicative
Denmark	Not allowed	Obligatory
Estonia	Obligatory	Obligatory
Finland	Allowed, indicative	Obligatory
France	Obligatory	Allowed, indicative
Germany	Allowed, indicative	Obligatory
Greece	Obligatory	Obligatory
Hungary	Allowed, indicative	Allowed, indicative
Iceland	Allowed, indicative	Obligatory
Ireland	Allowed, indicative	Allowed, indicative
Israel	Allowed, indicative	Allowed, indicative
Italy	Obligatory	Obligatory
Kazakhstan	Allowed, indicative	Allowed, indicative
Kyrgyzstan	Obligatory	Allowed, indicative
Latvia	Allowed, in general indicative but obligatory for newly diagnosed patients	Allowed, indicative
Lithuania	Obligatory	Allowed, indicative
Luxembourg	Allowed, indicative	Not allowed
Malta	Obligatory	Obligatory
Netherlands	Allowed, indicative	Allowed, indicative
Norway	Allowed, indicative	Allowed, indicative

Table 4.8 | Continued

Country	INN prescribing	Generic substitution
Poland	Allowed, indicative	Allowed indicative
Portugal	Obligatory	Allowed, indicative
Republic of Moldova	Obligatory	Allowed, indicative
Romania	Obligatory for all reimbursed medicines; in special circumstances the physician may issue a reasoned brand-name prescription or in case of transplant medication	Allowed, indicative (unless for transplant medication)
Russian Federation	Obligatory	Allowed, indicative
Serbia	Not allowed	Allowed, indicative
Slovakia	Obligatory for all reimbursed medicines on the List of active substances to be prescribed only by stating the name of the medicine (INN)	Obligatory
Slovenia	Allowed, indicative	Allowed, indicative
Spain	Obligatory except for non-substitutable medicines which can be prescribed by brand name	Obligatory
Sweden	Not allowed	Obligatory
Switzerland	Allowed, indicative	Allowed, indicative
Tajikistan	Obligatory	Allowed, indicative
Turkey	Allowed, indicative	Allowed, indicative
Ukraine	Obligatory	Obligatory
United Kingdom	Allowed, indicative	Not allowed
Uzbekistan	Obligatory	Allowed, indicative

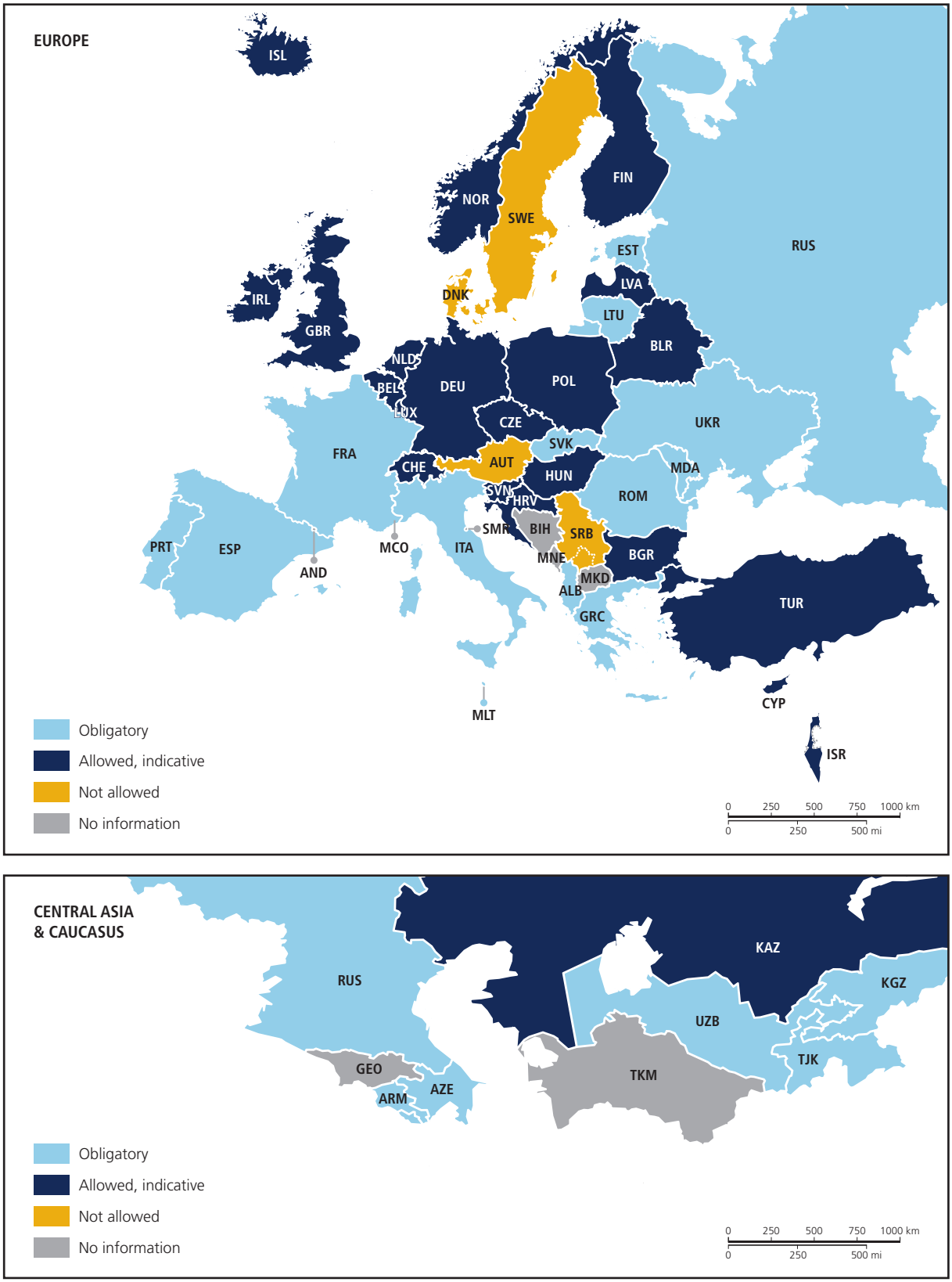
Another measure to enhance generic uptake is the prescription of medicines by their INNs, active ingredients or generic names, instead of their brand names. INN prescribing has been implemented in many countries and may be allowed (indicative) or required (obligatory/mandatory). INN prescribing is permitted in 22 of the countries surveyed and mandatory in 19 (see Fig. 4.7). It is not allowed in Austria, Denmark, Serbia or Sweden. In Latvia INN prescribing is generally indicative, but is mandatory for newly diagnosed patients. In Belgium mandatory dispensing of the lowest-priced alternative applies for INN prescriptions.

Several countries use both generic substitution and INN prescribing, and most have at least one of the two measures in place. Austria is the only country where neither generic substitution nor INN prescribing is allowed. There has been a trend in recent years to towards mandatory generic substitution and INN prescribing to increase generic uptake *(10)*.

4.4.2 Policy options related to biosimilar medicines

While pricing and use-enhancing policies for generics have been widely implemented in countries in the WHO European Region, policies for pricing and promoting the use of biosimilar medicines have yet to be defined. A recent study found that the pricing strategy commonly applied for generic and biosimilar medicines is to set the price of generics and biosimilars at a particular percentage beneath the price of the originator (a concept similar to the "generic price link") *(44)*.

Fig. 4.7 | INN prescribing in countries in the WHO European Region, 2017



Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO EURO, Division of Health Systems and Public Health. ©WHO 2018. All rights reserved.
Notes: **ALB:** obligatory for all reimbursed medicines. **ESP:** except for non-substitutable medicines which can be prescribed by brand name. **LVA:** in general indicative, but obligatory for newly diagnosed patients. **ROM:** obligatory for all reimbursed medicines except for transplant rejection medication. **SVK:** obligatory for all reimbursed medicines.

The Moorkens et al. study surveyed 24 countries in the Region in 2016. The most frequent biosimilar pricing mechanisms reported in outpatient care are a biosimilar price link and use of a maximum price. The percentage of the price link can be fixed or be a range subject to negotiation. Maximum prices of originator medicines are often set by external reference pricing, as is the case in Bulgaria, Czechia, Iceland, Malta, Latvia, Serbia and Slovenia *(44)*.

The study also found that approximately half of the surveyed countries have incentives targeting physicians to prescribe biosimilars. Within the context of a contractual arrangement between the National Health Insurance Fund and physicians' representatives providing specific supplementary remuneration based on attaining public health objectives, a new measure was introduced in France in 2016 that encourages physicians to prescribe at least 20% of insulin glargine as biosimilars in outpatient care. In some countries, physician incentives have been incorporated into pricing and reimbursement mechanisms with a view to stimulating biosimilar uptake. A ranking of tendered products is then made by the Norwegian Hospital Procurement Trust's Division of Pharmaceuticals based on price, and a recommendation is written. Physicians have to follow the ranking and use the lowest-priced product, which is often a biosimilar, except when there is a clinical reason not to use it. With this system, biosimilar infliximab has reached a market share above 95%, and the market share of biosimilar etanercept has increased to above 82% *(44)*.

The Moorkens et al. study also described various situations concerning biosimilar substitution. Latvia allows substitution at the pharmacy level: if a doctor has prescribed the originator medicine and has not indicated on the prescription that the prescribed medicine may not be substituted, it is the duty of the pharmacist to inform the patient about the lowest-priced alternative. Patients can refuse biosimilar substitution, but they then have to pay the price difference between the originator and the biosimilar. In Poland substitution is allowed by law within reference groups, and the pharmacist should discuss it with the patient. In Germany subgroups of "bioidenticals" are defined for some biologicals, for which pharmacist substitution is allowed unless specifically forbidden by the prescribing physician – the so-called "Aut-idem-Regelung" (i.e. rules regarding same-substance substitution). In France substitution of biosimilars is allowed in theory but has not yet been enforced in practice *(44)*.

Finally, as with generics, acceptance and trust of biosimilar medicines by patients and health professionals (such as prescribing doctors and pharmacists) is of key importance to enhance biosimilar uptake (for example, by prescribing biosimilar medicines to treat naive patients or switching from a biological to a biosimilar medicine). A variety of educational policies have been implemented, and in most countries local initiatives exist among physicians in hospitals or outpatient care. Prescribing guidelines and clinical guidelines can also inform physicians. In some countries, including the Netherlands and Portugal, scientific conferences are organized by health authorities, among others, to educate stakeholders and stimulate the use of biosimilars *(44)*.

5. Country case studies

Nine case studies from the WHO European Region were developed focusing on either a country's specific reimbursement policies or its progress towards UHC (for details on case study selection see methodology section 2.4). The case studies reflect a mix of countries at different levels of progress towards achieving UHC and were organized based on different reimbursement frameworks.

Three of the case studies are from CIS countries that have struggled with reducing OOPs in the outpatient sector. High OOPs lead to a risk – also evidenced by household surveys (in Kyrgyzstan, for example) – that patients may not purchase medicines they need. In these countries patients were required to purchase most outpatient medicines for chronic use 100% out-of-pocket or with a high co-payment. The reimbursement lists for outpatient medicines are small, with rather high co-payments (e.g. up to 50% of the pharmacy retail price). While coverage through an SHI or NHS provides a supportive framework, the mere existence of a mandatory health insurance fund does not automatically ensure financial protection for patients. This is the case in Kyrgyzstan and the Republic of Moldova, where mandatory health insurance was established some years ago.

The case studies on the CIS countries and Turkey confirm the need to work on different aspects of reimbursement and price regulation. Price regulation helps to bring prices down, which is beneficial to both public payers and patients who must currently pay out-of-pocket or provide a co-payment. Lower-priced medicines such as generics and biosimilars help to address the challenge of high OOPs for patients. Finland, for instance, has a strong focus on the use of lower-priced medicines. Mandatory generic substitution in combination with an RPS helps to reduce prices, making medicines accessible to patients through reduced expenditure while contributing considerable savings to the SHI system. The Finnish example, however, also confirmed the necessity of a "strategic design" of the policy framework, with ongoing changes where needed. Turkey stated that the need for better tools to assess therapeutic benefit (for example, through HTA) was a major challenge for the future.

Two case studies relate to European countries that were hit hard by the global financial crisis: Greece and Spain. In return for financial support from European institutions, both countries had to implement somewhat severe cost-containment measures, including in the pharmaceutical sector. Several measures were targeted at actors in the supply chain, and some activities (related to generics, for instance) were aimed at reducing identified inefficiencies. Nevertheless, some measures concerned the financial contributions of patients when filling prescriptions or purchasing non-prescription medicines.

Spain, for instance, increased co-payments for medicines. Since the cost-containment measures were implemented, both countries have had reductions in public pharmaceutical expenditure and in medicine consumption. It remains to be seen whether patients decided to forego needed medication (as shown for other health services in Greece) or whether high consumption before the crisis was also attributable to some inefficiencies. The example of a reimbursement restriction in the Dutch case study highlights the impact of that measure on prescribing, and suggests its effectiveness. While cost-containment was one policy objective connected to the reimbursement restriction, it also aimed to improve the quality of prescribing to make it more responsible.

Co-payments and OOPs are an issue in the outpatient sector in countries in the Region, whereas no co-payments are made in hospitals. From a health system perspective, such fragmentation can provide incentives for providers in the different sectors to shift patients between sectors. There is also a likelihood of differences in the provision and coverage of medicines between the outpatient sector and hospitals, potentially leading to equity issues for patients. The Scottish case study presents the approach of joint reimbursement lists and guidelines to improve coordination between the two sectors.

5.1 Azerbaijan

Surface area: **86 600 km²**

Population size (in 2017, in millions): **9.828**

Gross domestic product (GDP) per capita (in 2017, in current USD): **5 438.7**

Total health expenditure as a proportion of GDP (in 2017): **6%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **20.2%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **78.6%**

Sources: United Nations and World Bank data (45, 46).

This case study provides an overview of the pharmaceutical reimbursement system and the compulsory medical insurance pilot programme.

The health system in Azerbaijan is financed through a combination of tax revenues, transfers from the State Oil Fund, OOPs and aid from international organizations. Funding for services provided at the local level is channelled through district authorities, while the Ministry of Health is responsible for the financing of national-level providers. In addition, so-called "parallel state health systems" are publicly funded. These include health expenditure by the Ministry of Defence, Ministry of the Interior, Ministry of National Security, State Railway Company and State Oil Company of Azerbaijan.

Azerbaijan is making progress towards UHC through a pilot project on the introduction of a mandatory health insurance, which will be rolled out across the entire country from 2018 (see Box 5.1).

During the Soviet era, OOPs existed formally for outpatient medicines. Following the country's independence in 1991, a reorientation towards outpatient care was not prioritized and the structures of the old system remained. As a result, medicines in the outpatient sector are still predominantly purchased out-of-pocket and at full cost by the population. The public health budget theoretically covers medicines included on the essential medicines list (EML). This is a list of vital medicines managed by

the Ministry of Health, which includes 305 medicines, but not all are reimbursed. Medicines included in various state health programmes for specific conditions (such as cancer, TB, prevention of AIDS, haemophilia, multiple sclerosis, chronic renal insufficiency and diabetes) are exempt from co-payment. However, shortages in the supply of medicines have been frequent in the past, resulting in people eligible for subsidized medicines having to buy them out-of-pocket. Further, rural areas are reported to experience geographical access problems, since most retail pharmacies are located in urban areas (Schneider P, Vogler S, Gesundheit Österreich Beratungs GmbH, unpublished report on pharmaceutical pricing and reimbursement in Azerbaijan, 2014).

Box 5.1

Pilot project on compulsory health insurance in Azerbaijan

The State Agency for Compulsory Health Care Insurance was established in Azerbaijan in February 2016. In early 2017 a pilot project of compulsory health insurance was launched under the Agency in two districts of the country. The system aims to ensure accessibility and equal distribution of health services and insurance benefits nationwide. In both pilot study districts all residents were provided with a universal health insurance card, which entitles them to receive treatment and prescription medicines included in the basic benefit package free of charge at the point of care during the project. This pilot will be rolled out across the entire country from 2018.

In 2015 the government started to regulate prices (both reimbursed and non-reimbursed) of medicines and the Tariff Council substantially reduced prices for 1057 medicines. Every pharmacy in the country is required to dispense and sell medicines at a uniform price.

Voluntary health insurance was introduced in 1995, but population coverage is estimated to be below 1%, and most clients are employees of big companies in the oil sector. The low prevalence of voluntary health insurance may be explained by relatively high prices, which are unaffordable for the majority of the population (Schneider P, Vogler S, Gesundheit Österreich Beratungs GmbH, unpublished report on pharmaceutical pricing and reimbursement in Azerbaijan, 2014).

Key findings from the case study in Azerbaijan

- The country has made progress towards UHC and reached a major milestone by introducing compulsory health insurance (currently at the pilot stage).
- Azerbaijan has traditionally been characterized by high OOPs and no price regulation.
- Price regulation, in place since 2015, has helped to reduce medicine prices.

5.2 Finland

Surface area: **338 440 km²**

Population size (in 2017, in millions): **5.523**

GDP per capita (in 2017, in current USD): **42 148.1**

Total health expenditure as a proportion of GDP (in 2017): **9.7%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **77.4%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **19.9%**

Sources: United Nations and World Bank data *(45, 46).*

This case study investigates the outpatient off-patent sector in Finland, with a focus on generic substitution and the RPS (internal price referencing). The reimbursement and co-payment framework for medicines (based on deductibles and percentage co-payments) is described in Box 4.8 in section 4.3.1.

The Finnish pharmaceutical system has relative high OOPs for medicines, as the annual ceiling is relatively high (€605.13) compared to other European countries, which may lead to barriers for patients in accessing medicines. As the ceiling is not related to income, some people may face difficulties in making the co-payments. Further, the annual ceiling is personal and therefore several members of the same family may end up paying individually.

In April 2003 Finland introduced mandatory generic substitution. This policy measure requires dispensing pharmacies to substitute the prescribed medicine with the lowest-priced generic or parallel-imported medicine available, if the price of the prescribed medicine exceeds the so-called "price corridor". The price corridor is calculated every quarter based on the lowest-priced medicine in the group (ATC level 5) plus an additional small margin (€2 or €3 before 2009; €1.50 or €2 between 2009 and 2017; and €0.50 since 2017). The Finnish Medicines Agency determines the list of substitutable medicines, which is updated quarterly. Mandatory generic substitution provides the patient with the option to have a medicine substituted for a lower-priced generic alternative: even if the pharmacist is obliged to provide a lower-priced alternative, the patient may still reject it. There are no financial consequences for patients who do not want to substitute, apart from paying a higher percentage co-payment for the higher-priced medicine. One year after the introduction of mandatory generic substitution, average prices of substitutable medicines decreased by at least 10% *(47).*

In April 2009 Finland adopted an RPS and extended the range of generically substitutable medicines. Reference groups in the Finnish RPS are based on the previously defined groups used for generic substitution, where mutually interchangeable medicines (defined as medicines that contain the same active ingredient(s) in the same dose and the same form, that are bioequivalent and sold in comparable package sizes) are clustered in a reference group for which a common reference price is set. This reference price is set at the maximum of the price corridor, which is calculated as for generic substitution.

Patients who do not wish to substitute a prescribed medicine included in the RPS (whose price exceeds the reference price) with a lower-priced medicine are required to pay the difference between the retail price of the prescribed medicine and the reference price out-of-pocket, in addition to the regular co-payment. The excess payment does not contribute to the calculation of the annual ceiling (the deductible). The RPS incentivizes patients to opt for a medicine priced at or below the reference price.

In cases where the prescribing physician opposes generic substitution on medical or therapeutic grounds, the patient's reimbursement is calculated based on the purchase price instead of the reference price of the prescribed medicine. Nevertheless, other OOPs (such as fixed co-payments) still apply. It should be noted that some medicines remain included only in the mandatory generic substitution and not in the RPS. As such, there are no financial consequences for patients who refuse to substitute, as described above for generic substitution.

The Finnish government wanted to increase the savings produced by generic substitution further by introducing the RPS in 2009 *(48)*. It was hoped that manufacturers would reduce their prices to reference price levels in order not to lose customers who may shift to less expensive alternatives *(49)*. Until March 2017 a reference price group could be established only after generic products were available. Since April 2017 a reference price group (including originator medicines) can also be established when parallel-imported medicines are marketed.

For high-priced medicines, applying generic substitution and the RPS may not be as effective, since these medicines usually do not have pharmacy-level substitutes. Thus, new policies and measures need to be developed for high-priced medicines. In 2017 a new measure was introduced which obligated prescribers to prescribe the lowest-priced option, including biosimilars where available. Prescribers have to justify their reasons for not prescribing the lowest-priced option in the patient's medical records.

In 2010, one year after the adoption of the RPS and the extension of the range of generically substitutable products in Finland, Koskinen et al. *(48)* found a considerable reduction in the daily cost (including expenditure for the public payer, the national health insurance) of antipsychotic medicines clozapine, risperidone, olanzapine and quetiapine. The strength of impact varied across the four medicines studied, however, ranging from -29.9% to -66.3%. The greatest reduction in the daily cost was observed for olanzapine (-66.3%), which was available for generic substitution and had been included in the RPS since 2009. Risperidone had the second highest cost savings and was available for generic substitution one year prior to the introduction of the RPS. Study outcomes suggest that most savings were generated by generic substitution, with a relatively small additional impact on cost containment attributable to the RPS *(50, 51)*. Nevertheless, Pohjolainen *(51)* found that the average prices of all medicines decreased significantly, resulting in €109 million in savings the first year the Finnish RPS was introduced.

Helin-Salmivaara et al. *(52)* assessed how OOPs of medicines affected adherence. Two years after generic substitution was implemented in Finland (2005), the risk of a patient discontinuing statin treatment within one year was 20% lower among patients initiating with generic simvastatin compared to branded atorvastatin. At that time, OOPs of atorvastatin were five times higher than generic simvastatin. Helin-Salmivaara et al. further found no difference in adherence between atorvastatin and generic simvastatin in patients eligible for full reimbursement at the end of the year of initiation.

Key findings from the case study in Finland

- The Finnish reimbursement system requires high co-payments and OOPs from patients and does not account for either social status or income, which can create barriers for patients in accessing medicines.
- To improve the efficiency of the system, Finland is committed to promoting generics (as well as parallel-imported medicines) as a strategy to lower prices.
- Since 2003 Finland has had mandatory generic substitution, supplemented by an RPS (introduced in 2009). This helps patients because they pay lower prices for medicines that must be co-paid as a percentage rate or fully out-of-pocket. The public payer also benefits from the savings.

- Based on these policies, high savings in public pharmaceutical expenditure were documented. These were mainly attributed to generic substitution and less to the RPS, although savings from the RPS were recorded in the first year of its introduction.
- The existing evidence does not identify any adherence issues related to generic substitution.

5.3 Greece

Surface area: **131 957 km²**

Population size (in 2017, in millions): **11.160**

GDP per capita (in 2017, in current USD): **17 788**

Total health expenditure as a proportion of GDP (in 2017): **8.1%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **59%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **35.5%**

Sources: United Nations and World Bank data *(45, 46).*

This case study examines a country that was hit hard by the global financial crisis and had to implement cost-containment measures.

Greece was one of the euro-zone countries hardest hit by the financial crisis after 2008, and has struggled with high public deficits and debts. As stipulated in the Economic Adjustment Programme signed in May 2010 between Greece and the "troika" of the International Monetary Fund, the European Commission and the European Central Bank, the Greek government implemented a number of cost-containment and efficiency-enhancing measures to reduce public sector expenditure. Given the considerable share of pharmaceutical expenditure in public sector expenditure, some of the effort to reduce public spending has concentrated on pharmaceutical markets (Box 5.2).

Greece applies the following reimbursement (and co-payment) rates:

- 100% of the reference price is reimbursed for medicines for defined severe diseases (and for vulnerable social groups) (0% co-payment);
- 90% of the reference price is reimbursed for medicines for defined conditions and for pensioners on low income (10% co-payment);
- 75% of the reference price is reimbursed as the standard rate of reimbursement (25% standard co-payment);
- 0% for non-prescription medicines (100% out-of-pocket).

A fixed co-payment of €1 per prescription is applied. The €1 is not requested in cases of 0% co-payment. A deductible is not in place.

Diseases with 10% co-payment include Parkinson's disease, type 2 diabetes, Charcot disease, Alzheimer's disease, Wilson disease, TB, myasthenia, epilepsy, Buerger disease etc. Diseases exempted from any co-payment include thalassemia, type 1 diabetes, neoplasms, sickle cell anaemia, psychoses, hepatitis B and C, cystic fibrosis, Gaucher disease, chronic kidney disease (stage 3 and 4) and multiple sclerosis.

Box 5.2

Cost-containment measures related to medicines implemented by the Greek government in response to the global financial crisis

In 2010 the Greek government adopted price cuts applied to the wholesale price of medicines, amounting to a weighted average reduction of 21.5%. Another wholesale price cut was implemented in 2011, with a weighted average reduction of 10.2% *(53)*. Nevertheless, pharmaceutical expenditure remained high at 2.6% of gross domestic product *(54)*.

Since 2013 new pricing legislation requires pricing reviews every six months. The price for on-patent medicines is set based on the average of the three lowest prices of the 27 EU Member States. The price of the generic is set at 65% of the originator price marketed in Greece. Mandatory INN prescribing and generic substitution has been introduced and over 90% of physicians now use e-prescribing, including software that can set INNs to replace brand names automatically on prescription forms, for example *(55)*.

Policy measures related to reimbursement included the reintroduction of a positive list and the introduction of a non-prescription medicines list.

Thus, co-payment for reimbursable medicines dispensed in community pharmacies contains three elements: the statutory percentage co-payment, a prescription fee of €1 introduced in 2014 and the difference between the reference price and the pharmacy retail price for products under the RPS. Patients on low income and those with defined severe diseases are exempted from co-payments, while pensioners on low income who are eligible for benefits through the Pensioners' Social Solidarity Benefit pay a maximum co-payment of 10%.

Greece operates an RPS (internal price referencing), under which, for a medicine with a higher retail price than the reference price, the patient pays the difference up to €20 per pack of a medicine. If selecting a medicine with no generic or whole therapeutic class which contains one or more active substances, the patient pays beyond statutory participation: half of the difference between the reference and retail prices of the medicine, if the retail price is higher than price compensation. The remainder is charged to the pharmaceutical company or the MAH in the form of a rebate.

High-priced medicines included in the positive list are fully reimbursed without co-payment. These are divided into high-priced medicines for hospital use only (such as products used intravenously) and medicines whose administration starts in the hospital, with continued use at home. High-priced medicines are dispensed through public hospitals or pharmacies affiliated with the National Organization for Healthcare Service Provision (EOPYY), with the latter also dispensing to private clinics and private pharmacies, without any kind of co-payment. In 2017 almost the entire population (99%) was covered by EOPYY-affiliated pharmacies.

Public hospitals and EOPYY-affiliated pharmacies are entitled to purchase medicines directly from the manufacturers. The purchase price is the hospital price, which is 8.74% lower than the ex-factory price throughout the country.

The extensive changes in the Greek pharmaceutical sector led to a sharp decline in pharmaceutical expenditure from €4.37 billion in 2010 to €2.88 billion in 2012 *(56)*. In 2017 the pharmaceutical expenditure ceiling in the outpatient sector amounted to €1.94 billion (the same rate as 2016), while the closed budget for pharmaceutical expenditure in public hospitals amounted to around €500 million. A budget of €60 million was set for high-priced medicines for hospital use in private clinics. Looking ahead, EOPYY has identified

that Greece needs to develop effective strategies to increase awareness of and develop positive attitudes towards generic medicines among both health care professionals and the general public.

Vandoros et al. *(57)* found empirical evidence that the economic crisis in Greece had had a negative impact on self-rated health – in particular on mental health. Hessel et al. *(58)* compared self-rated health trends after the onset of the crisis in Greece and Ireland, applying a difference-in-differences approach by using a control population that had not experienced a recession. Difference-in-differences estimates suggested that the financial crisis led to an increase in the prevalence of poor self-rated health in Greece but not in Ireland. The extent of unemployment benefits and employment protection was deemed to be a possible factor for the differential effect in both countries.

Key findings from the case study in Greece

- Greece was strongly hit by the global financial crisis. In return for financial support, the country's government was obliged to implement cost-containment and efficiency-enhancing measures, including in the pharmaceutical sector.
- Major measures included price cuts and the introduction of measures to promote the uptake of lower-priced medicines.
- Patients in Greece are charged a co-payment for medicines (percentage co-payments plus a prescription fee in most cases). Exemptions are provided for patients with defined diseases.
- There is evidence that cost-containment measures in response to the global financial crisis have limited the accessibility of health services, since patients might forego needed treatment. The impact of the crisis and cost-containment related to medicines is yet to be explored.

5.4 Kyrgyzstan

Surface area: **199 949 km²**

Population size (in 2017, in millions): **6.045**

GDP per capita (in 2017, in current USD): **1 106.4**

Total health expenditure as a proportion of GDP (in 2017): **6.5%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **44.9%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **48.2%**

Sources: United Nations and World Bank data *(45, 46)*.

This case study explores the affordability of medicines in the outpatient system in Kyrgyzstan.

A mandatory health insurance fund was introduced in Kyrgyzstan in 1997, and currently covers 76.3% of the Kyrgyz population. Its revenues are collected from insurance premiums deducted via payroll tax. The government allocates funds for those unable to pay their contributions. Individuals that are not covered carry the full cost of consumed health care services themselves.

Public coverage of medicines is provided through two schemes: the state-guaranteed benefit package (SGBP) and the additional drug package (ADP). The SGBP ensures free access to a set of defined health services, including medicines, for all Kyrgyz people with specified medical conditions, independent of insurance status. The disease-specific scheme was introduced in 2001 to increase access to defined health services (in the outpatient and inpatient sectors) for vulnerable population groups and to improve health system efficiency. Under the scheme, medicines for conditions such as TB, HIV/AIDS, cancer, acute cardiac infarction, epilepsy and diabetes should (theoretically) be fully covered by the mandatory health insurance fund or through other channels. However, medicines coverage under the SGBP amounts to 80-90% of the retail price.

In 2001 the government introduced the ADP on a pilot basis before it was implemented nationally. Similar to the SGBP, its objective is to increase access to medicines and improve financial risk protection by limiting OOPs for Kyrgyz patients. The list includes evidence-based medicines, aiming to promote more rational prescribing and use of medicines. As the package is only available for patients with mandatory health insurance and predominantly targets noncommunicable diseases, it can be considered as a reimbursement scheme with disease-specific and population groups-specific elements.

After enrolment at their family group practice, insured patients are eligible for a special prescription from their doctor, which can only be used in pharmacies contracted by the mandatory health insurance fund. In 2015 the ADP list comprised 58 INNs. Medicines included in the ADP list are only partially reimbursed: patients are required to co-pay approximately 50% of a centrally determined reimbursement price – the so-called "baseline" price – which is based on prices collected from wholesalers. The remaining difference between the reimbursed baseline price and the retail price is charged to the patient; this can amount to more than 50% of the medicine price, as prices are not regulated at the retail level.

Medicines included on the ADP list do not fully align with medicines included in WHO's Model Lists of Essential Medicines *(26)*. In 2015 the average share of co-payments for medicines dispensed under the ADP was 50.7% (a reduction of 1.1 percentage points compared to 2014, after an increase of 2.0 percentage points from 2013 to 2014), with varying shares of co-payment depending on the ATC level *(59)*. Of respondents to a 2014 WHO survey, 64% reported that the high cost of medicines in Kyrgyzstan was the main reason for not purchasing them, compared to 40% in 2009 *(60)*. Kyrgyz policy-makers have been attempting to address pricing issues; however, there is still no price regulation for outpatient medicines in place.

Between 2013 and 2015 a 14% reduction in the number of medicines prescribed and reimbursed under the ADP was observed, while public expenditure on these medicines increased by 17% (for commonly prescribed medicines, such as treatment for cardiovascular diseases) *(59)*. The study found that the Kyrgyz population has faced not only high but increasing co-payments for reimbursed medicines in the outpatient sector, including a 20% increase for prescribed medicines on the ADP list in 2015 compared to 2013. The absence of price regulation of medicines was regarded as one possible reason for the increase in co-payments. For non-funded medicines, patients have to pay the full amount out-of-pocket. An increasing challenge in securing access to medicines and improving financial risk protection for the population has been the continuing rise of informal payments, which threatens to undermine the credibility of the SGBP and its promise to guarantee free access to medicines.

Key findings from the case study in Kyrgyzstan

- Kyrgyzstan has had a mandatory health insurance system for the last 20 years, which covers three out of four inhabitants.

- Concerns are rising about limited accessibility of medicines in the outpatient sector. The outpatient ADP list is rather small (58 INNs in 2015) and does not fully align with medicines included in the WHO Model Lists of Essential Medicines. Further, patients still have to co-pay around 50% of the price of the medicines on the list.
- There is evidence that patients have refrained from purchasing medicines due to high expenditure, and that the percentage of patients doing so has increased over recent years.
- Kyrgyzstan has no price regulation. The lack of price control is considered to be a major cause of the high costs of medicines, leading to the high payments by patients.
- In addition, high informal payments pose another financial burden for patients.

5.5 Republic of Moldova

Surface area: **33 846 km²**

Population size (in 2017, in millions): **4.051**

GDP per capita (in 2017, in current USD): **1 591.4**

Total health expenditure as a proportion of GDP (in 2017): **10.3%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **45.5%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **46.2%**

Sources: United Nations and World Bank data *(45, 46).*

This case study provides a comprehensive description of the pharmaceutical reimbursement system in the outpatient and inpatient sectors. The investigation focused on how access to and affordability of medicines are ensured.

Funding of medicines in the outpatient sector is provided by four different sources.

- The National Health Insurance Company (NHIC) funds medicines eligible for reimbursement. It is the sole institution responsible for the pooling and management of funds. Mandatory health insurance premiums amount to 9% of payroll, with employer and employee contributing the same 4.5% share.
- The Ministry of Health oversees a national programme (known as the "vertical programme"), which covers costs for selected treatments (specific diseases for which medicines are centrally procured in collaboration with the United Nations Development Programme) for both the inpatient and outpatient sectors. Medicines are provided for the treatment of toxoplasmosis, mental health, diabetes mellitus (insulin analogues) and diabetes insipidus, as well as selected rare diseases (such as phenylketonuria, pituitary insufficiency, juvenile arthritis and epidermolysis bullosa).
- International donors constitute a further source of funding; however, compared to other sources they play a minor role. They mainly procure antiretrovirals and TB medicines (second line).
- Another important funding source is private health expenditure. In the Republic of Moldova, the share of private health expenditure as proportion of total health expenditure is very high: 40% of health expenditure is paid out-of-pocket, of which 80% is spent on medicines. Although playing a minor role in terms of services provided and user charges, voluntary health insurance also exists in the country. In total, voluntary health insurance expenditure accounted for approximately 0.1% of total health expenditure in 2010 (Schneider P, Vogler S, Gesundheit Österreich Beratungs GmbH, unpublished report on pharmaceutical pricing and reimbursement in Moldova, 2014).

Medicines in the inpatient sector are funded by the NHIC. Since 2012 diagnosis-related groups have been developed for 168 condition groups and piloted in nine hospitals. There are no official user fees or co-payments for inpatient services (including medicines) in the Republic of Moldova; however, informal payments may be high.

The national EML is used in the outpatient sector. In 2012 around 900 medicines (counted by brand names of around 90 different active ingredients) were on the list. The Ministry of Health decides which medicines are in the EML via expert consultation. A positive list also exists but, in theory, reimbursed medicines first have to be on the EML. Additions or deletions from the reimbursement list are made by the Council for the Reimbursement of Medicine. This meets at the Ministry of Health and gathers representatives from there. The reimbursement list is revised at least once a year.

The costs of these medicines are, at least partially, covered by the NHIC, which determines the level of reimbursement. Reimbursement decisions are based on several criteria, such as eligibility for priority diseases, efficiency, safety and pharmacoeconomic criteria, and rates are set at 100%, 70%, 50% or 30% (Box 5.3).

Box 5.3

Percentage co-payments for outpatient medicines in the Republic of Moldova, 2017

The list of medicines for sustained (long-term) treatment in outpatient care has the following reimbursement rates:

- 100% for medicines to treat diabetes mellitus, anaemias in pregnant women, selected diseases of children aged up to 18 years, epilepsy, Parkinson's disease, psychological diseases, selected autoimmune diseases and rare diseases;
- 70% for selected cardiovascular medicines and medicines to treat thyroid disorders, asthma and hepatitis cirrhosis;
- 50% for selected cardiovascular and digestive medicines;
- 30% for Alzheimer's disease and depression medicines.

The list of medicines for episodic treatment (day hospital/day care room, procedures room and home treatment) of diseases commonly found in the practice of family physicians corresponds to short prescriptions (5-30 days). Their reimbursement rates are:

- 100% for children aged up to 18 years;
- 70% for adults.

In addition to the EML for outpatient medicines, a hospital medicine list is in place, which is longer than the EML. All medicines on this list are *de facto* 100% reimbursed by the NHIC, since inpatient medicines are funded through the diagnosis-related group system. This list is called the "pharmacotherapeutic formulary" and is developed by a specific council. Hospitals can only dispense medicines that are either on this list or mentioned in national protocols.

In 2014 Ferrario et al. *(61)* reviewed national outpatient reimbursement lists between 2005 and 2013 to study the progress in achieving access to essential medicines for noncommunicable diseases in the Republic of Moldova after mandatory health insurance had been introduced in 2004. Between

2005 and 2012 the budget allocated for reimbursement of outpatient medicines increased more than twentyfold, from €489 000 to €10 805 000, which translated into a higher number of reimbursable medicines. Three generic medicines for diabetes and one for respiratory disease were included in the list with 100% reimbursement. Further, 15 generic medicines for cardiovascular conditions were included and reimbursed at 50%. By using the number of days of monthly disposable income needed to buy one month of treatment, however, it was estimated that eight of these 15 medicines continued to be unaffordable for the first income quintile, and three remained too expensive for the second and third quintile of the Moldavan population. In 2013 insulin was included on the list and reimbursed at 100%. An increased budget led to improved medicine coverage; however, challenges in ensuring access to medicines remain. Introducing mandatory health insurance alone was not enough to provide access to essential medicines. Further efforts need to be focused on, for example, expanding the breadth and depth of medicines coverage and promoting rational use of medicines.

In a later study, Ferrario et al. *(62)* further evaluated the progress in increasing affordability of medicines for noncommunicable diseases after a decade of introducing mandatory health insurance in the Republic of Moldova. It was found that affordability of partially reimbursed medicines had gradually improved for all income and expenditure quintiles since 2006, the year the first reimbursement list was introduced. Nevertheless, the improvement could largely be explained by increased household incomes and spending, rather than increased percentage coverage of medicines through the reimbursement list. The study concluded that if the aim of mandatory health insurance is to increase affordability of medicines, there is a need to allocate higher budgets to ensure deeper coverage of essential medicines. In addition, efficient processes within the health system have to be established to secure its long-term sustainability. It should be noted that some medicines are not part of WHO Model Lists of Essential Medicines, and there may be other more cost-effective options instead of the products on the reimbursement list.

Key findings from the case study in the Republic of Moldova

- In the outpatient sector the Republic of Moldova has a complex funding system that involves social insurance, the Ministry of Health, international donor funding and private expenditure.
- Official co-payments in the outpatient sector exist and are considered high. In addition, informal payments are made in hospitals.
- Among others, the vertical programme plays an important role. This covers the costs for selected diseases for which medicines are centrally procured.
- The EML is the basis for the positive list in the outpatient sector. Only certain medicines on the reimbursement list are fully reimbursed; for others patients have to co-pay 30%, 50% or 70%. The criterion to decide the extent of the reimbursement rate is the disease for which the medicine is used.
- Studies have shown progress in affordability of outpatient medicines for noncommunicable diseases. This was partially attributed to the mandatory health insurance fund, but concerns about affordability remain, given high co-payments.

5.6 The Netherlands

Surface area: **41 542 km²**

Population size (in 2017, in millions): **17.036**

GDP per capita (in 2017, in current USD): **44 332.1**

Total health expenditure as a proportion of GDP (in 2017): **10.9%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **80.7%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **12.2%**

Sources: United Nations and World Bank data *(45, 46)*.

This case study evaluates the impact of the reimbursement restriction policy measure on benzodiazepine usage.

Hoebert et al. *(63)* investigated the impact of the reimbursement restriction on benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorders in the outpatient sector. The study found that the reimbursement restriction led to a moderate reduction in the number of incident diagnoses and a reduction of initiation of benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorders. Hoebert et al. concluded that these results suggest that in settings where reimbursement restriction as a policy measure is not available, prescribing doctors have some flexibility in reducing benzodiazepine prescribing. Nonetheless, ongoing monitoring of prescribing behaviour by doctors and health care provider organizations is recommended, alongside amending treatment guidelines to improve prescribing practices (where required).

The Netherlands has co-payment due to the RPS and the mandatory deductible of €385 per year. For medicines excluded from reimbursement, like benzodiazepines, patients have to pay the full price themselves.

Outpatient medicines are reimbursed if they are included in the RPS (called the reimbursement system), based on the classification of medicines into groups (clusters) of interchangeable medicines. The extent of reimbursement for medicines can vary, since the reimbursement limit is set based on the average list price of medicines within the same cluster. Thus, medicines within the same cluster have a fixed reimbursement price, but medicines priced above this reimbursement limit are only reimbursed to this reference price limit.

Further, any new medicine which cannot be clustered is not reimbursed, unless there is an additional clinical benefit compared to standard therapy and it is also cost-effective. When multiple generics are available, a health insurer has the opportunity to select only one specific medicine per active substance for reimbursement – the so-called "preference policy". Medicines other than the preferred product will not be reimbursed at all, except in some cases when the prescriber specifies "medical need" on the prescription. This procedure is not regulated at a central level: it is the responsibility of the health insurance funds. Furthermore, all citizens aged 18 years and over are required to pay the first €385 of health care costs per year out-of-pocket (deductible). This includes expenditure on outpatient medicines prescribed by general practitioners but excludes co-payments for medicines. The mandatory deductible does not apply for general practice consultations, maternity care and home nursing care.

There is no co-payment in the inpatient sector.

Key findings from the case study in the Netherlands

- In January 2009, the Netherlands excluded benzodiazepines from reimbursement when used as an anxiolytic, hypnotic or sedative. Full reimbursement was retained for selected indications (e.g. epilepsy, multiple psychiatric disorders) when treatment alternatives were not available. The aim of the measure was twofold: improvement of responsible use of medicines and cost-containment.
- The reimbursement restriction led to a moderate reduction in the number of incident diagnoses and initiation of benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorder.

5.7 Scotland, United Kingdom

Surface area: **80 077 km²**

Population size (in 2017, in millions): **5.424**

GDP per capita (in 2017, in current USD): **n/a**[6]

Total health expenditure as a proportion of GDP (in 2017): **n/a**[6]

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **n/a**[6]

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **n/a**[6]

Sources: United Nations data *(45)*.

The United Kingdom comprises four territories – England, Scotland, Wales and Northern Ireland – and each has its own system of publicly funded health care. In Scotland, UHC is predominantly financed out of general taxation; thus, health services are generally free at the point of care for all inhabitants. Since 2011, co-payments for prescription medicines have been abolished to ensure access to medicines for all, and in particular for deprived populations.

In many European countries a major issue in pharmaceutical policy is the split of competencies. In several countries different reimbursement agencies are responsible for the outpatient and inpatient sectors, resulting in different policies. The case study on Scotland looks at mechanisms to ensure more aligned coordination in pharmaceutical policies across sectors.

Joint lists of recommended medicines for primary and hospital care were implemented in Scotland over 20 years ago, with both primary and hospital physicians on the drug and therapeutics committee developing joint guidance and guidelines. The initial driver to establish this joined-up working approach was to ensure safe, appropriate and high-quality prescribing. Prior to this, primary care prescribing had increasingly been influenced by hospital recommendations. In addition, health professionals recognized the clinical risk in the use of too many medicines and switching between medicines. Cost-containment soon became another factor, equally in primary and hospital care, which led to the adoption of a single budget for inpatient and outpatient care.

Almost all guidelines in Scotland are now jointly written, reflecting inputs from primary and hospital care, with full declarations of interest required from all contributors. Guidelines are evidence-based and

6 This information could not be retrieved at the time of writing of the report.

specifically address interface issues, such as guidance on referral to hospital care. Formulary content is informed by guideline advice and vice versa; if the guideline recommends a class of medicines, the formulary may define individual medicines. Guidelines follow the advice of the Scottish Medicines Consortium, which is the HTA body in the country. The Consortium was a pioneer in work with horizon scanning to facilitate safe and rational introduction of new medicines into the health care system. Apart from doctors, pharmacists and industry, patients are also represented in the Consortium's decision-making bodies.

All formularies are equally applied in primary and hospital care. Prescribing of medicines is monitored and formulary adherence assessed. Prescribing medicines not included in the formulary (on the grounds of cost–effectiveness, for example) have to be justified. In case of non-coverage of medicines, patients may appeal to the health board and request individual patient treatment, stating specific reasons. If the health board rejects these reasons, the expenses of the medicine has to be borne entirely by the patient. The number of such cases is very small. The formulary is published in paper and electronic versions. There are regular formulary updates, including advice on good prescribing, "medicine of choice" initiatives and prescribing newsletters.

Key findings from the case study in Scotland

- Scotland has been working for more than 20 years on ensuring a more coordinated approach in pharmaceutical policies across sectors.
- A major point of reference is the joint lists of recommended medicines for outpatient and hospital sectors. These have been developed based on the advice and involvement of both primary and hospital care physicians on the drug and therapeutics committee, who have contributed to developing joint guidance and guidelines.
- Decision-makers of the national HTA body include all relevant stakeholders, such as doctors, pharmacists, industry and patients.

5.8 Spain

Surface area: **505 944 km²**

Population size (in 2017, in millions): **46.354**

GDP per capita (in 2017, in current USD): **25 865.4**

Total health expenditure as a proportion of GDP (in 2017): **9%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **71%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **24.2%**

Sources: United Nations and World Bank data *(45, 46).*

The Spanish case study focuses on the impact of the medicines co-payment reform during the financial crisis.

Prior to 2012, all Spanish residents had free health care coverage provided by the NHS, with exception of a percentage co-payment for outpatient reimbursable medicines. From the early 1980s the general co-payment rate was 40% of the pharmacy retail price. A lower percentage co-payment rate of 10%

was applied mainly to medicines prescribed for chronic diseases, with a price ceiling of €2.64 per prescription. Medicines in the inpatient sector were provided free of charge. Percentage co-payment rates were charged only to economically active (working) people and their dependants, independent of their socioeconomic status. As an exception, some civil servants (those with a specific mutual health insurance) incurred a co-payment rate of 30% of the full pharmacy retail price (applied to both economically active and pensioner civil servants). Pensioners and their dependants were exempt from the co-payment.

In July 2012, in the context of the severe economic crisis in Spain and the need to reduce public spending, the Spanish government established a set of three new co-payment policies for outpatient prescription medicines. The first entailed reforms of national co-payment provisions.

- After decades of free access to medicines for the elderly, a 10% co-payment on medicines for pensioners was introduced, subject to a monthly income-related cap (€8.23 for pensioners with an annual income below €18 000; €18.52 for incomes between €18 000 and 100 000; and €61.75 for incomes above €100,000).
- The percentage co-payment for non-pensioners with an annual income below €18 000 remained 40% of the medicine price. The percentage co-payment for non-pensioners with an annual income between €18 000 and €100 000 increased to 50%, and non-pensioners with an annual income above €100 000 now pay 60% of the medicine price. No cap on expenses for medicines exists for non-pensioners. Selected medicines for chronic diseases have a 10% co-payment rate, along with a maximum fee per prescription.
- The reforms continued to exempt disadvantaged people from medicines co-payments, such as those on very low incomes. Long-term unemployed people (those unemployed for a minimum of two years) who do not receive any social benefits and their dependants are also exempt from co-payments for medicines.

The second policy was a €1 fixed co-payment per prescription in two regions – Catalunya and Madrid – which was introduced temporarily until suspended in January 2013.

The final policy involved discontinuation of funding (delisting) for over 400 medicines accounting for most specific therapeutic categories indicated for minor symptoms in the outpatient setting, thus imposing full co-payment for those medicines. These medicines remain free for disadvantaged people, however.

The three policies also intended to promote public awareness that UHC does not equate to cost-free medicines. Puig-Junoy *(64)* analysed the impact of the co-payment reforms on the quantity of dispensed medicines in Spain at the regional level. Catalunya, the first region to introduce a fixed €1 co-payment per prescription alongside the adoption of the national co-payment reforms experienced a significant 23.9% reduction in the number of prescriptions in the first 14 months. Of the 17 other Spanish regions, 15 experienced a reduction in prescription numbers by more than one tenth. The study concluded that, after decades of unsuccessful attempts to cut pharmaceutical expenditure in the Spanish NHS, the 2012 reforms in co-payment policies led to a substantial reduction in the total number of dispensed prescriptions. It is not known whether the reduction was generated by a cut in the practice of overprescribing or by patients not being able to access the medicines they needed.

Puig-Junoy et al. *(65)* later examined the impact of the 2012 co-payment reform on medicine consumption for three therapeutic subgroups: antidiabetics, antithrombotics and chronic obstructive pulmonary disease (COPD) and asthma medicines. The results showed an abrupt and substantial reduction in the number of DDDs of all three therapeutic subgroups. A substantial reduction in expenditure was noted in the subgroup of asthma and COPD medicines.

Key findings from the case study in Spain

- During the global financial crisis Spain implemented savings measures to reduce public pharmaceutical expenditure.
- The extent of reimbursed (publicly co-funded) medicines was reduced (with around 400 delistings from the outpatient positive list), mainly for minor ailments. Co-payments were introduced: the percentage co-payment rates were raised (from 40% to 50% and 60% of the pharmacy retail price of a medicine) and pensioners, a previously exempted group, were asked to co-pay (10%) as well.
- The reforms have led to a considerable reduction in the number of prescriptions. Nevertheless, it is yet not known whether irresponsible overprescribing has been reduced, or whether patients are excluded from accessing needed medicines. The policy objective of cutting public pharmaceutical expenditure has been achieved in the short term.

5.9 Turkey

Surface area: **783 562 km²**

Population size (in 2017, in millions): **80.745**

GDP per capita (in 2017, in current USD): **9 125.8**

Total health expenditure as a proportion of GDP (in 2017): **5.4%**

Domestic general government health expenditure as a proportion of current health expenditure (in 2015): **78.1%**

Out-of-pocket expenditure as a proportion of current health expenditure (in 2015): **16.9%**

Sources: United Nations and World Bank data *(45, 46)*.

The Turkish case study investigates the country's health care reforms and possible impacts on affordable access to medicines.

Turkey has a social security-based health care system under a single payer: the Social Security Institution. This pools funds from contributory health insurance (with premiums based on employer and employee contributions). Further, the Ministry of Finance transfers tax-based money for the government-financed green card scheme, which covers those on low income. Since 2010 all Turkish citizens have been required to be registered with a family practitioner; however, as there is no mandatory referral system in place, patients may seek care directly at a secondary or tertiary care provider, even for minor complaints *(66)*.

The implementation of health care reforms, in particular between 2003 and 2013, increased health insurance coverage, especially among the poorest population groups *(67)*. Meanwhile, nearly 99% of Turkish citizens were covered by the universal health insurance (general health insurance) scheme, compared to 67% in 2002 *(66, 68)*. Due to increased coverage and access to health care services, out-of-pocket spending per capita has steadily decreased over the past decade, from 22.8% in 2005 to 16.6% in 2015 *(66)*. The introduction of external price referencing in 2004 had a significant impact in limiting co-payments and decreasing prices.

Reimbursement eligibility for medicines in the outpatient sector is mainly population group-specific. Pensioners and their dependants are eligible for a reduced co-payment rate of 10%, whereas green

card holders and active workers and their dependants pay 20% of the medicine price (green card holders can claim for reimbursement from the health insurance scheme of the 20% co-payment). Pensioners do not advance money; they are charged directly from their monthly pensions. In addition, further charges of 3 Turkish lira (€0.68)[7] apply for each prescription of up to three items and 1 Turkish lira (€0.23) per additional item on the prescription (no waiver is possible for this prescription fee). Exemptions from outpatient co-payments apply to emergency care services, treatment of occupational diseases and accidents and defined chronic diseases, such as cancer, hypertension, hepatitis, asthma, cardiovascular diseases or HIV/AIDS. There is only one positive list with an appendix for hospital-only products.

The reimbursement amount is calculated based on the lowest-priced medicine of the reference group. If a patient wishes to opt for a more expensive medicine, she or he must pay the difference between the pharmacy retail price and the reference price, in addition to the regular co-payment.

Since the inception of the country's health transformation programme in 2003, the Turkish government has put emphasis on containing pharmaceutical expenditure. A number of policies have been adopted by the Ministry of Health and the Social Security Institution (such as policies for MA, pricing and reimbursement and rational use of medicines), with the goal of changing prescription and utilization behaviour among both patients and providers. The use of therapeutically effective, safe, high-quality, cost-effective and affordable medicines has been declared the most important policy goal in the pharmaceutical sector *(66)*.

Key findings from the case study in Turkey

- Turkey has an SHI system in place. Between 2003 and 2013 major reforms were undertaken to achieve the policy objectives of therapeutically effective, safe, high-quality, cost-effective and affordable medicines.
- The pharmaceutical reimbursement framework is mainly population group-based, supplemented by a disease-oriented approach. Patients have to co-pay 20% for medicines in general, with a reduced co-payment rate (10%) for pensioners. Exemptions from co-payments for outpatient medicines are in place for defined diseases; there is no co-payment for hospital-only medicines.
- The health care reforms were found to have steadily increased health insurance coverage, and OOPs have decreased over the years. Turkey has been working on different aspects of the reforms (such as price regulation to reduce pharmaceutical prices and alternative reimbursement agreements for high-priced products).

7 At currency exchange rates checked on 30 October 2017, 1 Turkish lira = €0.227.

6. Findings from the literature: analysis of reimbursement policies

6.1 Impact on accessibility, affordability and health outcomes

The literature review (for the methodology see section 2.5) found both descriptive and, to a lesser extent, analytical literature about reimbursement models, systems and policies. Descriptive literature surveyed existing pharmaceutical reimbursement policies, models and frameworks, while the analytical literature aimed to assess such policies based on defined goals (such as cost-containment and affordability).

The literature search identified 43 studies on countries in the WHO European Region that appeared to be potentially analytical. After studying the full texts of all 43, 22 were relevant to the search criteria. The other 21 were excluded for various reasons: the studies were not analytical, too descriptive or out of geographical scope. A description of the 22 studies is available in Annex 6; Table 6.1 provides a brief overview.

The literature review of analytical studies suggests that reimbursement policy measures can have an impact on affordability, accessibility, medication adherence, health outcomes, expenditure and utilization of medicines. In particular, it concluded the following.

- Eliminating or reducing co-payments was seen to have a positive impact on medication adherence and helped achieve better health outcomes. Several studies showed that the introduction of or increases in co-payments resulted in reductions in the per capita number of prescriptions, lower public pharmaceutical expenditure, a higher financial burden for patients and reduced medication adherence.
- Some studies reported that the introduction of an RPS and generic substitution resulted in lower public pharmaceutical expenditure in the medicine classes studied and even a reduction in medicine prices. Pricing policies that supplement reimbursement models, such as an RPS and generic substitution, were also found to contribute positively to more affordable medicine prices and higher use of generics.

While there are many descriptive studies on pharmaceutical pricing and reimbursement policies and descriptions of pharmaceutical expenditure and consumption data, few studies analysed the impact of a reimbursement policy intervention in Europe. Thus, more research needs to be conducted to assess

the impact of reimbursement policies on policy objectives (such as affordability, accessibility, equity, adherence, outcome and consumption) in countries in the WHO European Region.

Table 6.1 | Key findings from the literature review addressing pharmaceutical reimbursement policies

Reimbursement policy	Country of analysis	Impact	Reference
Increasing co-payments	Italy	Reduction in the per capita number of prescriptions, and lower per capita public pharmaceutical expenditure	*(69)*
	Ireland	Reduction in medication adherence to essential and less essential medicines	*(70)*
	Spain	Reduction in number of dispensed prescriptions and consumption (in DDD) and reduced public pharmaceutical spending	*(64, 65)*
Eliminating co-payments	Israel	Increase in medication adherence among lower economic residents with chronic conditions	*(71)*
	Italy	Possible positive effect on health outcomes and medication compliance	*(73)*
Introduction of co-payment policy	Italy	Increase in trends of statin use and a negligible reduction in selective serotonin reuptake inhibitors use	*(74, 75)*
	Sweden	No impact on medicine use, with the exception of reduction in female use of antidepressants	*(76)*
	Multiple European countries	Inverse association with medicine use	*(72)*
		Possible reduction in medicine use and reduction of pharmaceutical expenditure	*(19)*
Generic policies (internal reference pricing and generic substitution)	Finland	Contribution to a reduction in daily costs (for payer) of antipsychotic medications	*(48)*
	Sweden	Reductions in expenditure and volumes of all medicines	*(77, 78)*
		Reduction in the average price of medicines	*(78)*
	Spain	Not effective in containing expenditure in the medium or long term	*(79)*
	Portugal	Not effective in controlling pharmaceutical expenditure	*(80)*
	Denmark	Positive impact on affordability of medicines	*(81)*

Table 6.1 | Continued

Reimbursement policy	Country of analysis	Impact	Reference
	Austria	Increase in the proportion of overall expenditure spent on generic medicines, increase in prescriptions for generic medicines and reduction in expenditure per prescription	*(82)*
Reimbursement restriction	Netherlands	Reduction in number of prescriptions and use	*(83)*
	Italy	Immediate reduction in trend and level of statin use	*(74)*

Notes: Two studies provided cross-country comparisons (84, 85). They are not included here but are described in Table A6.1 in Annex 6. Some studies looked into multiple policy measures and thus appear under more than one category.

6.2 Vulnerability

All studies included in this review of the literature were also analysed to identify whether they specifically detailed information on vulnerable populations. This involved searching on whether the term "vulnerability" (vulnerable groups) was defined and how. The Cochrane review *(19)* used the term "vulnerable populations" in the context of the policy analysis on direct patient payments for medicines. One publication used the same definition of vulnerability as defined by the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2016: "People whose situations or contexts make them especially vulnerable, or who experience inequality, prejudice, marginalization and limits on their social, economic, cultural and other right" *(86)*. None of the other studies provided a definition or specification of vulnerability.

7. Cross-country analysis of financial burden for patients

This chapter assesses and compares the actual financial burden patients encounter when filling prescriptions. An illustrative sample of different reimbursable outpatient medicines for defined patient groups in selected countries (Albania, Austria, France, Germany, Greece, Hungary, Kyrgyzstan, Sweden and the United Kingdom[8]) was used. Details of the methodology applied are outlined in section 2.6 and Annex 7.

7.1 Co-payment regulation and scenarios considered

Of the countries studied, those where a prescription fee is the only form of co-payment for outpatient medicines are Austria, Germany[9] and the United Kingdom. All three charge a prescription fee for each item on the form. Prescription fees are typically considered a "fixed co-payment". It is mandated that the co-payment due to the prescription fee in Austria and Germany can never exceed the medicine price per pack. Conversely, in the United Kingdom patients may, in principle, pay a prescription fee that is higher than the price of the medicine.

In Albania, Hungary (except for life-threatening diseases where there is 100% reimbursement) and Kyrgyzstan a percentage co-payment is applied based on the price of the medicine. This percentage usually varies for different indications, and other patient group characteristics may also play a role.

In France and Greece a combination of a fixed co-payment (prescription fee) and percentage co-payment applies.

Sweden is the only country included in the analysis whose co-payments for medicines are fully based on a comprehensive deductible system: patients pay out-of-pocket up to a defined threshold (deductible), above which no further co-payments apply. Between the lower and upper threshold the Swedish deductible system includes various scales that define areas in which patients pay different percentage co-payments based on the medicine's price.

8 As with the rest of the study, the financial burden analysis for the United Kingdom refers to England.

9 The design of the German co-payment (calculated as a percentage of the price of each prescribed medicine pack, with an absolute figure of €5 and €10 as the minimum and maximum limits) would also have allowed it to be classified as a percentage co-payment. For the purposes of this report, however, the decision was made to classify it as a fixed but price-dependent co-payment.

Some countries (such as Germany, Greece and Hungary) have an RPS (internal price referencing). This means that similar medicines are clustered, and that patients have to pay the difference between this reimbursement price (the so-called "reference price"), or the publicly funded share of the reference price in some countries, and the pharmacy retail price. This co-payment has to be paid in all cases, even by patients who are exempt from other co-payments. In Germany, for instance, there are two different terms to describe these co-payments: the "normal" co-payment and the payment to cover the difference from the pharmacy retail price.

In addition, most countries included in the analysis have exemptions to these co-payments for defined patient groups. For the analysis, mechanisms for reductions or exemptions from co-payments were investigated for some defined populations – children, low-income groups, retired people, unemployed people and high spenders on medicines – or according to disease-specific programmes. (Annex 7 provides more details on these groups.) No exemptions exist in Kyrgyzstan for medicines included in the outpatient medicines reimbursement list (the ADP), however: co-payment for insured patients represents 50% of a calculated reference price (but actual co-payment may be higher due to higher but unknown pharmacy retail prices). Also, children (usually defined as under 18 years) are exempt from co-payments in most countries analysed except Austria, Greece, Hungary (where exemption is solely for children in social care) and Kyrgyzstan.

Table 7.1 provides a summary of the relevant co-payment provisions for each of the scenarios considered in the countries selected for the analysis (for details and a more comprehensive picture please consult Table A5.5 in Annex 5).

Table 7.1 | Co-payments of reimbursable medicines for defined patients groups or programmes in countries of the financial burden analysis, 2017

Country	Standard co-payment	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines[a]	Disease-specific programme[b]
Albania	• Co-payment of 5-50% of the medicine price depending on the indication considered • No prescription fee, no deductible • If applicable, difference between reference price and pharmacy retail price has to be paid out-of-pocket	Exempt	No specific provision	Exempt	No specific provision	No specific provision	Disease determines the percentage co-payment
Austria	• Prescription fee of €5.85 per item on the prescription (capped[c]) • No percentage co-payment, no deductible	No specific provision	Exempt (net monthly income <€889.94 for a single person; different rates for couples and children)	No specific provision	No specific provision	Exemption for people with "increased medicines need" in combination with low income (net monthly income <€1023.32 for a single person) Exemption after a spending threshold of 2% of net annual income on prescription fees within a year	No specific provision related to the medicines of the survey
France	• Prescription fee of €0.50 for each item on the prescription • Percentage co-payment of 35%, 70% or 85% depending on the medicine • No deductible • If applicable, difference between reference price and pharmacy retail price has to be paid out-of-pocket	Exempt from prescription fee	Exempt from prescription fee and percentage co-payment	No specific provision	No specific provision	Exemption after annual spend of €50 on prescription fees	Disease determines the percentage co-payment

Table 7.1 | Continued

Country	Standard co-payment	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines[a]	Disease-specific programme[b]
Germany	• Prescription fee as a proportion of 10% of the medicine price for each item (pack) on the prescription (minimum €5, maximum €10), but not more than the price of the medicine • No further percentage co-payment; no deductible • Exemption from co-payment for medicines with pharmacy retail price 30% below reference price • If applicable, difference between reference price and pharmacy retail price has to be paid out-of-pocket	Exempt	No specific provision	No specific provision	No specific provision	Exempt from co-payment at 2% of annual gross income	Chronically ill people exempt from co-payment at 1% of annual gross income
Greece	• Prescription of €1 (except in cases of no percentage co-payment) • Standard percentage co-payment of 25% (10% reduced) • No deductible • If applicable, difference between reference price and pharmacy retail price has to be paid out-of-pocket	No specific provision	Exemption from co-payment (no prescription fee and no percentage co-payment for vulnerable groups)	No specific provision, except for pensioners on low income: reduced percentage co-payment of 10% and prescription fee of €1	No specific provision (in practice, provision as for patients in low-income groups apply)	No specific provision	Exempt from co-payment and reduced co-payment for defined diseases
Hungary	• Co-payment of 75%, 45% or 20% of the medicine price ("normative reimbursement") • Co-payment of 50%, 30% and 10% of the price for medicines of severe chronic diseases ("indication-based reimbursement") • No prescription fee apart from a fee of 300 Hungarian forints (€0.96) for medicines exempt from percentage co-payment under the indication-based reimbursement • No deductible • If applicable, difference between reference price and pharmacy retail price has to be paid out-of-pocket	Children in social care are exempt from co-payment within a defined monthly budget ceiling (12 000 Hungarian forints/ around €40)	Exempt from co-payment within a defined monthly budget ceiling (12 000 Hungarian forints/around €40)	Exempt from co-payment within a defined monthly budget ceiling (12 000 Hungarian forints/around €40) if in receipt of retirement benefits due to disabilities and accidents	No specific provision	Exempt from co-payment due to a defined monthly budget ceiling (12 000 Hungarian forints/around €40) in case of low household income	Disease determines the percentage co-payment

Table 7.1 | Continued

Country	Standard co-payment	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines[a]	Disease-specific programme[b]
Kyrgyzstan	• Co-payment of minimum 50% of the pharmacy retail price, given reimbursement of 50% of a reference price (tariff) – higher co-payment is likely due to higher (but unknown) pharmacy retail prices	No specific provision	No specific provision	No specific provision	No specific provision	No specific provision	No specific provision
Sweden	• 100% OOP below a deductible of 1100 Swedish krona (€113); above this limit (lower threshold), percentage co-payments depend on accumulated expenses (50% co-payment for expenses between 1101 and 2100 Swedish krona; 25% co-payment for 2101–3900 Swedish krona and 10% co-payment for 3901–5400 Swedish krona) within 12 months • Maximum amount paid by the patient is 2200 Swedish krona[d]	Exempt	No specific provision	No specific provision	No specific provision	No co-payment above accumulated expenses of 5400 Swedish krona (upper threshold) within 12 months	Not applicable for the medicines selected
United Kingdom	• A prescription fee of £8.60 (€9.70) per item on the prescription • No percentage co-payment, no deductible	Children aged 16 years and below exempt; aged 16-18 years exempt only if in full-time education	Exempt based on certain criteria	People aged 60 years and over exempt	Exempt based on receipt of certain benefits and other criteria	Possibility to buy a three-month (£29.10) or 12-month (£104) prescription prepayment certificate to allow unlimited prescriptions	Exemption for those with one of 10 medical conditions, including cancer and diabetes

a A situation when patients' expenses on medicines reach a specific threshold; see Annex 7 for more details
b Possible regulation with regard to indications of the selected medicines (chronic conditions such as asthma and diabetes)
c If the gross reimbursement price is below the prescription fee, the pharmacy cannot dispense the medicine at the expense of the Austrian SHI. Thus, the patient will fully pay the gross pharmacy retail price out-of-pocket, but never more than the prescription fee.
d Thresholds refer to 2017. They were changed in 2018.

7.2 Data availability

Overall, data availability was a major limitation since price data were not always available for the originator or generic medicine (or even both) in each country. This might be due to selected presentations (in the defined pharmaceutical form, dosage and pack size) not being marketed in the countries analysed, or medicines being on the market but not reimbursed and therefore not included in price databases (which tend to include only reimbursed medicines).

Further, if price data were available for medicines of the same pharmaceutical form and dosage but for a different pack size, the nearest pack size was selected for the analysis (using the price per pack, with no weighting of prices). Table A7.2 in Annex 7 provides more information about data availability and alternative presentations used in cases of data gaps.

7.3 Cross-country analysis

7.3.1 Co-payment and exemptions

Table 7.2 shows the results of the analysis and outlines the co-payments for the prescribed originator and the lowest-priced generic version of the selected medicines for each patient group and country analysed.

As Table 7.2 shows, for the standard co-payments high variations were found between countries.

- For amlodipine co-payments ranged from US$ 26.90 PPP (Germany) to US$ 3.72 PPP (France) for the originator and from US$ 12.25 PPP (United Kingdom) to US$ 0.35 PPP (Albania) for the lowest-priced generic.
- For amoxicillin/clavulanic acid co-payments ranged from US$ 64.51 PPP (Germany) to US$ 7.01 PPP (Greece) for the originator and from US$ 12.25 PPP (United Kingdom) to US$ 5.21 (Albania) for the lowest-priced generic.
- For ibuprofen co-payments ranged from US$ 8.00 PPP (Sweden) to US$ 3.22 PPP (Greece) for the originator and from US$ 12.25 PPP (United Kingdom) to US$ 2.43 PPP (Greece) for the lowest-priced generic.
- For salbutamol co-payments ranged from US$ 12.25 PPP (United Kingdom) to US$ 0.67 PPP (Hungary) for the originator and from US$ 12.25 PPP (United Kingdom) to US$ 1.19 PPP (Albania) for the lowest-priced generic.
- For metformin co-payments ranged from US$ 16.22 PPP (Albania) to US$ 0.00 PPP (United Kingdom) for the originator and from US$ 7.33 PPP (Austria) to US$ 0.00 PPP (United Kingdom) for the lowest-priced generic.

Table 7.2 also displays the various co-payment exemptions considered in the analysis Patients on low income are among the groups frequently exempt from co-payments. In five of the nine countries surveyed (Austria, France, Greece, Hungary and the United Kingdom) this group does not make any form of co-payment for the medicines analysed (apart from the possible difference between the pharmacy retail price and the reference price), although the extent of their co-payment does not differ from the standard in the other four countries.

In certain countries patients with high medication needs (defined in terms of medicine expenditure above a certain threshold) are exempt from some co-payments based on defined criteria such as defined expenditure for medicines spend as a proportion of income (Austria, Germany, France and Sweden) or upon purchase of a prepayment prescription certificate for three or 12 months (United Kingdom).

Table 7.2 | Co-payments for the medicines surveyed expressed in US dollar PPP and as a share of the gross pharmacy retail price for defined patient groups in countries of the financial burden analysis, September 2017

Country	Medicine	Standard co-payment		Children		Patients on low income		Retired people		Unemployed people		High spenders on medicines	
		O	LPG	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
Albania	Amlodipine	n/a	0.35 (20%)	Not applicable		n/a	0.35 (20%)	0 (0%)	0 (0%)	n/a	0.35 (20%)	n/a	0.35 (20%)
	Amoxicillin/ clavulanic acid	8.95 (48%)	5.21 (35%)	Not applicable		8.95 (48%)	5.21 (35%)	0 (0%)	0 (0%)	8.95 (48%)	5.21 (35%)	8.95 (48%)	5.21 (35%)
	Ibuprofen	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Salbutamol	2.69 (36%)	1.19 (20%)	0 (0%)	0 (0%)	2.69 (36%)	1.19 (20%)	0 (0%)	0 (0%)	2.69 (36%)	1.19 20%)	2.69 (36%)	1.19 (20%)
	Metformin	16.22 (76%)	0.23 (4%)	Not applicable		16.22 (76%)	0.23 (4%)	0 (0%)	0 (0%)	16.22 (76%)	0.23 (4%)	16.22 (76%)	0.23 (4%)
Austria	Amlodipine	7.33 (88%)	6.45 (100%)	Not applicable		0 (0%)	0 (0%)	7.33 (88%)	6.45 (100%)	7.33 (88%)	6.45 (100%)	0 (0%)	0 (0%)
	Amoxicillin/ clavulanic acid	7.33 (38%)	7.33 (42%)	Not applicable		0 (0%)	0 (0%)	7.33 (38%)	7.33 (42%)	7.33 (38%)	7.33 (42%)	0 (0%)	0 (0%)
	Ibuprofen	7.33 (98%)	7.33 (98%)	Not applicable		0 (0%)	0 (0%)	7.33 (98%)	7.33 (98%)	7.33 (98%)	7.33 (98%)	0 (0%)	0 (0%)
	Salbutamol	7.33 (84%)	n/a	7.33 (84%)	n/a	0 (0%)	0 (0%)	7.33 (84%)	n/a	7.33 (84%)	n/a	0 (0%)	0 (0%)
	Metformin	7.33 (32%)	7.33 (35%)	Not applicable		0 (0%)	0 (0%)	7.33 (32%)	7.33 (35%)	7.33 (32%)	7.33 (35%)	0 (0%)	0 (0%)
France	Amlodipine	3.72 (42%)	3.16 (44%)	Not applicable		0 (0%)	0 (0%)	3.72 (42%)	3.16 (44%)	3.72 (42%)	3.16 (44%)	3.10 (35%)	2.54 (35%)
	Amoxicillin/ clavulanic acid	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Ibuprofen	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Table 7.2 | Continued

Country	Medicine	Standard co-payment		Children		Patients on low income		Retired people		Unemployed people		High spenders on medicines	
		O	LPG	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
France	Salbutamol	2.81 (45%)	2.81 (45%)	2.19 (35%)	2.19 (35%)	0 (0%)	0 (0%)	2.81 (45%)	2.81 (45%)	2.81 (45%)	2.81 (45%)	2.19 (35%)	2.19 (35%)
	Metformin	0.62 (7%)	0.62 (9%)	Not applicable		0 (0%)	0 (0%)	0.62 (7%)	0.62 (9%)	0.62 (7%)	0.62 (9%)	0 (0%)	0 (0%)
Germany	Amlodipine	26.90 (75%)	6.43 (42%)	Not applicable		26.90 (75%)	6.43 (42%)	26.90 (75%)	6.43 (42%)	26.90 (75%)	6.43 (42%)	20.48 (57%)	0 (0%)
	Amoxicillin/ clavulanic acid	64.51 (53%)	6.43 (12%)	Not applicable		64.51 (53%)	6.43 (12%)	64.51 (53%)	6.43 (12%)	64.51 (53%)	6.43 (12%)	52.31 (43%)	0 (0%)
	Ibuprofen	n/a	6.43 (42%)	Not applicable		n/a	6.43 (42%)	n/a	6.43 (42%)	n/a	6.43 (42%)	n/a	0 (0%)
	Salbutamol	6.43 (32%)	6.43 (36%)	0 (0%)	0 (0%)	6.43 (32%)	6.43 (36%)	6.43 (32%)	6.43 (36%)	6.43 (32%)	6.43 (36%)	0 (0%)	0 (0%)
	Metformin	n/a	6.43 (39%)	Not applicable		n/a	6.43 (39%)	n/a	6.43 (39%)	n/a	6.43 (39%)	n/a	0 (0%)
Greece	Amlodipine	5.62 (79%)	4.20 (74%)	Not applicable		2.91 (41%)	1.49 (26%)	5.62 (79%)	4.20 (74%)	5.62 (79%)[a]	4.20 (74%)[a]	5.62 (79%)	4.20 (74%)
	Amoxicillin/ clavulanic acid	7.01 (71%)	6.28 (69%)	Not applicable		3.86 (39%)	3.13 (34%)	7.01 (71%)	6.28 (69%)	7.01 (71%)[a]	6.28 (69%)[a]	7.01 (71%)	6.28 (69%)
	Ibuprofen	3.22 (74%)	2.43 (79%)	Not applicable		0.65 (15%)	0 (0%)	3.22 (74%)	2.43 (79%)	3.22 (74%)[a]	2.43 (79%)[a]	3.22 (74%)	2.43 (79%)
	Salbutamol	2.66 (66%)	n/a	2.66 (66%)	n/a	0 (0%)	n/a	2.66 (66%)	n/a	2.66 (66%)[a]	n/a	2.66 (66%)	n/a
	Metformin	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Table 7.2 | Continued

Country	Medicine	Standard co-payment		Children		Patients on low income		Retired people		Unemployed people		High spenders on medicines	
		O	LPG	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
Hungary	Amlodipine	n/a	0.40 (20%)	Not applicable		n/a	0 (0%)	n/a	0.40 (20%)	n/a	0.40 (20%)	n/a	0.40 (20%)
	Amoxicillin/ clavulanic acid	13.12 (76%)	10.94 (75%)	Not applicable		0.49 (3%)	0 (0%)	13.12 (76%)	10.94 (75%)	13.12 (76%)	10.94 (75%)	13.12 (76%)	10.94 (75%)
	Ibuprofen	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Salbutamol	0.67 (10%)	n/a	0.67 (10%)	n/a	0 (0%)	n/a	0.67 (10%)	n/a	0.67 (10%)	n/a	0.67 (10%)	n/a
	Metformin	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Kyrgyzstan	Amlodipine	n/a	min 4.63 (min 50%)	Not applicable		n/a	min 4.63 (min 50%)	n/a	min 4.63 (min 50%)	n/a	min 4.63 (min 50%)	n/a	min 4.63 (min 50%)
	Amoxicillin/ clavulanic acid	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Ibuprofen	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Salbutamol	min 3.50 (min 50%)	min 2.10 (min 50%)	min 3.50 (min 50%)	min 2.10 (min 50%)	min 3.50 (min 50%)	min 2.10 (min 50%)	min 3.50 (min 50%)	min 2.10 (min 50%)	min 3.50 (min 50%)	min 2.10 (min 50%)	min 3.50 (min 50%)	min 2.10 (min 50%)
	Metformin	n/a	n/a	Not applicable		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sweden[b]	Amlodipine	max 10.85 (100%)	max 6.33 (100%)	Not applicable		max 10.85 (100%)	max 6.33 (100%)	max 10.85 (100%)	max 6.33 (100%)	max 10.85 (100%)	max 6.33 (100%)	0 (0%)	0 (0%)
	Amoxicillin/ clavulanic acid	n/a	max 5.41 (100%)	Not applicable		n/a	max 5.41 (100)	n/a	max 5.41 (100)	n/a	max 5.41 (100%)	n/a	0 (0%)
	Ibuprofen	max 8.0 (100%)	max 5.57 (100%)	Not applicable		max 8.0 (100%)	max 5.57 (100%)	max 8.0 (100%)	max 5.57 (100%)	max 8.0 (100%)	max 5.57 (100%)	0 (0%)	0 (0%)
	Salbutamol	max 6.42 (100%)	max 6.0 (100%)	0 (0%)	0 (0%)	max 6.42 (100%)	max 6.0 (100%)	max 6.42 (100%)	max 6.0 (100%)	max 6.42 (100%)	max 6.0 (100%)	0 (0%)	0 (0%)
	Metformin	n/a	max 5.97 (100%)	Not applicable		n/a	max 5.97 (100%)	n/a	max 5.97 (100%)	n/a	max 5.97 (100%)	n/a	0 (0%)

Table 7.2 | Continued

Country	Medicine	Standard co-payment		Children		Patients on low income		Retired people		Unemployed people		High spenders on medicines	
		O	LPG	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
United Kingdom	Amlodipine	12.25 (78%)	12.25 (1284%)	Not applicable		0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)[c]	0 (0%)[c]
	Amoxicillin/ clavulanic acid	n/a	12.25 (48%)	Not applicable		0 (0%)	0 (0%)	0 (0%)	0 (0%)	n/a	0 (0%)	n/a	0 (0%)[c]
	Ibuprofen	n/a	12.25 (236%)	Not applicable		0 (0%)	0 (0%)	0 (0%)	0 (0%)	n/a	0 (0%)	n/a	0 (0%)[c]
	Salbutamol	12.25 (573%)	12.25 (589%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)[c]	0 (0%)[c]
	Metformin	0 (0%)	0 (0%)	Not applicable		0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)[c]	0 (0%)[c]

Notes: O = originator; LPG = lowest-priced generic; n/a = price data not available.

a Co-payments for unemployed people might be lower since, in practice, provisions as for patients in low-income groups apply.

b Apart from co-payments for children and high spenders, the indicated co-payment data for Sweden refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines, the co-payments amount to 50%, 25% and 10% of the value included in the table, and even 0% in case of high spending.

c Based on the assumption that a three-month or 12-month certificate has been purchased and thus the patient has no co-payment for further prescription medicines within the time period of the certificate.

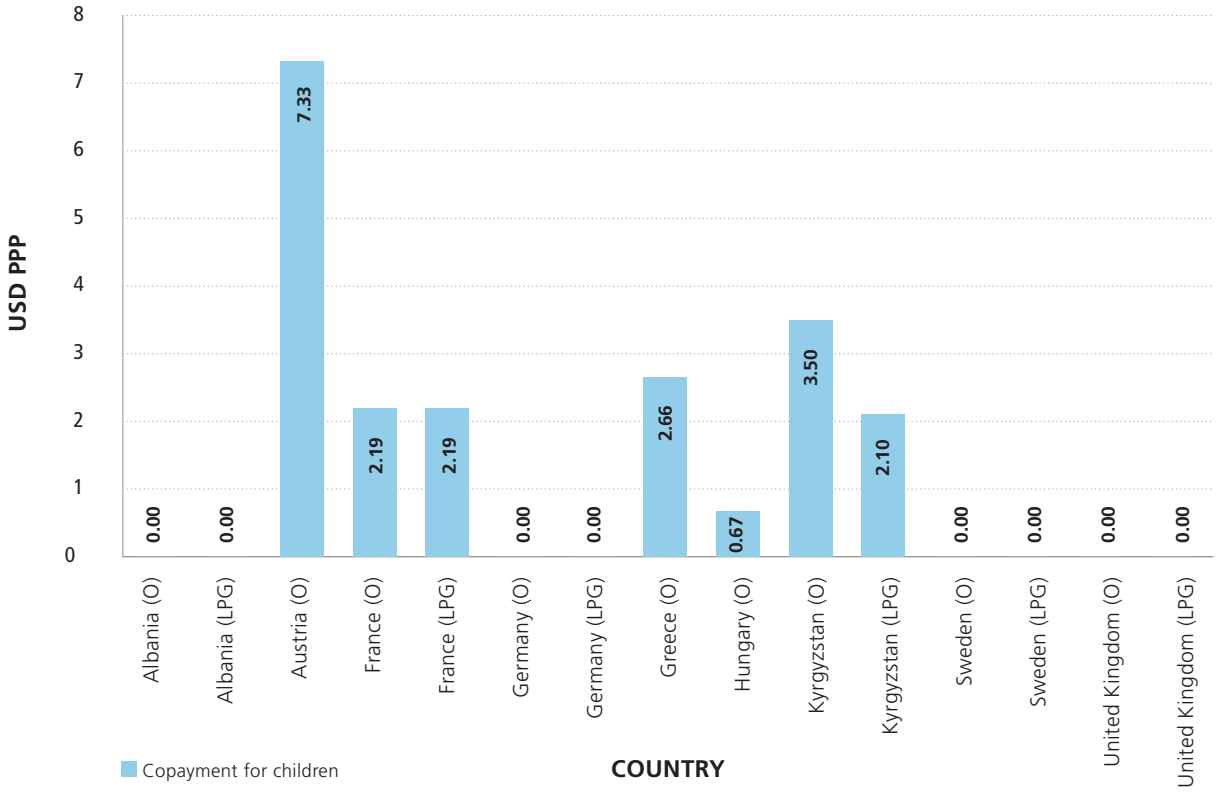
Unless other criteria (such as low income) are relevant, unemployed patients and retirees pay the standard co-payment in all countries surveyed. Exceptions include no co-payments for Albanian pensioners and for patients aged over 60 years and unemployed people in receipt of certain benefits in the United Kingdom.

Finally, one of the medicines surveyed (salbutamol) was also available in a paediatric presentation. Fig. 7.1 shows that in four countries children are exempt from co-payments and in the other countries either the full co-payment (Austria, Greece, Hungary and Kyrgyzstan) or a reduced co-payment (France: no prescription fee but percentage co-payment) was charged. For more information see Fig. A7.1 in Annex 7.

Table 7.2 also notes the share of co-payments as a proportion of the gross pharmacy retail price. If co-payment is linked to the price of the medicines, patients have the option to ask for the lower-priced generic, since in some cases (for example, in Sweden at the beginning of the 12-month period of calculation) the co-payment for originator and generic medicines can differ substantially due to differences in price).

In Germany patients benefit from taking lower-priced generics in terms of lower or no co-payment. If the price is 30% below the reference price, they are usually exempt. This exemption did not occur for any of the five medicines analysed, however: for all these, German patients co-paid the prescription fee of €5 (US$ 6.43 PPP), but they did not pay the difference between the reference price and the pharmacy retail price because all generics were priced below the reference price.

Fig. 7.1 | Co-payments for originator and generic salbutamol for children in countries of the financial burden analysis, September 2017



O = originator; LPG = lowest-priced generic;
Note: in Kyrgyzstan co-payments may also be higher.

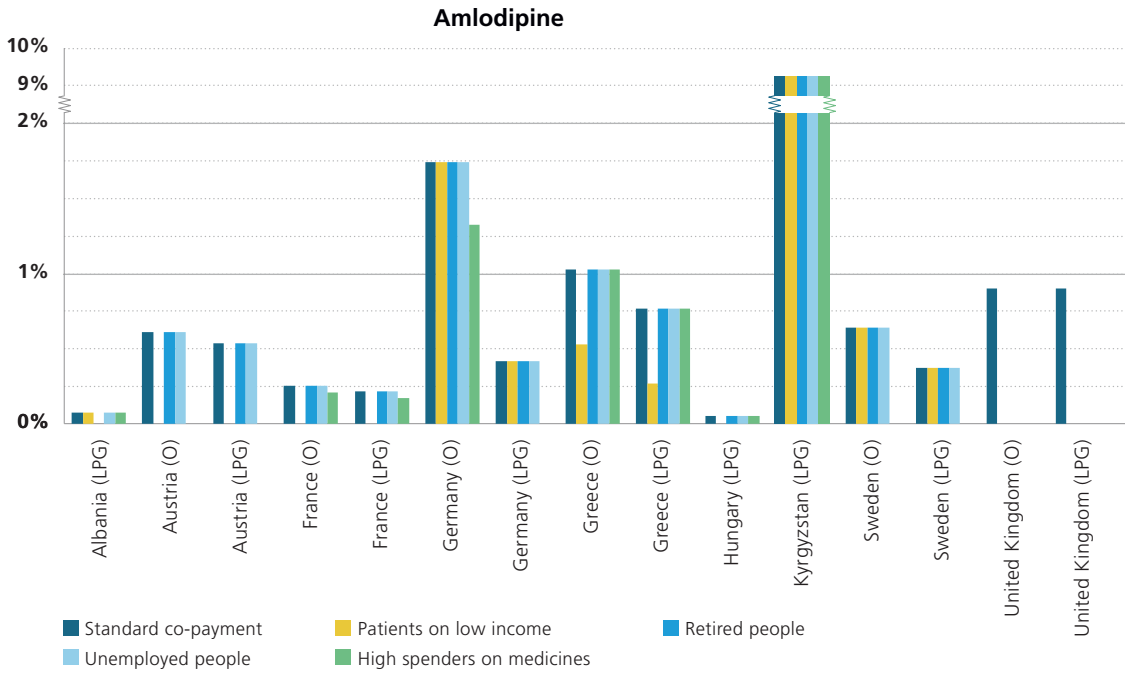
Differences between co-payments for different diseases were observed. For instance, asthma patients paid full co-payments for salbutamol in France (prescription fee and percentage co-payment, resulting in a total co-payment of US$ 2.81 PPP) and in the United Kingdom (prescription fee of US$ 12.25 PPP). For diabetes, patients in the United Kingdom were exempt from co-payment for metformin (because diabetes provides eligibility for exemption for all medicines, whether or not the medicine is for the treatment of their diabetes) while French patients paid a reduced co-payment (solely the prescription fee of US$ 0.62 PPP).

In some countries (e.g. Germany, Sweden), some co-payments could have been avoided since they resulted from patients insisting on being dispensed a higher-priced originator.

7.3.2 Financial burden of co-payments

Fig. 7.2 sets out the financial burden of co-payments on patients. Co-payments posed a significant financial burden in Kyrgyzstan: 9% of the minimum wage for a one-month pack of generic amlodipine and 2–4% for salbutamol required for one month of treatment. Co-payment for these medicines was around or less than 1% for these two medicines in other countries. The financial burden of co-payments is also comparatively high in Albania and for originator medicines in Germany.

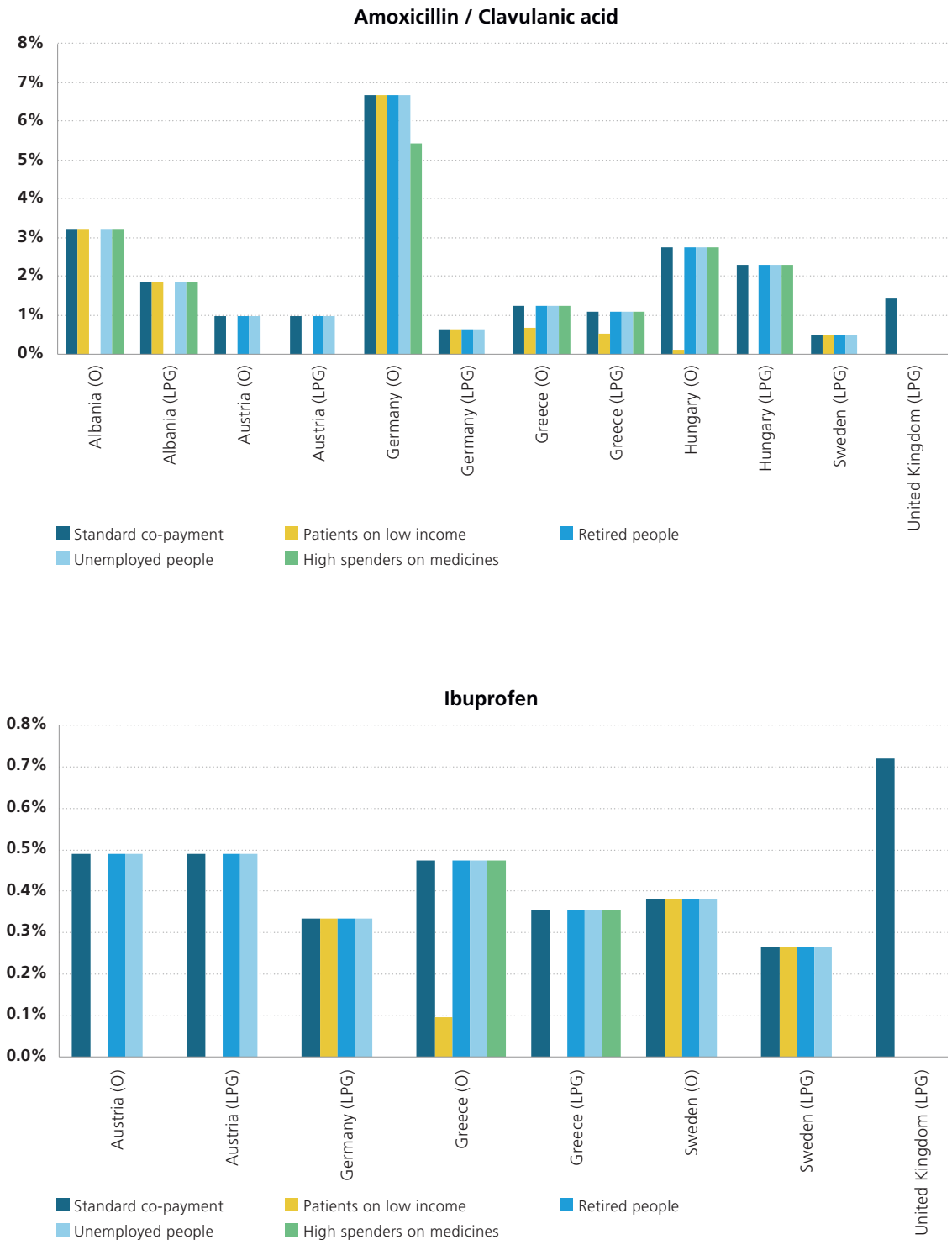
Fig. 7.2 | Co-payments for a one-month or episode treatment as a proportion of the monthly minimum wage for defined patient groups in countries of the financial burden analysis, September 2017



Notes:

- Amlodipine: no data available for Albania (O), Hungary (O) and Kyrgyzstan (O); co-payment calculated for one pack because this pack size corresponds to one month's treatment.
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.

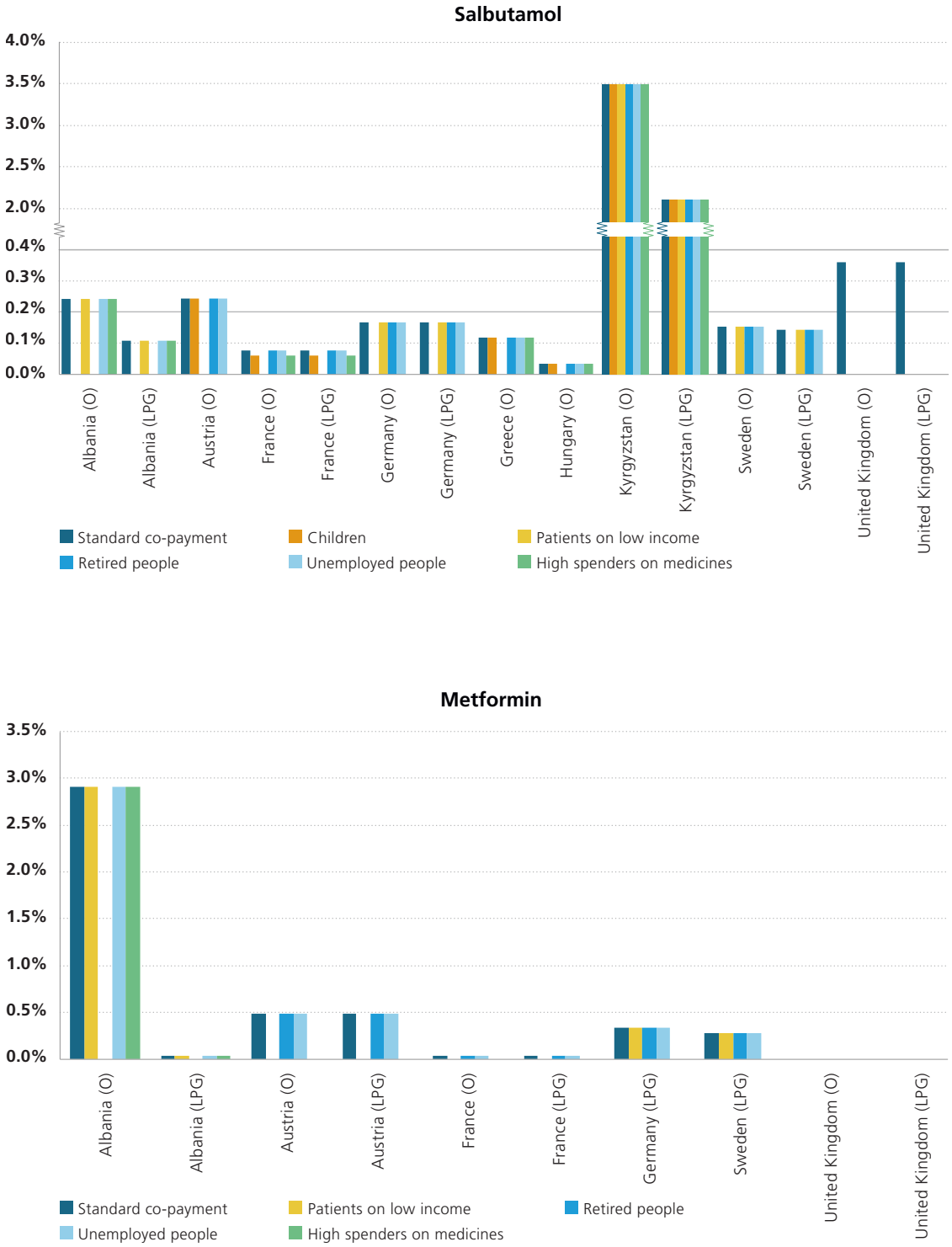
Fig. 7.2 | Continued



Notes:

- Amoxicillin/clavulanic acid: no data available for France (O + LPG), Kyrgyzstan (O + LPG), Sweden (O), United Kingdom (O); co-payments calculated for two packs because two packs required to treat one episode.
- Ibuprofen: no data available for Albania (O + LPG), France (O + LPG), Germany (O), Greece (O), Hungary (O + LPG), Kyrgyzstan (O + LPG); co-payment calculated for one pack because this pack size is required to treat one episode.
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.

Fig. 7.2 | Continued



Notes:

- Salbutamol: no data available for Austria (LPG), Greece (LPG), Hungary (LPG); 50% of the co-payment was considered because this pack size corresponds to two months' treatment.
- Metformin: no data available for Germany (O), Greece (O + LPG), Kyrgyzstan (O+ LPG), Sweden (O); co-payment calculated for one pack because this pack size corresponds to one month's treatment.
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.
- In Kyrgyzstan co-payments may also be higher.
- Co-payments for Sweden are maximum data and refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines, co-payments amount to 50%, 25% and 10% of the medicine price, please refer to the specific section in Table A7.1 in Annex 7 for further details.

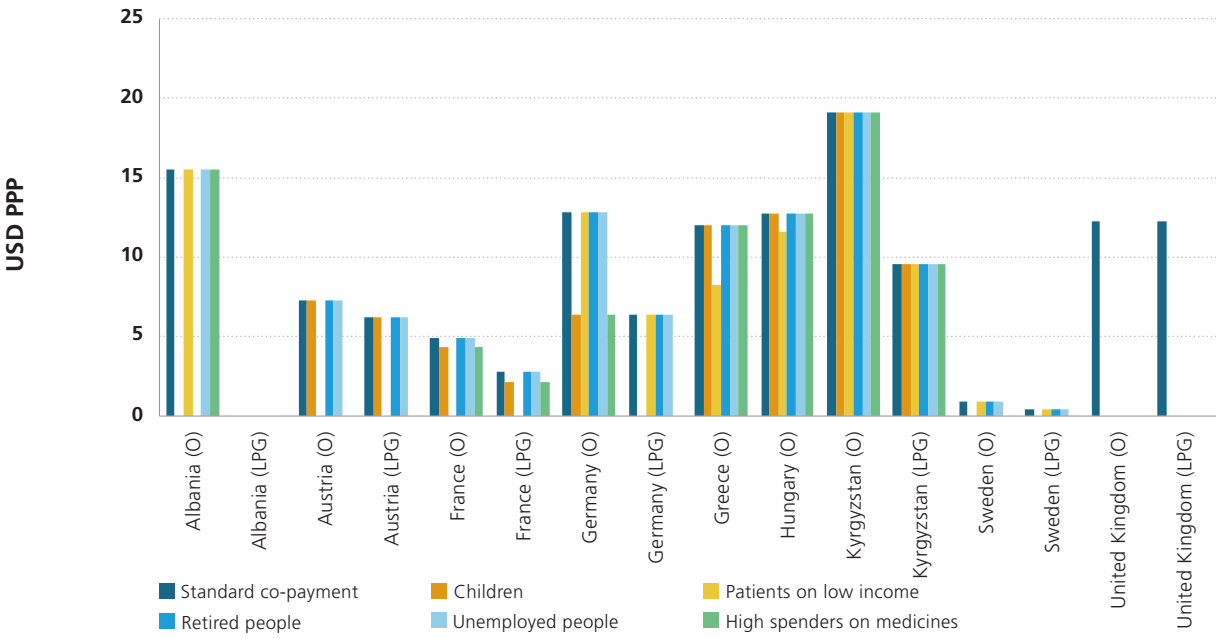
7.3.3 Financial burden with a uniform price

Cross-country differences in co-payments arise from co-payment regulations and the prices of medicines where co-payments have a price-dependent element. As outlined in Chapter 2, to control the price component, co-payments were also determined and compared based on the assumption that all countries used the same price. It was assumed that in all surveyed countries the originator price corresponded to €10, and the price of the lower-priced generic and the reimbursement/reference price equalled €5.

The calculations based on fictitious price data provide different results from those for real price data. Fig. 7.3 shows the co-payments in United States dollars (USD) PPP in the case of a uniform price across countries for salbutamol. Results for the other medicines are included in Fig. A7.3 in Annex 7. The extent of co-payments expressed in USD PPP based on indicated price data was high in Germany, Sweden and the United Kingdom. In the scenario of uniform prices, Albania, Hungary and Kyrgyzstan had high co-payments.

Fig. A7.3 in Annex 7 presents the same information expressed as a proportion of the minimum wage. Considering the variation in the minimum wage across countries, it was decided only to compare countries with similar minimum wage amounts (Austria, France, Germany, Sweden and the United Kingdom). This also shows the variability of reimbursement policy performance across countries when the price component is neutralized.

Fig. 7.3 | Co-payments for originator and generic salbutamol (one pack) expressed in USD PPP for different patient groups based on the assumption of a uniform price in countries of the financial burden analysis, September 2017



Notes:

- Calculations are based on the assumption that the price of the originator is €10 and that of the lowest-priced generic and the reimbursement/reference is €5.
- Data availability of the real-life price data was assumed for the calculation based on fictitious prices, since otherwise assumptions of the extent of co-payments (e.g. percentage co-payment) in the case of missing data would have been necessary.
- No data were available for Greece (LPG) and Hungary (LPG).
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.
- In Kyrgyzstan co-payments may also be higher.
- Co-payments for Sweden are maximum data and refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines, the co-payments amount to 50%, 25% and 10% of the medicine price, please refer to ad hoc section in Table A7.1 in Annex 7 for further details.

7.4 Limitations

The findings of this cross-country comparison of the financial burden have to be treated with caution. Indeed, this work has important limitations.

First, the scope of the analysis is rather limited. Although attempts were made to balance the countries chosen (in terms of income and population size), the analysis was conducted in only nine settings, which may not reflect the whole variety of situations encountered. Also, only five medicines were studied: findings cannot therefore be generalized to the entire pharmaceutical system.

Various scenarios that amend the base case reimbursement system in the countries were analysed, but it is likely that other options could have been studied and discussed. Further, if other fictitious prices had been used in the analysis based on a uniform price, this might have led to differences in the findings. The analysis of co-payments based on a uniform price as a proportion of the minimum wage could not be done for all countries because differences in national income would have distorted the results.

As shown in Annex 7, price data needed for this exercise were only available on a limited basis for the reasons discussed (see section 7.2). Some countries (such as Austria and Sweden) did not have official data on the minimum wage so alternative data from surveys had to be used.

Some assumptions were made in order to conduct the analysis (see Annex 7): all of these can, of course, be discussed and challenged.

Overall, this work does not pretend to provide the only possible picture of a quantitative analysis of medicines co-payment policies.

8. Conclusions

As highlighted in this report, in order to move towards or maintain UHC policy-makers face important challenges when implementing pharmaceutical policies aimed at achieving the goal of affordable, equitable and sustainable access to (essential) medicines. To support policy decisions in this field, this study aimed to review and analyse the different pharmaceutical reimbursement policies applied in countries in the WHO European Region, with a view to identifying whether any arrangements were specifically designed to protect vulnerable groups from excessive medicines-related OOPs.

8.1 Main findings

Across the 53 countries in the WHO European Region there is high variation in both per capita income (from US$ 3551 PPP for Kyrgyzstan to US$ 105 882 PPP for Luxemburg) and per capita investment in medicines (from US$ 310 PPP for the Russian Federation to US$ 1056 PPP for Switzerland) *(7, 87)*. The survey results show that all the countries in the Region have put mechanisms in place to grant some type of access to medicines to their populations. The design and implementation of relevant policies vary considerably across countries, however, especially reimbursement policies for outpatient medicines (as patients in all 53 countries can access medicines in hospitals without any payment, with the exception of Belgium).

Medicines considered reimbursable are usually placed on a positive list, and some countries have more than one list. A few countries use negative lists, indicating that a medicine is explicitly excluded from reimbursement. The range of medicines reimbursed varies considerably among countries.

Reimbursement policies do not necessarily protect citizens from high co-payments. Indeed, reimbursement eligibility does not guarantee that a medicine is provided for free: the survey identified high co-payments for reimbursable medicines in several countries. The extent of co-payments for reimbursable medicines often depends on the disease the medicine is intended to treat. A few countries also reported having co-payment exemptions and/or reductions for people of various classifications, including specific age groups (such as children aged under 18 years), pensioners, pregnant women, disabled people and socially disadvantaged people.

This report also illustrates that reimbursement policy models can explain some differences in accessibility and affordability of essential medicines. The key findings are outlined below.

Increased financial investment on medicines is critical. Some countries in the Region have made important progress in recent years towards UHC, particularly in the dimension of the population covered. Nevertheless, several high-income European countries hit hard by the global financial crisis have reduced public expenditure on medicines, and this has had significant consequences on access to medicines for some parts of the population.

Public investment in pharmaceutical expenditure associated with careful consideration of the three components of UHC (the population covered, the range of services made available and the extent of financial protection from the costs of health services) contributes to developing an equitable reimbursement policy framework, while health system inefficiencies and insufficient consideration of the needs of some vulnerable population groups may undermine efforts. Hence, increased investment does not automatically result in affordable access to medicines for all if certain components of UHC are not prioritized.

Disease orientation may leave socially disadvantaged people behind. The analysis shows that some countries have a strong focus on disease-oriented approaches through co-payment reductions or exemptions for medicines to treat specific diseases. If this is not accompanied by a "social safety net" element, socially disadvantaged people and those on low income with chronic diseases who are not granted an exemption or reduction may encounter a high financial burden.

Different designs of system lead to different outcomes. In many cases, countries in the Region have adopted the same reimbursement measures out of a "toolbox" of policy options. Countries' varying national policy objectives, resource capacity and political and financial pressures, however, have resulted in different designs of the policies. The results of the analysis suggest that the design of a policy has a significant impact on its effectiveness, as illustrated by the design of policies to promote generic uptake (implementation on a mandatory basis proved to be more effective than on a voluntary basis) or the consideration of exemptions and reductions of co-payments for defined groups.

General policy options beyond reimbursement may be supportive or hindering. Countries that consider medicines reimbursement measures as part of an overall policy framework are likely to be more effective in achieving their defined policy objectives than countries that do not consider other policy-related aspects. For instance, low quality of (lower-priced) medicines and mistrust of generics by patients, physicians and pharmacists will most probably limit the effectiveness of measures to enhance generic uptake. Also, reimbursement policies should be implemented with corresponding pricing policies and regulations; otherwise, medicine prices can remain high, limiting affordability for patients and the ability of public payers to support patients financially in a sustainable way. Taking a broad perspective, policies to improve access could cover a range of measures, from product development to considerations about disinvestment, in accordance with the respective phase in the lifecycle of the medicine. Collaborative approaches (such as between institutions, across sectors and among stakeholder groups) are of high importance.

8.2 Good practices

The findings of this study clearly show that there is no "one size fits all" reimbursement policy model, and policy-makers have developed a balanced mix of pharmaceutical options that are designed to meet the defined general public health objectives of their countries. While there is no formally defined "ideal" reimbursement policy model, several key principles can still be described as supports to policy frameworks that increase affordable access and protect vulnerable groups from excessive OOPs for essential medicines.

The following list is neither exhaustive nor meant to be prescriptive. It simply reflects and synthesizes the main findings extracted from the various reimbursement models analysed.

Clear prioritization is crucial. Given budgetary constraints, public payers cannot fund the full price of all medicines. Policy-makers have to make hard choices and trade-offs on the priority needs in their countries. Transparency in the priority-setting process is important, and disclosure of potential vested interests of the parties consulted and involved should be enforced.

Evidence-based decision-making and real-world data generation are fundamental requirements. Instruments such as HTAs and pharmacoeconomic evaluations help to anchor reimbursement decisions in the best available evidence. Since these tools are resource-intensive and their use requires highly qualified staff, however, their implementation can be a challenge for lower-income countries where other activities may need to be prioritized and in countries that lack the resource capacity. To address this challenge, cross-country cooperation can play an important role. While reimbursement decisions are taken individually by each country, collaboration can support the sharing of clinical evidence, procurement, negotiations and capacity-building. Lower-resourced and small countries that do not have the capacity to establish their own HTA capabilities can benefit from assessments performed by other countries with local adaptation. Existing collaborations in HTA, including the EUnetHTA cooperation among EU Member States, can contribute to the evidence generation process.

In situations where limited evidence about a medicine is available at the time of a reimbursement decision, the decision can be conditional until more data (real-world evidence) is collected. MEAs in the form of performance-based schemes combine both financial and evidence generation arrangements. A more transparent outline of the evidence generation requirements of and results from a MEA could potentially enable other countries to reference this data.

Processes should be transparent and smooth. A well developed and functional reimbursement process is an essential principle for any policy model to ensure accessibility of needed medicines. This report illustrates that transparency includes, among others, publication of reimbursement decisions and their justification (independently of whether the medicine is reimbursed) and disclosure of the members of the reimbursement committees, including declarations of potential conflicts of interest. While a smooth process appears to be beneficial for patients in terms of speeding up their access to medicines, this has to be balanced against the robustness of evidence: sufficient timing for thorough analyses and assessments is necessary.

Since the competences for reimbursement may be divided among different bodies, a regular and systematic intracountry collaboration between public institutions in the field of pharmaceutical regulation and policy has been described as an asset for successful reimbursement processes.

Vulnerable population groups need to be identified. While diseases are one cause of vulnerability, specific socioeconomic settings (such as no regular income, unemployment, income below subsistence level or a need to provide a living for several dependants) also make people vulnerable. Analysis that indicates which population groups experience catastrophic and impoverishing OOPs or forego needed medicines helps to identify those for whom a coverage policy framework could provide particular protection *(88)*.

Price regulation is required. Medicine price control is another key element of the pharmaceutical policy framework to ensure financial protection. Price regulation helps to bring prices down: its introduction provided major progress in settings where patients had to pay for many medicines fully out-of-pocket. This study shows that in most European countries the prices of reimbursable medicines

have been regulated. As such, price control supports public payers to contain their costs and thus offer a larger range of services (more reimbursable medicines) and/or provide them at lower co-payments.

Use of generic, biosimilar and further lower-priced medicines should be fostered. Lower-priced medicines such as generics offer excellent opportunities to make medicines accessible at lower expenses. This translates into lower expenses for patients in terms of OOPs and options for savings and cost-containment for public payers. Evidence from the literature and analysis done for this study show the importance of ensuring trust in the quality of generics and the relevance of demand-side measures to promote the uptake of generics and other lower-priced medicines.

Patient involvement should be encouraged. In most countries different stakeholders are involved in pharmaceutical reimbursement but groups of patients and citizens are rarely represented. Consultation and involvement of patients is considered desirable, based on the outcomes in countries with experience in this domain. Having patients on board that understand the rationale of policy-makers could help in the public debate when it comes to communicating sensitive decisions to the public (such as non-funding of medicines with limited added therapeutic benefit).

Evaluations, monitoring and adjustments are needed. Findings from analyses and assessments of reimbursement policies help policy-makers to assess the effectiveness of measures and to decide whether a possible correction is needed. It was noted that authorities that had planned monitoring and evaluation from immediately after implementation of a measure could benefit from these analyses. Since evaluations are resource-intensive, a focus on a few but meaningful indicators would be a feasible approach for resource-restrained settings. For instance, the three components of UHC can be taken as a basis from which to derive key indicators. Some public authorities have research departments and employ staff to monitor reimbursement policies. Strong evidence could also support policy-makers' communications about potentially unpopular decisions to the general public.

It is important to create an appropriate strategic design of individual measures and appropriate policy mix. While there is no checklist for developing an "ideal" reimbursement package, policy-makers have some room for flexibility in the design of policies. The survey showed that reimbursement lists, coverage criteria (reimbursement rates and reductions/exemptions for defined patient groups targeted on the basis of vulnerability), evidence generation and assessments (such as HTA) and measures to make use of the potential of lower-priced medicines are standard tools. As highlighted by the differences among countries, however, there are various approaches to designing each specific measure. As a result, it is important that public decision-makers carefully consider the implications of the policies developed and ensure that these are consistent with general public health objectives and priorities. Each pharmaceutical reimbursement system, with its individual features, should always reflect the balance between affordable access to essential medicines – including protecting patients from excessive OOPs – and systemic constraints, particularly budget limitations.

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Annexes

Annex 1. Overview of reimbursement and OOPs in countries in the WHO European Region not covered by the primary data collection survey

This table provides, as far as possible, data and information from the literature for those eight of the 53 countries in the WHO European Region that were not included in the primary data collection (through the PPRI survey and/or provision of information in brief country profiles in the case of the CIS countries).

Country	Data year	Reimbursement models and systems for medicines	OOPs (including co-payments and informal payments)	Reference
Andorra	2004	Andorra's health care system is governed by three central institutions: • The General Council, Ministry of Health and Welfare – responsible for pharmaceutical legislation, provision of national pharmaceutical needs and pharmaceutical regulation; • The Office of Social Security covers about 92% of the population of Andorra and is mainly responsible for reimbursement coverage of health care services and medicines; • The Andorran NHS. The government's share of pharmaceutical expenditure is said to have been constant at about 75% since 2002, which corresponds to the reimbursement rate by the Office of Social Security.	Co-payments are made by citizens covered by the Office of Social Security; otherwise direct payments are made. The health authority reimburses at a rate of 90% of established fees for hospital care and at a rate of 75% for outpatient medicine costs.	*(1)*

Country	Data year	Reimbursement models and systems for medicines	OOPs (including co-payments and informal payments)	Reference
Bosnia and Herzegovina	2002	The Federation of Bosnia and Herzegovina has 10 federal units/ cantons. Each canton has its own fund that covers finances for primary care reimbursement lists, and hospitals apply their own lists of medicines. The health system nominally offers coverage to all citizens in Bosnia and Herzegovina, but many people are not fully covered and thus pay out-of-pocket when utilizing health services. Each canton determines the level of co-payments. With assistance from WHO and the United Nations Children's Fund, the Federation of Bosnia and Herzegovina introduced an EML, which consists of 202 medicines. This serves as the basis for a "positive list" developed by each canton, which lists the reimbursable medicines covered by canton insurance funds. Citizens are required to pay out-of-pocket for many medicines not included on the list.	Co-payments are highly dependent on available resources or social status. In the outpatient sector the government has no control over OOPs, whose prices are mostly determined by free market mechanisms. The patient is expected to pay 50% of the formal co-payment to the health insurance fund and 50% to the provider but, in practice, patients pay only the provider and provider institutions retain all co-payments. There is also evidence of under-the-table payments made by patients. Due to limited canton insurance funds, insurers do not meet demand for medicines and burden patients with OOPs for a number of medicines. Although in most cases medicines are available, the prices exceed many patients' ability to pay.	*(2)*
Georgia	2009	The EML came into force in 1995. Around 235 generic medicines are listed. With the exception of medicines that are supplied free of charge and medicines that require co-payments under public health and municipal programmes, all medicines are required to be purchased directly by patients and have to be paid in full out-of-pocket.	Due to a high level of OOPs, a large proportion of the population is deterred from seeking medicines and medical services. OOPs in Georgia include official co-payments, direct formal payments to health facilities and informal payments to health providers. More significant direct payments are seen for medicines in the outpatient sector. These are not covered under any insurance schemes or state health programmes and are purchased by the patient at a full price. Regarding official co-payments, the system has been simplified so that the level and amount of co-payment is printed on vouchers. These are given to the patients when they are allowed to seek medical care of their choice for the respective treatment. Fees for services not covered by the state are paid to health institutions according to internal standards developed by the institution. Patients believe that they are charged less through informal payments since providers endorse reducing patient charges.	*(3)*
Monaco		No information available	No information available	–

Country	Data year	Reimbursement models and systems for medicines	OOPs (including co-payments and informal payments)	Reference
Montenegro		No information available	No information available	–
San Marino	2002	A positive list for reimbursement is applied in the outpatient sector. The medicines on the positive list are provided free of charge. There is no prescription fee or further co-payment.	Cost-sharing is not applied to primary, outpatient or inpatient care. Beneficiaries (insured citizens of San Marino) do not pay co-payments for the medicines listed on the national positive list in the outpatient sector. OOPs mainly refer to payments for medicines sold to patients who are not beneficiaries or to outsiders (such as tourists), in particular Italians or cross-border workers.	*(4)*
The former Yugoslav Republic of Macedonia	2011/ 2012	Medicines are reimbursed by the national health insurance fund if they are included in the positive list, which is managed by the health insurance fund and prescribed by a physician contracted by the fund.	In general, three types of OOPs can be distinguished in the outpatient sector: • Over-the-counter medicines for self-medication are paid fully out-of-pocket; • A co-payment applies for prescription medicines dispensed on behalf of the health insurance fund in pharmacies or health aisles of supermarkets: patients pay a proportion of a maximum 20% of the medicine price (minimum 5.00 Macedonian denari and maximum 600.00 Macedonian denari) – in 2010 the average co-payment rate was 90%; • The difference between the health insurance fund reference price and the pharmacy retail price has to be covered by the patient. For inpatient medicines, no OOPs are charged to patients. The same applies to medicines covered by 15 specific therapeutic programmes (e.g. rare diseases). Specific population groups, such as children with special needs or pensioners on low income, are exempt from co-payments.	(Habl C, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, unpublished comments on the proposed pharmaceutical pricing policy in Macedonia, 2012)
Turkmenistan	2000	The reimbursement system is based on the state voluntary health insurance system, which covers approximately 77% of the population. The insurance covers medicine expenses, excluding 10% of patient co-payments. The list of services for which a fee is levied is determined by the Ministry of Health.	Official user charges are applied to all medicines prescribed for outpatients unless covered under the voluntary state health insurance scheme. Informal payments are common, although they cannot be quantified. Over 50% of people interviewed in a 1997 World Bank survey had made under-the-table payments for medical services, including obtaining medicines.	*(5)*

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Annex 2. Survey questionnaire

Please note that this questionnaire only includes the headings and questions. In practice, it was pre-filled with available information and data.

Questionnaire on pharmaceutical reimbursement models 2017

Status and contacts for the responses to this PPRI network questionnaire

Country	Respondent(s)	Contact details of respondents	Notes (about completion of the survey)

1. General framework of pharmaceutical reimbursement and pricing

1.1 National competent authorities that decide on marketing authorization, pricing and reimbursement of medicines and institutions that perform reimbursement/funding of medicines, 2017

Country	Competent authority that decides on:				Public payers for medicines	
	Marketing authorization	Pricing	Reimbursement (outpatient)	Reimbursement (inpatient)	outpatient	inpatient

1.2 Scope of price regulation for medicines at ex-factory price (or wholesale) level, including information about external price referencing and scope for wholesale and pharmacy remuneration, 2017

Country	Price regulation at ex-factory* price level (outpatient)	Price regulation at ex-factory* price level (inpatient)	External price referencing in place	Scope of medicines under wholesale remuneration regulation	Scope of medicines under pharmacy remuneration regulation

* In some countries (e.g. Croatia, Cyprus, Denmark, Finland, Iceland, Malta (public sector), the Netherlands, Norway, Sweden and United Kingdom) initial price regulation is not done at the ex-factory price level but at the wholesale level.

2. Co-payments

2.1 Co-payments for medicines in the outpatient sector, 2017
Definition: a co-payment is an insured patient's contribution towards the cost of a medical service covered by the insurer. This can be expressed as a percentage of the total cost of the service or as a fixed amount. Co-payment is a form of out-of-pocket payment.

- A fixed co-payment is, for instance, a prescription fee.
- If your country applies percentage reimbursement, then you also have percentage co-payment.
- A deductible is an 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; thereafter all – or a percentage of – the rest of the cost is covered by a public payer.

Please indicate which co-payments are in place for outpatient medicines, how they are designed (for example, does the prescription fee relate to the items dispensed on the prescription or is it a unique flat fee for each prescription, regardless of the number of medicines dispensed) and their extent. Be as precise as possible, and provide information on the amounts of the prescription fee or the deductible, which are the exact ceilings or thresholds, if relevant. (A link to relevant legislation is also appreciated).

Country	Fixed co-payment (e.g. prescription fee)	Percentage co-payment	Deductible	Any further comments

2.2 Reductions of and exemptions from co-payments in the outpatient sector, 2017

Kindly provide information on whether specific population groups are exempted from co-payments or have reduced co-payments. Are there different reimbursement and co-payment rules for specific medicines (such as generics)? Are there ceilings in co-payments once specific expenditure is reached? Be as precise and specific as possible – provide the extent of ceilings and similar. (A link to relevant legislation is also appreciated).

2.3 Co-payments for medicines in the inpatient sector, and their exemptions and reductions, 2017

Country	Inpatient co-payment for medicines in public hospitals	Content and extent	Exemptions and reductions	Co-payment for medicines in private hospitals

3. Reimbursement models for medicines, 2017

3.1 Reimbursement eligibility schemes for medicines, 2017
Definition: the reimbursement eligibility scheme outlines for which "group" reimbursement status is defined. In general, there are four eligibility schemes.

- In product-specific reimbursement eligibility for reimbursement depends on the medicine in question (a medicine is considered either as reimbursable or non-reimbursable).
- In disease-specific reimbursement eligibility for reimbursement is linked to the underlying disease to be treated. It targets both the reimbursement status and the reimbursement rate. A medicine may be reimbursed at different rates for the treatment of different diseases. Specific programmes for some indications also fall under disease-specific reimbursement.
- In population groups-specific reimbursement specific population groups (such as children or pensioners) are eligible for free medicines, or medicines at higher reimbursement rates, while others are not.
- In consumption-based reimbursement the level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption).

Please note that in one country more than one reimbursement eligibility scheme can be in place (for example, there tend to be specific regulations for vulnerable groups = population group-specific reimbursement in all cases), but typically there is one key (dominant) scheme.

Please indicate which reimbursement eligibility schemes (as defined above) are in place, in which sectors, and what roles they play.

Country	Product-specific reimbursement	Disease-specific reimbursement	Population group-specific reimbursement	Consumption-based reimbursement

3.2 Reimbursement processes for medicines in the outpatient sector, 2017

Country	Decision-making process (involved committees/stakeholders)	Criteria	HTA assessment	Regular reviews

3.3 Reimbursement processes for medicines in the inpatient sector, 2017

Country	Decision-making process (involved committees/stakeholders)	Criteria	HTA assessment	Regular reviews

3.4 Reimbursement lists in the outpatient and inpatient sectors, 2017 (and latest available year for numbers)

Country	Outpatient sector				Inpatient sector			
	List in place	Form of the list	Number of medicines listed (absolute and as a percentage)	Link to publication	Hospital pharmaceutical formulary in place	Form of the list	Number of medicines listed (absolute and as a percentage)	Link to publication

3.5 Percentage reimbursement rates in the outpatient sector, 2017

Please provide information on which percentage reimbursement rates are applied, or for which indications, medicines, patient groups and so on.

Country	Percentage reimbursement	Notes

3.6 Managed entry agreements (MEAs), 2017 or latest available year (and latest available year for numbers)

Definition: an MEA is 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 to address uncertainty about the performance of technologies or to

manage the adoption of technologies to maximize their effective use or limit their budget impact. MEAs can take different forms, such as access with evidence development, conditional coverage, conditional treatment continuation, only in research, only with research, outcome guarantees, pattern or process care, price–volume agreements or risk-sharing schemes, and they are referred to under different names (such as "patient access schemes" in the United Kingdom). The key feature for distinction is between financial-based MEA and performance-based (health outcome-based) MEAs.

Country	Outpatient sector				Inpatient sector			
	(Rough) number of MEAs	Key types of MEA	Key indications	Degree of confidentiality, possible link to publications	(Rough) number of MEAs	Key types of MEA	Key indications	Degree of confidentiality, possible link to publications

4. Generic policies for medicines

4.1 Reference price systems (RPSs) in the outpatient sector, 2017

Definition: an RPS is a reimbursement policy in which identical medicines (Anatomic Therapeutic Chemical (ATC) level 5) or similar medicines (ATC level 4) are clustered (reference group). The public payer funds a maximum amount (the 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 co-payments (such as prescription fees or percentage co-payment rates). An RPS is different from external price referencing, which is a pricing policy that compares to pharmaceutical prices in other countries.

Country	RPS	ATC level	Methodology to calculate the reference price	Medicines included in reference groups (clusters)	Any further comments

4.2 Policies to promote the uptake of generics and off-patent medicines, 2017

Definitions: international nonproprietary name (INN) prescribing requires prescribers (such as physicians) to prescribe medicines by their INNs, using the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing). Generic substitution is the practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (such as a 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).

Country	INN prescribing	Generic substitution	Exemptions from or lower co-payments for generics	Other measures to promote uptake of off-patent medicines

5 Overall assessment

5.1 Barriers and success factors in pharmaceutical reimbursement

Country	Key challenges	Success factors	Lessons learned to be shared	What I would like to add to this survey

Annex 3. Country profile template

The CIS countries were asked to provide a short country profile about their pharmaceutical system based on a reporting template.

Health system overview	**Organization of the health care system:** • National health service or social health insurance (single/ multipayer) • Degree of centralization/decentralization of the health system • Health care delivery organization • Coverage of the population • Institution in charge of the general planning of the system **Health financing:** • Sources of funding (general taxation, contributions on wages, external funding) • Responsible institution for health financing planning and adoption of health system budget • General out-of-pocket payments (level and evolution during the past five years) **Recent health system reforms:** • Recent health system reforms • Reforms to be implemented in the short term **Health technology assessment (HTA)** • Is there any utilization of HTA in the pharmaceutical sector? • Does a legal framework defining the use of HTA exist in the country? • Is there an institution in charge of conducting HTA activities (*de jure* and/or *de facto*)? • What is the utilization of HTA reports: – Coverage decisions? – Pricing decisions? – For the elaboration of clinical guidelines? • If HTA is used in the country, specific information on the method and doctrine should be provided on the following. • What evidence is considered (burden of disease, clinical efficacy, safety, clinical novelty, social impact, place in the therapeutic strategy, etc.)? • Is economic evaluation used? • Are reports from foreign HTA agencies considered?
Pharmaceutical sector overview	**Figures *(countries can rely also on the latest data available from either WHO or the World Bank, but national data, if available, are highly recommended):*** • Total health expenditure as a percentage of gross domestic product (GDP) • Total pharmaceutical expenditure in absolute value (US dollars) • Out-of-pocket payments on medicines (level and evolution during the past five years) • Public share of spending on pharmaceuticals compared with health services and: – Development of total, public and private pharmaceutical expenditure (in absolute value, US dollars) during the past five years, if feasible – Development of public and private pharmaceutical expenditure (as a percentage of total health expenditure) during the past five years, if feasible • Number of medicines registered in the country
Pricing and reimbursement overview	**Pricing** *Outpatient medicines:* • Are outpatient medicine prices centrally (i.e. by the authorities) regulated? If yes, which medicines are concerned (national essential medicines list or any specific different list)? • Does a legal framework (law, decree, etc.) defining the outpatient medicines pricing policy exist? • Which institution is in charge of the pricing of outpatient medicines? • What is the pricing procedure? – Are stakeholders involved? – How are selected medicines to be priced? – At which level are the prices regulated (ex-factory, wholesale, retail)? – What is the method used? – Is external price referencing used as a tool (see specific section below)?

Pricing and reimbursement overview	• How is the coverage procedure linked to the pricing procedure?
	• What is the price-setting mechanism defining:
	  – A price for each medicine
	  – A reimbursement tariff?
	• How often are prices revised?
	
	Inpatient medicines:
	• Are inpatient medicine prices centrally regulated? If yes, which medicines are concerned (national essential medicines list or any specific different list)?
	• Does a legal framework (law, decree, etc.) defining the inpatient medicines pricing policy exist?
	• Which institutions are in charge of the pricing of inpatient medicines?
	• How is the coverage procedure linked to the pricing procedure?
	• Who is the main payer for inpatient medicines? Are hospitals responsible for medicines purchasing? Are they allowed to collaborate with each other for procurement?
	• Are hospitals allowed to receive any discounts or paybacks from sellers?
	• If hospitals are responsible for buying medicines, are those reimbursed separately by the health system payer or included in the budget allocated to hospitals?
	
	External price referencing (if applicable)*:*
	• Since when has external price referencing been used as a tool to set medicine prices?
	• Which medicines are concerned by the utilization of external price referencing?
	• What is the general method used?
	  – How many countries are referenced?
	  – Which are these countries?
	  – Is there any weighting of the reference countries (e.g. by GDP, PPP)?
	  – What is the reference price calculation mechanism (e.g. average of the countries in the basket, average of the lowest prices, etc.)?
	  – At which ATC level is external price referencing used?
	• Since external price referencing implementation, is there any information available on its the consequences:
	  – In terms of prices
	  – In terms of availability?
	
	Reimbursement
	• Which institutions are involved in the coverage of medicines decisions?
	
	• *National essential medicine list:*
	  – Does a national essential medicine list exist?
	  – What is the role of this list (list of medicines reimbursed, list of medicines purchasable by hospitals, etc.)
	  – How many medicines are listed?
	  – What is the procedure for listing and delisting medicines?
	  – Does it address inpatient and/or outpatient medicines?
	
	• *Outpatient medicines:*
	  – Are some outpatient medicines publicly reimbursed in the country?
	  – Which medicines? Is there a list?
	  – How are decisions made? What is the legal framework?
	  – Which institution is in charge of this decision? Which institution is in charge of reimbursement?
	  – What are patients' eligibility criteria for reimbursement?
	  – How often are reimbursement decisions revised?
	
	• *Inpatient medicines:*
	  – Do patients pay for inpatient medicines?
	  – Is there a list of medicines available in hospitals?
	  – How are decisions made to procure a medicine in hospital? What is the legal framework?
	  – Which institution is in charge of the inpatient medicines policy? Who is in charge of payment for inpatient medicines?
	
	• Does any national governmental disease programme exist which includes coverage of specific medicines?

Pricing and reimbursement overview	**Contracting** • At the national level, is there any utilization of managed entry agreement and/or specific agreements with companies on paybacks? • Do other type of programme exist, such as named patient programmes/compassionate use/ etc.?
Pharmaceutical regulation and governance	• Does a national medicine policy exist? • Does a legal framework organizing the pharmaceutical sector exist? – Does a legal framework (law, decree, etc.) regulating the coverage of medicines exist in the country? • What is the significance (size) of the local production sector? • Are there any pharmaceutical sector reforms: – Recent pharmaceutical sector reforms – Reforms to be implemented in the short term? • Market authorization: – Which institution is in charge of market authorization decisions? – Is there regional collaboration/integration regarding market authorization decisions (mutual recognition of approval, etc.)?
Purchasing, distribution and value chain	• Are there VAT and other add-on/ duties (not including distribution remunerations)? – What is the VAT/other duties for general goods? – What is the VAT/other duties for reimbursed medicines? – What is the VAT/other duties for non-reimbursed medicines? – What is the VAT/other duties for hospital medicines? • Wholesaler: – What is the size of the wholesaler market? How many companies are present in the country? What percentage of market share is held by the 10 biggest wholesale companies? – Are the wholesalers margins regulated? If yes, how (linear mark-up, regressive scheme)? For which medicines? – Are wholesalers allowed to receive discounts/rebates from manufacturers? If yes, are these discounts/rebates regulated and/or capped? If yes, are discounts/rebates common practice? • Pharmacists: – Are pharmacists' margins regulated? If yes, how (linear mark-up, regressive scheme)? For which medicines? – Are prices of reimbursed medicines the same in any pharmacy throughout the country? – What is the remuneration system of pharmacists? Is there any dispensation fee or is remuneration based on the price of the medicines (e.g. linear mark-up, regressive margin scheme)?
Responsible use of medicines	• Prescription: – Is there an electronic prescribing system? – Are prescribers assigned pharmaceutical budgets? – Are there any financial incentives, or sanctions, to prescribers in relation to prescription behaviour? • Are there any clinical guidelines? – Which institution is in charge of developing them? – Do prescribers have to follow them? – Are there any sanctions if they do not prescribe in accordance with guidelines?
Generics	• What are general figures on the generic market (share as volume and value of total or outpatient market, etc.), if available? • What is the perception on generics (please specify by patient, physicians and pharmacist)? • Is international nonproprietary name prescribing allowed, and if yes, is it mandatory? • Is generic substitution allowed, and if yes, is it mandatory? • If margins are regulated, are the pharmacists' margins for generics different from those for other products?

Annex 4. Sample interview guide

A sample interview guide was used for the interviews. It was adjusted for each to take account of country-specific particularities and the defined reimbursement policy/policies surveyed.

Reimbursement models for medicines in Europe – impact of out-of-pocket payments on affordability, accessibility, equity and cost-containment

Questionnaire and brief factsheet – COUNTRY

General information about the respondent

Response date	
Respondent (name)	
Contact details	
Institution	
Stakeholder group	

Background

European countries with advanced universal health coverage (UHC) and social protection have developed pharmaceutical pricing and particularly reimbursement systems that aim to offer a range of essential, and even more, medicines to their citizens at no or low cost, with a particular focus on access for vulnerable groups. These reimbursement systems include a mix of supply-side and demand-side measures that address different stakeholders (such as industry, doctors and pharmacists) and are focused on price and/or volume control. Robust evidence is lacking, however, on which reimbursement systems and policies could be taken as best-practice models to ensure equitable access to needed medicines.

Purpose of the interview

The WHO Collaborating Centre for Pricing and Reimbursement Policies, affiliated to the Pharmacoeconomics Department of the Austrian Public Health Institute (Gesundheit Österreich GmbH), was commissioned by the WHO Regional Office for Europe to conduct an assessment of current pharmaceutical reimbursement models, systems and policies for medicines in the WHO European Region, with a view to clarifying which models, systems and policies best protect vulnerable groups from excessive out-of-pocket payments on medicines. In line with this, the aim of this interview is to gather information on the impact of specific reimbursement policies and/or cost-containment reforms on affordability, accessibility and equity of measures in COUNTRY.

Information about the reimbursement system

Information and figures about the reimbursement system in the outpatient sector in COUNTRY have been collected. Below is a summary, focusing on [….], which is the focus of this interview. Please confirm that the information is up to date, or add explanations where information is missing or misunderstood.

Questions	Answers Please also answer the specific questions included in italics
Is there anything to correct and add to this summary? Do you have any further evidence (including anecdotal) on the impact of these measures?	
What was the reason/rationale for adjustment of the *[policy change mentioned]?* Do you have any evidence that the policy change met the expectation (e.g. fewer availability issues)?	
More generally, is there evidence on specific reimbursement policies for medicines in COUNTRY that can be considered good-practice examples in terms of ensuring: • Accessibility/affordability (equity); • Budget impact; • Health outcomes?	
Is there evidence on cost-containment measures that led to higher co-payments or out-of-pocket payments that could cause either impoverishment or catastrophic expenditure, or may lead the patient to forego access altogether?	
Lessons learnt *How would you assess, in general, the effects of generic substitution and the reference price system in your country? What would be the key lessons learned?*	
Recommendations for further research *Do you have any recommendations for any further studies, statistics, materials and similar to consider?*	
Further comments	

May we mention your name in the acknowledgements of the report? ☐ Yes ☐ NO

Annex 5. Reimbursement of medicines in the WHO European Region

Table A5.1 presents information about eligibility schemes for reimbursement of medicines collected from competent authorities through a questionnaire survey of countries represented in the PPRI network and, in the case of CIS countries, data provision in brief country profiles of pharmaceutical systems. Data were collected for 45 of the 53 countries in the Region (all but Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia and Turkmenistan).

Table A5.1 | Eligibility for reimbursement of medicines in the outpatient sector in countries in the WHO European Region, 2017

Country	Product-specific	Disease-specific	Population groups-specific	Consumption-based
Albania	☑	✓	✓	-
Armenia		☑	✓	
Austria	☑	-	✓	-
Azerbaijan	☑	✓	-	-
Belarus	☑	✓	✓	-
Belgium	☑	-	✓	-
Bulgaria	☑	✓	-	-
Croatia	☑	✓	✓	-
Cyprus	-	-	☑	-
Czechia	☑	-	-	-
Denmark	✓	-	-	☑
Estonia	-	☑	-	-
Finland	☑	✓	✓	✓
France	☑	✓	-	-
Germany	☑	✓	✓	
Greece	☑	-	-	-
Hungary	☑	✓	✓	-
Iceland	☑	✓	✓	-
Ireland	✓	✓	☑	✓
Israel	☑	-	-	-
Italy	☑	-	-	-
Kazakhstan	✓	☑	-	-
Kyrgyzstan	☑	✓	-	-
Latvia	-	☑	✓	-
Lithuania	-	☑	✓	-
Luxembourg	☑	-	-	-
Malta	-	☑	✓	

Table A5.1 | Continued

Country	Product-specific	Disease-specific	Population groups-specific	Consumption-based
Netherlands	☑	-	-	-
Norway	☑	✓	✓	-
Poland	☑	✓	✓	-
Portugal	☑	✓	✓	-
Republic of Moldova	☑	✓	-	-
Romania	☑	✓	✓	-
Russian Federation	☑	✓	✓	-
Serbia	☑	-	✓	-
Slovakia	☑	-	-	-
Slovenia	☑	-	-	-
Spain	☑	-	-	-
Sweden	✓	✓	✓	☑
Switzerland	☑	-	-	-
Tajikistan	-	☑	✓	-
Turkey	-	✓	☑	-
Ukraine	☑	✓	-	-
United Kingdom	☑	-	✓	-
Uzbekistan	-	☑	-	-

Legend: ☑ = key scheme ✓ = supplementary scheme – = not applicable

Definitions:[10]

- In product-specific reimbursement eligibility for reimbursement depends on the medicine in question (a medicine is considered either as reimbursable or non-reimbursable).
- In disease-specific reimbursement eligibility for reimbursement is linked to the underlying disease to be treated. It targets both the reimbursement status and the reimbursement rate. A medicine may be reimbursed at different rates for the treatment of different diseases. Specific programmes for some indications also fall under disease-specific reimbursement.
- In population group-specific reimbursement specific population groups (such as children or pensioners) are eligible for free medicines, or medicines at higher reimbursement rates, while others are not.
- In consumption-based reimbursement the level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption).

Table A5.2 presents data collected from competent authorities through a questionnaire survey of countries represented in the PPRI network and, in the case of CIS countries, data provision in brief country profiles of pharmaceutical systems. Data were collected for 45 of the 53 countries in the Region (all but Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia and Turkmenistan). Some responding countries could not provide answers to the questions addressed in this table (see notes).

10 *Source:* Vogler S, Zimmermann N. Glossary of pharmaceutical terms: 2016 update. Vienna: Gesundheit Österreich GmbH; 2016 (http://whocc.goeg.at/Publications/Methodology, accessed 6 November 2017).

Table A5.2 | Criteria for reimbursement, responsible agent for HTA, and decision review in reimbursement decision-making in countries in the WHO European Region, 2017

Country	Criteria for reimbursement	Responsible agent for HTA	Decision review
Armenia	• Efficacy and safety of medicines • Financial aspects • Morbidity and mortality rate in the country – prevalence of diseases • Economic, genetic and demographic parameters • Structure of health care institutions • Experience and level of education of health care professionals	Ministry of Health	Every two years
Austria	• Pharmacological evaluation • Medical-therapeutic evaluation • Health-economic evaluation	Internal evaluations of Main Association of Austrian Social Security Institutions No systematic inclusion of HTA institution in the outpatient reimbursement process	Ad hoc reviews
Belarus	• National clinical guidelines • Pharmacoeconomics • Current and expected importance to the national health care system	Working on implementation of HTA	No information available
Belgium	• Therapeutic benefit • Added therapeutic benefit compared to existing therapy • Price and budget impact • Relationship between budgetary implication and therapeutic value	National Institute for Health and Disability Insurance Assessment report prepared by expert assessor(s) HTA assessment in the first 90 days of the 180-day procedure HTA report used as the basis for proposals of reimbursement and financial negotiations	Review period stipulated in the decision on reimbursement Innovative medicines reviewed within a period of 18 months to three years after admission, or ad hoc upon request (ministry or reimbursement committee)
Bulgaria	• Efficacy • Effectiveness • Safety • Disease burden • Pharmaco-economic indicators • Budget impact	HTA introduced in 2015 HTA Commission assigned to the National Centre for Public Health and Analyses, subordinate to the Ministry of Health HTA applied for medicines belonging to a new INN group not included in the positive list Assessment and final decision on inclusion of medicine in positive drug list by the HTA Commission	Revision of the reimbursement status every three years from inclusion of the medicines in the positive list
Croatia	• Therapeutic value • Relative therapeutic value • Ethical aspects • Quality and reliability of data • Budget impact	Agency for Quality and Accreditation in Health Care and Social Welfare for medicines included on list of expensive drugs	Information not available
Czechia	• Pharmacological evaluation • Medical-therapeutic evaluations • Health-economic evaluation	HTA analyses (cost–effectiveness, budget impact) usually submitted by MAH or health insurance funds evaluated by Medicines Agency HTA analyses not conducted by Medicines Agency	Every five years

Table A5.2 | Continued

Country	Criteria for reimbursement	Responsible agent for HTA	Decision review
Denmark	• Medicine with a safe and valuable therapeutic effect on a well-defined indication • Product price reasonable in relation to the therapeutic value • According to the Danish Health Act, health-economic analysis may be relevant in reimbursement decisions – applying company may submit a health-economic analysis to justify a higher price, but this is not mandatory • Health-economic analysis as part of a reimbursement decision only relevant for medicines containing a new active substance or known substance in a new pharmaceutical form and almost exclusively for prescription-only medicine(s). Generics and parallel-imported medicines granted reimbursement if originator has been granted reimbursement	Decentralized HTA, mainly conducted at regional level No regulatory mechanism requiring use of HTA in policy-making	Reimbursement status of all medicines reassessed regularly by Danish Medicines Agency to ensure that medicines which bear reimbursement automatically (so-called general reimbursement) satisfy eligibility criteria, and that medicines without general reimbursement do not
Estonia	• Necessity • Approved efficacy • Economic justification • Presence of alternatives • Presence of budgetary means	Centre for Health Technology Assessment, University of Tartu	Annual review of price agreements of reimbursed innovative outpatient medicines
Finland	For basic reimbursement status: • Therapeutic value • Reasonable price For special reimbursement status: • Type of disease • Proven therapeutic value • Necessity of the medicinal product • Economic impact • Funds available for special reimbursement • Reasonable price • Treatment costs and benefits to be gained both by the patient and as total costs of health care and social services • Benefits and costs of other available treatment alternatives • Prices of comparable medicines in Finland • Prices of medicinal product in other countries in the European Economic Area • Manufacture, research and product development costs of medicines and • Funds available for reimbursements	Internal evaluation conducted by Pharmaceutical Pricing Board (pricing and reimbursement authority)	Temporary decisions on reimbursement, with a maximum length of three and five years for new medicines and existing medicines, respectively Re-evaluation during renewal.

Table A5.2 | Continued

Country	Criteria for reimbursement	Responsible agent for HTA	Decision review
Germany	All new medicines in principle reimbursable	Benefit assessment of newly authorized medicines containing a new active substance or new combination of active substances conducted by the HTA agency Institute for Quality and Efficiency in Health Care commissioned by the FJC	FJC may initiate or pharmaceutical company may apply for a renewed benefit evaluation if new scientific findings available Re-evaluation may, however, only start as early as one year after publication of initial FJC resolution
Greece	External criteria: • Medicine reimbursed in 2/3 of the EU countries where it is marketed • Medicine reimbursed in at least nine EU countries • 50% of the reimbursing countries have HTA mechanism in place Internal criteria: • Clinical benefit • Added therapeutic value • Robust clinical evidence • Cost–effectiveness ratio • Budget impact	No (HTA centre to be established by the end of 2017)	No review procedure is defined in the current regulation.
Iceland	• Safety • Clear indication • Price in relation to efficacy and in comparisons to already reimbursed medicines • Budget impact • Reimbursement status in Denmark, Norway, Sweden and Finland	• HTA largely not carried out in Iceland, but Minister of Health may consider HTAs conducted in other Nordic countries and United Kingdom	Ad hoc reviews
Israel	• Saving life with full recovery or preventing illness/mortality • Saving life for long duration with a defined illness • Extending and improving quality of life • Economic burden for the public • Number of patients that will use the technology	HTA assessment is not systematically done	No information available
Kazakhstan	• Efficacy • Health system need	Limited use of HTA Institution in charge is the Centre for Rational Clinical Practice within the structure of the Republican Centre for Health Development under the Ministry of Health	In principle annually, but in practice reimbursement reviews done every 3–4 years
Kyrgyzstan	No information available	No regulatory and legislative framework for HTA; no HTA agency	No information available

Table A5.2 | Continued

Country	Criteria for reimbursement	Responsible agent for HTA	Decision review
Latvia	• Therapeutic benefit • Relevance to the treatment schemes and international treatment guidelines • Justified price, based on comparison with other available treatments and prices in reference countries • Cost–effectiveness data • Budget impact	National Health Service	Legal framework provides revisions of reimbursable medicines (including internal and external price referencing, revision of the treatment schemes and reimbursement conditions), but frequency not determined
Lithuania	• Therapeutic benefit (innovativeness and therapeutic benefit) • Pharmacoeconomic benefit (price and pharmacoeconomic benefit) • Budget impact	Reimbursement committee Pharmacoeconomic analysis to be submitted by the applicant and evaluated during reimbursement decision procedure	No information available
Malta	• Innovation • Therapeutic effectiveness/improvement • Cost and economic evaluation • Cost–effectiveness • Safety • Efficacy • Impact on quality of life • Availability and versatility of medicine	HTAs drawn up by pharmacists with the involvement of finance staff at the Directorate for Pharmaceutical Affairs within the Ministry of Health	No
Netherlands	• Therapeutic benefit (including efficacy and safety) • Costs and cost–effectiveness • Feasibility • Necessity	Based on specified criteria, Ministry of Health, Welfare and Sport advises on which products to include in the basic health insurance package by the National Health Care Institute, using a societal perspective	Regular reviews and ad hoc reviews (earliest six months after reimbursement decision)
Norway	• Treatment of serious diseases • Necessity • Effectiveness • Cost–effectiveness • Budget impact	A single technology assessment applying a limited societal perspective carried out by individual hospital trusts for most medicines Full HTAs at the national level including all relevant interventions for a disease also undertaken HTAs at the national level conducted by the Norwegian Knowledge Centre for Health Services and Medicines Agency	No process for regular review Possible reassessment of a medicine if new information is available
Poland	• Importance of the clinical condition • Efficacy and effectiveness • Safety • Cost–effectiveness • Price competitiveness • Budget impact • Existence of alternative medical technology and its efficacy and safety • Health priorities (identified in existing legislation)	Ministry of Health consulted and advised by Agency for Health Technology Assessment Agency performs analysis of data presented by the company in the reimbursement application, including clinical analysis, economic analysis and budget impact analysis	Ad hoc reviews Negotiations carried out again every 2-5 years to verify the legitimacy of reimbursement status and price
Portugal	• Pharmacotherapeutic evaluation • Health-economic evaluation	HTA necessary if it is concluded that the medicine has added therapeutic advantage and a higher price than the comparator	In the case of an MEA, regular reviews every two years (or any other time frame if agreed otherwise)

Table A5.2 | Continued

Country	Criteria for reimbursement	Responsible agent for HTA	Decision review
Republic of Moldova	• Priority diseases • Efficiency • Safety • Pharmacoeconomics	Done by a secretariat of the National Health Insurance	Revision of reimbursement decisions once a year
Romania	• Score point system created to evaluate each medicine to be introduced in the National Medicines Catalogue: medicines with positive evaluations from one of the foreign HTA agencies considered granted 50 points and compared with existing alternatives • Medicines with fewer than 60 points receive negative evaluation • Medicines with 60–80 points receive conditional authorization, with consideration of volume and outcomes	HTA assessments performed by a dedicated team within the medicines regulatory agency	Information not available
Russian Federation	• Clinical (safety and efficacy) criteria • Elements of HTA linked to restriction of expenditure	No formal HTA appraisal	Annual review of EML and ad hoc review of reimbursement programmes
Serbia	• Pharmacological evaluation • Medical-therapeutic evaluation • Health-economic evaluation	National health insurance fund Internal evaluations	Information not available
Slovenia	• Public health aspect of the disease • Clinical aspect (therapeutic value of the medicine and relative effectiveness) • Pharmacoeconomic study and budget impact • Ethical aspect (rare diseases)	Elements of HTA assessment included in pricing (the exceptional higher price) and reimbursement procedures of the Agency of Medicinal Products and Medical Devices and Health Insurance Institute; no dedicated HTA agency yet in place	Regulated prices of medicine reviewed every six months – full review of national portfolio of publicly financed medicines by Agency of Medicinal Products and Medical Devices
Spain	• Therapeutic and economic data	HTA not linked to procedure Therapeutic positioning reports issued by the Spanish Agency of Medicines and taken into account in the procedure	On a case-by-case basis or regularly in the context of internal RPS
Tajikistan	• No information available	No HTA agency	No information available
Turkey	• Economic evaluation available to support decision-making (cost–minimization, cost–effectiveness, cost-utility, budget impact) • Not performed systematically	HTA assessment not done systematically	Once a year
Ukraine	• Therapeutic benefit • Medical necessity	No	Insulin prices are reviewed every six months. "Affordable medicines" prices are reviewed every six months

Note: no data were available for Albania, Azerbaijan, Cyprus, France, Hungary, Ireland, Italy, Kyrgyzstan, Luxembourg, Slovakia, Sweden, Switzerland, Tajikistan, the United Kingdom and Uzbekistan.

Table A5.3 presents reimbursement lists and rates for outpatient medicines. Information was collected from competent authorities through a questionnaire survey of countries represented in the PPRI network and, in the case of the CIS countries, data provision in brief country profiles of pharmaceutical systems. Data were collected for 45 of the 53 countries in the Region (all but Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia and Turkmenistan).

Table A5.3 | Reimbursement lists and reimbursement rates for subsidized medicines in the outpatient sector in the Region, 2017

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
Albania	Positive list	Yes	Rates fall within the following categories: • 100%: medicines to treat cancer, multiple sclerosis, growth hormone deficiency, etc.; • 85-95%: insulin for diabetics, medicines treating epilepsy, depression, Parkinson's disease, osteoporosis, etc.; • 75-85%: medicines for chronic conditions such as coronary heart disease, hypertension, asthma, etc.; • 65-75%: gynaecological medicines, other medicines treating ulcers, urinary infections, etc.; • 55-65%: medicines treating coughs, mycosis, rheumatism, etc.; • 50%: antibiotics, dermatologic medicines, etc. Pensioners, war veterans and children aged under 12 months are also exempt from co-payment for the lowest-priced generic version of any reimbursed medicine prescribed.
Armenia	Positive list	Yes	• 100% reimbursement for eight specific population groups • 50% reimbursement for six specific population groups • 30% reimbursement for one specific population group (for pensioners) • 100% reimbursement for medicines for specific diseases (TB, mental health diseases, malignant neoplasms, diabetes, epilepsy, myocardial infarction, familial Mediterranean fever, heart valve defects, malaria, chronic kidney failure, phenylketonuria, premature infants with respiratory distress syndrome)
Austria	Positive list	No	No percentage reimbursement rates are applied.
Azerbaijan	Positive list	No	-
Belarus	Positive list	Yes	• 100% for patients under special categories (e.g. Second World War veterans, survivors of the Chernobyl clean-up operation etc.) and with specific diseases (diabetes, TB, bronchial asthma etc.) • 90% and 50% for welfare beneficiaries
Belgium	Positive list	Yes	Reimbursement rates of 75%, 50% and 40% of the ex-factory prices depending on the reimbursement category, sometimes increased with a supplement (the difference between the applied price and the reimbursement level).

Table A5.3 | Continued

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
Bulgaria	Positive list	Yes	Rates fall within the following categories: • 100%: medicines intended for treatment of AIDS or infectious diseases, as well as vaccines for compulsory immunizations and boosters, vaccines on special indications and in an emergency, specific sera, immunoglobulins; • 100%: medicines for diseases with a chronic course, leading to severe disruptions in the quality of life or disability and requiring prolonged treatment; • 75%: medicines for diseases with a chronic course and widespread prevalence; • Up to 50%: medicines for diseases other than those referred to above.
Croatia	Positive list	No	All outpatient reimbursable medicines included in basic list (one part of the positive list) are 100% funded. No percentage reimbursement rates are applied. However, patients have to make co-payments between pharmacy retail price and reference price for outpatient reimbursable medicines included in the supplementary list (RPS) if a higher-priced medicine compared to the generic or other clinically substitutable medicine included in the basic list is dispensed.
Cyprus	Positive list	No	About 80% of the population (whose family income is below a certain percentage) has access to state-financed public health care free of charge (100% reimbursement of the pharmacy retail price; a fixed service fee per prescribed item is applied); the remaining population has to rely on the private health care sector (100% OOP). Patients eligible for the public sector can access medicines in the private sector (not available in the public sector) against a defined co-payment (defined as share of the pharmacy retail price).
Czechia	Positive list	Yes, but not defined	No fixed reimbursement rates are defined, but reimbursable medicines can be reimbursed at certain rates. All pharmaceuticals within the same reference group have the same reimbursement price for the usual daily therapeutic dose (determined by the Medicines Agency).
Denmark	Positive list	Yes	Rates fall within the following categories: 100%, 85%, 75%, 50%. A consumption-based reimbursement rate is applied depending on the patient's pharmaceutical expenditure for reimbursable pharmaceuticals within a year.
Estonia	Positive list	Yes	Rates fall within the following categories: • 100%: serious or epidemic diseases; • 75% (or 90% for vulnerable groups): chronic diseases; • 50%: general diseases.
Finland	Positive list	Yes	Rates fall within the following categories: • 100%: medicines for 34 severe chronic conditions where pharmaceutical treatment is necessary and restores or replaces normal bodily functions; • 65%: medicines for 12 chronic diseases where pharmaceutical treatment is necessary; • 40%: basic rate for reimbursement.

Table A5.3 | Continued

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
France	Positive list	Yes	Rates fall within the following categories: • 100%: severe and/or chronic diseases; • 65%: medicines with major clinical benefit by serious disease; • 30%: medicines with less clinical benefit by serious diseases and those for non-serious disease with a form of clinical benefit; • 15%: medicines with weak clinical benefit by serious disease and those for non-serious disease with a form of clinical benefit.
Germany	Negative list for prescription-only medicines; non-prescription medicines can be reimbursed in exceptional cases	No	No percentage reimbursement rates are applied: if considered eligible for reimbursement, the price of outpatient reimbursable medicines is 100% funded, although further co-payments can apply. The prescription fee is price-dependent and includes a percentage element.
Greece	Positive list	Yes	Rates fall within the following categories: • 100%: medicines for severe diseases (and for vulnerable social groups); • 90%: medicines for chronic conditions and for pensioners on low incomes; • 75%: standard rate of reimbursement.
Hungary	Positive list	Yes	Rates fall within the following categories: • 80%, 55%, 25% for medicines on the positive list – the rate depends on the therapeutic value of the medicine and the severity and status of the disease; • 50% for substances of the pharmacopoeia and magistral products (prepared in pharmacies); • 100%, 90%, 70%, 50% for medicines for specific diseases.
Iceland	Positive list	Yes	Rates fall within 65-70% on average for medicines with general reimbursement status. The population is divided into two groups: • Group A: children, disabled people, elderly people (aged over 67 years); • Group B: Adults. Four levels of reimbursement by Icelandic Health Insurance up to full reimbursement (0%, 85%, 92.5% and 100%). Maximum 12-month payment for Group B is €496 and for Group A the annual cap is €328.
Ireland	Positive list	No	100% reimbursement is applied for a specific group of population (with certain long-term conditions); all others have 100% reimbursement of medicines only after a specific up-front co-payment (deductible).
Israel	Positive list	Yes	The reimbursement rate is set between 85% and 90%.
Italy	Positive list	No	100% reimbursement is applied.
Kazakhstan	Positive list	No	-
Kyrgyzstan	Positive list	Yes	No different reimbursement rates for different medicines or patients, but 50% reimbursement of a calculated tariff for medicines that are part of the ADP scheme

Table A5.3 | Continued

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
Latvia	Positive list	Yes	Rates fall within the following categories: • 100%: chronic, life-threatening diseases or diseases causing irreversible disability where medicines ensure and maintain the patient's life functions; • 75%: chronic diseases or diseases causing disability where medicines maintain or improve the patient's health; • 50%: chronic or acute diseases where medicines are necessary to improve the patient's health, vaccines. • Prescription-only medicines not included in the positive list are reimbursed for children aged up to 24 months (reimbursement rate 50%) and for pregnant women and women within 42 days of postnatal period (reimbursement rate 25%).
Lithuania	Positive list	Yes	Rates fall within the following categories: 100%, 90%, 80%, 50%, depending on the severity of the disease.
Luxembourg	Positive list	Yes	Rates fall within the following categories: • 100%: medicines with precise indication of therapeutic application, which is generally medicines for chronic diseases; • 80%: all other medicines without special destination, prescription prepared as directed by physician; • 40%: medicines with more limited indications.
Malta	Positive list	No	Medicines on the formulary (public sector) are 100% free of charge to entitled patients. Medicines in the private sector have to be paid entirely out-of-pocket.
Netherlands	Positive list	No	No defined percentage reimbursement rates are applied. Co-payments arise for outpatient reimbursable medicines under the RPS if patients insist on being dispensed a higher-priced medicine.
Norway	Positive list	Yes	Rates fall within the following categories: • 100%: children under 16 years, pensioners on low income and medicines for serious contagious diseases; • 61%: the general rate for reimbursement of medicines in outpatient treatment.
Poland	Positive list	Yes	The reimbursement rate is 100% for medicines for specific indications (e.g. treatment of malignant tumours, psychotic disorders, intellectual disability or developmental disorders, infectious diseases, epidemics, medicines and food for special medical purposes used in pharmaceutical programmes and oncology chemotherapy), and for specific population groups (e.g. war invalids); inpatient sector medicines are free of charge. Further reimbursement rates of 70% and 50% are applied, depending on the disease duration (up to 30 days or more than 30 days), with correlation to the cost of treatment and the minimum wage.
Portugal	Positive list	Yes	Rates fall within the following categories: • 100%: lifesaving medicines; • 90%: essential medicines for chronic diseases; • 69%: essential medicines for serious illnesses; • 37%: non-priority medicines with proven therapeutic value; • 15%: new medicines with not yet proven therapeutic value.
Republic of Moldova	Positive list	Yes	Rates fall within the following ranges, depending on the pathology considered: • 100% • 70% • 50% • 30%

Table A5.3 | Continued

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
Romania	Positive list	Yes	Rates fall within the following categories: • 100%: medicines for severe chronic diseases; • 90%: essential and cost-effective medicines; • 50%: essential but less cost-effective medicines; • 20%: non-essential and less cost-effective medicines.
Russian Federation	Positive list	Yes	The reimbursement rate is 100% for medicines on the positive lists (federal, regional, hospital formularies).
Serbia	Positive list	Yes	The reimbursement rate range is 10-90%, depending on the pharmaceutical price (higher price means a lower rate).
Slovakia	Positive list	Yes, but not defined	Reimbursement rates include 100% and partial reimbursement; there are no defined percentage reimbursement rates. The partial reimbursement results from the fact that the reimbursement price is lower than the price patients pay.
Slovenia	Two positive lists	Yes	Rates fall within the following categories: • 100%: specific therapeutic areas as stipulated by law (e.g. oncology, diabetes); • 70%: medicines on positive list (previously 75%); • 10%: medicines on intermediate list (previously 25%).
Spain	Negative list Positive list	Yes	Rates fall within the following categories: • 100%: unemployed, lowest social pension, occupational disease; • 90%: for specific medicines treating chronic diseases, with a ceiling system (for total accumulated co-payments); • 90%: retired people, up to a maximum; • 60-40%: standard rate linked to income.
Sweden	Positive list	Yes	The reimbursement rate is 100% for insulin, contraceptives for young adults (aged under 21 years) and medicines for treatment of communicable diseases such as HIV and hepatitis. Other rates include 0%, 50%, 75%, 90% and 100%, depending on pharmaceutical expenditure (higher expenditure means a higher rate). The maximum outpatient payment is 2200 Swedish krona (~€232)[11] in a 12-month period.
Switzerland	Positive list	Yes	90% or 80% of the price after reaching the deductible
Tajikistan	Positive list	No	-
Turkey	Positive list	Yes	Rates fall within the following categories: • 100%: chronic patients; • 90%: medicines for retired people; • 80%: medicines for active workers.
Ukraine	Positive list	Yes	Rates fall within the following categories: • 100%: medicines for eight categories of patients (veterans of the Second World War, veterans of Chernobyl, children aged under 3 years, disabled children aged under 16 years, etc.); • 50%: medicines for five categories of patients (children aged 3-6 years, disabled people, honorary donors etc.). • No fixed reimbursement rates are defined for pilot projects.

[11] At currency exchange rates checked on 30 October 2017, 1 Swedish krona = €0.103.

Table A5.3 | Continued

Country	Reimbursement list	Percentage reimbursement	Reimbursement rates
United Kingdom	Two negative lists Positive list	No	100% reimbursement is applied. The two negative lists are called the blacklist and the greylist. Indicative (though not necessarily binding) positive lists are also in place through locally developed primary care formularies in England. Similar arrangements may apply to Wales, Scotland and Northern Ireland.
Uzbekistan	Positive list	No	-

Table A5.4 presents data collected from competent authorities through a questionnaire survey of countries represented in the PPRI network. Data were collected for 37 of the 53 countries in the Region. Data on MEAs were not collected in the brief country profiles of pharmaceutical systems in CIS countries, so data are missing for Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan as well as those countries (Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia and Turkmenistan) not included in the survey. Some responding countries could not provide answers to the questions addressed in this table (see notes).

Table A5.4 | Numbers and types of MEA in countries in the WHO European Region, 2017

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Austria	MEAs in place	n/a	n/a	Confidential information (but if pharmaceutical company agrees, medicines under an MEA marked in the reimbursement list)	MEAs concluded by nearly all hospital pharmacies	Mainly financial-based schemes (simple discounts) MEAs to manage budgets (discount agreements, price–volume agreements) in nearly all hospital pharmacies; a few also with performance-based schemes	Oncology for performance-based schemes	Confidential data
Belgium	MEAs in place (approximately 100 – mainly inpatient)	• Cost reduction, but keeping the original list price (e.g. rebate percentage of turnover) • Fixed amount per unit • Budget cap • Reduced price on other medicines produced by applicant (cross deal) • Price–volume • Pay-for-performance scheme • Reduction of list price in combination with one of the above • Compensation data collection and combinations	n/a	Confidential information	MEAs in place (approximately 100 – mainly inpatient)	• Cost reduction, but keeping the original list price (e.g. rebate percentage of turnover) • Fixed amount per unit • Budget cap • Reduced price other medicines applicant (cross deal) • Price–volume • Pay-for-performance scheme • Reduction of list price in combination with one of the above • Compensation data collection and combinations	Oncology	n/a
Bulgaria	10 MEAs concluded in 2016 for new medicines included in the positive list	Financial-based MEAs (simple discount, price–volume agreements and discount in the form of payback)	Pulmonology, cardiology, endocrinology, gastroenterology, rheumatology	Confidential information	Two MEAs concluded in 2016 for new oncology medicines included in positive list	Financial-based MEAs (simple discount and discount in the form of payback)	Oncology	Confidential information

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Croatia	MEAs in place; no number indicated	Financial-based MEA	n/a	Confidential information	MEAs in place; no number indicated	Financial-based MEA	n/a	Confidential information
Czechia	Not known – estimated at several dozen	Financial-based MEAs	Oncology, rheumatology, biological treatment	Mainly confidential information; some information publicly accessible	n/a	n/a	n/a	Mainly confidential information; some information publicly accessible (register of hospital agreements)
Denmark	n/a	2006 price agreement set up between the Ministry of Health and Danish Association of the Pharmaceutical Industry entailing a ceiling on prices – parties negotiated new price cap agreements every 2-3 years since 2006	n/a	n/a	n/a	n/a	n/a	n/a
Estonia	MEAs in place; prices agreed for 1062 packages and 33% of these include some kind of MEA	Permanent discount, packages free of charge, different payback schemes	Not indication-based	Confidential	None	Not applicable	Not applicable	Not applicable

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Finland	Possible since 1 January 2017; seven MEAs signed during 2017	All MEAs signed during 2017 were financial-based	Medications for which there is special medical need, but with costs, benefits or cost–effectiveness associated with major uncertainty	Existence and type (financial- or outcome-based) of an MEA public, but all further information confidential	Hospitals may negotiate on medicine prices with the manufacturer and receive discounts	Information on other than simple discounts not available	n/a	n/a
Germany	Discount agreements in place	n/a	n/a	Confidentiality of discount agreements at discretion of contracting parties	Discount agreements in place, in particular with hospital pharmacies	n/a	n/a	Confidentiality of discount agreements at discretion of the contracting parties
Greece	Currently no MEAs in place	Not applicable	Not applicable	Not applicable	Currently no MEAs in place	Not applicable	Not applicable	Not applicable
Hungary	MEAs in place (approximately 170 packages concerned)	Reimbursement volume agreements	Oncology, diabetes, neurology, psychiatry	Confidential, but list of MEAs published	No MEAs in place in the inpatient sector	Not applicable	Not applicable	Not applicable
Iceland	No MEAs in place	Not applicable	Not applicable	Not applicable	No MEAs in place	Not applicable	Not applicable	Not applicable
Israel	17 MEAs	Quantitative hedging/pay-for-performance	n/a	n/a	n/a	n/a	n/a	n/a
Latvia	45 MEAs	Price–volume, payback, pay-for-performance	Oncology, rheumatology, infectious diseases, multiple sclerosis	Confidential information	No MEAs in place	Not applicable	Not applicable	Not applicable

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Lithuania	100 MEAs	• Cost reduction, but keeping the original list price (e.g. rebate percentage of turnover) • Fixed amount per unit • Budget cap • Reduced price on other medicines produced by applicant (cross deal) • Price–volume • Pay-for-performance scheme • Reduction of list price in combination with one of the above	n/a	Confidential information	MEAs in place (approximately 100 – mainly inpatient)	• Cost reduction, but keeping the original list price (e.g. rebate percentage of turnover) • Fixed amount per unit • Budget cap • Reduced price other medicines applicant (cross deal) • Price–volume • Pay-for-performance scheme • Reduction of list price in combination with one of the above	Oncology	n/a
Malta	MEAs in place in the public sector	Financial-based (simple reductions, price–volume agreements, bundling)	Medicines still under patent	Confidential information	MEAs in place	Financial-based (simple reductions, price–volume agreements, bundling)	Medicines still under patent	n/a
Netherlands	Approximately 15 MEAs	Financial arrangements	Oral anticoagulants, hepatitis C	Mostly confidential	Approximately five MEAs	Financial arrangements	Oncology	n/a
Norway	Two MEAs), signed in and valid since May 2017	n/a	Cholesterol treatment	Mostly confidential	n/a	n/a	n/a	n/a
Poland	Roughly 170 MEAs	Making the statutory ex-factory price conditional on a partial payback of reimbursement	Phenylketonuria, diabetes, cancer	Confidential information	Roughly 300 MEAs	Making the statutory ex-factory price conditional on a partial payback of reimbursement	Medicines programmes	Confidential information

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Portugal	65 MEAs	Mainly financial-based MEAs: • Price–volume agreement – manufacturer required to reimburse NHS if expenditure exceeds agreed budget • Coverage with evidence development – reimbursement extension after initial two-year period conditional on provision of additional data on cost–effectiveness	Mostly for diabetes mellitus; rheumatoid arthritis, hepatitis C	Confidential information	128 MEAs	Mainly financial-based MEAs; a few performance-based MEAs combined with financial schemes MEAs for all inpatient medicines assessed since 2007 have	Mostly for HIV, oncology and hepatitis C	n/a
Romania	14 MEAs	Cost-volume and cost-volume-outcome	Oncology, hepatitis, rheumatism, diabetes	Price confidential; list of INNs published in the government decision containing the positive list	Not in place	Not applicable	Not applicable	Not applicable
Russian Federation	MEAs not used so far but implementation into practice under development	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Serbia	MEAs in place	Confidential information	Confidential information	Confidential information	MEAs in place	Confidential information	Confidential information	Confidential information

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Slovenia	544 agreements in place in 2016 for innovative, biosimilar and generic medicines	Portfolio discounts, price–volume, payback, risk-sharing scheme, simple discount	Oncology, haematology, rheumatology, gastroenterology	Lower agreed prices not published; available to demand-side stakeholders	Data for the outpatient sector include medicines for inpatient sector	Price –volume for medicines on the hospital reimbursement list; agreements linked to institutional or central public procurement process Early-access schemes for orphan medicines	Oncology, haematology, rheumatology, gastroenterology	Lower agreed prices not published; available to demand-side stakeholders
Spain	Information provided for inpatient sector include some medicines granted models from the outpatient sector (mainly dispensed in hospitals)	n/a	n/a	n/a	41 active ingredients approved for reimbursement: so-called "new reimbursement models" (May 2017); 168 active ingredients with confidential discounts (March 2017)	Maximum cost/patient, subgroups of patients, patient registries, risk-sharing, price–volume, cap for expenditure	n/a	Confidential information
Sweden	MEAs in place	n/a	n/a	n/a	MEAs in place	n/a	n/a	n/a
Switzerland	MEAs in place for expensive medicines – about 25% of the positive list	Conditional treatment continuation (25% of the list), access with evidence development (30% of new medicines), financial-based MEAs for very expensive medicines or medicines with a high budget impact: payback models (indication-based prices, combination therapies), price–volume agreements, risk-sharing schemes	Oncology, orphan indications, hepatitis C,	Most MEAs published; volume agreements and risk-sharing models confidential	MEAs concluded by all hospital pharmacies	Mainly financial-based schemes to manage budgets (discount agreements)	All indications	Confidential information

Table A5.4 | Continued

Country	Outpatient sector				Inpatient sector			
	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality	Number of MEAs	Key types of MEA	Key indications	Degree of confidentiality
Turkey	16 MEAs (early 2016 to April 2017)	Generally financial-based agreements (price–volume, simple discounts)	n/a	MEAs confidential and prices not listed	4 MEAs (early 2016 to April 2017)	Generally financial-based agreements (price–volume, simple discounts); MEA decisions and agreements made between the social security institution and manufacturer	n/a	Social security institution pays manufacturers directly; prices of medicines confidential
Ukraine	No MEAs in place	Not applicable	Not applicable	Not applicable	No MEAs in place	Not applicable	Not applicable	Not applicable
United Kingdom	Variety of MEAs (mainly for inpatient care) in England Similar, though not identical, arrangements for Scotland, Wales and Northern Ireland – e.g. the Cancer Drugs Fund applies to Wales	Patient access schemes – linked to HTA (simple discount or a complex scheme requiring health care provider to supply manufacturer with data to receive benefit: additional free doses, rebate or other mechanism) Cancer Drugs Fund – time-limited funding for new cancer drugs to enable sufficient evidence to be gathered to facilitate HTA Commercial access agreements with NHS England – available for medicines not undergoing HTA	n/a	Usually confidential	Variety of MEAs operate to enable NHS to purchase medicines at reduced prices Similar, though not identical, arrangements for Scotland, Wales and Northern Ireland – e.g. the Cancer Drugs Fund applies to Wales	Patient access schemes – linked to HTA (simple discount or a complex scheme requiring health care provider to supply manufacturer with data to receive benefit: additional free doses, rebate or other mechanism) Cancer Drugs Fund – time-limited funding for new cancer medicines to enable sufficient evidence to be gathered to facilitate HTA Commercial access agreements with NHS England – available for medicines not undergoing HTA	n/a	Usually confidential

Notes: no data were available for Albania, Armenia, Cyprus, France, Ireland, Italy, Luxembourg and Slovakia; n/a = no information available.

Table A5.5 presents data on co-payments for outpatient medicines and potential reductions and exemptions collected from competent authorities through a questionnaire survey of countries represented in the PPRI network and, in the case of CIS countries, data provision in brief country profiles of pharmaceutical systems. Data were collected for 45 of the 53 countries in the Region (all but Andorra, Bosnia and Herzegovina, Georgia, Monaco, Montenegro, San Marino, the former Yugoslav Republic of Macedonia and Turkmenistan). Some responding countries could not provide answers to the questions addressed in this table.

Table A5.5 | Co-payments for outpatient medicines and their reductions and exemptions in countries in the WHO European Region, 2017

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Albania	No	5-50%	No	Yes	Exempt from co-payment: • Medicines treating cancer, multiple sclerosis, growth hormone deficiency • People with severe disabilities Percentage co-payment: • 5-15%: insulin for diabetics, medicines treating epilepsy, depression, Parkinson's disease, osteoporosis, etc. • 15-25%: medicines for chronic conditions such as coronary heart disease, hypertension, asthma, etc. • 25-35%: gynaecological medicines, other medicines treating ulcer, urinary infections, etc. • 35-45%: medicines treating coughs, mycosis, rheumatisms, etc. • 50%: antibiotics, dermatologic medicines, etc. Percentage co-payment ranging between 5% and 50% for people with mild and moderate disabilities	Exempt from percentage co-payment: • Children aged below 18 years • Pensioners	Exempt from percentage co-payment: • War veterans Percentage co-payment ranging between 5% and 50% for • Social welfare recipients • Students • Pregnant women and mothers of newborn babies • Soldiers
Armenia	No	70% and 50%	No	No RPS	-	No or reduced percentage co-payment for defined population groups (no information available on type of population groups)	

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Austria	Prescription fee of €5.85 per item on the prescription	No All outpatient reimbursable medicines 100% funded	No	No RPS	Exempt from prescription fee: • People with infectious diseases that are subject to mandatory reporting (exemption is only valid for medicines to treat these infectious diseases)	No specific provision	Exempt from prescription fee: • Defined people subject to vulnerability –single people with net income of below of €889.84 per month • Couples with net monthly income of €1334.17 • People with increased need of medicines with net monthly income of €1,023.32 for single people and €1,534.30 for couples (these amounts increase by €137.30 for each child, given that the child lives in the same household and has no independent income) Ceiling on co-payments of 2% of net annual (family) income on medicines (as soon as this is reached, no further prescription fee to be paid in the calendar year)
Azerbaijan	No co-payments for medicines listed in the positive list			No RPS	Not applicable	Not applicable	Not applicable
Belarus	No	50% and 10%	No	No RPS	• Exemption from co-payment for specific diseases (e.g. diabetes, TB, bronchial asthma) • Reduced co-payment for people with disabilities	-	Exemption from co-payment for specific population groups (e.g. Second World War veterans, survivors of the Chernobyl clean-up operation)

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Belgium	No	25%, 50%, 60% or 80%, depending on reimbursement rate	No	Yes	• Financial protection for the chronic ill • All costs exceeding a maximum amount covered by the system • Reduced co-payment rates of 15% instead of 25% for patients with so-called "preferential" reimbursement status (widows, orphans, retired people, disabled people, those on low income, etc.) • Annual threshold for vulnerable groups (criteria: income, age, social status) and maximum co-payment per prescription of €6.70–26.10 in certain reimbursement categories	Financial protection for children aged up to 19 years All costs exceeding a maximum amount covered by the system	Financial protection for people on low income and in vulnerable social situations (reduced co-payment rates, annual threshold; see column on the left) All costs exceeding a maximum amount covered by the system
Bulgaria	No	25%, 50% or 75%	No	Yes	Exempt from percentage co-payment: • Medicines for diseases with a chronic course, leading to severe disruptions in the quality of life or disability and requiring prolonged treatment – medicines for asthma and COPD are paid 100% Percentage co-payment: • 25% for medicines for diseases with a chronic course and widespread prevalence – COPD alone 50-100%: medicines for diseases other than those referred to above; no fixed reimbursement rates defined	No specific provision	No specific provision
Croatia	10 Croatian kuna (€1.32) per prescription[1] for all reimbursable medicines	No	No	Yes (supplementary list)	Exempt from fixed co-payment: • Psychiatric and oncological patients and some other groups of patients	Exempt from fixed co-payment: • Children (aged 0-18 years)	Exempt from fixed co-payment: • Pregnant women • War veterans • People on low income

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Cyprus[a]	Service fee of €0.50 per item prescribed (public sector) up to a ceiling of €10.00 per prescription	No	No	No RPS	Medicines for defined diseases eligible for public sector access to medicines (i.e. medicines are free apart from the service fee)	No specific provision	People below a defined family income eligible to access to public sector medicines (i.e. medicines are free apart from the service fee)
Czechia	No	Yes, but no defined percentage rates (co-payment equals difference between reimbursement amount and pharmacy retail price)	No	Yes	No specific provision	Annual co-payment ceilings for specific age groups: 2500 Czech koruna (€97.37) for patients aged under 18 and above 65 years and 5000 Czech koruna (€194.75) for others[2] Only accountable co-payments counted (amount of co-payment for the lowest-priced medicine with the same active substance)	No specific provision
Denmark	Yes	Adults: 15%, 25%, 50% of medicine price depending on patient's pharmaceutical expenditure during a year (if deductible is reached)	Yes	Yes	Supplementary reimbursement schemes for disabled people No co-payment, percentage co-payment or deductibles for terminally ill patients Maximum limit of DKK 3995 (€532) per 12 months for patients with large consumption	Reduced co-payment for children aged up to 18 years: 0%, 15%, 25%, 40% of the medicine price depending on patient's pharmaceutical expenditure for reimbursable medicines within a year	Supplementary reimbursement schemes for people on low income and lower co-payment for pensioners

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Estonia	€1.27 for prescribed medicines of 100% and 75% (or 90%) reimbursement and €3.19 for prescribed medicines of 50% reimbursement	50% for general disease; 25% (or 10%) co-payment for chronic diseases	No	Yes	Exempt from co-payment: • Serious or epidemic disease Lower percentage co-payment: • 25% co-payment for chronically ill Lower co-payment (10% instead of 25%) for medicines of chronic diseases for disabled and retired people	Children aged under 4 years exempt from co-payment Lower co-payment (10% instead of 25%) for children aged under 16 and people aged over 63 years	Lower co-payment (10% instead of 25%) for medicines for chronic diseases for retired people Annual ceiling of €300 for co-payment Payback system applied if patient's yearly co-payment falls between €300–500: 50% of sum, paid over €300 paid back to the patient by SHI For co-payments of €500 and above, 90% of sum paid back (prescription fee (€1.27 or €3.19) and part of price paid over the reference price or price agreement not taken into account)
Finland	€4.50 in diseases eligible for "special reimbursement" for full (100%) reimbursement Prescription fee of €2.50 after reaching the annual ceiling (no further percentage co-payment)	60% after reaching the annual deductible (40% basic reimbursement rate)	Annual deductible of €50 (before reaching the deductible patients have to pay fully out-of-pocket) Annual ceiling of €605.13 (in 2017) per calendar year	Yes	Higher reimbursement (fixed co-payment): • Medicines for 34 severe chronic conditions where pharmaceutical treatment is necessary and restores or replaces normal bodily functions Lower percentage co-payment: • 35%: medicines for 12 chronic diseases where pharmaceutical treatment is necessary	Exempt from annual deductible: children aged 0-18 years	10% discount for war veterans on the retail price of medicines reimbursed at basic reimbursement rate

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
France	€0.50 for each medicine pack or unit of medicine dispensed	35%, 70% and 85%, depending on reimbursement rate	No	Yes	Exempt from percentage co-payment: • Severe chronic diseases, diseases listed in the long duration disease list (30 diseases)	Exempt from fixed co-payment: • Children aged under 18 years	Exempt from fixed and percentage co-payment: • People on low income • Pregnant women (after six months of pregnancy) Annual cap for fixed co-payment: €50
Germany	Yes, 10% of the medicine price (minimum €5; maximum €10), but not more than the medicine price	No	No	Yes	Lower annual limit of co-payments for people with severe chronic diseases up to 1% of annual gross income Medicines priced 30% below their fixed reference price exempted from co-payments	Non-prescription medicines reimbursed for insured children up to the age of 12 years and for adolescents with developmental disorders up to the age of 18 years Children aged below 18 years exempted from co-payment	Annual limit of co-payments at 2% of annual gross income

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Greece	€1 per prescription (the €1 is not requested in cases of no co-payment)	Standard co-payment of 25%	No	Yes	Exempt from co-payment: patients with the severe diseases thalassemia, type 1 diabetes, neoplasms, sickle cell anaemia, psychoses, hepatitis B and C, cystic fibrosis, Gaucher disease, chronic kidney disease (stage 3 and 4), multiple sclerosis Diseases with 10% co-payment: • Parkinson's disease, type II diabetes, Charcot disease, Alzheimer's disease, Wilson disease, TB, myasthenia, epilepsy, Buerger disease Under the RPS: • For a selected medicine with a higher retail price than the reference price, patient covers the difference up to €20 per pack of a medicine • If selecting a medicine with no generic or whole therapeutic class which contains one or more active substances, patient pays beyond statutory participation: half the difference between the reference and retail price of the medicine, if retail price is higher than price compensation; remainder charged to the pharmaceutical company or the MAH in the form of a rebate	No specific provision	• Exempt from co-payment: medicines for vulnerable social groups Reduced co-payment: • Reduced co-payment of 10% for pensioners on low income (but they still have to pay the prescription fee)

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Hungary	Fee of 300 Hungarian forints (€0.96) for 100% reimbursed medicines under "indication-linked reimbursement" conditions	75%, 45% or 20% for reimbursable medicines in normal circumstances ("normative reimbursement") 50%, 30% or 10% for medicines for specific conditions ("indication-linked reimbursement") 0% co-payment for severe, life-threatening diseases also possible	No	Yes	Exempt from co-payments up to a monthly amount of around 12 000 Hungarian forints (€40) + an additional yearly amount of 6000 Hungarian forints (€20) for acute diseases for: • Serious disabilities (blindness, schizophrenia, physical or mental disabilities etc.)	Exempt from co-payment up to a monthly amount of around 12 000 Hungarian forints (€40) + an additional yearly amount of 6000 Hungarian forints (€20) for acute diseases for: • Children in social care for various reasons (illness, economic conditions of the family, orphans)	Exempt from co-payments up to a monthly amount of around12 000 Hungarian forints (€40) + an additional yearly amount of 6000 Hungarian forints (€20) for acute diseases for: • Pensioners who receive retirement benefits due to disabilities or accidents • People eligible for defined social cash benefits • People with low household incomes and high pharmaceutical expenditure

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Iceland	No	65-70% on average for medicine with general reimbursement status Three co-payment steps of 15%, 7.5% and 0%, between reaching deductible and ceiling, depending on pharmaceutical expenditure within a 12-month period	Maximum 12-month payment for elderly or children of 41 001 Icelandic krona (€328)[3] For people aged 22–67 years, 0% co-payment after OOPs of 62 001 Icelandic krona (€496)	Yes	Maximum 12-month payment for disabled people of 41 001 Icelandic krona (€328)	Reduced deductibles For elderly, disabled, children aged under 22 years: • 100% OOP up to 14 500 Icelandic krona (€116) • 15% co-payment from 14 501 to 20 875 Icelandic krona (€167) • 7.5% co-payment from 20 876 to 41 000 Icelandic krona (€328) • 0% co-payment from 41 001 Icelandic krona For people aged 22–67 years: • 100% OOP up to 22 000 Icelandic krona (€176) • 15% co-payment from 22 001 to 37 150 Icelandic krona (€297) • 7.5% co-payment from 37 151 to 62 000 Icelandic krona (€496) • 0% co-payment from 62 001 Icelandic krona	No specific provision

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Ireland	Yes	No	Yes, for most patients (Drug Payment Scheme)	Yes	Exempt from co-payment: • Patients receiving medicines for certain long-term illnesses and disabilities, which are free of charge (long-term illness scheme)	No specific provision	No specific provision
Israel	No	Yes 10-15% for all medicines in the positive list; otherwise co-payment is 100%	No	Yes	For chronically ill patients a quarterly payment ceiling of ~950 NIS (changes between different HMOs)	No specific provision	No specific provision
Italy	Prescription fees vary between regions; can be applied to type of medical prescription or packages from €1 to €8	No	No	Yes	n/a	n/a	n/a
Kazakhstan	No co-payment for medicines included in the guaranteed free health care package			No RPS	Not applicable	Not applicable	Not applicable
Kyrgyzstan	No	No different co-payment rates for different medicines or patients, but 50% reimbursement of a calculated tariff for medicines part of the ADP scheme	No	Yes	No specific provision	No specific provision	No specific provision

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Latvia	€0.71 per prescription for medicines which are 100% reimbursed	25% and 50%, depending on reimbursement rate	No	Yes	Exempt from co-payment: • Patients suffering from chronic, life-threatening diseases or diseases causing irreversible disability where medicines ensure and maintain the patient's life functions Percentage co-payment: • 25%: medicines for chronic diseases or diseases causing disability where medicines maintain or improve the patient's health • 50%: medicines for chronic or acute diseases where medicines are necessary to improve the patient's health, vaccines	Exempt from co-payment: • Children aged 0-18 years (if reference/ cheapest product prescribed) Prescription-only medicines not in the positive list reimbursed for children aged up to 24 months (reimbursement rate: 50%)	Exempt from co-payment: • People on low income (if reference/ cheapest product prescribed) Prescription-only medicines not in the positive list reimbursed for pregnant women and women within 42 days of postnatal period (reimbursement rate: 25%)
Lithuania	No	10%, 20%, and 50%, rate, depending on severity of disease	No	Yes	Exempt from co-payment: • Medicines for treatment of severely disabled people reimbursed 100% and co-payment does not exceed €1.50	Exempt from co-payment: • Medicines for treatment of children aged under 18 years reimbursed 100% and co-payment does not exceed €1.50	No specific provision
Luxembourg	No	20% or 60%, depending on reimbursement rate	No	No RPS	Exempt from co-payment: • Medicines with precise indication of therapeutic application – generally medicines for chronic diseases Percentage co-payment: • 20%: all other medicines without special destination, prescription prepared as directed by physician • 60%: medicines with more limited indications	No specific provision	No specific provision
Malta	No OOPs in the public sector. Full (100%) OOPs in the private sector			No RPS	n/a	n/a	n/a

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Netherlands	No	No percentage reimbursement rates	Yes, of €385 of health care expenditure (not only medicines) per year for all citizens aged over 18 years	Yes	No specific provision	Exempt from deductible: • Children up to 18 years	No specific provision
Norway	No	39%, to a maximum of 520 Norwegian krone (€54.79)	Annual ceiling of 2200 Norwegian krone (€226) for co-payments for physician visits, radiology, laboratory tests and medicines	Yes	Exempt from co-payment: • Medicines for serious contagious diseases	Exempt from co-payment: • Children aged under 16 years	Exempt from co-payment: • Pensioners on low income
Poland	Prescription fee of 3.20 Polish zloty (approx. €0.75)[4] per unit containing 30 DDDs	30% and 50%: co-payment depends on the disease duration (up to 30 days or more than 30 days), with correlation to the cost of treatment and the minimum wage	No	Yes	Medicines for specific indications exempt from co-payment: • Medicines for treatment of malignant tumours, psychotic disorders, intellectual disability or developmental disorders, infectious diseases, epidemics • Medicines and food for special medical purposes used in pharmaceutical programmes, oncology chemotherapy; inpatient sector free of charge	Exempt from co-payment: • Patients aged 75 years and over	Exempt from co-payment: • War invalids and persecuted people (for prescription-only medicines) • Soldiers serving basic military service • Meritorious honorary blood donors • Meritorious transplant donors Limit to co-payment when monthly cost of the standard therapy for longer than a month with the 30% co-payment level would exceed 5% of the minimum wage (minimum wage 2000 Polish zloty in 2017)

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Portugal	No	10%, 31%, 63% and 85%, depending on reimbursement rate	No	Yes	Exempt from co-payment: • Medicines for certain diseases (e.g. rheumatoid arthritis) • Lifesaving medicines (insulins and immunomodulators)	No specific provision	Lower co-payment rates (5%; 16%, 48% and 70%) for pensioners on low income
Republic of Moldova	No	30%, 50% and 70%	No	No RPS	Exemption from co-payment for defined diseases (e.g. cardiovascular diseases, endocrine diseases, bronchial asthma, Parkinson's disease, autoimmune diseases, rare diseases)	Exemption from co-payment for children up to 18 years with some defined diseases	-
Romania	No	10%, 50%, 80%, depending on reimbursement rate	No	Yes	Exempt from co-payment: • Medicines for severe chronic diseases • Treatment of diseases included in national programmes like oncology, HIV, diabetes, TB	Lower co-payments: • Children and students aged under 26 years	Lower co-payments: • Pregnant women • Pensioners on low income (for those with a maximum pension of €155, the 50% co-payment becomes 10% for prescriptions up to €70/month)
Russian Federation	No	13% (for some cases/medications patients can be refunded 87% of the expense)	No	Yes	Exempt from percentage co-payment: • Defined vulnerable groups (disabled children aged under 18 years, patients with oncological diseases, post-organ transplantation patients) Exempt from co-payment or lower co-payments: • Rare/severe diseases: haemophilia, pituitary fascism, multiple sclerosis, cystic fibrosis Gaucher disease, malignant neoplasms of haematopoietic and lymphoid tissues (chronic myeloleukemia), post-organ or tissue transplantation	Exempt from percentage co-payment: • Disabled children aged under 18 years	Lower co-payments: • War veterans

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Serbia	50 dinar (around €0.42)[5] per prescription	Range between 10% and 90%, depending on medicine price (higher price means a lower rate)	No	No RPS	No	Specific population groups (e.g. children, pregnant women) eligible for free medicines, or medicines at higher reimbursement rates Exemption from the prescription fee for defined vulnerable groups	
Slovakia	No	Yes, but no defined percentage rates (co-payment equals difference between reimbursement amount and pharmacy retail price)	No	Yes	Limit of €25 co-payment per quarter for disabled people Exemption from co-payment for disabled children up to the age of 6 years	Limit of €8 co-payment per quarter for children up to age 6 years	Limit of €25 co-payment per quarter for retired people
Slovenia	No	30% and 90%, depending on reimbursement rate	No	Yes	Exempt from co-payment: • Medicines for specific therapeutic areas as stipulated by the law (e.g. oncology, diabetes)	Children, young people in education (students aged up to 26 years): 30%, 90%: coverage of voluntary health insurance by the state	People on low income: 30%, 90%: coverage of voluntary health insurance by the state
Spain	No	Yes, depending on the income and status: 40-60% as standard co-payment rate	No	Yes	Percentage co-payment: 10% for defined therapeutic groups (chronic diseases and some other predefined specific molecules)	No specific provision	Exempt are: • People on the lowest social pension • Unemployed people without benefits • Patients with occupational diseases Reduced co-payments of 10% for retired people and those on lower incomes

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Sweden[b]	No	10%, 25%, 50%, 100% Percentage co-payment rates decrease with rising pharmaceutical expenses during a 12-month period (12-month period starts after the first purchase is made). 100% OOP below a deductible of 1100 Swedish krona (€113): above this threshold co-payments depend on accumulated expenses (50% co- payment for expenses of 1101–2100 Swedish krona; 25% co-payment for 2101–3900 Swedish krona and 10% co-payment for 3901–5400 Swedish krona) within 12 months. If expenses within the 12-month period exceed 5400 Swedish krona, the co-payment for further expenses is zero. Thus, the accumulated total OOPs within a 12-month period can amount to a maximum of 2200 Swedish krona (€226).		No RPS	Exempt from co-payment: • Insulin, medicines prescribed for preventing contamination of certain communicable diseases (hepatitis C and HIV) and medicines for people lacking perception of their own illness • Contraceptives for young adults (between 18 and 21 years)	Exempt from co-payment: • Children below 18 years	Patient fully subsidized after expenses of 2200 Swedish krona (€226) on medicines within 12 month, giving a maximum deductible limit
Switzerland	No	20% or 10% of the medicine price upon reaching the deductible	The insured person chooses the type of the deductible according to the level of monthly premiums (different deductible per health insurer)	No RPS	Percentage co-payment: • 10% percentage co-payment for generics instead of higher-priced originator medicines	No specific provision	Maximum annual threshold of 700 Swiss francs (€605)[6]

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
Tajikistan	No co-payments for a limited number of medicines included in the state-guaranteed package			No RPS	Not applicable	Not applicable	Not applicable
Turkey	Prescription fee for up to three packages of medicines (3 Turkish lira for up to three packages) and an additional fixed fee (1 Turkish lira) for each further package	Percentage co-payment of 20% (and reduced: 10%)	No	Yes	Exempt from co-payments: • Chronic diseases (e.g. cancer, hypertension, diabetes)	No specific provision	Lower co-payments: 10%: retired people
Ukraine	No	50% for defined medicines Eight categories of patients exempted from co-payment	No	Yes	Exempt from co-payments: • Insulin for children aged under 18 years and pregnant women Lower co-payments: • 50%: medicines for defined disabled people	Exempt from co-payments: • Children aged under 3 years • Disabled children aged under 16 years Lower co-payments: • 50%: medicines for children aged 3-6 years	Exempt from co-payments: • Second World War veterans • Chernobyl veterans Lower co-payments: • 50%: medicines for honorary donors

Table A5.5 | Continued

Country	Co-payment				Condition/disease/medicine	Age group	Income, social and other conditions
	Fixed co-payment	Percentage co-payment	Deductible	Due to RPS			
United Kingdom	Prescription fee of £8.60 (€9.76)[7] per medicine (England)	No	No	No RPS	Exempt from co-payments: • Patients with certain medical conditions (e.g. cancer, epilepsy, diabetes, permanent fistula, a form of hypoadrenalism, hypoparathyroidism, myasthenia gravis, myxoedema) • Patients with a continuing physical disability	Exempt from co-payments: • Children aged under 16 years • People aged 60 years and over • Students aged 16-18 years in full-time education	Exempt from co-payments: • People on low income, including those in receipt of various benefits • Pregnant women and new mothers (who had a baby within the previous 12 months) • War veterans • If multiple prescriptions needed, prescription prepayment certificates can be purchased, allowing unlimited prescriptions within a specified time period; certificates cost £29.10 (€33.02) for three months and £104 (€118.02) for 12 months
Uzbekistan	No co-payments for "socially important medicines"			No RPS	Not applicable	Not applicable	Not applicable

Notes: Information relates to reimbursable outpatient medicines and to outpatient medicines in the public sector.

a Patients not eligible to use the public sector have to access medicines in the private sector. They have to pay fully out-of-pocket or through private insurances (paying a service fee of 1 Euro per prescription +VAT). Availability of medicines in the private sector is higher than in the public sector. There is a so-called "co-payment scheme" that allows patients eligible to use the public sector to access medicines in the private sector: these patients have access to interchangeable medicines (e.g. originators) not procured in the public sector by presenting a prescription issued in the public sector to a private pharmacy. Patients eligible pay a service fee of 1 Euro per prescription +VAT, as for prescriptions in the private sector. Medicines eligible for this co-payment scheme are on a list – their pharmacy retail price and a co-payment rate is indicated. Private pharmacies can claim for reimbursement.

b Co-payment thresholds in Sweden were changed in 2018.

1 At currency exchange rates checked on 30 October 2017, 1 Croatian kuna = €0.132.
2 At currency exchange rates checked on 30 October 2017, 1 Czech koruna = €0.038.
3 At currency exchange rates checked on 30 October 2017, 1 Icelandic krona = €0.008.
4 At currency exchange rates checked on 30 October 2017, 1 Polish zloty = €0.235.
5 At currency exchange rates checked on 30 October 2017, 1 Serbian dinar = €0.008.
6 At currency exchange rates checked on 30 October 2017, 1 Swiss franc = €0.863.
7 At currency exchange rates checked on 30 October 2017, £1 = €1.134.

Annex 6. Literature review – detailed results

Impact of co-payment-related policy changes

Increasing co-payments

Research into the effect of increasing co-payments by €1 per prescription across Italian regions found a reduction in the number of prescriptions per capita by 4%. This resulted in lower per capita public pharmaceutical expenditure of 3.4% *(1)*. A study in Ireland assessed the impact of introducing a €0.50 prescription co-payment, which was later increased to €1.50, on adherence to essential and less essential medicines among the publicly insured population. The results reported reductions in medication adherence, and particularly larger reductions in adherence to essential and less essential medicines following the increase to a €1.50 co-payment *(2)*.

Eliminating co-payments

An analysis from Israel demonstrated that eliminating co-payments for residents on lower incomes with chronic conditions increased medication adherence/compliance and resulted in better health outcomes *(3)*. An Italian study looked into the correlation between co-payments, medication adherence and health outcomes in patients with hypertension. The findings shows an immediate impact of the abolishment of the prescription fee, leading to an improved average compliance of "low-compliance patients" *(4)*.

Introducing a co-payment

Another research project in Italy examined the impact of a co-payment policy on statin use. In Italian regions where a prescription fee was introduced, patients were asked to pay prescription fees ranging from €1-5 to contribute to the cost of the medicine. At the national level, reimbursement of statins was periodically revised to contain costs and ensure appropriate use. While the implementation of fixed prescription fees in the regions was associated with a small increase in overall use of statins during the study period, national restrictions to reimbursement of statins were associated with decreased usage *(5)*. With the prescription fee being fixed (and not proportional), the co-payment policy had no long-term impact on a patient's price-oriented behaviour. A further Italian study *(6)* showed a negligible reduction (1%) in the monthly growth rate of selective serotonin reuptake inhibitor) consumption after the regional co-payment policy of paying a prescription fee was implemented.

A literature review analysis of several high-income countries including European countries reported that medicine co-payments (prescription fees) may be inversely associated with medication use *(7)*. A Cochrane review concluded that fixed co-payments with a ceiling and tiered fixed co-payments may be less likely to decrease the use of essential medicines or to increase utilization of health services *(8)*.

Evidence from a study on the co-payment reform in Sweden reported that the increase in co-payments (raising deductibles to 400 Swedish krona (€43 in 2003), after which the patient must pay additional costs up to a limit of 1300 Swedish krona (€140 in 2003)) did not affect medicine use (measured for three classes of medicines), with the exception of a reduction in female antidepressant use *(9)*.

Impact of generic policies

Internal reference pricing and generic substitution

According to a retrospective analysis, a significant reduction in the daily cost of antipsychotic medications was seen following the introduction of mandatory generic substitution (2003) and internal reference pricing (2009) in Finland *(10)*. A linear segmented regression analysis conducted in Sweden showed that the introduction of a new reimbursement benefits scheme that included an RPS (2002) was likely to have contributed to lower expenditure and consumption of medicines *(11)*. Also in Sweden, average prices of pharmaceuticals experienced a downfall after generic substitution was introduced in 2002 *(12)*.

A study in Portugal reported that the introduction of the RPS in 2003 and increased generic competition in the market contributed to a transfer of the financial burden from government to patients, and was thus unsuccessful at controlling pharmaceutical expenditure *(13)*. In addition, Spanish research found that the RPS introduced in 2000 failed to be effective in containing costs in the medium or long term *(14)*.

Reduced prescription fee for generics

In Austria an analysis was conducted to observe the effect of a pilot project: one sickness fund introduced a split prescription fee and patients paid €1 less (on standard prescription fees of €4.45 in 2005 and €4.60 in 2006) if they were dispensed a generic medicine in one of five selected classes. The result was a 45% increase in the proportion of overall costs on generic drugs, with a 38% increase in prescriptions for generic medicines, while costs per prescription decreased for the five selected classes of medicine *(15)*.

Impact of reimbursement restrictions

Hoebert et al. studied the effect of delisting benzodiazepines from the Dutch reimbursement list in 2009, in a retrospective observational study *(16)*. The delisting was done to limit a possible misuse of these medicines and to contain health care costs. The authors found that the probability of benzodiazepines being prescribed was reduced after the policy change.

In Italy, results showed an immediate and sustained reduction in statin use following a reimbursement restriction intervention in 2004 *(6)*.

Mix of measures

In 2012 Spain initiated a set of co-payment reforms (introducing a national co-insurance rate of 10% for retirees with a monthly income-related cap and a temporary prescription fee of €1 to regions like Madrid and Catalonia, and eliminating public funding for medicines indicated for minor symptoms medicines) that curbed the continued year-on-year increase in the number of prescriptions dispensed *(17)*. The author concluded that these reforms contributed to reducing medicine use and public medicine spending.

The extraction table (Table A6.1) provides a brief description of the evidence identified in the literature review.

Table A6.1 | Literature review details

Author(s) Title	Country/ countries	Year of survey	Intervention/ policy	Impact			Description
				A	O	C	
Aaltonen et al. *(18)*	Finland	2007	OOPs	x			Regarding concerns over high costs of medicines and patient access to them, a study compared the range of medicines available and subsidized in Finland and New Zealand. Results show that, out of 779 and 495 available and subsidized medicines, 30.9% and 41.4% accounted for non-available and non-subsidized medicines respectively in Finland. The authors found that although a number of new medicines were subsidized and available, the level of coverage of subsidy was lower in Finland than New Zealand, resulting in a higher burden of costs to patients. Also, though Finland has enabled more choice for individual tailoring of therapies, it showed a significant rise in OOPs.
Andersson et al. *(11)*	Sweden	1986–2002	Increased co-payments, new reimbursement scheme and reference-based pricing			x	Results from the linear segmented regression analysis done on the reforms investigated (increased co-payments, introduction of a new benefits scheme, RPS) indicate that increased co-payments were not associated with changed levels or slope of cost or volume of drugs. On the other hand, the analysis revealed that changes in the reimbursement system like the introduction of a new benefits scheme and reference-based pricing were associated with reductions in cost and volume of all medicines.
Atella et al. *(4)*	Italy	1997-2002	Abolition of co-payment on medicine prescriptions and reintroduction of co-payment		x	x	The study uses a disease-specific approach, focusing on hypertensive patients treated with angiotensin-converting enzyme inhibitors. The Italian government first abolished prescription charges on 1 January 2001, then reintroduced them on 1 March 2002. Results indicate that changes in co-payments have a strong immediate effect on the average compliance of patients that previously had low compliance rates and have almost no effect on average compliance of patients that previously had high compliance rates. Study calculations indicate that eliminating co-payments on medicine prescriptions affects the health outcomes of patients with low compliance; these showed lower hospitalization and mortality rates after the co-payments were abolished.
Barros & Nunes *(13)*	Portugal	1995-2008	RPS and increasing generic completion in the market			x	This study adopted a structural time-series approach to analyse the impact of policy measures on aggregate pharmaceutical consumption from 1995 to 2008. The findings reported that policy measures aimed at controlling pharmaceutical expenditure had failed. The introduction of RPS and measures targeted at increasing generic competition in the market had no effect on government spending on pharmaceutical products. This led to a transfer of financial burden from the government to patient, failing to control public pharmaceutical expenditure.

Table A6.1 | Continued

Author(s) Title	Country/ countries	Year of survey	Intervention/ policy	Impact			Description
				A	O	C	
Damiani et al. *(5)*	Italy	2001-2007	Introduction of co-payment (prescription fee), reimbursement restriction			x	A segmented regression analysis was performed to assess the impact of a regional co-payment policy (introduction of a prescription fee) and reimbursement criteria (containing specific indications and guidelines on whether statins should be prescribed) on the consumption of statins. From the results, the introduction of co-payments was associated with a significant change in trend of consumption, resulting in an increase in the post-intervention period, while the restriction to the reimbursement intervention was associated with a reduction in trends of statin use.
Damiani et al. *(6)*	Italy	2001-2007	Introduction of co-payment (prescription fee)			x	The results confirmed that the introduction of a co-payment policy (introduction of a prescription fee) had shown a 1% reduction in the monthly growth rate of selective serotonin reuptake inhibitor consumption, while the impact on expenditure was negligible. The authors concluded that implementation of co-payment policies had a minor effect on use and expenditure.
Elhayany & Vinker *(3)*	Israel	2006 – 2008	Eliminating co-payments		x		A study in Israel assessed the impact of eliminating co-payments for groups with lower socioeconomic status on medication adherence and health outcomes. Patients with hyperlipidaemia, hypertension and diabetes were selected and given a credit card (where the co-payment amount was debited) to pay for the prescribed class of medicines. Results illustrated that the HbA1c, BP and LDL levels had declined after initiation of the subsidizing co-payment programme in patients of low-income groups. The authors concluded that eliminating prescription co-payments (direct costs) for people with low socioeconomic status improved medication adherence and health outcomes.
Fiorio & Siciliani *(1)*	Italy	2001-2003	Co-payments			x	This study utilized a natural experiment to investigate the effect of co-payments on demand for prescriptions across Italian regions. Using the difference-in-differences approach, it found that an increase in co-payments reduced the per capita number of prescriptions and public expenditure. Conversely, when co-payments were reduced in 2006, the number of prescriptions and public expenditure increased.
Gemmill et al. *(7)*	Multiple EU countries	To 2006	User charges/ prescription charges for drugs	x			The authors reviewed 173 articles from 15 countries – particularly high-income OECD countries, assessing the impact of cost-sharing measures for prescription drugs and insurance coverage on prescription medicine use. They highlighted the impact of RPSs, which reduced prescription drug expenditure in the short term but were ineffective in the long term. Further, several studies in the review showed that prescription fees were found to have a negative effect on prescription medicine use and strongly suggested a negative impact on health. The authors concluded that medicine co-payments are also likely to lower equity in the use of health care and suggested as policy options to introduce mechanisms to protect poorer people and heavy users of prescription medicines.

Table A6.1 | Continued

Author(s) Title	Country/ countries	Year of survey	Intervention/ policy	Impact			Description
				A	O	C	
Gouya et al. *(15)*	Austria	2005-2006	Partial reimbursement			x	The economic benefits of reduced prescription charges (the sickness fund introduced a split prescription fee and patients paid €1 less: normal prescription fees were €4.45 in 2005 and €4.60 in 2006) for generic medicines and selected classes of generic medicines were analysed between 2005 and 2006. Results show a 45% increase in the proportion of overall costs for generic drugs, along with a 38% increase in prescriptions of generic drugs. In the selected five drug classes, the proportion of generic drugs increased from 23% to 40%, with a cost reduction of €2.47 per prescription after the intervention was introduced. An overall increase in prescriptions of selected drugs with a cost reduction from €188 811.45 to €173 677.15 was reported.
Granlund *(12)*	Sweden	1997-2007	Swedish generic substitution reform			x	The study analysed how the Swedish substitution reform had affected pharmaceutical prices and found that, on average, prices of pharmaceuticals had reduced by approximately 10%. Price decreases for originators were significantly larger than for generics.
Helin-Salmivaara et al. *(19)*	Finland	2003-2008	Generic substitution		x		The study analysed one-year discontinuation rates between cohorts initiating therapy with either generic simvastatin or non-generic atorvastatin. In 2003, shortly after the introduction of generic substitution, the risk of discontinuation of therapy did not differ between the two groups of users (generic simvastatin and non-generic atorvastatin). At that time, the out-of-pocket expenses for the two medicines differed by approximately 50%. In 2005 the one-year risk of discontinuation of statin therapy was 20% greater among people starting with non-generic atorvastatin than with generic simvastatin. Further, patients' out-of-pocket expenses with generic simvastatin amounted to only one fifth of that of the non-generics atorvastatin. This finding did not, however, apply to those who had their medicinal expenses fully reimbursed towards the end of the year of initiation.
Hoebert et al. *(16)*	Netherlands	2008-2009	Reimbursement restriction	x		x	In the context of eliminating benzodiazepines from the Dutch reimbursement list in 2009, the authors investigated the impact of the reimbursement restriction on use in patients with newly diagnosed anxiety/sleeping disorders. This retrospective observational study identified 13 596 patients diagnosed with anxiety or sleeping disorder, patients with an incident diagnosis of anxiety (3769 in 2008 and 3710 in 2009) and sleeping disorder (3254 in 2008 and 2863 in 2009). The probability of patients being prescribed a benzodiazepine after a diagnosis was lower in 2009 than in 2008 for both anxiety (30.1% versus 33.7%, P <.05) and sleeping disorder (59.1% versus 67.0%, P <.05). Thus, the policy change led to a moderate reduction in prescription of benzodiazepines in the Netherlands.

Table A6.1 | Continued

Author(s) Title	Country/ countries	Year of survey	Intervention/ policy	Impact			Description
				A	O	C	
Koskinen et al. *(10)*	Finland	2006 – 2010	Reference pricing and extension of generic substitution			x	A retrospective analysis was conducted in Finland to assess the impact of an RPS and the extension of generic substitution on the daily costs of four antipsychotic drugs. In addition, the impact of reference pricing on previously implemented generic substitution was assessed. Results found a reduction in the daily costs of antipsychotic medicines one year after the schemes' introductions. Most of the savings were generated by generic substitution, which had been adopted before the RPS.
Luiza et al. *(8)*	Multiple countries	2012, 2013, 2014	Effects of cap and co-payment	x			A Cochrane review was done to determine the effects of cap and co-payment policies on use of medicines, health care utilization, health outcomes and costs (expenditure). It identified 32 articles and reported 39 interventions. The authors concluded that co-payment policies decrease the use of medicines and reduce medicine expenditure for health insurers. They also found that caps and co-payments reduce access to therapies that are important to treat chronic, life-threatening conditions, which may increase utilization of health care services.
Moreno-Torres et al. *(14)*	Spain	1995-2006	Mark-ups, ex-factory prices and RPSs			x	This study utilized a time-series model to assess the impact of cost-containment measures on expenditure per capita, prescriptions per capita and average price of pharmaceuticals. Results found that four of the 16 public interventions analysed had a significant impact on reducing public pharmaceutical spending. The findings reported that although there was a reduction in the four interventions – mark-ups for both wholesalers and retailers in 1997 and 2000, compulsory reductions of ex-factory prices and revision of the RPSs, they were not effective in the long term.
Ong et al. *(9)*	Sweden	1990-1999	Increased co-payments	x			Evidence from this study revealed that accessibility and affordability were not majorly affected even after a co-payment reform in 1997 (raising deductibles to 400 Swedish krona, after which the patient pays an additional cost up to a limit of 1300 Swedish krona). An exception was seen in the use of antidepressants among women, which decreased to a lesser extent compared to the other products surveyed following the 1997 co-payment reform in Sweden.
Puig-Junoy et al. *(17)*	Spain	2010	Introduction of co-payment reform			x	As a result of the 2012 co-payment reform, the number of dispensed prescriptions decreased dramatically in the first year (following continuous increases in the decade before). The co-payment reforms included introducing a national co-payment rate of 10% for retirees with a monthly income-related cap; regions including Madrid and Catalunya temporarily charging a €1 co-payment per prescription; and national reforms eliminating funding for a long list of medicines indicated for minor symptoms, equivalent to a 100% co-insurance rate for those medicines. The reform clearly caused an abrupt reduction in the number of dispensed medications, although it appeared previously to have been unchanged in most regions.

Table A6.1 | Continued

Author(s) Title	Country/ countries	Year of survey	Intervention/ policy	Impact			Description
				A	O	C	
Puig-Junoy et al. *(20)*	Spain	2010-2015	Pharmaceutical co-payment reform			x	A study in Spain examined the impact of pharmaceutical co-payment reform in 2012 on drug consumption for chronic diseases such as antidiabetics, antithrombotics and COPD drugs. The co-payment reforms included introducing a national co-insurance rate of 10% for retirees with a monthly income-related cap; regions including Madrid and Catalunya temporarily charging a €1 co-payment per prescription; and national reforms eliminating funding for a long list of medicines indicated for minor symptoms, equivalent to a 100% co-insurance rate for those medicines. Results showed that there was an immediate and significant reduction in DDDs of all three therapeutic subgroups selected. A substantial reduction in expenditure was noted in the subgroups of asthma and COPD drugs.
Sinnott et al. *(2)*	Ireland	2010	Introducing co-payment policies		x		Following the introduction of co-payment policies (a €0.50 prescription co-payment, which increased to €1.50), a pre-post longitudinal repeated measure study identified sample sizes ranging from 7145 (thyroid hormone users) to 13 611) (NSAID users). It found that the €0.50 co-payment was associated with reductions in adherence ranging from 2.1% (thyroid hormone) to 8.3% (antidepressants) for essential medicines and reductions in adherence of 2% (anxiolytics/hypnotics) to 9.5% for less essential medicines. The €1.50 co-payment resulted in smaller reductions in adherence to essential medicines. Antidepressant medications were the exception, with a reduction of 10.0% after the co-payment increase. Thus, there was a significant reduction for non-essential medicines compared to essential medicines, particularly antidepressants.
Vogler et al. *(21)*	Bulgaria, Czechia, Hungary Latvia, Poland, Romania, Slovenia, Slovakia	2006-2009	Pharmaceutical policy framework and its implementation	x		x	The authors performed a multivariate regression analysis to determine the association between socioeconomic status and medicine use using cross-sectional data from the European Health Interview Survey in eight countries. In addition, a pharmaceutical policy analysis was done based on indicators in four policy dimensions: sustainable funding, affordability, availability, accessibility and rational use. Results found that there was an overall increase in consumption of non-prescribed medicines among higher socioeconomic groups in eight countries and prescribed medicines in three countries. The authors also reported that pharmaceutical systems in the eight countries lacked public funding, which resulted in increasing shares of private financing (including co-payments for prescription medicines), inappropriate medicine selections in reimbursement lists and limitations in medicine availability.
Vogler et al. *(22)*	Denmark	2016	Tendering and reimbursement model	x		x	Of the three countries analysed through stakeholder interviews and a literature search, Denmark was considered to have a successful pro-generic reimbursement model with tendering elements. These elements included mandatory generic substitution, a short-term tendering period of two weeks, support tools that kept workload at a low level and a lack of medicine shortages, contributing to affordability, accessibility and availability of medicines.

Notes: A = availability/accessibility/affordability; C = cost/volume/utilization, expenditure; O = health outcome/adherence.

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Annex 7. Financial burden analysis data

Assumptions for the scenarios analysed

Table A7.1 details the assumptions made for the cross-country analysis of financial burden for patients (Chapter 7). These can be summarized as follows.

- **United Kingdom:** regulations and calculations for the United Kingdom relate to England.
- **RPS:** as explained in section 2.6 on the methodology, co-payments due to the RPS (i.e. price differences between the reimbursed reference price and the pharmacy retail price) are also considered. Population groups exempt from co-payments still have to pay the price difference.
- **Children:** in Hungary children are only exempt from co-payment if they are in social care. For the analysis, a standard case was assumed and children in Hungary were considered to be subject to full co-payment. In general, the age at which exemptions from co-payments are no longer applicable varies between countries (for example, in the United Kingdom it is 16 years, although those aged 16–18 in full-time education are also categorized as children). For the analysis, the country-specific definitions were used.
- **People on low income:** the income threshold for exemptions from and reductions of co-payment differs between countries, reflecting different national income levels. For the analysis it was assumed that people on low income (independently from the country-specific thresholds) were, apart from the possible differences between the pharmacy retail price and the reference price, exempt from co-payments in Austria, France, Greece, Hungary (in this case people on low income were assumed to be below the monthly threshold for free medication) and the United Kingdom.
- **Retired people:** in Greece the regulation applicable for pensioners on low income (reduced co-payment of 10%) was assumed for all pensioners.
- **Unemployed people:** among the countries analysed, specific provisions for exemptions or lower co-payments for unemployed people were only found in the United Kingdom. Thus, the standard rules were applied. It may be assumed, however, that in some cases other provisions (such as those for people on low income) might come into play. In the United Kingdom, exemptions for those in receipt of certain out-of-work benefits apply. For Greece, it was stressed that unemployed people are usually from socially vulnerable groups and that exemptions as for people on low incomes are likely to apply.
- **High spenders on medicines:** for patients with considerable medication expenses (above a defined threshold, for instance) or with increased medication needs, it was assumed that the threshold was reached for patients in Austria, France and Germany and that they were exempt (as per each country's specific regulation) from base case co-payments. No exemption from co-payment was considered for chronically ill patients in Germany, however (despite the fact that they could be exempt upon reaching a certain amount of expenses). Further, no exemptions were considered for high spenders in Hungary because this provision would only apply in conjunction with low household income. For the United Kingdom it was assumed that people with high medication consumption had bought a prescription prepayment certificate that offers access to as many medicines as patients need at a set price (the cost of buying these certificates (£29.10 (€33.02) for three months or £104.00 (€118.02) for 12 months) was not taken into account). Finally, in Sweden it was considered that patients had passed the upper threshold within the deductible system that allows free medication upon its payment.
- **Disease:** several countries had specific co-payment provisions (usually expressed in percentage co-payments) related to the diseases the medicines are intended to treat. The study checked the rules applicable to the five medicines analysed in the survey. In several price databases the reimbursement/co-payment amounts or rates were indicated for the specific medicine. In France, patients taking medicines for a disease that is part of the national chronic disease scheme are

entitled to an exemption from the percentage co-payments for the medicines treating the disease. For this study, this case applies to metformin.

- **Generic promotion provision:** Germany has a mechanism that medicines priced 30% below their fixed reference price (reimbursement price) are exempt from co-payment. This provision aims to promote the uptake of lower-priced medicines and was considered when the co-payment was determined. None of the five medicines studied had a pharmacy retail price 30% below the reimbursement price, however.
- **Estimations:** it must be acknowledged that the co-payment exercise is based on estimation, since not all real-life scenarios could be considered. In Sweden, for simplicity, the analysis only investigated co-payments (full OOP) before patients reach the first threshold and the exemption case upon reaching the final threshold within the deductible system. Nevertheless, different co-payments are possible at other thresholds within a 12-month period. Thus, apart from the high spender scenario, the co-payments for Sweden are overestimated. Co-payment data on Kyrgyzstan are, on the other hand, underestimated since the difference from the pharmacy retail price (higher than the calculated reference price) could not be determined due to a lack of price data.

Table A7.1 | Definitions and assumptions for the different scenarios in the selected countries of the financial burden analysis

Country	Standard co-payment (base case)	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines
Albania	Percentage co-payment rates for medicines surveyed: amo (G): 20% co-payment; a/c: 48% (O), 35% (G); sal: 36% (O), 20% (G); met: 76% (O), 4% (G)	Exempt from co-payment: 0% co-payment for sal (O+G)	No specific provision: same co-payment as base case for the medicines surveyed (amo (G): 20% co-payment; a/c: 48% (O), 35% (G); sal: 36% (O), 20% (G); met: 76% (O), 4% (G))	Pensioners are exempt: Albanian lek co-payment for the medicines surveyed (amo (G): 20% co-payment; a/c: 48% (O), 35% (G); sal: 36% (O), 20% (G); met: 76% (O), 4% (G))	No specific provision: same co-payment as base case for the medicines surveyed (amo (G): 20% co-payment; a/c: 48% (O), 35% (G); sal: 36% (O), 20% (G); met: 76% (O), 4% (G))	No specific provision: same co-payment as base case for the medicines surveyed (amo (G): 20% co-payment; a/c: 48% (O), 35% (G); sal: 36% (O), 20% (G); met: 76% (O), 4% (G))
Austria	Standard prescription fee of €5.85 for amo (O+G); a/c (O+G); ibu (O+G); sal (O); met (O+G) Co-payment of €5.15 (pharmacy retail price) for amo (G) because prescription fee exceeds reference price	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G), a/c (O+G), ibu (O+G), sal (O) and met (O+G))	On assumption that patients have a net monthly income eligible to be defined as people on low income and are thus exempt from the prescription fee: €0 for all medicines surveyed (amo (O+G); a/c (O+G); ibu (O+G); sal (O); met (O+G))	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G); a/c (O+G); ibu (O+G); sal (O); met (O+G))	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G); a/c (O+G); ibu (O+G); sal (O); met (O+G))	Defined as people with "increased medicines need" in combination with low income according to defined thresholds OR patients who have already spent 2% of net annual income on prescription fees within a year: exempt from the prescription fee for all medicines surveyed (amo (O+G); a/c (O+G); ibu (O+G); sal (O); met (O+G))
France	Prescription fee of €0.50 for each item on the prescription: amo (O+G): prescription fee of €0.50 and 35% co-payment; sal (O+G): prescription fee of €0.50 and 35% co-payment; met (O+G): under the ALD scheme for chronic diseases with prescription fee (€0.50) but 0% co-payment	No prescription fee (children are exempt); 35% co-payment for sal (O+G)	Exempt from prescription fee and % co-payment: €0 co-payment for all medicines surveyed (amo (O+G), sal (O+G) and met (O+G))	No specific provision: same co-payment as base case for amo (O+G) and sal (O+G) met: regulation for ALD, same as base case	No specific provision: same co-payment as base case for for amo (O+G) and sal (O+G); met: regulation for ALD, same as base case	Defined as people with annual spending of €50 – exempt from prescription fee but not the percentage co-payment: €0 prescription fee and 35% co-payment for amo (O+G) and sal (O+G); met: regulation for ALD, same as base case

Table A7.1 | Continued

Country	Standard co-payment (base case)	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines
Germany	Price-dependent prescription fee: amo (O) €5.00, (G) €5.00; a/c (O) €9.48, (G) €5.00; ibu (G) €5.00; sal (O) €5.00, (G) €5.00; met (G) €5.00 In addition, co-payment of €15.93 for amo (O) and €40.70 for a/c (O) to cover difference between reference price and pharmacy retail price: exemption from co-payment for medicines with pharmacy retail price 30% below reference price not applicable for any of the medicines surveyed	Exempt from co-payment: €0 co-payment for sal (O+G)	Cap on co-payment for people defined as on low income that receive subsidies on reaching a threshold was not considered: same co-payment as base case for all medicines surveyed ((amo (O+G); c/a (O+G); ibu (G); sal (O+G); met (G))	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G); c/a (O+G); ibu (G); sal (O+G); met (G))	Cap on co-payment for people defined as on low income that receive subsidies (e.g. through long-term unemployment) on reaching a threshold was not considered: same co-payment as base case for all medicines surveyed ((amo (O+G); c/a (O+G); ibu (G); sal (O+G); met (G))	Defined as people who have spent 2% of their annual gross income on co-payments (1% in the case of chronically ill people) – exempt: €0 prescription fee for all medicines surveyed (amo (O+G); c/a (O+G); ibu (G); sal (O+G); met (G)) Additional co-payment of €15.93 for amo (O), and €40.70 for a/c (O) to cover difference between reference price and pharmacy retail price
Greece	Prescription fee of €1 and standard co-payment of 25% for all medicines surveyed (amo (O+G), a/c (O+G), ibu (O+G), sal (O)); in addition, co-payment of €1.76 for amo (O) and €0.90 for amo (G), €2.33 for a/c (O) and € 1.89 for a/c (G) and €0.39 for ibu (O) to cover difference between reference price and pharmacy retail price; no difference to pay for ibu (G) and sal (O)	No specific provision: same co-payment as for base case for sal (O)	Exempt from prescription fee and co-payment: €0 co-payment	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G), a/c (O+G), ibu (O+G), sal (O)), although they might be exempted or benefit from reduced co-payment due to other criteria (e.g. low income)	No specific provision: same co-payment as base case for all medicines surveyed (amo (O+G), a/c (O+G), ibu (O+G), sal (O)), although they might be exempted or benefit from reduced co-payment due to other criteria (e.g. low income)	No specific provision: same co-payment as for base case for all medicines surveyed (amo (O+G), a/c (O+G), ibu (O+G), sal (O))

Table A7.1 | Continued

Country	Standard co-payment (base case)	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines
Hungary	Percentage co-payment for all medicines surveyed (amo (G) 20%; a/c (O+G) 75%; sal (O) 10%); in addition, co-payment of €0.21 for a/c (O) to cover difference between reference price and pharmacy retail price; no difference to pay for amo (G), a/c (G) and sal (O)	Children in social care are exempt from co-payment within a defined monthly budget ceiling (12 000 Hungarian forints). Assumption made for study that children were not in social care: same co-payment as base case for sal (O)	Assumption made that people on low income eligible for coverage for prescription medicines within a defined monthly budget ceiling (12 000 Hungarian forints) have not used this budget and are thus still exempt from co-payment: 0 Hungarian forints co-payment	Exemption from co-payment within a defined monthly budget (12 000 Hungarian forints) for those on retirement benefits due to disabilities and accidents. Assumption made of a scenario of pensioners that receive "standard" retirement benefits: same co-payment as base case for all medicines surveyed (amo (G) 20%; a/c (O+G) 75%; sal (O) 10%)	No specific provision: same co-payment as base case for all medicines surveyed (amo (G) 20%; a/c (O+G) 75%; sal (O) 10%)	Exemption from co-payment within a defined monthly budget (12 000 Hungarian forints) in case of low household income and high pharmaceutical expenditure. Assumption made of a scenario of high spenders that were not on low income: same co-payment as base case for all medicines surveyed (amo (G) 20%; a/c (O+G) 75%; sal (O) 10%)
Kyrgyzstan	No pharmacy retail price data available; assumption of 50% of the reference price for the medicines surveyed (amo (G), sal (O+G)) – results likely to be underestimated as higher co-payment is likely due to higher pharmacy retail price	No specific provision: same co-payment as base case for all medicines surveyed (sal (G), amo (G), sal (O+G)) – Results likely to be underestimated	No specific provision: same co-payment as base case for all medicines surveyed (amo (G), sal (O+G)) – results likely to be underestimated	No specific provision: same co-payment as base case for all medicines surveyed (amo (G), sal (O+G)) – results likely to be underestimated	No specific provision: same co-payment as base case for all medicines surveyed (amo (G), sal (O+G)) – results likely to be underestimated	No specific provision: same co-payment as base case for all medicines surveyed (amo (G), sal (O+G)) – results likely to be underestimated

Table A7.1 | Continued

Country	Standard co-payment (base case)	Children	Patients on low income	Retired people	Unemployed people	High spenders on medicines
Sweden	On assumption that the first threshold in the deductible system (1100 Swedish krona) has not yet been reached: full OOP for the price of all medicines surveyed (amo (O+G), a/c (G), ibu (O+G), sal (O+G), met (G)) Co-payment may be overestimated because patient might have reached another threshold that permits lower co-payment rates of 50%, 25% or 10%	Exempt: 0 Swedish krona co-payment for sal (O+G)	No specific provision: same co-payment (full OOP) as base case for all medicines surveyed (amo (O+G), a/c (G), ibu (O+G), sal (O+G), met (G)). Co-payment may be overestimated because patient might have reached another threshold that permits lower co-payment rates of 50%, 25% or 10%	No specific provision: same co-payment (full OOP) as base case for all medicines surveyed (amo (O+G), a/c (G), ibu (O+G), sal (O+G), met (G)). Co-payment may be overestimated because patient might have reached another threshold that permits lower co-payment rates of 50%, 25% or 10%	No specific provision → same co-payment (full OOP) as for base case for all medicines surveyed (amo (O+G), a/c (G), ibu (O+G), sal (O+G), met (G)). Co-payment may be overestimated because patient might have reached another threshold that permits lower co-payment rates of 50%, 25% or 10%	Assumption of patient's accumulated expenses of above 5400 Swedish krona within 12 months (upper threshold in the deductible system): 0 Swedish krona co-payment for all medicines surveyed (amo (O+G), a/c (G), ibu (O+G), sal (O+G), met (G))
United Kingdom	Prescription fee of £8.60 for amo (O+G), a/c (G), ibu (G) and sal (O+G) Met (O+G): exempted from any co-payment as chronic disease medication for diabetes	Children under 16 and those aged 16-18 in full-time education are exempt: £0 co-payment for all medicines surveyed (amo (O+G), a/c (G), ibu (G) and sal (O+G), met (G)) Met (O+G) exempted from co-payment as chronic disease medication for diabetes	People on low income are exempt: £0 co-payment for all medicines surveyed (amo (O+G), a/c (G), ibu (G) and sal (O+G), met (G)) Met (O+G) exempted from co-payment as chronic disease medication for diabetes	People aged 60 and above are exempt: £0 co-payment for all medicines surveyed (amo (O+G), a/c (G), ibu (G) and sal (O+G), met (G)). Met (O+G) exempted from co-payment as chronic disease medication for diabetes	Some unemployed people (on receipt of certain benefits) are exempt: £0 co-payment for all medicines surveyed: amo (O+G), a/c (G), ibu (G) and sal (O+G)). Met (O+G) exempted from co-payment as chronic disease medication for diabetes	Assumption that people with high medication expenses buy a three- or 12-month prescription prepayment certificate that allows unlimited prescriptions: exempt from prescription fee for amo (O+G), a/c (G), ibu (G) and sal (O+G)). Met (O+G) exempted from co-payment as chronic disease medication for diabetes

Notes:

- ALD = chronic disease scheme in France; a/c = amoxicillin/clavulanic acid; amo = amlodipine; G = generic medicine (in the case of this analysis referring to the lowest price generic); ibu = ibuprofen; met = metformin; O= originator product; sal= salbutamol.
- The table refers only to those medicines for which price data were available.
- For full descriptions of the co-payment regulation see Table 7.1 in Chapter 7 and Table A5.5 in Annex 5; for full descriptions of the co-payment regulation see Table 7.1 in Chapter 7 and Table A5.5 in Annex 5).

Data availability

Table A7.2 shows the availability of price data for the originator and lowest-priced generic versions of the five medicines in the selected countries. Price data may be lacking because the medicines are not marketed or are not reimbursed (some price databases in European countries only include prices for reimbursed medicines). If no defined pack size exists, a different pack size closest to that initially selected was used; this is indicated in the table. If the medicine was not available in the defined pharmaceutical form or dosage no alternative medicine was chosen.

Table A7.2 | Availability of price data of originator and lowest-priced generic version of the medicines in the selected countries of the financial burden analysis, September 2017

Country	Amlodipine 5 mg, 30 tablets		Amoxicillin/ clavulanic acid 875/125 mg, 21 tablets		Ibuprofen 600 mg, 30 tablets		Salbutamol 100 µg, 200 inhalation solution/ pressurized inhalation		Metformin 500 mg, 100 tablets	
	O	LPG	O	LPG	O	LPG	O	LPG	O	LPG
Albania	n/a	√	√	√	n/a	n/a	√	√	√	√
Austria	28 tablets	√	14 tablets	15 tablets	√	√	√	n/a	200 tablets	200 tablets
France	√	√	n/a	n/a	n/a	n/a	√	√	90 tablets	90 tablets
Germany	√	√	20 tablets	20 tablets	n/a	20 tablets	√	√	n/a	√
Greece	14 tablets	14 tablets	12 tablets	12 tablets	24 tablets	20 tablets	n/a	√	n/a	n/a
Hungary	n/a	√	14 tablets	14 tablets	n/a	n/a	√	n/a	n/a	n/a
Kyrgyzstan	n/a	√	n/a	n/a	n/a	n/a	√	120	n/a	n/a
Sweden	28 tablets	28 tablets	n/a	20 tablets	√	√	√	√	n/a	√
United Kingdom	28 tablets	28 tablets	n/a	14 tablets	n/a	84 tablets	√	√	√	√

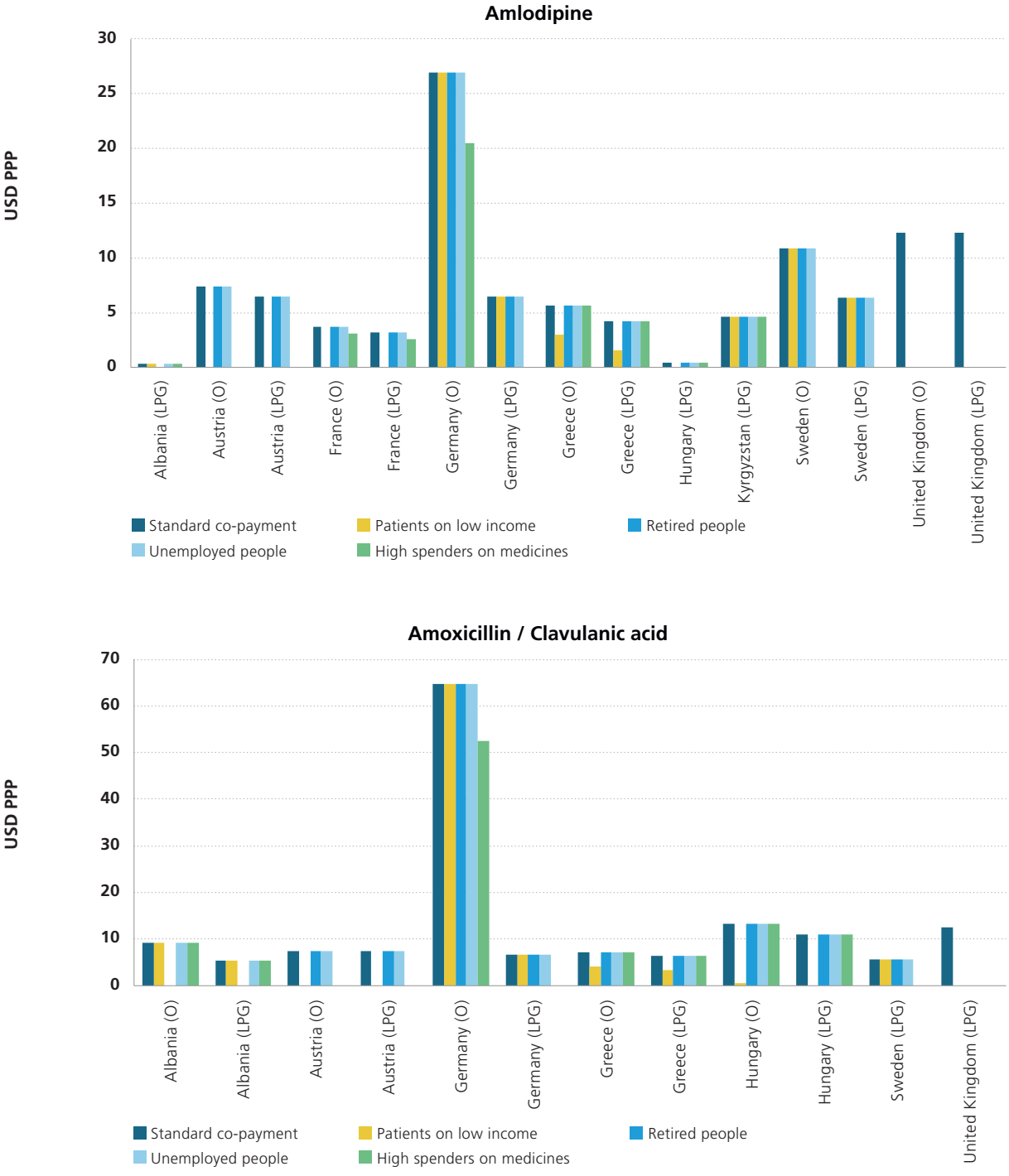
Notes:

- √ = available in the selected presentation (defined as pharmaceutical form, dosage and pack size), LPG = lowed-priced generic, n/a = no price data available for the selected medicines (defined pharmaceutical form, dosage and pack size, or a different pack size), O = originator.
- Information about pack size in the table refers to alternative medicines of the same pharmaceutical form or dosage, but in a different pack size from that selected for the analysis.
- No information on the pack size in the price list was available for Albania: only a reference price per pill was available so price per pack was inferred from this information.
- The unit related to salbutamol is dosage presentations.

Cross-country analysis – extra figures

Fig. A7.1 completes the information displayed in Table 7.2 in Chapter 7 and compares co-payments for the surveyed medicines across the countries analysed for all the different scenarios considered.

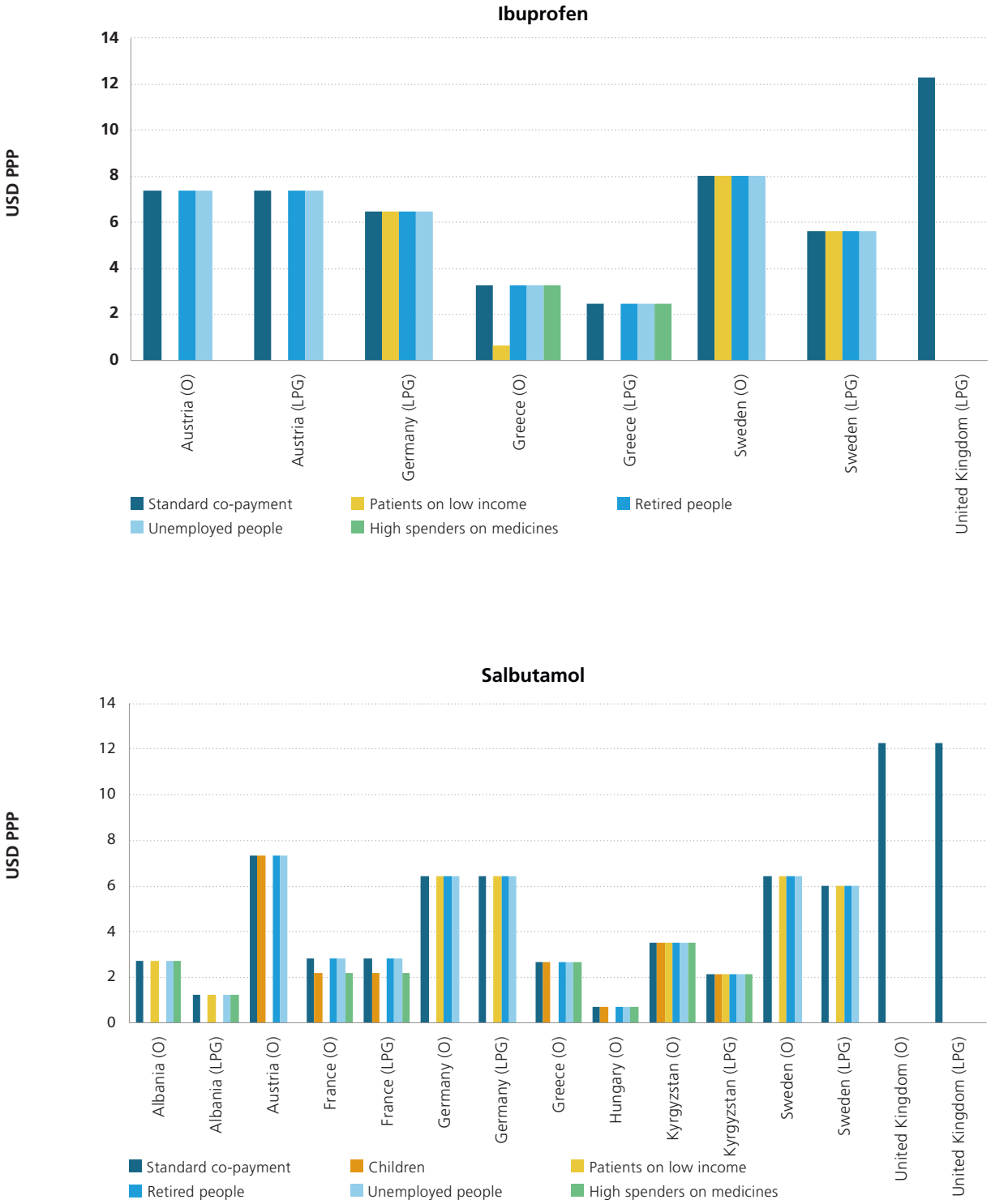
Fig. A7.1 | Co-payments of surveyed medicines expressed in USD PPP for different patient groups in the selected countries of the financial burden analysis, one pack, September 2017



Notes:

- Amlodipine: no data available for Albania (O), Hungary (O) and Kyrgyzstan (O).
- Amoxicillin/clavulanic acid: no data available for France (O + LPG), Kyrgyzstan (O + LPG), Sweden (O), United Kingdom (O).

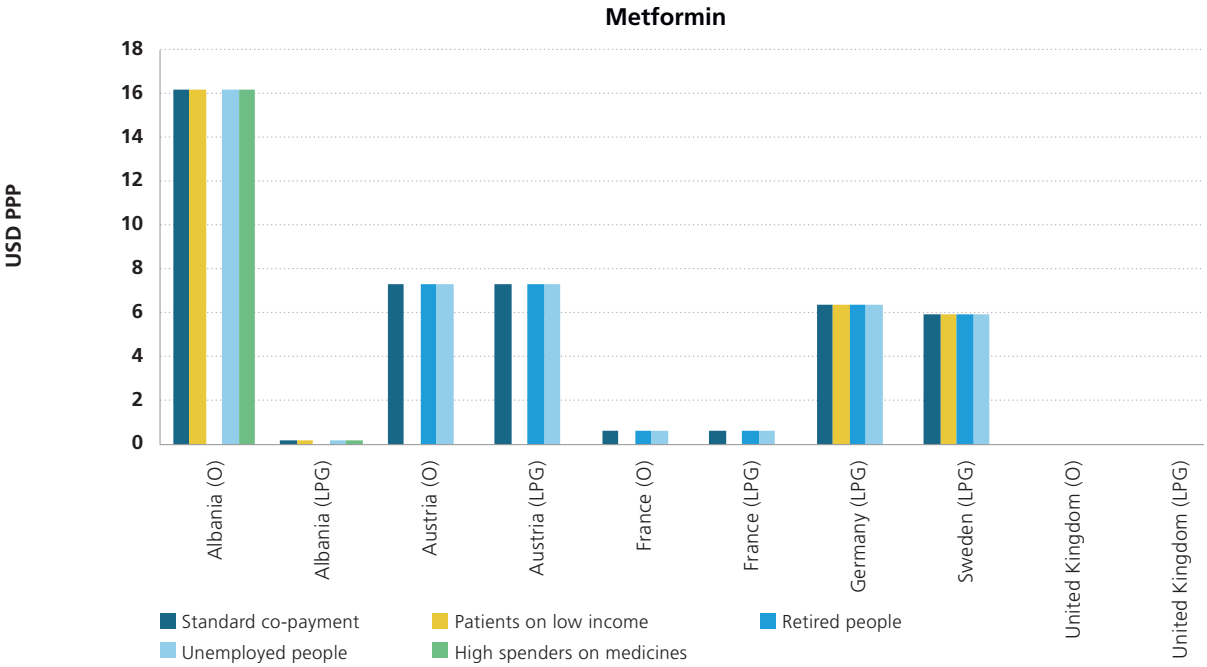
Fig. A7.1 | Continued



Notes:

- Ibuprofen: no data available for Albania (O + LPG), France (O + LPG), Germany (O), Hungary (O + LPG), Kyrgyzstan (O + LPG).
- Salbutamol: no data available for Austria (LPG), Greece (LPG), Hungary (LPG).

Fig. A7.1 | Continued

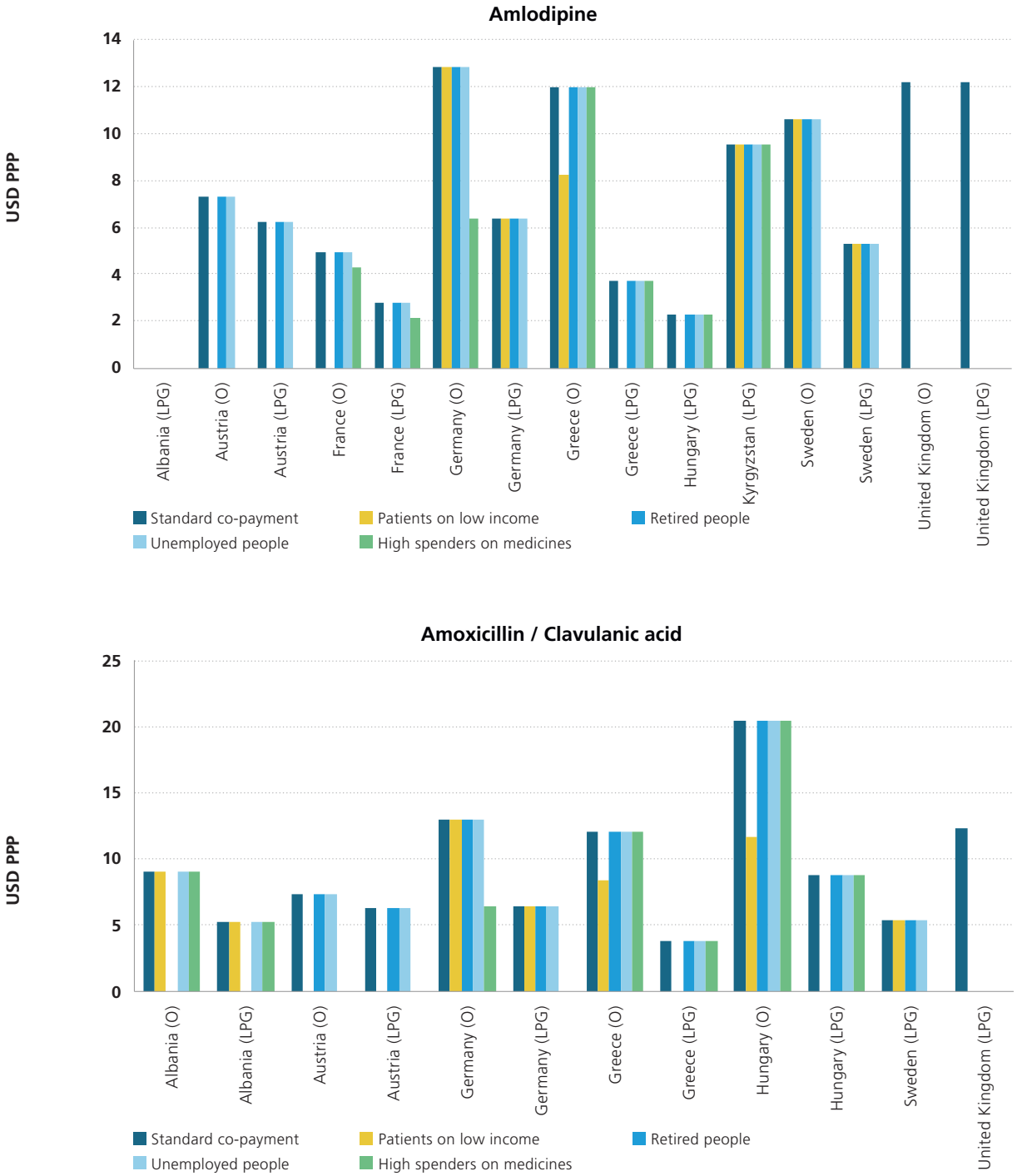


Notes:

- Metformin: no data available for Germany (O), Greece (O + LPG), Kyrgyzstan (O+ LPG), Sweden (O).
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.
- Co-payments for Sweden are maximum data and refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines co-payments amount to 50%, 25% and 10% of the medicine price; please refer to ad hoc section in Table A7.1 in Annex 7 for further details.

Fig. **A7.2** completes the information presented in section 7.3.3 and displays the co-payments (expressed in USD PPP) for a uniform price in each country and for all the scenarios considered.

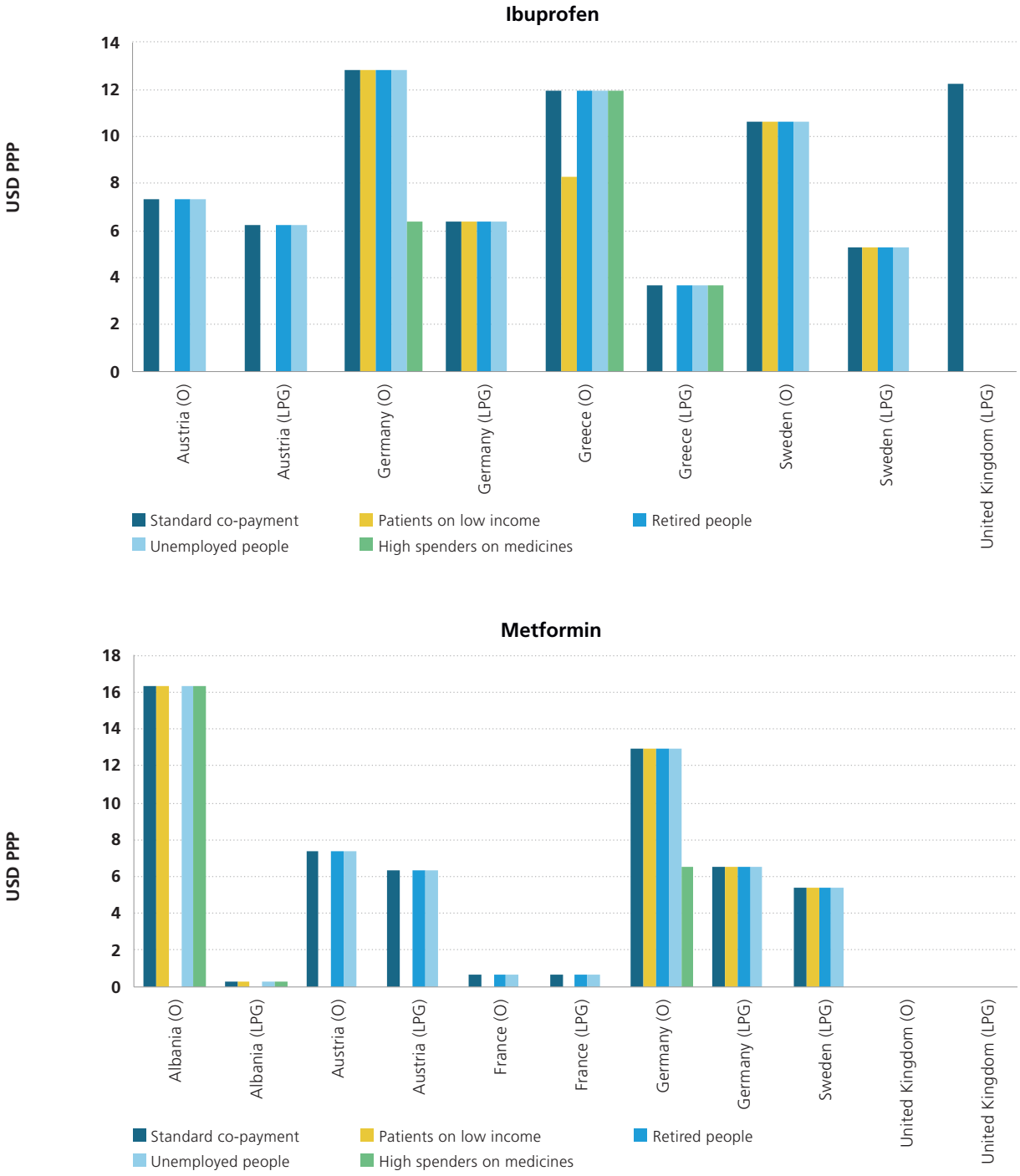
Fig. A7.2 | Co-payments of surveyed medicines (one pack) expressed in USD PPP for different patient groups in the selected countries of the financial burden analysis based on the assumption of a uniform price for all analysed countries, September 2017



Notes:

- Amlodipine: no data available for Albania (O), Hungary (O) and Kyrgyzstan (O).
- Amoxicillin/clavulanic acid: no data available for France (O + LPG), Kyrgyzstan (O + LPG), Sweden (O), United Kingdom (O).

Fig. A7.2 | Continued

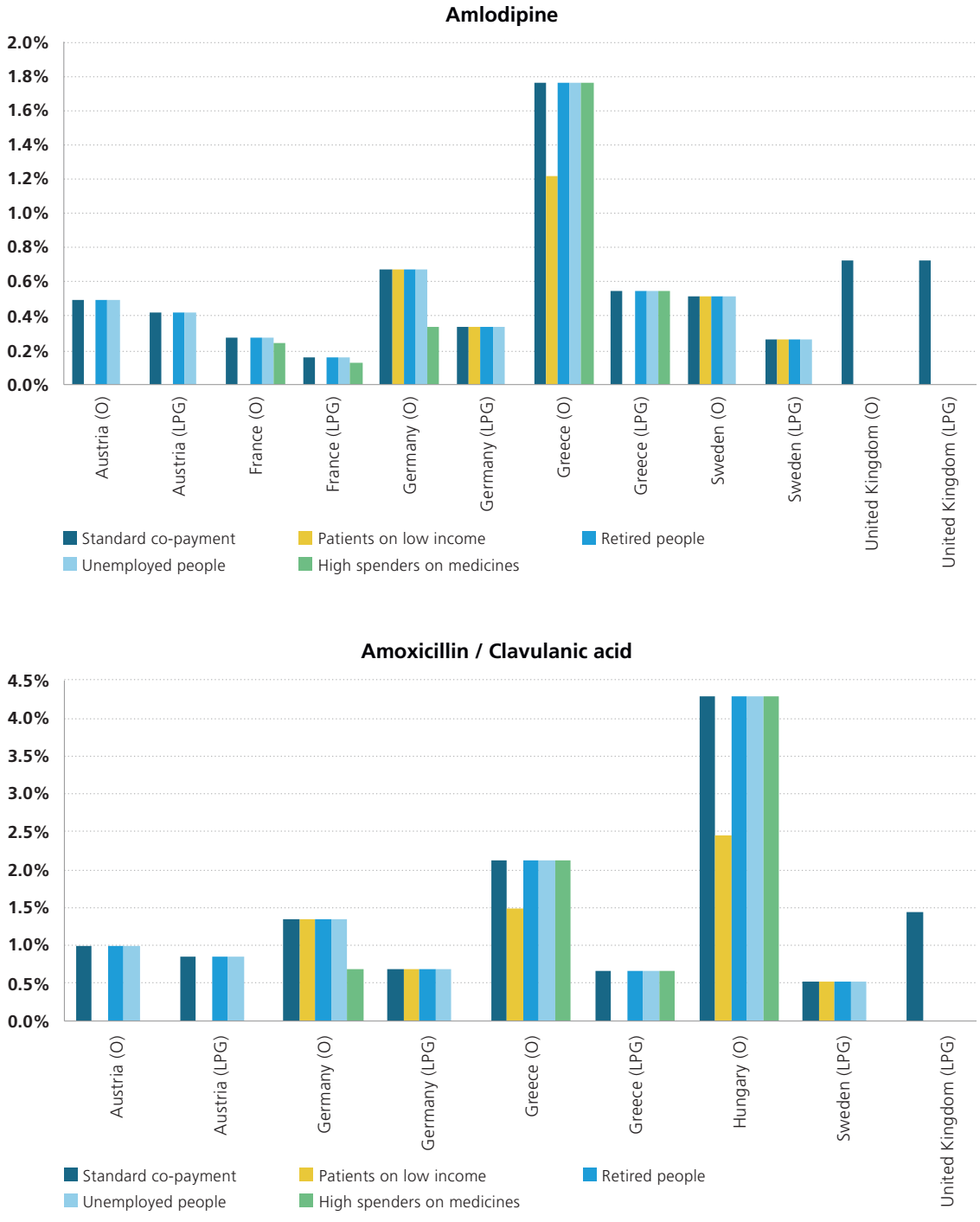


Notes:

- Calculations are based on the assumption that the price of the originator is €10 and that of the lowest--priced generic and the reimbursement/reference is €5.
- Data availability of the real-life price data was assumed for the calculation based on fictitious prices, since otherwise assumptions of the extent of co-payments (e.g. percentage co-payment) in the case of missing data would have been necessary.
- Ibuprofen: no data available for Albania (O + LPG), France (O + LPG), Germany (O), Greece (O), Hungary (O + LPG), Kyrgyzstan (O + LPG).
- Metformin: no data available for Germany (O), Greece (O + LPG), Kyrgyzstan (O+ LPG), Sweden (O).
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.
- In Kyrgyzstan co-payments may also be higher.
- Co-payments for Sweden are maximum data and refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines, the co-payments amount to 50%, 25% and 10% of the medicine price, please refer to the specific section in Table A7.1 in Annex 7 for further details.

Fig. A7.3 completes the information presented in section 7.3.3 and displays the co-payments (expressed as a percentage of the minimum wage) for a uniform price in each country with similar minimum wage amounts and for all the scenarios considered.

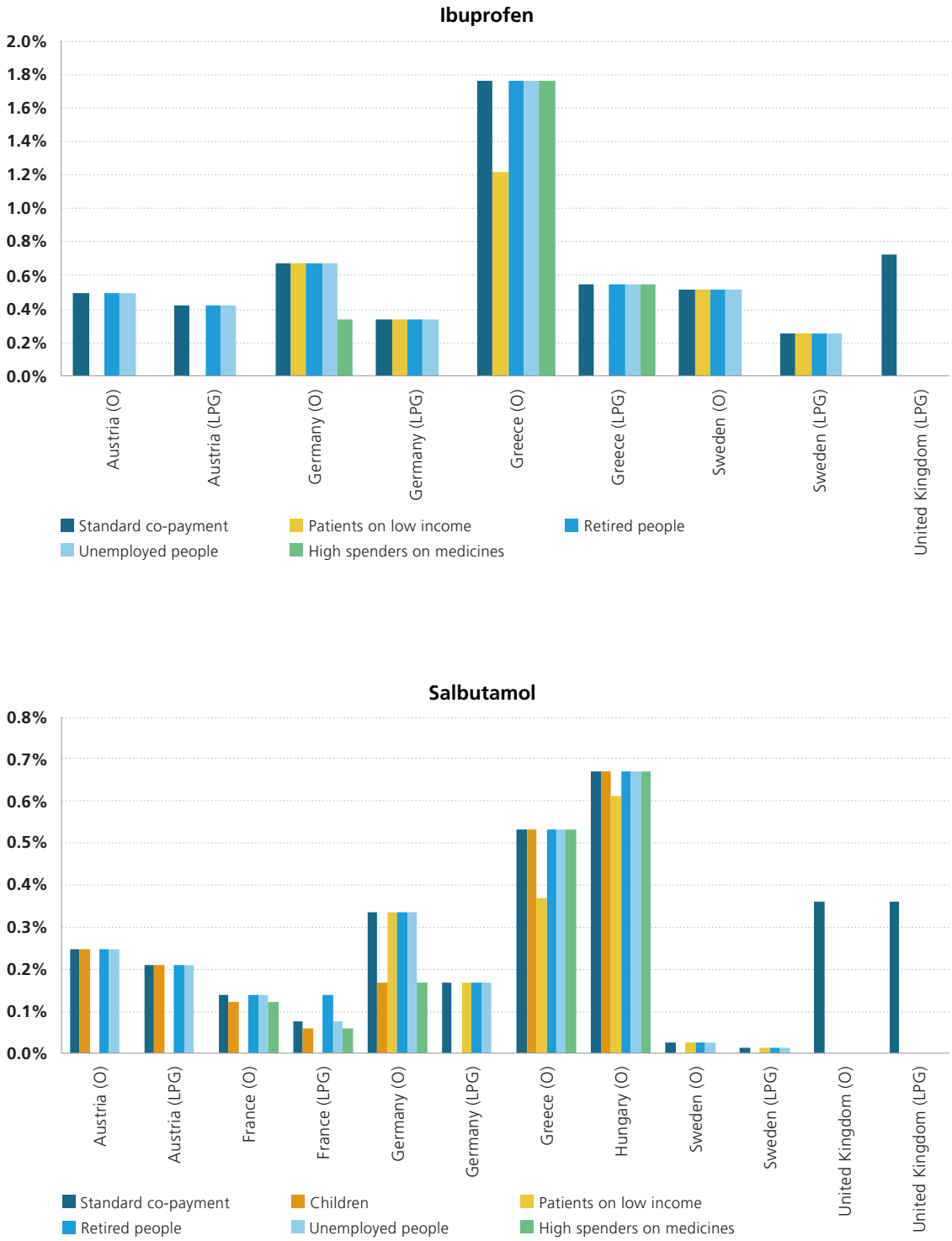
Fig. A7.3 | Co-payments of the surveyed medicines for a one-month or episode treatment as a proportion of the monthly minimum wage for defined patient groups in selected countries of similar income based on the assumption of uniform prices in all countries, September 2017



Notes:

- Amlodipine: co-payment calculated for one pack because this pack size corresponds to one month's treatment.
- Amoxicillin/clavulanic acid: no data available for France (O + LPG), Kyrgyzstan (O + LPG), Sweden (O), United Kingdom (O); co-payments calculated for two packs because two packs required to treat one episode.

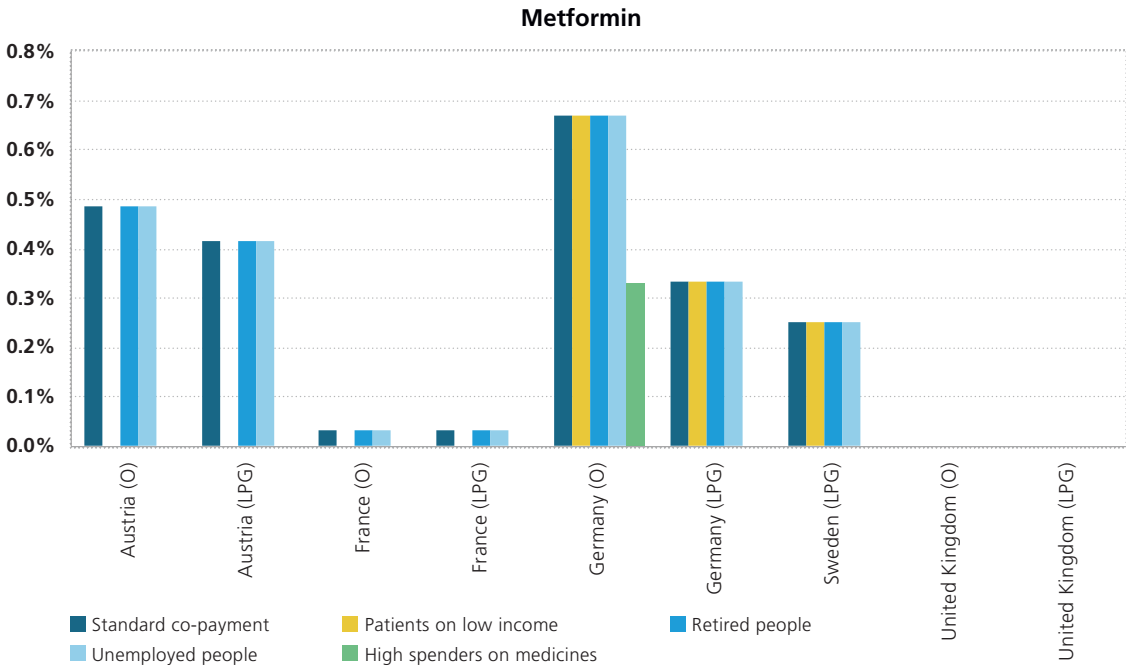
Fig. A7.3 | Continued



Notes:

- Ibuprofen: no data available for Germany (O), France (O + LPG); co-payment calculated for one pack because this pack size is required to treat one episode.
- Salbutamol: no data available for Austria (LPG); 50% of the co-payment were considered because this pack size corresponds to two months' treatment.

Fig. A7.3 | Continued



Notes:

- Calculations are based on the assumption that the price of the originator is €10 and that of the lowest-priced generic and the reimbursement/reference is €5.
- Only data of countries of similar income (Austria, Germany, France, United Kingdom and Sweden) are included.
- Data availability as perceived for the real-life price data was also assumed for the calculation based on fictitious prices since otherwise assumptions about the extent of co-payments (e.g. percentage co-payment) in the case of missing data would have been necessary.
- Metformin: no data available for Germany (O), Sweden (O); co-payment calculated for one pack because this pack size corresponds to one month's treatment.
- Where no data are available, the medicines are not displayed in the figures. If the country is included but no bar is shown in the figures, this means that no co-payment is charged.
- Co-payments for Sweden are maximum data and refer to a scenario at the beginning of a 12-month period in which patients pay 100% out-of-pocket. Above certain thresholds of expenses on medicines, co-payments amount to 50%, 25% and 10% of the medicine price, please refer to the specific section in Table A7.1 in Annex 7 for further details.

Annex 8. Glossary

Co-payments	Co-payments are a form of cost-sharing and are commonly applied in three variants of fixed co-payments, percentage co-payments and deductibles.
Deductible	An initial expense up to a fixed amount, which must be paid out-of-pocket for a service or product over a defined period of time by an insured person. Once the deductible is paid, all or a percentage of the rest of the cost occurred within the defined period is covered by a public payer.
External price referencing	The practice of using the price(s) of a medicine in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Essential medicines	Those that satisfy the priority health care needs of the population.
Fixed co-payment	An out-of-pocket payment in the form of a fixed amount (such as a prescription fee) to be paid for a service, medicine or medical device.
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 (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 summarizes 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.
International nonproprietary name (INN) prescribing	Requirements for prescribers (such as physicians) to prescribe medicines by the 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).
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 to address uncertainty about the performance of technologies or to manage the adoption of technologies to maximize their effective use or limit their budget impact.
Marketing authorization (MA)	A license 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.
National Health Service (NHS)	The system of social security and health services inspired by the Beveridge Report (1943) in England and Wales, which was implemented in both countries in 1948. An 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 services are often offered by public institutions.

Out-of-pocket payment (OOP)	Payments made by a person at the time of service use that are not reimbursed by a third-party payer. OOPs include expenses for non-reimbursable medicines and any form of co-payment for reimbursable medicines.
Percentage co-payment	Cost-sharing in the form of a set proportion of the cost of a service or product. The patient pays a certain fixed proportion of the cost of a service or product, with the public payer paying the remaining proportion.
Policy measures	Instruments, tools and approaches that allow policy-makers to achieve defined objectives.
Pricing	The act of setting a price for a medicine.
Reference price system (RPS)	A reimbursement policy in which identical medicines (Anatomic Therapeutic Chemical (ATC) level 5) or similar medicines (ATC level 4) are clustered (reference group). The public payer funds a maximum amount (the 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 co-payments (such as prescription fees or percentage co-payment rates).
Reimbursable	Medicines that are eligible for reimbursement by a third party. Costs of reimbursable medicines may be fully or partially (a specific percentage) covered by public payers.
Reimbursement	Coverage of the cost of reimbursable medicines by a public payer (such as social health insurance/national health service).
Reimbursement rate	The percentage share of the price of a medicine or medical service that is reimbursed/subsidized by a public payer. The difference between the reimbursed amount and the full price of the medicine or medicinal service is paid by the patient.
Reimbursement status	Defines whether a medicine is eligible for reimbursement (reimbursable medicines) or not (non-reimbursable medicines).
Social health insurance (SHI)	A system of financing health care often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) people whose income does not exceed a certain amount/limit (an insurance obligation) in place. SHI is often organized into different sickness funds – in some countries the patient is allowed to select a sickness fund (Germany) whereas in others the membership is determined to be mandatory – for example, depending on the type of occupation (Poland, Austria).
Voluntary health insurance	Health insurance that is taken up and paid for at the discretion of individuals or employers on behalf of individuals. Voluntary health insurance can be offered by public or quasi-public bodies and by for-profit (commercial) and non-profit private organizations.
Vulnerable population	Those facing higher risks of poverty and social exclusion compared to the general population. Pregnant women, children and older people, as well as people on low income and people with chronic conditions, are usually defined as vulnerable.

Source: adapted from Vogler S, Zimmermann N. Glossary of pharmaceutical terms: 2016 update. Vienna: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies; 2016 (http://whocc.goeg.at/Publications/Methodology, accessed 6 November 2017).

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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