World Health Organization
REGIONAL OFFICE FOR Europe

PHARMACEUTICAL PRICING AND REIMBURSEMENT SYSTEMS IN EASTERN EUROPE AND CENTRAL ASIA

REPORT OF THE PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION NETWORK FOR COUNTRIES IN EASTERN EUROPE AND CENTRAL ASIA

World Health Organization
REGIONAL OFFICE FOR Europe

PHARMACEUTICAL PRICING AND REIMBURSEMENT SYSTEMS IN EASTERN EUROPE AND CENTRAL ASIA

REPORT OF THE PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION NETWORK FOR COUNTRIES IN EASTERN EUROPE AND CENTRAL ASIA

Abstract

This report presents pharmaceutical policies related to pricing, purchasing and funding of medicines in 11 countries in eastern Europe and central Asia (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan). These are among the members of a regional subgroup of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network of competent authorities in the field of pharmaceutical pricing and reimbursement. They mainly provided evidence in the form of national profiles and posters, including information on access to HIV, hepatitis and tuberculosis medicines. The survey showed that seven countries have a form of price regulation in place for all or a limited number of outpatient medicines. Five of these have regulation at all price levels (with policies on the application of external price referencing mark-ups at the wholesale and pharmacy levels). In the hospital sector, medicines are mainly procured through tendering (predominantly via central procurement) and are provided free of charge to patients. Medicines included in national government disease programmes (such as those for HIV and tuberculosis) are also provided free of charge. Other outpatient medicines are purchased by the patient either fully out of pocket or against a co-payment where medicines are part of a benefit package (reimbursement list). These reimbursement lists are quite short at the time of writing, with plans to expand them over time. This report highlights limitations in equitable access to affordable medicines caused by, among others, high and increasing out-of-pocket payments for outpatient medicines.

Keywords

MEDICINES, PRICING, REIMBURSEMENT, HEALTH, REGULATION

TUBERCULOSIS, HEPATITIS, AIDS, EUROPE, CENTRAL ASIA

Address requests about publications of the WHO Regional Office for Europe to:

Publications

WHO Regional Office for Europe

UN City, Marmorvej 51

DK-2100 Copenhagen Ø, Denmark

Alternatively, complete an online request form for documentation, health information, or for permission to quote or translate, on the Regional Office website (http://www.euro.who.int/pubrequest).

Contents

List of figures and tables

Figures

Tables

Authors

This report was written by Sabine Vogler and Nina Zimmermann (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Austrian National Public Health Institute), Guillaume Dedet, Janice Lam and Hanne Bak Pedersen (WHO Regional Office for Europe), based on information provided by national competent authorities on pricing and reimbursement policies from 11 countries in eastern Europe and central Asia (EECA). These are among the members of a regional subgroup of the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, collectively referred to in this report as the EECA PPRI network.

Acknowledgements

The authors would like to express their appreciation to the following people for their inputs to the report:

- representatives of competent authorities responsible for pharmaceutical pricing and reimbursement in: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan for providing information and data about pharmaceutical policies in their countries during the EECA PPRI network meetings held in 2017–19, for writing country profiles and for reviewing the data in the final report;
- Ogtay Gozalov, Antons Mozalevskis and Elena Vovc (Joint Tuberculosis, HIV/AIDS & Hepatitis Programme, WHO Regional Office for Europe) and to Ihor Perhinets and Regina Winter (Division of Health Systems and Public Health, WHO Regional Office for Europe);
- Gayane Ghukasyan (WHO Country Office in Armenia), Javahir Suleymanova (WHO Country Office in Azerbaijan), Viatcheslav Grankov (WHO Country Office in Belarus), Nino Mamulashvili (WHO Country Office in Georgia), Saltanat Yegeubayeva (WHO Country Office in Kazakhstan), Kaliya Kasymbekova and Saltanat Moldoisaeva (WHO Country Office in Kyrgyzstan), Stela Gheorghita (WHO Country Office in the Republic of Moldova), Sergei Deshevoi (WHO Country Office in the Russian Federation), Zulfiya Pirova and Abdulakhad Safarov (WHO Country Office in Tajikistan), Leyla Imamkuliyeva and Ayjeren Myratdurdyyeva (WHO Country Office in Turkmenistan), Alexey Bobrik and Svetlana Pakhnutova (WHO Country Office in Ukraine) and Zafar Fayziev, Jamshid Gadoev and Khurshid Ibatov (WHO Country Office in Uzbekistan) for their significant contributions to this work.

Note

The information in this report is based on input provided by members of the EECA PPRI network. The authors recognize that countries continue to develop their health systems and to update their pricing and reimbursement policies to support this. As such, some of the information may have been updated by the time of publication. For the latest available data, contact the relevant WHO country office.

Abbreviations

EECA	Eastern Europe and central Asia
EECA PPRI network	Eastern Europe and central Asia Pharmaceutical Pricing and Reimbursement Information network [representing Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan]
EPR	external price referencing
HTA	health technology assessment
INN	international nonproprietary name
IPR	internal price referencing
MHIF	mandatory health insurance fund
NEML	national essential medicines list
NHS	national health service
OOP	out-of-pocket [payment]
PPRI	Pharmaceutical Pricing and Reimbursement Information
SHI	social health insurance
TB	tuberculosis
UHC	universal health coverage
VAT	value-added tax

Executive summary

Aim and methods

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network aims to exchange policy information and share experiences among competent authorities in the field of pharmaceutical pricing and reimbursement in 47 countries. The eastern Europe and central Asia (EECA) PPRI network is a regional subgroup formed of the following countries: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.

Given the lack of literature and information about the pharmaceutical policy framework – particularly related to pricing, purchasing and funding of medicines – in EECA PPRI network countries, this report aims to provide a comparative overview of their pharmaceutical pricing and reimbursement systems.

A specific focus on access to HIV, hepatitis and tuberculosis (TB) medicines in EECA countries can be found in Annex 1. This highlights the different stages of transition in funding and procurement of HIV, hepatitis and TB medicines from international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria to national competent authorities. The extent of coverage is also outlined in intercountry comparisons; these serve as basis for future action to increase and/or sustain access to these medicines.

This report was mainly informed by data provided by EECA PPRI network members through a national profile, using a template developed by the PPRI Secretariat, that each country was asked to complete.

Key findings

In the majority of the countries examined, health care is based on a single-payer national health service. Countries have made major progress towards universal health coverage and offer significant coverage of health care, although only for a limited set of health services. In many countries health care reforms are ongoing.

Several countries (such as the Republic of Moldova and Uzbekistan) have a national medicines policy in place, and a legal framework regulates coverage of medicines in all countries surveyed.

The number of medicines with a valid marketing authorization ranges from approximately 4300–4500 in Azerbaijan, Armenia, Belarus and Tajikistan and 5600 in Kyrgyzstan to 12 000 in Georgia. In Belarus, Turkmenistan and Ukraine, locally produced medicines account for important market shares, whereas local production appears to play a minor role in other EECA countries.

Out-of-pocket payments for health care are high, and medicines are one of the key drivers of patient payments.

Seven countries (Azerbaijan, Belarus, Kazakhstan, the Republic of Moldova, Turkmenistan, Ukraine and Uzbekistan) have a form of price regulation in place for all or a limited number of outpatient medicines.

Five of these have full regulation at all price levels (ex-factory prices and wholesale and pharmacy retail prices through distribution margins). In Belarus and Turkmenistan only distribution margins were regulated in 2018 (the year of the survey), but Belarus also piloted full price regulation for some medicines that year. Armenia, Georgia, Kyrgyzstan and Tajikistan have no form of price regulation for outpatient medicines apart from price setting where central procurement is undertaken.

All countries with full price regulation apply the policy of external price referencing (EPR), which is based on comparison of prices in other countries. Country benchmarking baskets tend to be large and usually include European countries. The benchmark price determined through EPR corresponds either to the lowest price found in the reference countries or to a weighted average. Countries that introduced EPR reported reductions in medicine prices. Internal price referencing (IPR – i.e. with reference to the price of identical or similar medicines within the country), or a variant of it, is only applied in Azerbaijan and the Republic of Moldova.

Seven (Azerbaijan, Belarus, Kazakhstan, the Republic of Moldova, Turkmenistan, Ukraine and Uzbekistan) of the 11 countries surveyed have or will have regulated wholesale and pharmacy remuneration. The scope of regulation of wholesale and pharmacy remuneration addresses all (authorized) medicines in some countries – not only those reimbursed. Regulation of the remuneration of supply chain actors is always designed to take into account the price of the medicines: countries have either a linear mark-up (Ukraine, Uzbekistan) or a regressive scheme (Belarus, the Republic of Moldova). None of the countries reimburse community pharmacies for services via a dispensing fee or through an alternative price-independent remuneration of similar value.

Some countries (such as Belarus, Georgia and Kyrgyzstan) have exempted medicines from value-added tax, but in Armenia, Azerbaijan and Tajikistan the tax on medicines is the same as other products.

In the hospital sector medicines are mainly procured through tendering. Several countries (such as Ukraine) have adopted central procurement.

Apart from Georgia, all countries reported having a national essential medicine list (NEML) that usually contains around 300–650 international non-proprietary names (INNs). These often serve as a basis for further reimbursement lists. Furthermore, medicines included in national government disease programmes ("vertical programmes") are provided free of charge to patients. These programmes, which are funded from state budgets, exist in all EECA PPRI network countries; typical indications include TB, HIV/AIDS, oncology, hepatitis C and type 1 diabetes. Reimbursement lists (formularies) have been developed, based on the NEML and vertical programmes, and apply to both outpatient and inpatient sectors or to outpatient medicines only.

Medicines in hospitals are usually provided free of charge (with no formal patient payments). In the outpatient sector, however, patients have to co-pay a percentage of the price of publicly subsidized medicines (so-called "reimbursable medicines") in some countries (such as Belarus, the Republic of Moldova and Ukraine). In several of these countries, far fewer than 100 INNs are included in the reimbursement lists of the outpatient benefits package schemes (for example, the schemes include 58 INNs and 3 medical devices in Kyrgyzstan and 23 INNs in Ukraine). An evaluation of Ukraine's Affordable Medicines Programme, which aims to improve access to 23 outpatient medicines for the treatment of chronic noncommunicable diseases, was completed in October 2018.

Health technology assessment (HTA) is not yet commonly used in EECA PPRI network countries: only three (Kazakhstan, the Republic of Moldova and Ukraine) apply HTA tools to support reimbursement decisions. Further, managed entry agreements (arrangements between a manufacturer and payer/

provider to enable access to a health technology, subject to specific clinical and financial conditions), which are increasingly used in high-income countries for new high-priced medicines, are not yet applied, although Kazakhstan and Ukraine are considering initiating such agreements.

Clinical guidelines are in place in all the countries profiled, but the degree of enforcement varies. Some countries have introduced electronic prescription systems, and a few are piloting or considering their implementation. Prescribing budgets for doctors (setting a maximum number of allowed prescriptions) are in place in Armenia and Kazakhstan, but they are not always accompanied by financial sanctions.

All the countries analysed have comparably high generic market shares of at least 60% in volume (where data are available). All have in place both prescribing by INN on a voluntary basis and generic substitution (either voluntary or mandatory).

While all surveyed countries have specific programmes for HIV and TB and provide free access to antiretroviral and TB medicines, this is not the case for hepatitis medicines (free access to these medicines is available in Azerbaijan, Belarus, Georgia, Kazakhstan, the Republic of Moldova and Turkmenistan).

Conclusions

While EECA PPRI network countries tend to look at the pharmaceutical policies and practices of European countries, there is also value in learning from and sharing experiences among the members of the EECA PPRI network, as some countries move forward with reforms in the pharmaceutical sector. As such, this report aims to contribute to information exchange among EECA PPRI network countries.

1 Introduction

Since the collapse of the Soviet Union in 1991, the newly independent countries have seen major transformations in several policy areas, including health care and pharmaceutical supply. A key change was the move from the Semashko health care model to a more market-oriented system; this was also accompanied by the creation of social health insurance in some instances *(1–3)*.

In recent years, these countries have been working towards universal health coverage (UHC). United Nations General Assembly Resolution 67/81 states that UHC "implies that all people have access, without discrimination, to nationally determined sets of the promotive, preventive, curative and rehabilitative basic health services needed and essential, safe, affordable, effective and quality medicines" *(4)*. It is therefore broadly acknowledged that the achievement of UHC will require enhancing access to medicines globally, as it is also an integral part of the right to health, as stated under article 12 of the United Nations International Covenant on Economic, Social and Cultural Rights: "The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: […] the prevention, treatment and control of epidemic, endemic, occupational and other diseases" *(5)*. The question of availability and accessibility of essential medicines for all patients that need them at affordable costs for public payers and patients is therefore central to the development agendas of eastern European and central Asian countries. Indeed, recent publications report that outpatient medicines are the main driver of catastrophic expenditure for populations of the region *(6–8)*.

While (both descriptive and analytical) literature tends to focus on high-income countries in western Europe, North America and the Asian-Pacific region, little knowledge is available about the pharmaceutical policy framework – in particular related to pricing, purchasing and funding of medicines – for EECA countries. Against this background, this report provides a comparative overview of the pharmaceutical pricing and reimbursement systems in those countries.

2 Methods

2.1 Countries included in the analysis

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network aims to exchange policy information and share experiences among competent authorities in the field of pharmaceutical pricing and reimbursement in 47 countries, mainly situated in the WHO European Region. The eastern Europe and central Asia (EECA) PPRI network is a regional subgroup of countries. Members of this network are representatives of public authorities in the field of medicines (particularly related to pricing, procurement and funding) from Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.

This report covers 11 of these 12 EECA PPRI members. Input provided and validated by country representatives was the key survey instrument (see section 2.3 for details). The Russian Federation was not included in the analysis as a brief summary of the country's pharmaceutical policy framework cannot be presented owing to the regionalization and fragmentation of the Russian health care system.

A specific focus on access to HIV, hepatitis and tuberculosis (TB) medicines in EECA countries can be found in Annex 1. This highlights the different stages of transition in funding and procurement of HIV, hepatitis and TB medicines from international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria to national competent authorities. The extent of coverage is also outlined in intercountry comparisons; these serve as a basis for future action to increase and/or sustain access to these medicines.

2.2 Terminology and indicators

This comparative analysis draws from survey and analysis tools developed by the overarching PPRI network, which developed system research and policy indicators to describe the pharmaceutical pricing and reimbursement policy framework of a country and to compare it across countries.

The PPRI Secretariat produced templates for national reports and invited representatives to write about their countries *(9)*. These templates were adjusted to the specificities of the EECA PPRI network countries. In addition, key terms to describe pharmaceutical systems were selected from a comprehensive glossary created by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in Vienna, Austria *(10)*, and a targeted small glossary was compiled. In summer 2017 the revised templates and accompanying glossary were made available in Russian to EECA PPRI network members, who were encouraged to write their reports.

2.3 Data survey and validation

Nine network members (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Tajikistan and Uzbekistan) compiled a PPRI country profile that formed the basis for the information included in this report. Information shared during the two EECA PPRI network meetings held in Chisinau, Republic of Moldova, in June 2017 and in Baku, Azerbaijan, in May 2018 was also considered. In addition to presentations by country representatives, posters providing updated summaries of the pharmaceutical systems were prepared by network members and were presented at these meetings.

Questions for clarification were asked between October 2017 and June 2018, mainly on a bilateral basis between the EECA PPRI member country and the WHO Regional Office for Europe.

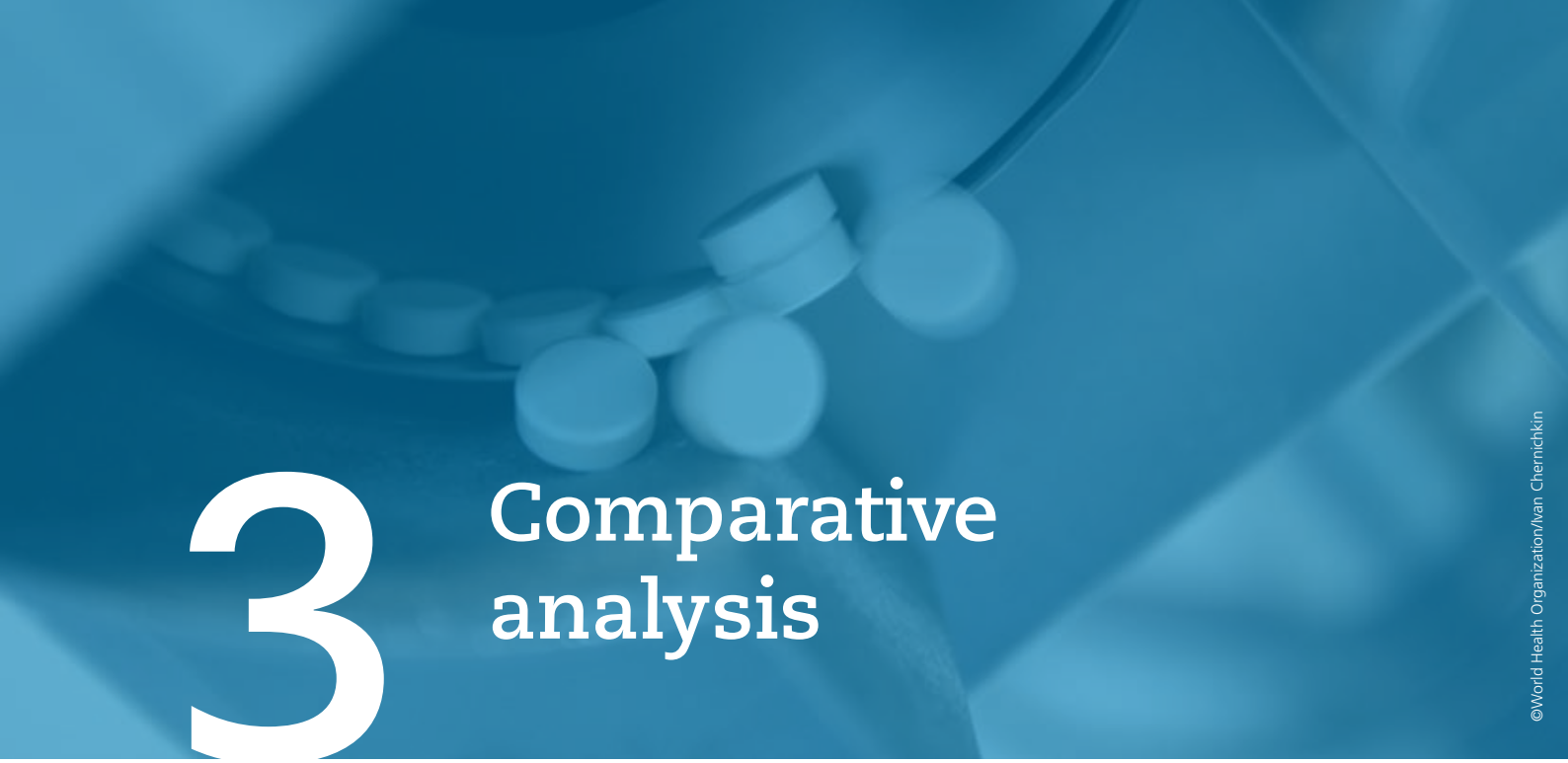
Major findings were summarized in a working document;[1] this was translated into Russian and shared with EECA PPRI network members for review. It was validated on a point-by-point basis by the network members during the EECA PPRI meeting in May 2018. Follow-up input (new information and corrections) was also considered, and the authors clarified some open points on a bilateral basis with a few countries.

Information was collected through other channels from the two countries (Turkmenistan and Ukraine) that had not produced a PPRI country profile: during a visit by WHO staff to Turkmenistan in November 2018, through information provided by Ukraine to the overarching PPRI network in recent years and via WHO's evaluation of the Affordable Medicines Programme in Ukraine.

In addition, general data and information pertaining to the organization and funding of nine of the countries' health care systems were retrieved from health system reviews in the Health Systems in Transition series published by the European Observatory on Health Systems and Policies *(11–19)*.

Annex 1 outlining the HIV, hepatitis and TB medicines in countries in eastern Europe and central Asia was mainly informed by data provided by EECA PPRI network members through a poster using a template developed by the PPRI Secretariat. Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Ukraine and Uzbekistan submitted country posters. Each country was asked to complete and present their findings during the meeting in Baku, Azerbaijan in 2018. The relevant WHO country office validated the information provided by each country.

[1] The working document did not contain information on Georgia, which submitted its PPRI country profile in September 2018.



3 Comparative analysis

This chapter provides a comparative overview of key facts and figures of the pharmaceutical policy framework in the 11 surveyed countries of the EECA PPRI network.

3.1 Health system organization and funding

In most of the countries surveyed, health care is based on a single-payer national health service (NHS) or on a mixed system (Armenia, Kyrgyzstan). Only the Republic of Moldova has a pure social health insurance (SHI) system. In accordance with the organization of the health system, funding is based on taxation (NHS), contributions (SHI) or a combination of both (Table 3.1).

Countries have made major progress towards UHC in recent years and have high coverage of health care, although only for a limited set of health services. At the same time, out-of-pocket (OOP) payments are still high; for example, OOP expenditure on health care represented 36% of total health care expenditure in Kazakhstan in 2016. In general, eastern European and central Asian countries including Armenia, Kazakhstan, Kyrgyzstan and Uzbekistan reported increases in OOP payments (see section 3.3 for more information).

Some countries have implemented reforms recently or are in the process of reforming health care services, including the pharmaceutical sector, as the following examples show.

- In Armenia a medicines law was adopted in 2016, covering both medicine safety and availability/affordability issues. During the country's "Overcoming diabetes together" programme of 2015–2019, children and young people below the age of 22 years are given free insulin analogues and insulin pen-injectors.
- In Azerbaijan external price referencing (EPR) and internal price referencing (IPR) were introduced as policies for medicines (see section 3.4.2), and in 2017 a pilot project was launched to implement compulsory health insurance. Mandatory health insurance implementation throughout the country is planned to start with effect from 1 January 2020. On 30 March 2019 the government adopted a decree to expand medicines coverage for the population. Socially vulnerable groups at the primary health care level (around 200 000 people) are able to access specific medicines free of charge, and antiretroviral treatment for hepatitis C is also available free of charge for the entire provision.

Table 3.1 | Organization and funding of the health care system in EECA PPRI network countries, 2018

Country	NHS/SHI	Centralization	Population coverage	Funding of publicly subsidized health services
Armenia[a]	Mixed NHS/SHI	Decentralized	99.9%[b]	Mixed funding: taxation, SHI contributions
Azerbaijan	NHS	Centralized	Universal	Predominantly tax-based funding
Belarus[c]	NHS	No information available	Universal	Predominantly tax-based funding
Georgia	NHS	Decentralized	Almost universal, but only for a small publicly funded benefit package	Predominantly tax-based funding
Kazakhstan	NHS	Decentralized	Universal	Predominantly tax-based funding
Kyrgyzstan	Mixed NHS/SHI	Centralized	Universal	SHI contributions and tax transfer from central government
Republic of Moldova	SHI	Centralized	87%	SHI contributions and tax transfer from central government
Tajikistan	NHS	Centralized	Universal	Predominantly tax-based funding
Turkmenistan	NHS	Centralized	Universal	Predominantly tax-based funding
Ukraine	NHS	Decentralized and centralized	Universal	Predominantly tax-based funding
Uzbekistan	NHS	Decentralized	Universal	Predominantly tax-based funding

a Armenia does not have a classic SHI system applied to the entire population. Instead, the government ensures the health of state employees (around 100 000 people) by contracting private insurance companies to provide mainly hospital treatment of diseases requiring surgery.

b The level of population health coverage in Armenia varies based on the type of service. In general, primary health care consultation and some diagnostic services are free of charge for the entire population. Hospital services for blood-borne pathogens only cover 19 vulnerable and special groups, according to a government decree of 2004, updated in 2019, representing 50–55% of the population.

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

Sources: WHO health system reviews (11–19).

- In Belarus a decree was adopted in 2018 to regulate, based on EPR, prices of 37 international nonproprietary names (INNs), including 21 INNs for cardiovascular medicines and 16 INNs for oncology medicines, as a pilot project from 2019 to 2020. The aim is to develop the methodology and eventually expand the list of medicines included.
- In Georgia a universal health care programme that provides access to outpatient care, emergency inpatient care, elective surgery, chemo-, hormone and radiotherapy, vaginal delivery and caesarean section and basic medicines was introduced in 2013; this led to a significant increase in service coverage of the population.
- Kazakhstan is working on the introduction of a mandatory health insurance fund (MHIF), which would act as the single pool of revenue and buyer of services (implementation is expected by 2020).
- In Kyrgyzstan a reform aiming to introduce medicine price regulation is ongoing.

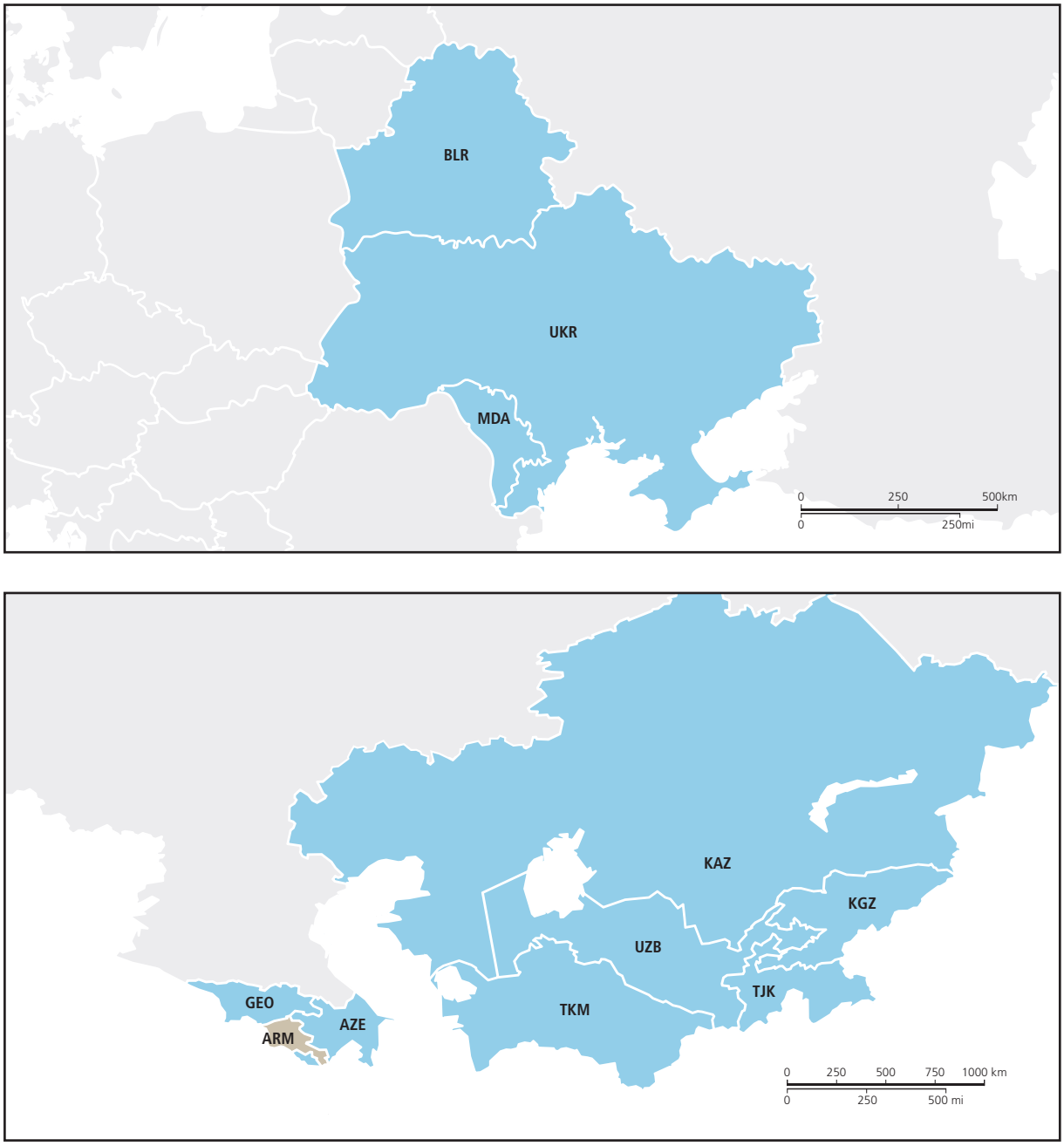
3.2 Pharmaceutical policy framework

Most surveyed EECA PPRI network countries have a national medicine policy in place (Fig. 3.1). A legal framework regulates coverage of medicines in all countries surveyed.

Table 3.2 | Key authorities for marketing authorization, pricing and reimbursement of medicines in EECA PPRI network countries, 2018

Country	Marketing authorization	Pricing		Reimbursement decision	
		Outpatient	Inpatient	Outpatient	Inpatient
Armenia	Scientific Centre of Drug and Medical Technology Expertise	Not applicable (no price regulation)	Not applicable (no price regulation)	Ministry of Health	Ministry of Health
Azerbaijan	Ministry of Health	Tariff (Price) Council	Tariff (Price) Council	Ministry of Health	Ministry of Health
Belarus	Ministry of Health	Ministry of Health, Ministry of Antimonopoly Regulation and Trade	Ministry of Health	Ministry of Health	Ministry of Health
Georgia	National Medicines Regulatory Authority	Not applicable (no price regulation)	Not applicable (no price regulation)	Ministry of Health	Ministry of Health
Kazakhstan	National Centre for Expertise of Medicines, Medical Devices and Medical Equipment	Ministry of Health	National Centre for Expertise of Medicines, Medical Devices and Medical Equipment	Ministry of Health	Ministry of Health
Kyrgyzstan	Department of Drug Provision and Medical Equipment under the Ministry of Health	Not applicable (no price regulation)	Not applicable (no price regulation)	Ministry of Health and MHIF	Ministry of Health and MHIF
Republic of Moldova	National Medicines Regulatory Authority	National Medicines Regulatory Authority	National Medicines Regulatory Authority	Ministry of Health (Reimbursement Committee within the Ministry)	Ministry of Health
Tajikistan	National Medicines Regulatory Authority (State Supervision Service for Health care and Social Protection)	Not applicable (no price regulation)	Not applicable (no price regulation)	Ministry of Health	Ministry of Health and Social Protection
Turkmenistan	Ministry of Health (Department of Medical Technical Appliances)	Not applicable (no price regulation)	Not applicable (no price regulation)	No information available	No information available
Ukraine	Ministry of Health, Ministry of Health State Expert Centre	Ministry of Health	Ministry of Health	Ministry of Health	Ministry of Health
Uzbekistan	State Centre for Evaluation and Standardization of Medicines, Medical Devices and Medical Equipment	Ministry of Trade	Treasury, a structure within the Ministry of Health	Ministry of Health and Ministry of Finance	Ministry of Health

Fig. 3.1 | Existence of national medicine policy in EECA PPRI network countries, 2018



The ministry of health is a key public authority responsible for pharmaceutical policy decisions, implementation of marketing authorization and pricing of medicines (if applicable; only in countries with price regulation) (Table 3.2). In some countries, marketing authorization is the responsibility of the national regulatory authority, usually within the remit of the ministry of health. Although the ministry of health may decide on reimbursement issues including which medicines, diseases and/or population groups are included in the benefit package scheme, the public payer (i.e. the entity that disburses funds) may be a different institution.

3.3 Key data on the pharmaceutical system

The number of medicines with a valid marketing authorization varies, ranging from approximately 4300–4500 in Azerbaijan, Armenia, Belarus and Tajikistan and 5600 in Kyrgyzstan to 10 300 in Ukraine and 12 000 in Georgia. In Belarus, Turkmenistan and Ukraine, locally produced medicines account for important market shares in both value and volume, and local production has also a growing role in Armenia, although it is comparatively low in other countries (Table 3.3).

OOP payments are high. WHO data show that patients in these countries bear important and sometimes the greatest share of total health expenditure. In addition, further analysis has demonstrated that outpatient medicines represent the main driver of OOP payments *(8)*.

Table 3.3 | Data on pharmaceutical production, market and funding of medicines in EECA PPRI network countries, 2018 (or latest year available)

Country	Local production	Number of medicines registered	Total pharmaceutical expenditure (US$, 2016)	OOP payments as a proportion of health expenditure[a]	Proportion of total pharmaceutical expenditure paid privately
Armenia	Growing, with an annual growth rate of 20% in the last five years (US$ 15 million in 2015)	4583	around 390 million (2017)[b]	81%	No information available
Azerbaijan	< 2%	4483	No information available	79%	No information available
Belarus[c]	Domestic medicines account for 53% of the market in value; around 70% in volume	4229 (1 February 2019)	around 406 million (2018)	36%	No information available
Georgia	Not considered large (US$ 362.3 million in 2016)	12 000	around 435.6 million	56%	65%
Kazakhstan[d]	10–15% of pharmaceutical market (in value)	around 8100	around 1369 billion	36%	86% (2016)
Kyrgyzstan	Volume of domestic medicines and medical devices around 3% of total imports of pharmaceutical products	5600	No data available	58%	No information available
Republic of Moldova	Around 8% of pharmaceutical market (in value)	5327	50 191 million	46%	66% (2016)
Tajikistan	Around 10% of pharmaceutical market (in volume)	4500	around 4.45 million	66%	63% (2017)

Table 3.3 | Contd.

Country	Local production	Number of medicines registered	Total pharmaceutical expenditure (US$, 2016)	OOP payments as a proportion of health expenditure[a]	Proportion of total pharmaceutical expenditure paid privately
Turkmenistan	Around 40% of the total market (in volume)	No information available	No information available	76%	No information available
Ukraine	Around 70% of the pharmaceutical market volume; 40% in value	10 268, of which 3404 produced locally and 6882 imported	No information available	54%	90%
Uzbekistan	No information available	8625	No information available	52%	No information available

a Data from WHO global health expenditure database *(20)*.

b According to the National Health Accounts of Armenia for 2018, total pharmaceutical expenditure was estimated at US$ 389 849 187.90 in 2017

c Medicines in Belarus are funded by a national budget; data on further expenditure for the purchase of medicines at a regional level are not available

d Data on pharmaceutical expenditure (including OOP payments) in Kazakhstan refer to pharmaceuticals and medical devices.

3.4 Pricing policies in the outpatient sector

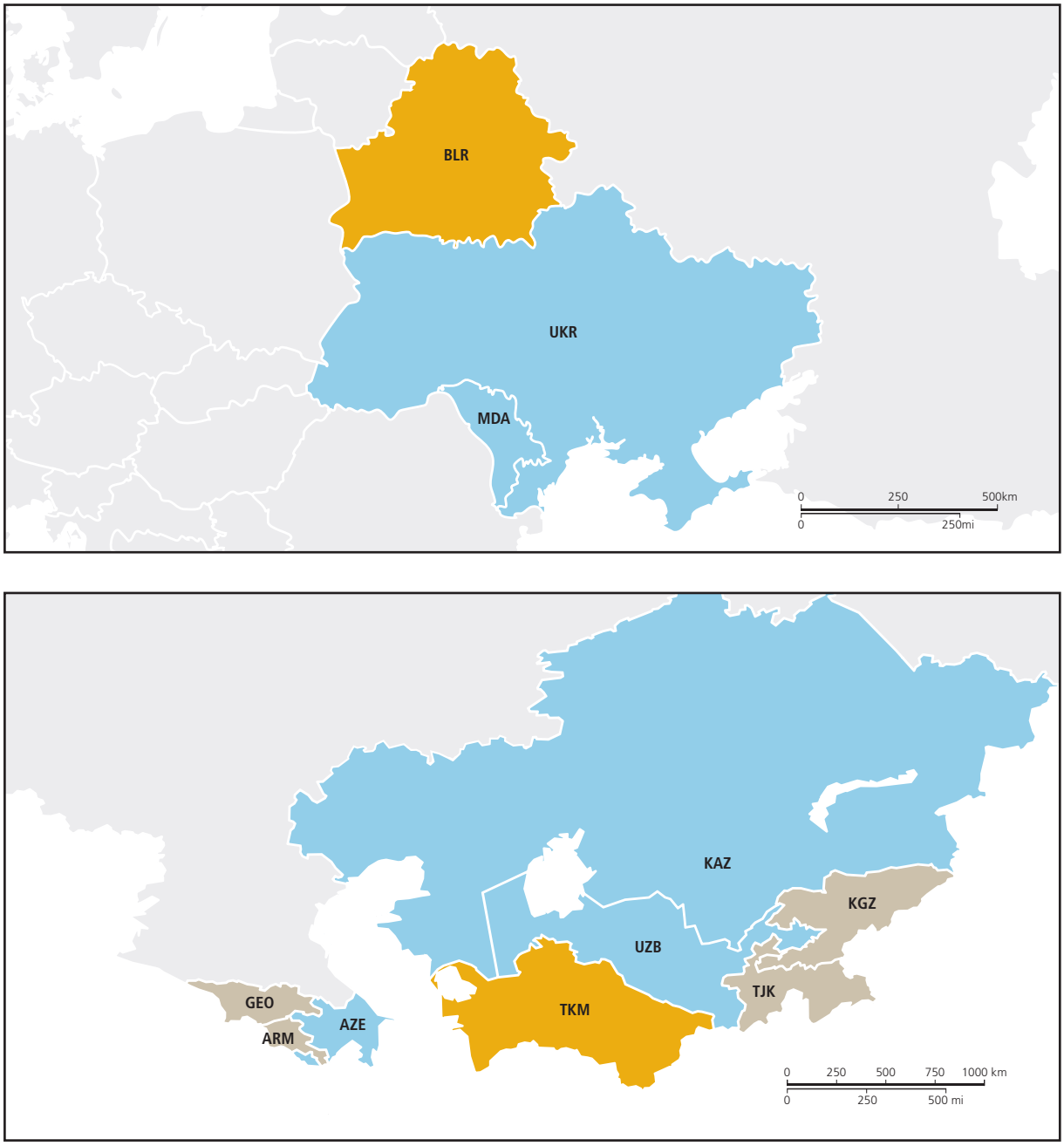
3.4.1 Types of price regulation

Seven (Azerbaijan, Belarus, Kazakhstan, the Republic of Moldova, Turkmenistan, Ukraine and Uzbekistan) of the 11 countries have a form of price regulation in place for at least some outpatient medicines. In some countries price regulation covers a small group of medicines (for example, 112 medicines in Uzbekistan that are considered "socially important"); in others all medicines are price-regulated. For example, Azerbaijan regulates wholesale and pharmacy retail prices of all state-registered medicines (in both the outpatient and inpatient sectors).

In countries with price regulation, price control involves setting the first regulated price (usually the ex-factory price) and prices along the supply chain. In Belarus and Turkmenistan only distribution margins are regulated, while the other five countries have full price regulation for some medicines.

Armenia, Georgia, Kyrgyzstan and Tajikistan have no form of price regulation. The only regulated prices are set when central procurement is undertaken. Armenia and Kyrgyzstan are working on the introduction of price regulation. In Kyrgyzstan, the legal basis that allows the government to regulate medicine prices was approved in 2017; the methodology is being developed and a pilot project is planned for 2019. In Armenia the Scientific Centre of Drug and Medical Technology Expertise developed a methodology for price regulation of medicines; the necessary normative documents are being established on this basis (Fig. 3.2).

Fig. 3.2 | Price regulation of outpatient medicines in EECA PPRI network countries, 2018



Full price regulation refers to the regulation of all price types, i.e. ex-factory, wholesale and pharmacy retail prices. In contrast, the regulation of distribution margins only relates to price regulation in the supply chain. Distribution margins are only applicable in the outpatient sector.

3.4.2 Pricing policies in countries with full price regulation

In five (Azerbaijan, Kazakhstan, the Republic of Moldova, Ukraine and Uzbekistan) of the seven countries with full price control (i.e. regulation of ex-factory, wholesale and pharmacy retail prices) for at least some of the outpatient medicines, price regulation has been introduced on a legislative basis, usually through enactment of a law and sometimes accompanied by procedural rules. Most countries regulate at the level of the ex-factory price; Ukraine determines the "reference price", which corresponds to the wholesale price level in other countries. Azerbaijan regulates prices at the wholesale and pharmacy retail level. A conditional ex-factory price is calculated using both EPR and IPR. In Belarus, the current regulation of distribution mark-ups has been extended to full regulation in 2019, as part of a pilot project applicable to 21 cardiovascular INNs and 16 cancer INNs. All countries with full price regulation apply the policy of EPR (Table 3.4).

The Republic of Moldova applies IPR to determine the median reimbursement price for similar medicines from different manufacturers; this is done based on the price of 50 pharmacies chosen at random. The generic medicine price is not permitted to exceed 75% of the originator price. In Azerbaijan a generic price link is applied: the generic medicine price is not permitted to exceed 80% of the originator price.

Azerbaijan, Kazakhstan and the Republic of Moldova usually have price revisions on an annual basis (see Table 3.2). Kazakhstan aims to shorten intervals between price revisions. Overall, EECA PPRI network countries with full price regulation envisage regular price reviews (Table 3.4).

Table 3.4 | Price regulation and pricing policies in EECA PPRI network countries, 2018

Country	Price type regulated	Medicines Covered	Policies		Revision
			EPR	IPR	
Armenia	*No price regulation*				
Azerbaijan [a]	Full price regulation	All state-registered medicines	Yes	Yes	On an annual basis
Belarus	Regulation of the distribution margins, pilot project for full price regulation from 2019	Regulation of distribution mark-up for all medicines, full price regulation (based on EPR) for 37 INNs (cardiovascular and cancer medicines)	Pilot project for two medicines groups from 2019	No	No information available
Georgia	*No price regulation*				
Kazakhstan[b]	Full price regulation	Since 2018: reimbursable medicines (since 2019: all medicines)	Yes	No	Currently annual; shorter intervals (twice a year) planned for the future
Kyrgyzstan	*No price regulation*				
Republic of Moldova	Full price regulation	All authorized medicines	Yes	Yes	Annually
Tajikistan	*No price regulation*				
Turkmenistan	Regulation of distribution margins	All medicines	No	No	No information available

Table 3.4 | Contd.

Country	Price type regulated	Medicines Covered	Policies		Revision
			EPR	IPR	
Ukraine[c]	Full price regulation	Reimbursable medicines (included in the Affordable Medicines Programme and state programme on insulin); regulation of distribution margins for all medicines in the national essential medicines list (NEML)	Yes	Yes	Every six months for medicines included in the Affordable Medicines Programme
Uzbekistan	Full price regulation	112 socially important medicines	Yes	No	Quarterly

Note: Full price regulation refers to the regulation of all price types – i.e. ex-factory, wholesale and pharmacy retail prices. In contrast, regulation of distribution margins only relates to price regulation in the supply chain. Distribution margins are only applicable in the outpatient sector.

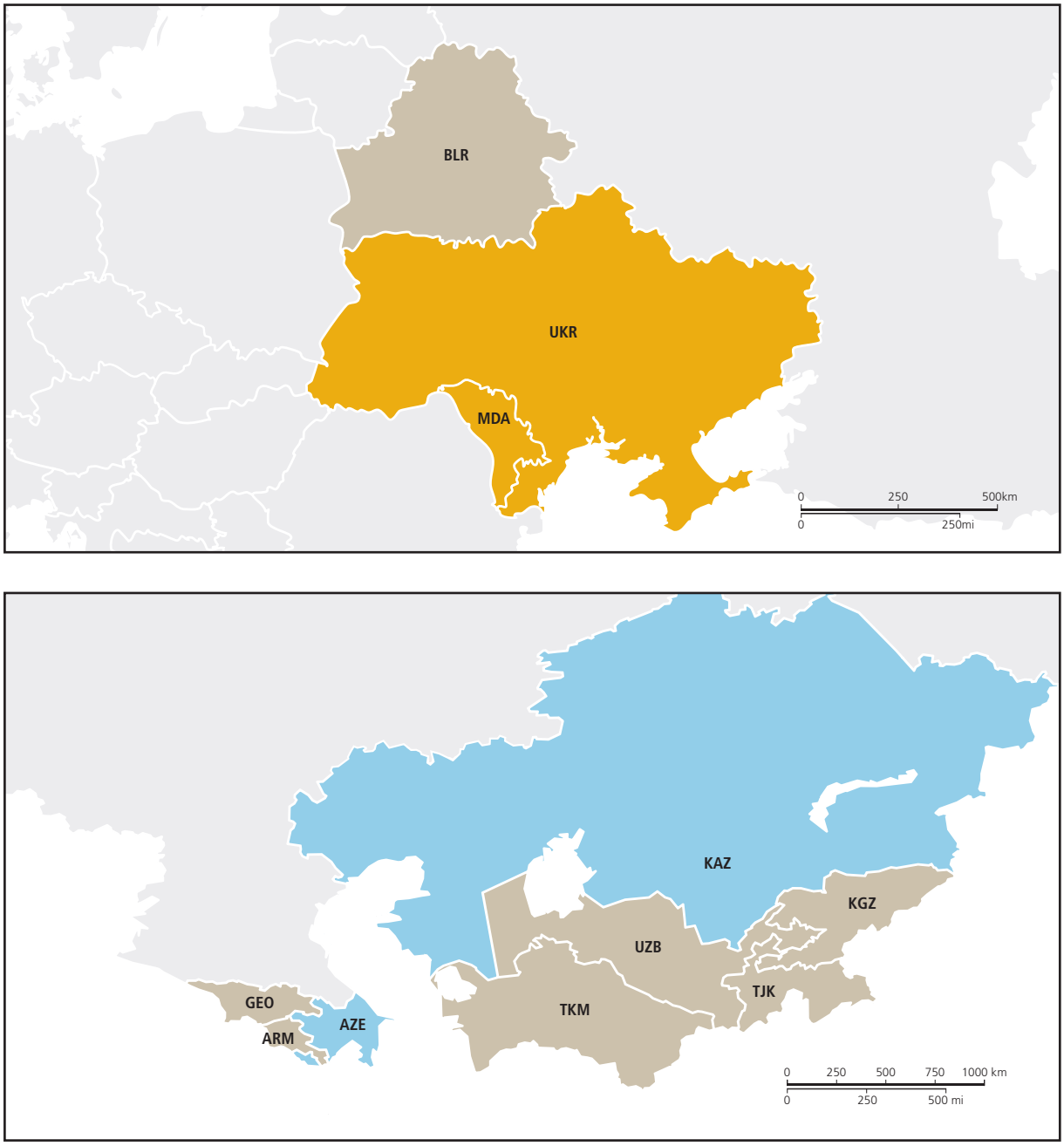
a In Azerbaijan regulation states that prices must be uniform across pharmacies throughout the country, but some variation still exists among pharmacies.

b In Kazakhstan medicines are subsidized through the Guaranteed Free Health Package.

c In Ukraine 23 INNs are included in the Affordable Medicines Programme. The extent of the pharmacy retail mark-up varies, depending on whether medicines are included in the Affordable Medicines Programme or purchased from centralized budget.

EPR is the practice of using the price of a medicine in one or several countries to derive a benchmark or reference for the purpose of setting or negotiating its price *(10)*. This policy is used all over the world. In 2018 (the year of the survey), five EECA PPRI network countries have introduced full price regulation (Fig. 3.3). Belarus introduced it on a pilot basis for a small sample of medicines in 2019. Price regulation at the ex-factory (or wholesale) level has only been implemented in the last few years, with these countries choosing to apply EPR as a pricing policy when regulation was introduced. In Kyrgyzstan, with the implementation of price regulation, a pilot project using EPR with 10 reference countries is planned. As part of its EPR policy, Azerbaijan also recognizes the importance of developing measures to address the impact of short-, medium- and long-term exchange rate fluctuations of various currencies that make up its external reference basket versus the Azerbaijani manat when calculating and updating medicine prices.

Fig. 3.3 | Use of EPR as pricing policy for outpatient medicines in EECA PPRI network countries, 2018



Belarus: more than 10 reference countries in the EPR pilot starting in January 2019.

Countries applying EPR tend to use a large basket (Fig. 3.3). The largest basket was found in Kazakhstan, which changed its EPR methodology in 2018 from nine to 39 reference countries. In 2019 Kazakhstan is expected to undergo another review of its reference countries list. The reference countries used by EECA PPRI network countries are usually European. Ukraine applies two different country baskets for two programmes.

To determine the benchmark price, countries take either the lowest price of the reference countries or some weighted average (such as the average of the lowest three or five reference countries in a larger country basket, Table 3.5). None of the countries surveyed apply purchasing power parity, gross domestic product or any other economic indicator to adjust the price data of the countries in the reference basket.

Table 3.5 | EPR as pricing policy for outpatient medicines in EECA PPRI network countries, 2018

Country	EPR applied	Reference countries	Calculation of reference price	Impact of EPR
Armenia	*No ex-factory price regulation, so no EPR*			
Azerbaijan	Yes, since June 2015	Bulgaria, France, Greece, Hungary, Italy, Poland, Portugal, Slovenia, Spain, Turkey (10 countries)	The price corresponds to the lowest official ex-factory price (excluding value-added tax (VAT)) in the reference countries. If the medicine has no official price in the reference countries, the reference price is calculated from the price in the country where the medicine was manufactured, imported or formed pharmaceutically. In the absence of any of such information, the price proposed by the manufacturer is taken as a basis.	Reductions in prices (by, on average, 27% in 2014–2015 and 41% in 2015–2016); increases in volume (by 20% in 2015–2016)
Belarus	From 2019 on as a pilot project	Armenia, Bulgaria, Czechia, Estonia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Poland, Republic of Moldova, Romania, Russian Federation, manufacturer country (14 countries)	Average of the lowest ex-factory prices per INN	Not applicable
Georgia	*No ex-factory price regulation, so no EPR*			
Kazakhstan[a]	Yes, for reimbursed medicines only	Armenia, Australia, Austria, Belarus, Belgium, Canada, Chile, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Israel, Ireland, Italy, Japan, Kyrgyzstan, Latvia, Luxemburg, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, United States of America (39 countries)	The ex-factory price must be equal to or lower than the average of the five lowest ex-factory prices in the reference countries.	Reductions in prices of new medicines and of generics, leading to considerable savings for the state budget

Table 3.5 | Contd.

Country	EPR applied	Reference countries	Calculation of reference price	Impact of EPR
Kyrgyzstan	*No ex-factory price regulation, so no EPR (introduction on pilot basis is planned)*			
Republic of Moldova	Yes, since 2010	Bulgaria, Croatia, Czechia, Greece, Hungary, Lithuania, Romania, Serbia, Slovakia (9 countries)	The price corresponds to the average of the lowest three prices in the reference countries.	Reductions in ex-factory prices, but a tendency to lower the number of medicines in the market
Tajikistan	*No ex-factory price regulation, so no EPR*			
Turkmenistan	*No ex-factory price regulation, so no EPR*			
Ukraine[b]	Yes	Czechia, Hungary, Latvia, Poland, Slovakia for the Affordable Medicines Programme. (5 countries) Bulgaria, Czechia, Hungary, Latvia, Republic of Moldova, Poland, Serbia, Slovakia for the state programme on insulin (8 countries)	For the 23 INNs included in the Affordable Medicines Programme, maximum wholesale prices (per defined daily dose) in five reference countries are collected and used to define a median reference price. Brand-name generics priced at the reference price or below are included in the reimbursement programme (thus, all brand-name generics priced higher are not reimbursed).	Reductions in prices for insulins and for medicines included in the Affordable Medicines Programme were observed with the introduction of EPR
Uzbekistan	Yes	No specific reference countries defined	No information available	No information available

a Kazakhstan used to have nine reference countries (Austria, Belarus, Czechia, Hungary, Latvia, the Russian Federation, Turkey, Ukraine and the United Kingdom); the basket was extended in 2017. Discussions are ongoing to reduce the number of reference countries and keep only Azerbaijan, Belarus, Bulgaria, Croatia, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Romania, the Russian Federation, Slovakia, Slovenia and Turkey.

b In Ukraine EPR is only used for reimbursed medicines included in the Affordable Medicines Programme and for the state programme on insulin (with different reference countries).

The evidence shows that some countries achieved reductions in medicine prices after the introduction of EPR. In Azerbaijan, for instance, the average import price of medicines per pack (99% of all medicines consumed are imported) dropped from US$ 3 in 2014 to US$ 2.2 in 2015 and US$ 1.3 in 2016. In some cases, pharmacy retail prices decreased 5–10 times, and consumption increased at the same time. In Kazakhstan savings for the state were also achieved through lower medicine prices, but the authorities were confronted with an announcement from manufacturers that they would withdraw approximately 30–40 medicines from the market. The amount was not considered to be of critical relevance, however. Similarly, indications for a possible withdrawal of medicines from the market were also reported in the Republic of Moldova.

3.4.3 Regulation of distribution margins

In addition to medicine price regulation at ex-factory price level, control of distribution margins is key for equitable access to affordable medicines, to ensure that patients can receive medicines at the same price across the whole country. As shown in Fig. 3.4, Azerbaijan and Kazakhstan have regulations in place to ensure that patients pay the same price at any pharmacy across the country for all medicines

or for price-regulated medicines, respectively. However, enforcement of these regulations can vary, resulting in differences in medicine prices across some pharmacies.

Seven (Azerbaijan, Belarus, Kazakhstan, the Republic of Moldova, Turkmenistan, Ukraine and Uzbekistan) of the 11 countries surveyed have (or will have, from January 2019) regulated wholesale and pharmacy remuneration. The scope of regulation of wholesale and pharmacy remuneration addresses all (authorized) medicines in some countries – not only those reimbursed. Regulation of the remuneration of supply chain actors is always designed to take into account the price of the medicines: countries have either a linear mark-up (Ukraine, Uzbekistan) or a regressive scheme (Belarus, the Republic of Moldova). In Ukraine, the maximum pharmacy retail mark-ups vary depending on the medicines (10% for medicines in the NEML procured from state budget, such as insulins in the state programme, 15% on medicines included in the Affordable Medicines Programme and 25% on medicines in the NEML not procured from the state budget), whereas wholesale mark-up for all these groups of medicines is defined as a maximum 10%. None of the countries reimburse community pharmacies for services via a dispensing fee or similar price-independent remuneration.

Even in countries with regulated wholesale mark-ups, wholesale companies are still allowed to receive discounts from manufacturers, and there is no cap on this. Such discounts were reported to be common practice, in countries both with and without wholesale mark-up regulation.

If remuneration for supply chain actors were not regulated, final consumer prices might increase considerably. Kazakhstan, which will introduce a pharmacy mark-up regulation in 2019, reported that although the generally accepted mark-up is around 25–30% (and the planned mark-up scheme will be in that range), in reality, pharmacy mark-ups of 100% and more were frequently observed, especially in cases of limited availability in the market. Tajikistan reported average wholesale mark-ups of 10–15% and average retail mark-ups of 20–25%.

Table 3.6 sets out information on VAT on medicines, which is another factor of the final pharmacy retail price. As also shown in Fig. 3.4, several EECA PPRI network countries (such as Belarus, Georgia and Kyrgyzstan) have exempted medicines from VAT.

Table 3.6 | Pricing policies in the supply chain: wholesale and pharmacy remuneration regulation and VAT on outpatient medicines in EECA PPRI network countries, 2018

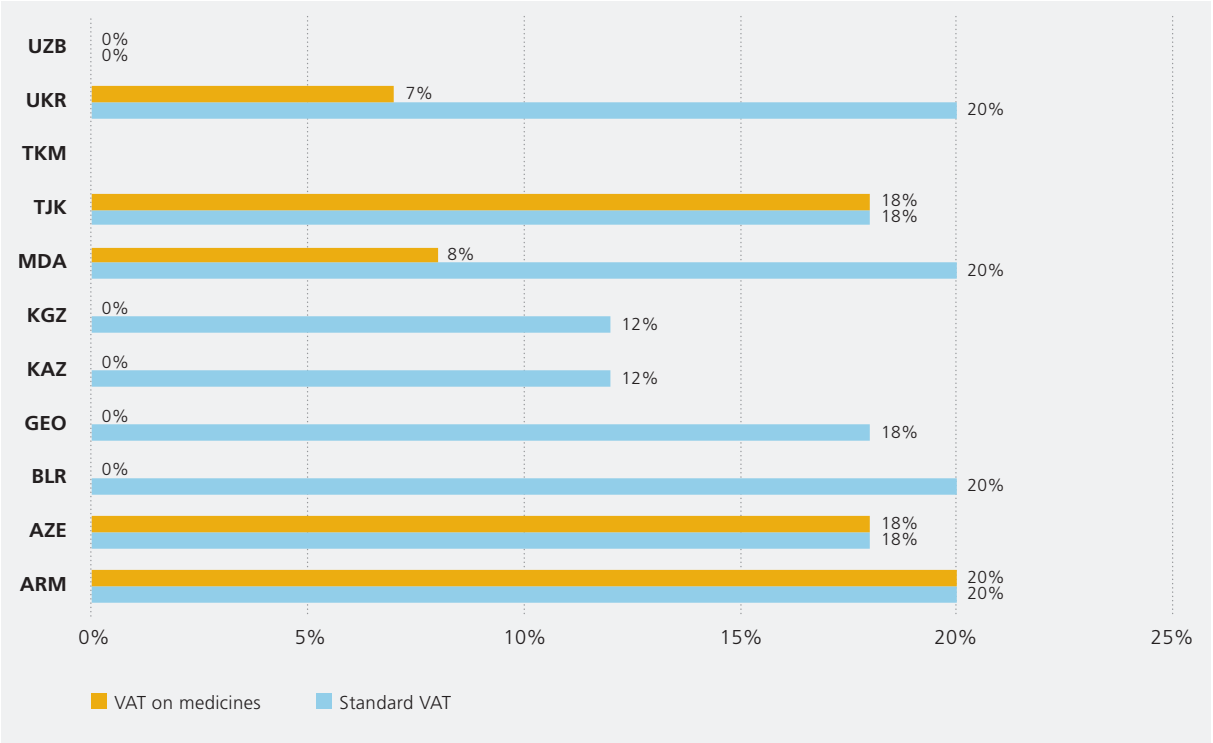
Country	Wholesale			Pharmacy			VAT on medicines
	Regulation	Scope	Type	Regulation	Scope	Type	
Armenia	No	Not applicable	Not applicable	No	Not applicable	Not applicable	20%
Azerbaijan	Yes	All medicines	Regressive mark-up scheme	Yes	All medicines	Regressive mark-up scheme	18%[a]
Belarus	Yes	All medicines	Regressive mark-up scheme	Yes	All medicines	Regressive mark-up scheme	0%
Georgia	No	Not applicable	Not applicable	No	Not applicable	Not applicable	0%
Kazakhstan	No	Not applicable	Not applicable	Not yet (under discussion)	Not applicable	Not applicable	0%
Kyrgyzstan[b]	No	Not applicable	Not applicable	No	Not applicable	Not applicable	0%/12%
Republic of Moldova	Yes	All medicines	Regressive mark-up scheme	Yes	All medicines	Regressive mark-up scheme	8%
Tajikistan[c]	No	Not applicable	Not applicable	No	Not applicable	Not applicable	18%
Turkmenistan	Yes	All medicines	Linear mark-up	Yes	All medicines	Linear mark-up	No information available
Ukraine	Yes	Reimbursed medicines (Affordable Medicines Programme, state programme on insulin) and medicines on the NEML	Linear mark-up	Yes	Reimbursed medicines (Affordable Medicines Programme, state programme on insulin) and medicines on the NEML	Linear mark-ups (different rates for reimbursed medicines and medicines on the NEML)	7%
Uzbekistan	Yes	All medicines	Linear mark-up of 15%	Yes	All medicines	Linear mark-up of 20%	0%

a Work is taking place in 2019 to reduce the VAT rate on medicines.

b Kyrgyzstan is working on introducing a wholesale and pharmacy remuneration regulation. Medicines included in the NEML are exempt from VAT; for all other medicines the standard VAT rate of 12% applies.

c In addition, Tajikistan applies 5% customs duty.

Fig. 3.4 | VAT rates on medicines, compared to other goods, in EECA PPRI network countries, 2018



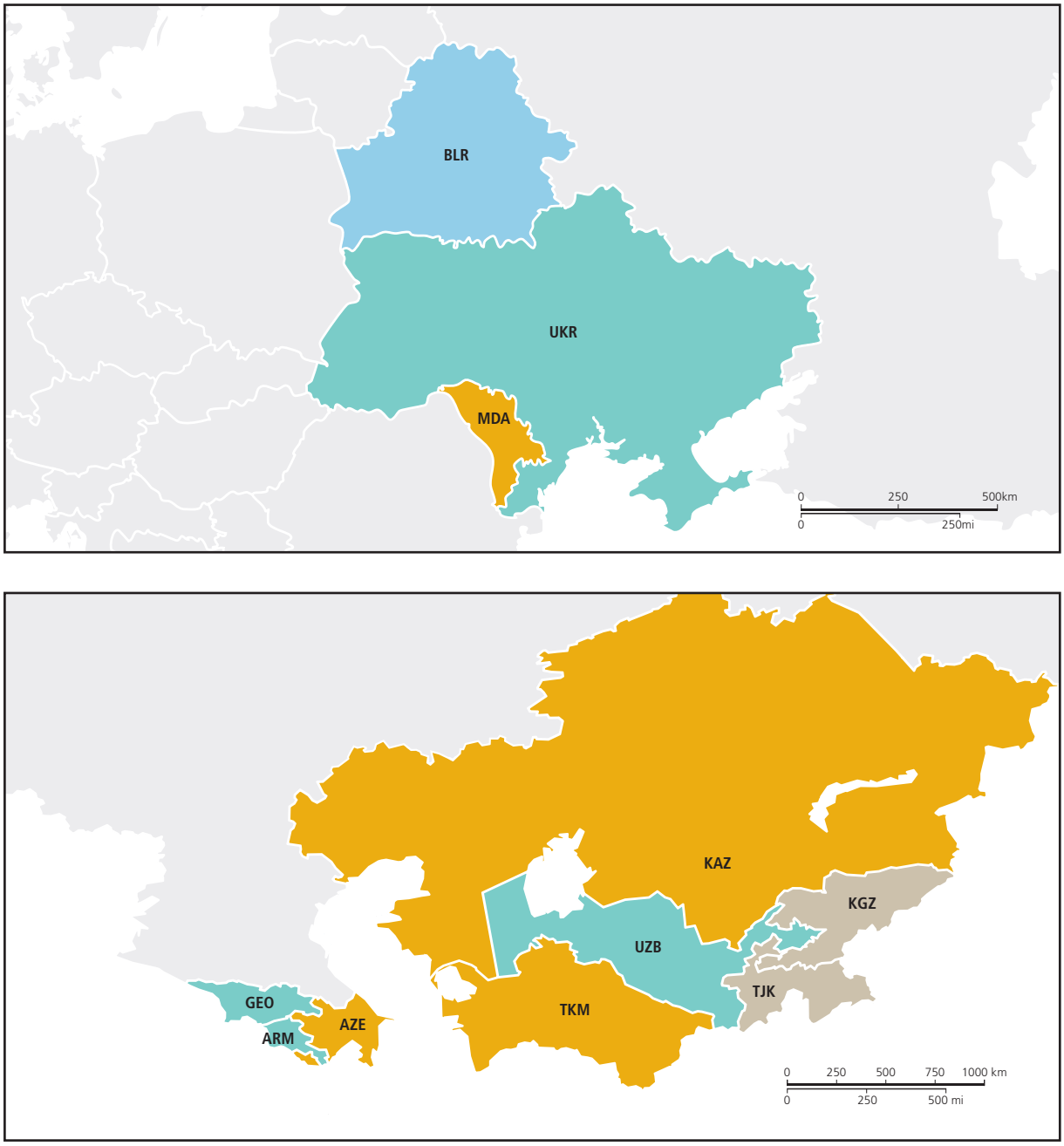
Notes: In Kyrgyzstan medicines in the NEML are exempt from VAT; for all other medicines the standard VAT rate of 12% applies. No information available was available for Turkmenistan.

3.5 Pricing and procurement policies in the inpatient sector

In the hospital sector medicines are mainly procured through a tendering process. In several countries (such as Ukraine), some medicines for the hospital setting are procured centrally, while others are procured individually by the hospitals. In Tajikistan, for instance, purchases at the level of hospitals are carried out by announcing an electronic tender through the Agency for State Procurement of Goods, Works and Services under the Government of Tajikistan, while centralized purchases of equipment are carried out through the Agency. Differences in hospital procurement exist between countries (Fig. 3.5). Hospitals in Belarus, for instance, do not engage in procurement individually, whereas in Kyrgyzstan each hospital is asked to develop a list of medicines (to be procured by their own means) and to have this list approved by the MHIF. Listed medicines must be included in the NEML, and up to 20% flexibility in the assortment is accepted. Purchase of medicines according to the NEML should not exceed 10% of the total funding directed to the purchase of medicines. In Kazakhstan procurement is done centrally as standard, through a sole distributor; in exceptional cases when the medicine in question has not been supplied – or not supplied on time – by the sole distributor, hospitals may purchase independently. Kazak hospitals are also allowed to collaborate and exchange medicines temporarily in cases of shortage. In the Republic of Moldova, centralized procurement is done by the Centre for Centralized Public Procurement in Health, which works separately from the National Medicines Regulatory Authority as the acting pricing authority (registering medicine prices after marketing authorization).

These procurement processes in the inpatient sector are usually separate from centralized purchases (e.g. for vertical programmes) from the national budget. In Kyrgyzstan, for instance, centralized purchases of insulin and its administration, vaccines, antihaemophilic factors, tuberculin and epochines are made based on national budget funds, while hospital facility procurement is as described above.

Fig. 3.5 | Central, regional and individual procurement of inpatient medicines in EECA PPRI network countries, 2018



Note: Kazakhstan has hospital facility procurement only in exceptional cases.

3.6 Reimbursement policies

3.6.1 NEML

Apart from Georgia, all countries investigated have a NEML (Fig. 3.6), containing around 300–650 INNs and often serving as a basis for further reimbursement lists, in either the outpatient or inpatient sectors, or both (Table 3.7).

Table 3.7 | NEMLs in EECA PPRI network countries, 2018

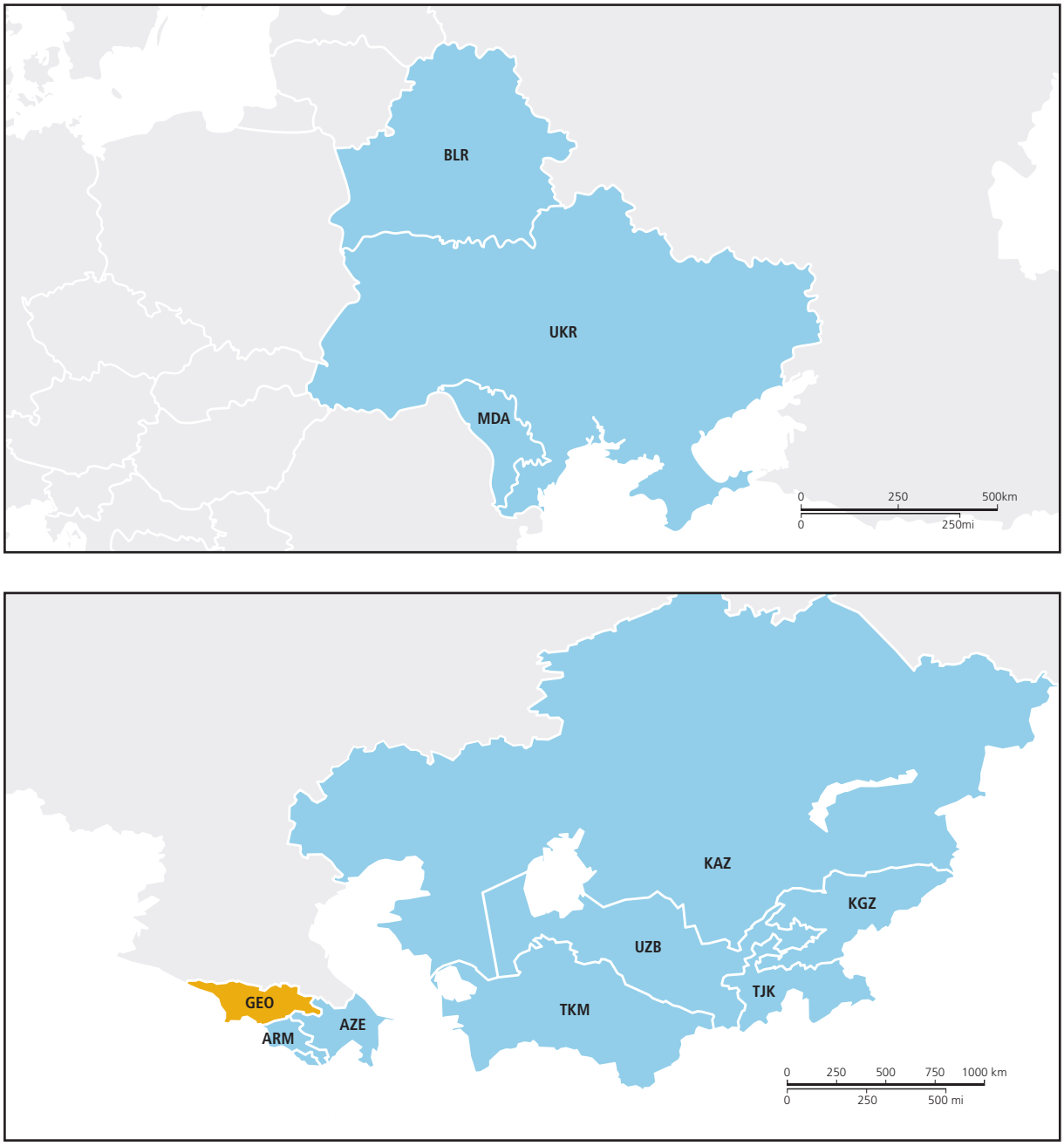
Country	Scope	Sector	Role	Procedure for listing/delisting
Armenia	409 INNs	No information available	Used for clinical guidelines, state purchase of medicines, donation management and reimbursement decisions	Decisions based on the following criteria: efficacy and safety of medicines; financial considerations; morbidity and mortality rates; structure of the prevalence of diseases; economic, genetic and demographic parameters; structure of health care institutions; experience and level of education of health care professionals
Azerbaijan	305 INNs	Outpatient and inpatient	Provides full state coverage (no OOP payments)	Ministry of Health responsible for development and revision of the NEML (every five years)
Belarus	460 INNs	Outpatient[a]	Provides partial or full coverage	Ministry of Health responsible for listing and delisting
Georgia	*No NEML*			
Kazakhstan[b]	930 INNs	Outpatient and inpatient	List of medicines that are publicly subsidized	Legal documents for revision being elaborated
Kyrgyzstan	409 INNs	Outpatient and inpatient	Basis for outpatient reimbursement list or hospital medicines lists	Based on government resolutions and MHIF rules
Republic of Moldova	650 INNs[c]	Outpatient and inpatient	Basis for the reimbursement list and hospital medicines lists	Permanent Commission of the Ministry of Health to evaluate the NEML, responsible for listing and delisting, based on a Ministry of Health decree
Tajikistan	340 INNs	Outpatient and inpatient	Basis for the reimbursement list, the public procurement of medicines, the preparation of clinical protocols and organization of donations	Revised every two years based on recommendations by WHO and national medical experts
Turkmenistan	432 INNs	Outpatient and inpatient	Some medicines may be dispensed free of charge (for oncology, opioids, insulin, etc.)	Defined by a joint decision from both the Ministry of Health and the medical industry
Ukraine	427 INNs	Outpatient and inpatient	Basis for other lists (list of outpatient medicines reimbursed via the Affordable Medicines Programme and list of hospital priority needs procured for state budget)	Not established
Uzbekistan	430 INNs	Inpatient	Corresponds to the list of medicines dispensed in hospitals	Based on criteria established in a Ministry of Health regulation

a In Belarus the NEML addresses the outpatient sector; in addition, a wider list of 820 INNs (the "Republican Formulary of Medicines") is provided to inpatients free of charge.

b In fact, there is no established NEML in Kazakhstan but a national formulary (which corresponds to the positive list of medicines reimbursed).

c In addition to the NEML the Republic of Moldova has a positive list (reimbursement list) for the outpatient sector of 148 INNs, since June 2018.

Fig. 3.6 | Existence of NEMLs in EECA PPRI network countries, 2018



3.6.2 National disease programmes

All countries surveyed have national government disease programmes (often called "vertical programmes") that include coverage of specific medicines. For instance, Ukraine has about 40 vertical programmes. As a rule, medicines included in these are provided free of charge to patients and are funded from the state budget.

Diseases and indications typically covered by these vertical programmes include:

- TB (all countries)
- HIV/AIDS (all countries)
- oncology (e.g. in Armenia, Azerbaijan, Belarus, Georgia, Ukraine, Uzbekistan)
- hepatitis C (e.g. in Belarus, Georgia, Kazakhstan, Turkmenistan, Ukraine)
- type 1 diabetes (e.g. in Armenia, Azerbaijan, Belarus, Georgia, Kyrgyzstan, Tajikistan, Ukraine)
- blood diseases (e.g. in Azerbaijan, Belarus, Ukraine)
- multiple sclerosis (e.g. in Azerbaijan, Belarus, Ukraine).

In addition, such programmes may also cover vaccines (as in Azerbaijan, Georgia and Ukraine), medication for mother-and-child health (as in Azerbaijan and Georgia) and mental health (as in Armenia, Georgia and Uzbekistan).

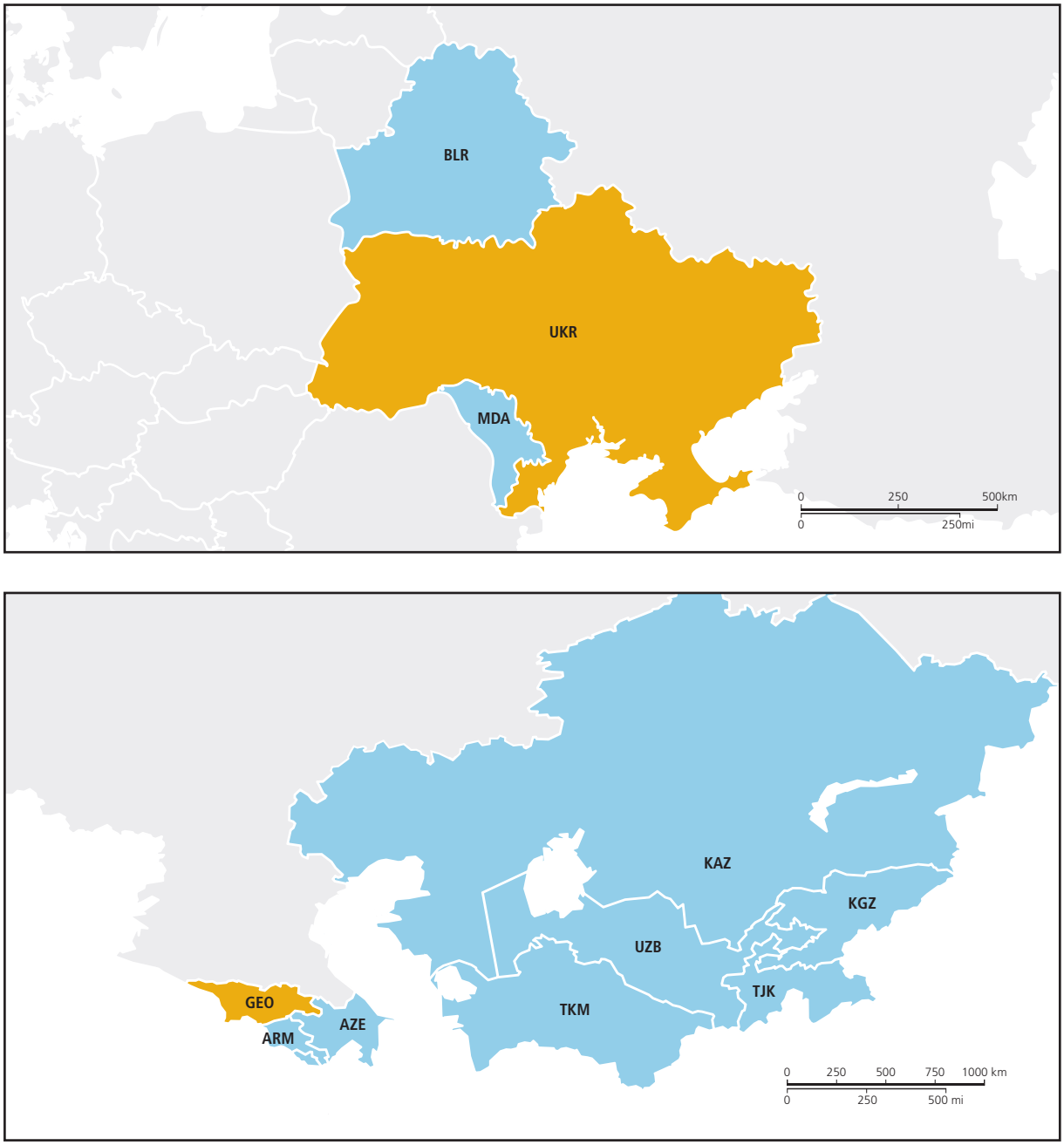
Details on HIV, hepatitis and TB medicines are provided in Annex 1: all surveyed countries have specific programmes for HIV and TB and provide free access to antiretroviral and TB medicines. Free access to hepatitis medicines is available in Azerbaijan, Belarus, Georgia, Kazakhstan, the Republic of Moldova and Turkmenistan.

In Azerbaijan and Kazakhstan, national authorities are solely responsible for the procurement of HIV, hepatitis and TB medicines; in the other countries procurement of some of these medicines is the responsibility of international donor organizations or the joint responsibility of national authorities and international organizations.

3.6.3 Reimbursement lists

Based on the NEML and vertical programmes, reimbursement lists (also called formularies or positive lists) have been developed. Most countries surveyed have such lists in place, either for both outpatient and inpatient sectors or for outpatient medicines only (Fig. 3.7).

Fig. 3.7 | Reimbursement lists for outpatient and inpatient medicines in EECA PPRI network countries, 2018



Reimbursement lists are usually based on the NEML (in Turkmenistan, for example) and are frequently guided by defined diseases whose treatment is considered of "social importance" (Table 3.8). While, except for Armenia and Uzbekistan, medicines in hospitals are provided free of charge (with no formal patient payments), patients have to co-pay a percentage share of the price of defined outpatient medicines included in the publicly subsidized benefits package scheme (so-called "reimbursable medicines") in some countries (including Belarus, the Republic of Moldova and Ukraine; Fig. 3.8).

Table 3.8 | Reimbursement lists for medicines in EECA PPRI network countries, 2018

Country	Reimbursement lists		Patient eligibility	Frequency of revision[a]
	Outpatient	Inpatient		
Armenia	Yes	Yes, national hospital pharmaceutical formulary	Outpatient and inpatient: due to specific diseases and population groups[b]	Three revisions since 2006
Azerbaijan	Yes (list of "vital medicines")	Yes, national hospital pharmaceutical formulary (146 INNs)	Outpatient: defined diseases; Inpatient: all inpatients	Every five years
Belarus	Yes (460 INNs)	Yes, national hospital pharmaceutical formulary (820 INNs)	Outpatient: depending on medicines listed, different reimbursement rates (100%, 90%, 50%) for different population groups; Inpatient: all inpatients	Annually
Georgia	Yes (> 100 medicines)	No, but clinical guidelines in place (medicines reimbursed as part of service)	Outpatient: depending on disease, social status and age of patients Inpatient: all medicines covered	Usually annually
Kazakhstan	Yes (399 INNs)	Yes	Outpatient: defined diseases and population groups; Inpatient: all inpatients	Outpatient: not specified by law – could be annually, but in practice every 3–4 years; inpatient: annually
Kyrgyzstan	Yes (58 INNs and 3 medical devices)	Yes, each hospital draws up its own pharmaceutical formulary (based on the NEML, with 20% flexibility allowed)	Outpatient: depending on medicines listed in Additional Drug Package against co-payment of around 50%; patients with chronic diseases on the list of medications included in the State-Guaranteed Benefits Programme against a co-payment of 10% Inpatient: all inpatients	Outpatient: as needed Inpatient: annually (in preparation of contracts for health care service with the MHIF)

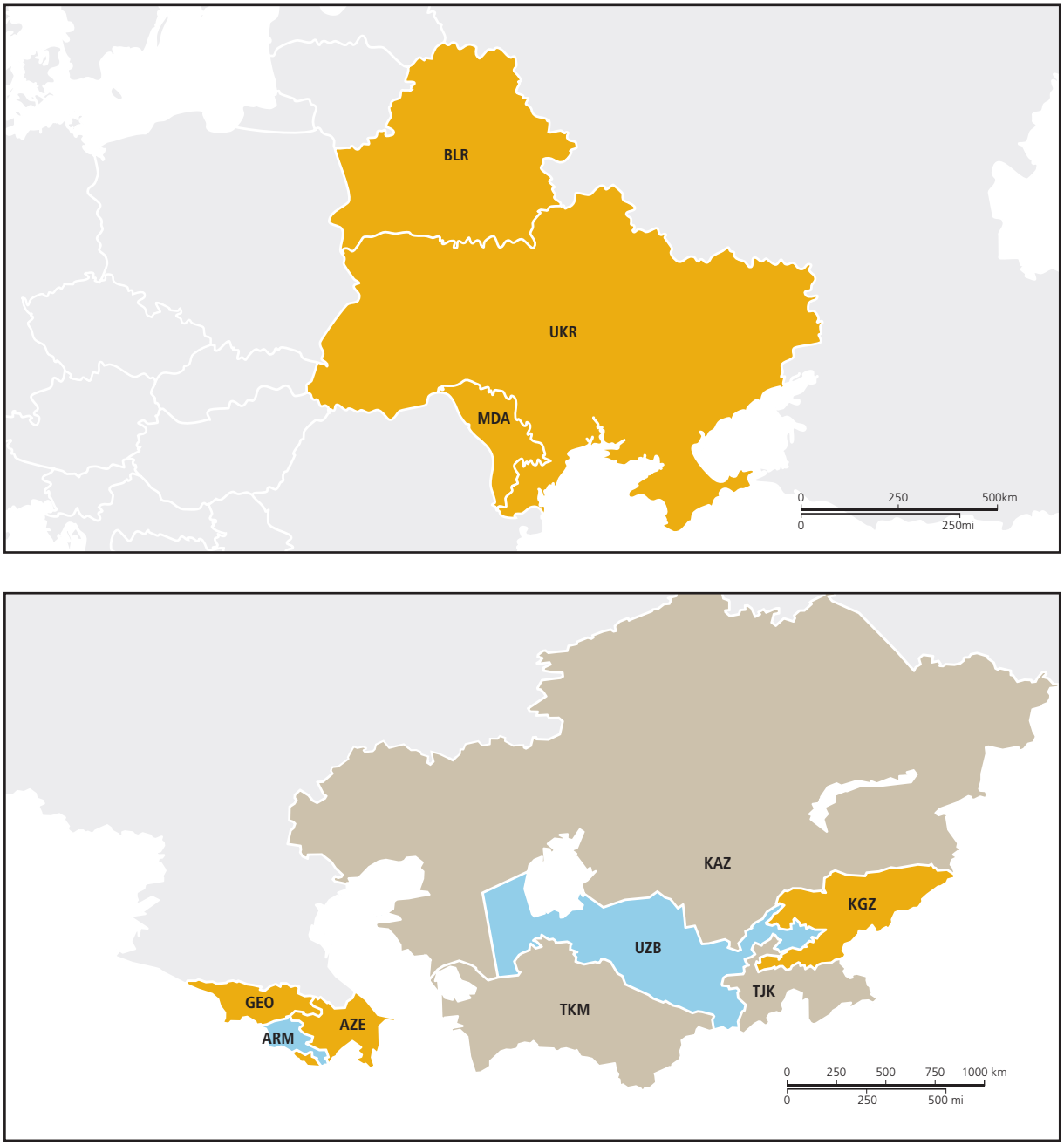
Table 3.8 | Contd.

Country	Reimbursement lists		Patient eligibility	Frequency of revision[a]
	Outpatient	Inpatient		
Republic of Moldova	Yes (148 INNs)	Yes, each hospital draws up its own pharmaceutical formulary, based on the national hospital pharmaceutical formulary (735 INNs, medicines included in vertical programmes are not included)	Outpatient: depending on medicines in defined disease groups as selected for inclusion in the reimbursement list (based on health technology assessment (HTA) and pharmacoeconomics); Inpatient: all inpatients	Outpatient: annually; inpatient: national hospital pharmaceutical formulary not changed since 2006 but annual revision of the hospital pharmaceutical formularies, in line with national clinical protocols and requirements for procurements
Tajikistan	Yes	Yes	Eligibility based on diseases (so-called "list 2") and on social status ("list 1")	At least every two years
Turkmenistan	Yes (some medicines included in the NEML)	Yes (some medicines included in the NEML)	All patients: some medicines are covered entirely (100%) and others only at 50%	
Ukraine	Yes (23 INNs)	No, but only medicines (427 INNs) included in the NEML can be dispensed	Outpatient: for all patients, a list of 23 INNs is reimbursed to cover cardiovascular diseases, type 2 diabetes and bronchial asthma – 100% reimbursement of the defined reimbursement tariff (but co-payments may still exist); Inpatient: all inpatients	No formal procedure in place
Uzbekistan	Yes	Yes, but must be part of the NEML (430 INNs)	Outpatient: list of socially important medicines for 13 defined diseases	As needed

a If not specified, this relates to outpatient reimbursement lists.

b Full coverage (100%) for patients with defined diseases and either full or partial (50% and 30%) coverage for defined population groups in outpatient and inpatient care.

Fig. 3.8 | Patient payments for publicly subsidized outpatient and inpatient medicines in EECA PPRI network countries, 2018



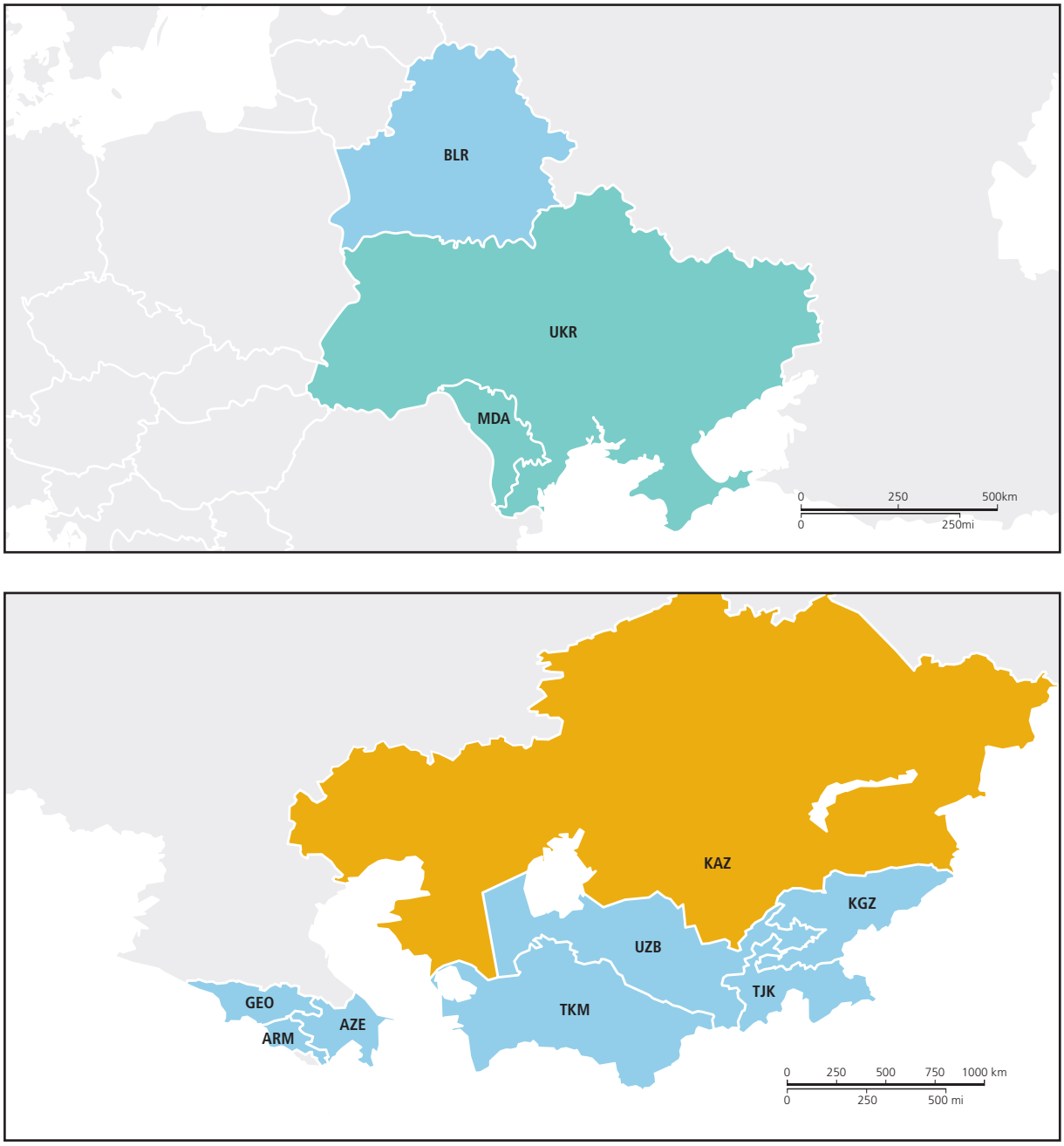
Note: the information refers to formal/official payments; informal "under-the-table" payments are not considered.

3.6.4 HTA

HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology, such as a medicine, 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 *(21)*.

HTA is not yet commonly used in EECA PPRI network countries: the majority of the countries surveyed reported that they did not apply HTA, but three use HTA to support reimbursement decisions. In the Republic of Moldova and Ukraine the public payer performs and considers HTA reports and pharmacoeconomic studies (including from other countries) to inform their reimbursement decisions, while Kazakhstan has an HTA agency: the Centre for Rational Clinical Practice. This agency considers HTA reports from other countries while producing its own reports. In Kazakhstan the HTA reports inform not only coverage decisions but also pricing decisions and development of clinical guidelines (Fig. 3.9).

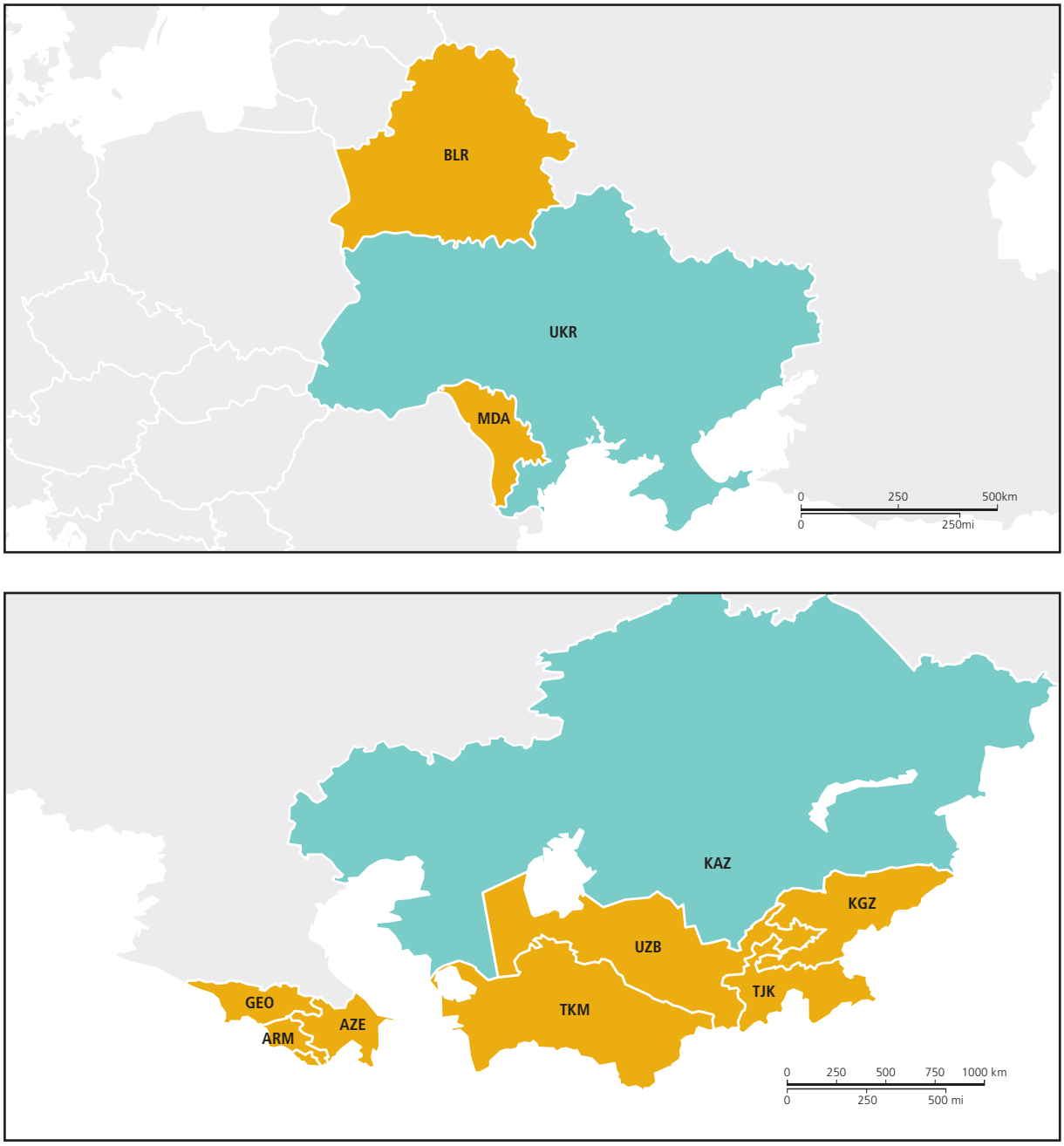
Fig. 3.9 | Use of HTA in EECA PPRI network countries, 2018



3.6.5 Managed entry agreements

A managed entry agreement is an arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology, such as a medicine, subject to specified conditions *(22)*. While these arrangements, which can take different forms, are increasingly used in many high-income countries as a tool to ensure access to high-priced medicines, they are not, as a rule, used in EECA PPRI network countries, although Kazakhstan and Ukraine are planning, or considering, their introduction (Fig. 3.10).

Fig. 3.10 | Utilization of managed entry agreement in EECA PPRI network countries, 2018



Note: Kazakhstan and Ukraine plan to initiate managed entry agreements during 2018 and 2019.

3.7 Responsible use of medicines

Some of the central Asian countries surveyed have introduced electronic prescription systems; others are piloting or considering their implementation. Prescribing budgets for doctors (setting a maximum number of allowed prescriptions) are not very common, and few countries have sanctions or financial incentives in cases of irresponsible prescribing.

Clinical guidelines are in place in all the countries surveyed. In some (such as Belarus) the guidelines serve as indicative recommendations; in others they are obligatory for prescribers, even involving financial sanctions (Table 3.9).

Table 3.9 | Prescription monitoring and clinical guidelines in EECA PPRI network countries, 2018

Country	Prescribing			Clinical guidelines		
	Electronic prescription system	Prescribing budget	Incentives/sanctions[a]	Status of elaboration	Responsible for development	Enforcement
Armenia	Yes (established but still testing)	Yes	No	78 guidelines developed; more in development	Several institutions, including National Institute of Health of the Ministry of Health	Two types of document according to the Law on medical assistance and service to the population: clinical guidelines, which serve as recommendations, and protocols, which are obligatory for doctors
Azerbaijan	No, but under development	No	Yes, financial sanctions for doctors due to incorrect prescription	Yes, developed	Ministry of Health	Obligatory for doctors to consider guidelines
Belarus	Yes (introduced)	No	No	Yes, developed	Ministry of Health	Indicative: guidelines serve as recommendations, no sanctions
Georgia	Yes	No	Yes, if hospitals in Tbilisi do not use electronic prescriptions	Yes, developed	Medical societies	Obligatory for prescribers but no enforcement and frequent non-consideration in practice; disciplinary sanctions
Kazakhstan	Yes, mandatory for publicly subsidized medicines	Yes	No	Yes, developed (also for non-subsidized medicines)	Republican Centre for Health Care Development	Indicative: guidelines serve as recommendations
Kyrgyzstan	No, but pilot planned	Yes – for the subsidized prescription	Yes, financial sanctions for non-issuance of prescription in case of medical need	Yes, > 400 guidelines developed	Ministry of Health with national centres and associations	Obligatory for prescribers; financial sanctions possible
Republic of Moldova	No, but under development: implementation planned for 2018	No (no longer from 2018)	Yes, sanctions for inappropriate prescribing (MHIF charges)	Yes, developed	Ministry of Health	Obligatory for prescribers; financial sanctions possible
Tajikistan	No	No	No	Yes, > 800 guidelines developed	Ministry of Health	Obligatory for prescribers; financial sanctions possible
Turkmenistan	No	No	No	Yes, developed for some pathologies	Not known	Indicative: guidelines serve as recommendations
Ukraine	Yes, pilot ongoing	No	No	Yes, developed[b]	Not known	Not known
Uzbekistan	No, but pilot under consideration	No	No	Yes, developed	Ministry of Health	Obligatory for prescribers, but no financial sanctions

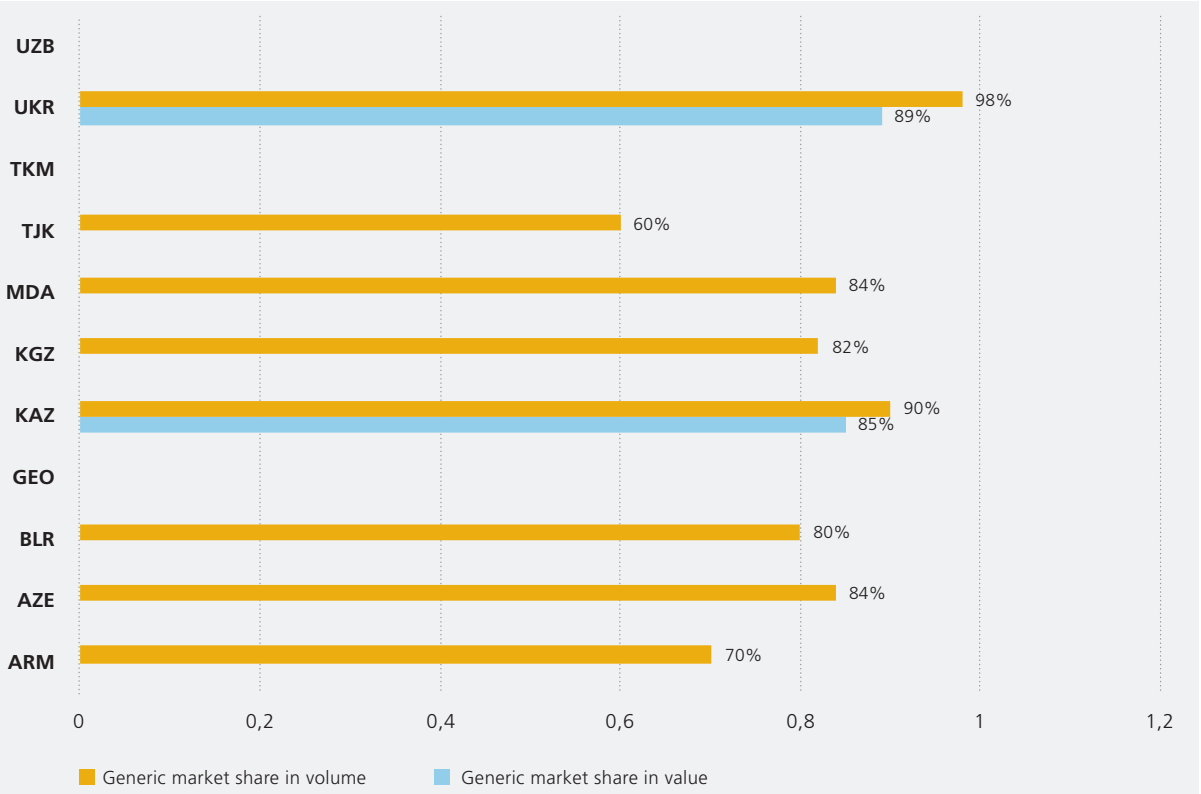
a Incentives/sanctions refers to the existence of any financial incentives or sanctions for prescribers with regard to their prescribing behaviour.

b On 28 April 2017 the Order of the Ministry of Health of Ukraine No. 1422 dated December 29, 2016 came into force, which allows Ukrainian doctors to use international clinical protocols in their work.

3.8 Generic policies

Generic medicines play an important role in pharmaceutical markets in EECA PPRI network countries, with generic market shares of at least 70–80% in volume in some countries (where data available; Fig. 3.11).

Fig. 3.11 | Generic market shares in EECA PPRI network countries 2018

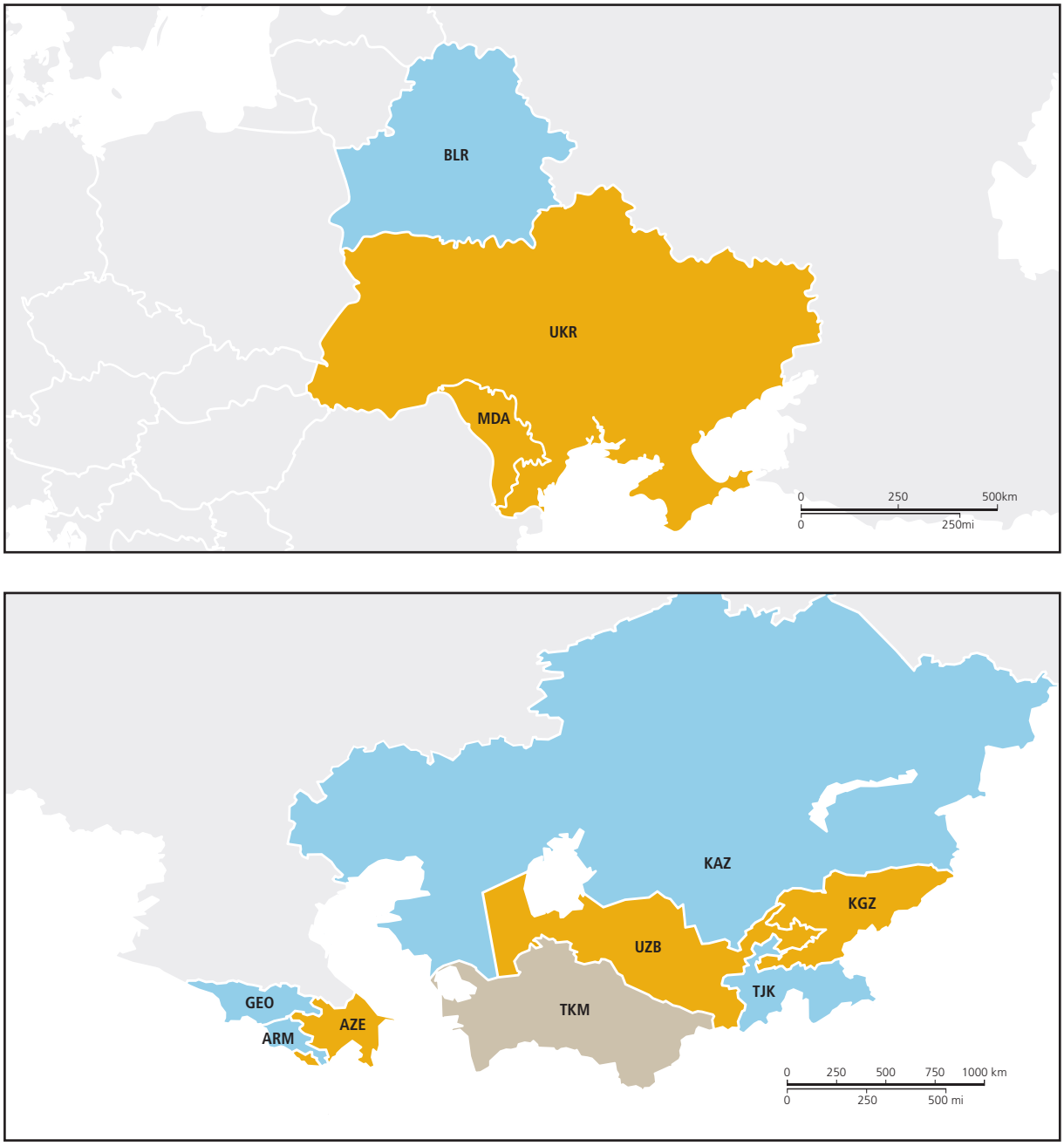


Notes: Information not available for Georgia, Turkmenistan and Uzbekistan. Some countries (such as Armenia, Kazakhstan and Uzbekistan) reported insufficient knowledge and a reluctance to use generics by health professionals (pharmacists, doctors) and particularly patients. At the same time, Belarus and the Republic of Moldova reported a positive perception of generics among patients and health professionals.

Pharmacists gain higher profits by dispensing higher-priced originator medicines compared to generics. None of the countries with regulated pharmacy mark-ups apply differentiated remuneration for dispensing originator medicines and generics. Also, as reported in Table 3.6, no price-independent pharmacy remuneration (such as through a dispensing fee) is in place.

Demand-side measures to promote the uptake of generics have been introduced in EECA PPRI network countries. All 11 countries surveyed have implemented INN prescribing (on a voluntary basis) and generic substitution – the latter on an indicative basis in some countries and mandatory in others (including Azerbaijan, Kyrgyzstan and Uzbekistan, Fig. 3.12).

Fig. 3.12 | Prescribing by INN and generic substitution in EECA PPRI network countries, 2018



4 Conclusions

To the knowledge of the authors, this is the first study to survey and compare pharmaceutical policies, in particular with regard to pricing and reimbursement of medicines, in EECA countries. The survey shows that, while these countries have some similarities in the organization of their pharmaceutical systems – which can partly be explained by shared history – differences exist, particularly in the details of the design of pharmaceutical policy measures and with regard to the uptake of "new" tools that high-income countries are already applying and experiencing. In some EECA PPRI network countries reforms are ongoing, and further changes are planned; this also contributes to differences in policy.

Overall, similar patterns and trends across the countries can be seen.

- In all the countries surveyed, progress towards UHC has been made in recent years. While the countries provide universal access to health care in principle, the scope of health services covered is often limited.
- Further, the publicly subsidized benefit package for outpatient medicines is usually very small; overall, patients in these countries face large OOP payments for outpatient medicines, which are a major driver of patient payments for health care.
- In the hospital sector, patients have free access to the medicines made available to them.
- The reimbursement system is strongly guided by disease-specific approaches (vertical programmes), which are a legacy of the Semashko system.
- Generic medicines tend to account for high market shares (particularly in volume). Measures to promote the uptake of generics (prescribing by INN and generic substitution) are in place in all the countries studied. At the same time, knowledge and acceptance of generics by health care professionals and patients is still considered insufficient.
- When countries decided to opt for full price regulation, they choose the policy of EPR.

Nevertheless, differences between countries were also noted.

- Local production plays an important role in some but not all countries.
- With regard to price regulation, there appear to be three groups of countries: those (Azerbaijan, Kazakhstan, the Republic of Moldova, Ukraine and Uzbekistan) with full price control (i.e. regulation at ex-factory price level and in the supply chain) for at least some outpatient medicines; those

(Belarus and Turkmenistan) that solely regulate distribution margins; and those (Armenia, Georgia, Kyrgyzstan and Tajikistan) without any price regulation.

- Regarding procurement of medicines for hospitals, not all countries have a degree of centralized/pooled procurement, which is concerning from the standpoint of efficiency of public expenditure.
- In terms of reimbursement, some countries (including Kazakhstan, the Republic of Moldova and Ukraine *(23)*) are progressing little by little towards a more common European approach. These countries also aim to apply tools such as HTA, and are considering the negotiation of managed entry agreements.

Overall, while countries in eastern Europe and central Asia tend to look at pharmaceutical policy practice in European countries, there is also value in learning from and sharing experiences among the members of the EECA PPRI network, as some of the countries move forward with reforms in the pharmaceutical sector. As such, this report aims to provide a contribution to information exchange among central Asian countries; it also sheds light on a region whose pharmaceutical policies are not broadly known.

References

1. Rechel B, McKee M. Health reform in central and eastern Europe and the former Soviet Union. Lancet. 2009;374(9696):1186–95.

2. Mathauer I, Theisling M, Mathivet B, Vilcu I. State budget transfers to health insurance funds: extending universal health coverage in low- and middle-income countries of the WHO European Region. Int J Equity Health. 2016;15(1):57.

3. Rechel B, Ahmedov M, Akkazieva B, Katsaga A, Khodjamurodov G, McKee M. Lessons from two decades of health reform in central Asia. Health Policy Plan. 2012;27(4):281–7.

4. Resolution 67/81 on Global health and foreign policy, adopted by the General Assembly on 12 December 2012. New York: United Nations; 2012 (http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/67/81, accessed 7 December 2018).

5. United Nations International Covenant on Economic, Social and Cultural Rights. New York: United Nations; 1966 (http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx, accessed 7 December 2018).

6. Goroshko A, Shapoval N, Lai T. Can people afford to pay for health care? New evidence on financial protection in Ukraine. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/countries/ukraine/publications/can-people-afford-to-pay-for-health-care-new-evidence-on-financial-protection-in-ukraine-2018, accessed 17 December 2018).

7. Jakab M, Akkazieva B, Habicht J. Can people afford to pay for health care? New evidence on financial protection in Kyrgyzstan. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/countries/kyrgyzstan/publications/can-people-afford-to-pay-for-health-care-new-evidence-on-financial-protection-in-kyrgyzstan-2018, accessed 17 December 2018).

8. Can people afford to pay for health care? New evidence on financial protection in Europe. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/about-us/governance/regional-committee-for-europe/68th-session/documentation/working-documents/eurrc6811, accessed 17 December 2018).

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

10. Glossary [website]. Vienna: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies; 2018 (https://ppri.goeg.at/ppri-glossary, accessed 10 February 2019).

11. Ibrahimov F, Ibrahimova A, Kehler J, Richardson E. Azerbaijan: health system review. Health Syst Transit. 2010;12(3):1–117.

12. Richardson E, Malakhova I, Novik I, Famenka A. Belarus: health system review. Health Syst Transit. 2013;15(5):1–118.

13. Richardson E, Berdzuli N (2017). Georgia: health system review. Health Syst Transit. 2017;19(4):1–90.

14. Katsaga A, Kulzhanov M, Karanikolos M, Rechel B. Kazakhstan: health system review. Health Syst Transit. 2012;14(4):1–154.

15. Ibraimova A, Akkazieva B, Ibraimov A, Manzhieva E, Rechel B. Kyrgyzstan: health system review. Health Syst Transit. 2011;13(3):1–152.

16. Turcanu G, Domente S, Buga M, Richardson E. Republic of Moldova: health system review. Health Syst Transit. 2012;14(7):1–151.

17. Khodjamurodov G, Sodiqova D, Akkazieva B, Rechel B. Tajikistan: health system review. Health Syst Transit. 2016;18(1):1–114.

18. Lekhan VN, Rudiy VM, Shevchenko MV, Nitzan Kaluski D, Richardson E. Ukraine: health system review. Health Syst Transit. 2015;17(2):1–153.

19. Ahmedov M, Azimov R, Mutalova Z, Huseynov S, Tsoyi E and Rechel B. Uzbekistan: health system review. Health Syst Transit. 2014;16(5):1–137.

20. Global health expenditure database [online database]. Geneva: World Health Organization; 2018 (http://apps.who.int/nha/database, accessed 18 December 2018).

21. What is health technology assessment? In: EUnetHTA [website]. Diemen: European Network for Health Technology Assessment; 2018 (https://www.eunethta.eu/services/submission-guidelines/submissions-faq/, accessed 10 December 2018).

22. Klemp M, Frønsdal KB, Facey K. What principles should govern the use of managed entry agreements? Int J Technol Assess Health Care. 2011;27(1):77–83.

23. Evaluation of the Affordable Medicines Programme in Ukraine. Copenhagen: WHO Regional Office for Europe; 2019 (http://www.euro.who.int/en/countries/ukraine/publications/evaluation-of-the-affordable-medicines-programme-in-ukraine-2019, accessed 10 December 2018).

Annex 1. Access to HIV, hepatitis and TB medicines in EECA countries

Contents

Abbreviations

ARV	antiretroviral
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
UNDP	United Nations Development Programme
USAID	United States Agency for International Development

Country profiles

2018

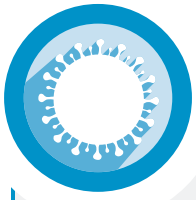
World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in Armenia

HIV

- Treatment for HIV is provided through a specific programme and follows the 2017–2021 national state target programme on HIV/AIDS prevention.
- Medicines are dispensed free of charge to patients in specialized centres, such as the National Centre of AIDS Prevention.
- Medicines are procured by national authorities and the Partnership for Supply Chain Management, using both domestic and donor funds.
- Most of the products procured do not have a valid market authorization.



Hepatitis

- No specific programme is in place to organize access to hepatitis treatment. A national strategy is under development.
- Medicines are not dispensed free of charge to patients.
- The government does not engage in any form of procurement for these products. Some neighbouring countries (such as Georgia) have made donations in recent times.
- Some medicines have a valid market authorization but no direct active antiretroviral (ARV) therapy is currently registered.

TB

- Only inpatient TB care is provided under a separate programme. A national strategy on TB management and related action plan has been adopted for 2016–2020.
- Medicines are dispensed free of charge to patients in specialized centres, such as the National TB Control Centre, but also in regular outpatient and inpatient facilities.
- The national authorities are responsible for procuring first-line medicines, using domestic funds. Until 2021 the Global Drug Facility will procure second-line medicines, using donor funds. Finally, Médecins Sans Frontières procures multidrug-resistant TB medicines, using its own funds. All first- and second-line TB medicines are formally registered in the country.
- In December 2017 the authorities introduced a regulatory change allowing bidders to participate in tenders without prior registration of medicines. Successful bidders are automatically allocated preregistration status and the fees associated with the medicines' registration are further covered by state funds.

2018

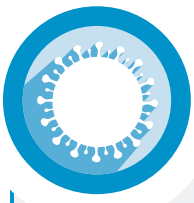
World Health Organization
REGIONAL OFFICE FOR Europe

Accesssto HIV, hepatitis and TB medicines

in Azerbaijan

HIV

- Treatment for HIV is provided through a specific programme and follows the 2016–2020 national strategy.
- Medicines are dispensed free of charge to patients in specialized centres (the National AIDS Centre and six regional ARV therapy units).
- Medicines are currently procured by the authorities (Innovation and Supply Centre of the Ministry of Health), using domestic funds. From 2019 the plan is to use the United Nations Development Programme (UNDP) platform to procure these medicines, still using domestic funds.
- A proportion of the products procured do not have a valid market authorization (but WHO prequalified medicines do not need registration).



Hepatitis

- No specific programme is in place to organize access to hepatitis treatment and no national strategy has been adopted.
- Medicines are dispensed free of charge as part of the general coverage provided to patients. Medicines are currently procured by the authorities (Innovation and Supply Centre of the Ministry of Health), using domestic funds.
- All hepatitis medicines used have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme and follows the 2016–2020 national strategy.
- Medicines are dispensed free of charge to patients in specialized TB care centres and at the primary health care level.
- First- and second-line TB medicines are currently procured by the national authorities (Innovation and Supply Centre of the Ministry of Health), using domestic funds and donations from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). From 2019 the plan is to use UNDP's platform to procure these medicines, still using the same funding sources.
- Medicines procured using domestic funds have a valid market authorization. Those procured using Global Fund money usually do not.
- Some medicines are donated (including bedaquiline by the United States Agency for International Development (USAID)).

2018

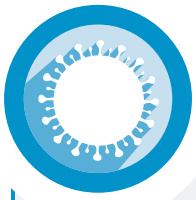
World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in Belarus

HIV

- Treatment for HIV is provided through a specific HIV prevention programme (as part of the National Health and Demographic Security Programme). Medicines are dispensed free of charge in general public health facilities.
- The national procurement agency Belfarmatsiya is responsible for the procurement of first- and second-line ARV therapies, using domestic funds. Third-line therapies are procured by the Global Fund's Project Implementation Unit and financed by a grant from the Global Fund (until at least 2021).
- Most ARV medicines have a valid market authorization.



Hepatitis

- No specific programme is in place to organize access to hepatitis treatment and no national strategy has been adopted.
- Medicines are dispensed free of charge to certain categories of patients (as part of the general benefit package arrangements) and are dispensed in general public health facilities.
- Belfarmatsiya is responsible for the procurement of hepatitis medicines, using domestic funds. All hepatitis medicines used have a valid market authorization.

TB

- Treatment for TB is provided through the "Tuberculosis" subprogramme, which focuses on TB prevention, treatment and care. Its objectives are to prevent TB mortality and incidence and to provide high-quality care for multidrug-resistant TB patients. Each objective has corresponding indicators. The subprogramme is part of the 2016–2020 National Health and Demographic Security Programme, developed to support sustainable social and economic development in Belarus.
- Medicines are dispensed free of charge to patients in specialized TB care centres and at the primary health care level.
- Belfarmatsiya is responsible for the procurement of first- and second-line TB medicines (using domestic funds; clofazimine has been covered since 2019), except bedaquiline and delamanid, which are procured via the Global Fund's Project Implementation Unit, using a grant from the Global Fund (until 2021).
- All TB medicines are formally registered except bedaquiline, delamanid and clofazimine.
- Some second-line medicines are donated by Médecins Sans Frontières.

2018

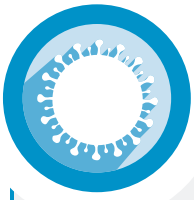
World Health Organization
REGIONAL OFFICE FOR Europe

Accesssto HIV, hepatitis and TB medicines

in Georgia

HIV

- Treatment for HIV is provided through a specific programme and a national strategy (2016–2018; undergoing revision) is in place.
- Medicines are dispensed free of charge in hospitals and specialized care centres such as the National Institute of Infectious Diseases.
- The National Centre for Disease Control and Public Health, which is the government agency under the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs, is in charge of procurement of ARV medicines under the national HIV programme. Procurement is conducted through the Global Fund's Wambo platform. Domestic funds cover first-line treatments and a quarter of the budget for second-line treatments, for which the remainder comes from the Global Fund.
- Most ARV medicines have a valid market authorization.



Hepatitis

- A specific programme is in place to organize access to hepatitis C treatment and a national strategy (Strategic Plan for the Elimination of Hepatitis C Virus, 2016–2020) was approved by the authorities. Medicines are dispensed free of charge to patients in specialized health care facilities.
- The combination sofosubuvir + ledipasvir is donated to the country by the originator company. The National Centre for Disease Control and Public Health is in charge of procurement of interferon and ribavirin. All hepatitis medicines used have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme and a national strategy exists (National Strategic Plan for TB Control, 2016–2020).
- Medicines are dispensed free of charge to patients in specialized TB care centres and at the primary health care level.
- The National Centre for Disease Control and Public Health is in charge of procurement of TB medicines under the TB programme. Domestic funds are used to procure first-line treatments and up to 50% of the second-line treatment budget. For Global Fund-funded treatments, procurement is done through the Global Drug Facility.
- Most TB medicines used are not formally registered.
- Bedaquiline is donated to the country by USAID.

2018

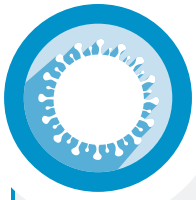
World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in Kazakhstan

HIV

- Treatment for HIV is provided through a specific programme and a national strategy exists.
- All ARV medicines are procured with domestic funds. National authorities are responsible for the procurement of ARV medicines, using United Nations Children's Fund Supply Division Procurement Services.
- Most ARV medicines have a valid market authorization.



Hepatitis

- Treatment for hepatitis is provided through a specific programme and a national strategy exists.
- Medicines are dispensed free of charge in specialized care centres.
- National authorities are responsible for the procurement of hepatitis medicines, using domestic funds. UNDP provides support for the procurement of some products. Most hepatitis medicines used have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme and a national strategy exists.
- Medicines are dispensed free of charge in specialized TB care centres.
- These centres are responsible for the procurement of TB medicines, using domestic funds. UNDP provides support for the procurement of some products. Most TB medicines used are registered in the country.
- Some quantities of bedaquiline are donated to the country by USAID.

2018

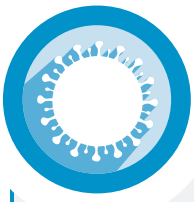
World Health Organization
REGIONAL OFFICE FOR Europe

Accesssto HIV, hepatitis and TB medicines

in Kyrgyzstan

HIV

- Treatment for HIV is provided through a specific programme. A national strategy is under development. ARV medicines are dispensed to patients free of charge through AIDS centres and primary care facilities.
- UNDP is responsible for the procurement of ARV medicines, using funds from the Global Fund.
- A significant proportion of the medicines procured to treat HIV are not registered.
- Some donations of medicines are made by USAID.



Hepatitis

- Treatment for hepatitis is provided through a specific programme and a national strategy has been developed, covering the period 2017–2022.
- Medicines are not dispensed free of charge. Only a very limited number of patients co-infected with HIV receive free treatment (100–200 patients per year). Otherwise, access to hepatitis treatment is paid entirely out of pocket.

TB

- Treatment for TB is provided through a specific programme. A national strategy has been developed and approved (covering the period 2017–2021).
- Medicines are dispensed free of charge in specialized TB care centres at the primary health care level.
- First-line TB medicines are procured by the National TB Centre, using domestic funds.
- Second-line medicines are procured by the Global Fund, using its own donation.
- Only first-line treatments (from Russian manufacturers only) are currently registered.

2018

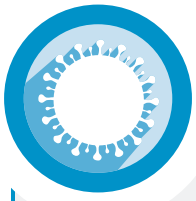
World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in the Republic of Moldova

HIV

- Treatment for HIV is provided via the general health insurance package, but a specific separate budget is dedicated to it. A national strategy for HIV/AIDS infection covers the period 2016–2020. ARV medicines are dispensed to patients free of charge in specialized health care centres.
- UNDP is in charge of the procurement of ARV medicines. Funds come from the domestic budget, with the exception of the products used in penitentiaries, which are funded by the Global Fund. Some ARV medicines procured do not have a valid market authorization and a waiver was granted to allow their use in the national context.



Hepatitis

- Treatment for hepatitis is provided through the general health insurance system and no specific programme exists. A national strategy to fight hepatitis B, C and D was adopted and covers the period 2017–2021.
- Medicines are dispensed free of charge to eligible patients (using criteria defined by the authorities) in specialized care centres.
- The Centre for Centralized Public Procurement in Health is the national institution in charge of procuring hepatitis medicines. It relies on domestic funds. All hepatitis medicines have a valid market authorization.

TB

- Treatment for TB is provided via the general health insurance package, but a specific separate budget is dedicated to it. A national strategy covers the period 2016–2020. Medicines are dispensed free of charge in specialized TB care centres and hospitals.
- UNDP is in charge of the procurement of first-line TB medicines, using domestic funds. Second-line therapies are procured via the Unit for Coordination, Implementation and Monitoring of the Project on Health System Restructuring, a public nongovernmental organization, using funds from the Global Fund (until 2020).
- Most TB medicines used are registered in the country (approximately 95%).
- Some quantities of bedaquiline are donated to the country by the Global Fund.

2018

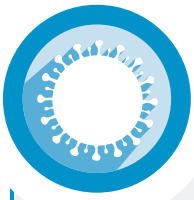
World Health Organization
REGIONAL OFFICE FOR Europe

Accesssto HIV, hepatitis and TB medicines

in Tajikistan

HIV

- Treatment for HIV is provided through a specific programme. A national strategy has also been developed and approved.
- ARV medicines are dispensed to patients free of charge in hospitals.
- UNDP and the Global Fund are in charge of the procurement of ARV medicines, using donations from the Global Fund.
- Some ARV medicines procured do not have a valid market authorization.



Hepatitis

- No specific programme is in place to organize access to hepatitis treatment and no national strategy has been adopted.
- Medicines for the treatment of hepatitis are partially covered by budgeted domestic funds. Patients who are registered at a medical institution are eligible to receive medicines purchased using this budget.
- Not all medicines needed for the treatment of hepatitis are purchased through budgeted funds; some are purchased via patient OOP payments.
- Medicinal products purchased using domestic funds undergo a centralized procurement procedure via electronic tender, in accordance with a law on public procurement of goods, works and services, which regulates the procurement process with established requirements.
- Most new molecules (direct-acting ARV therapies) have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme. A national strategy has also been developed and approved.
- Medicines are dispensed free of charge in specialized TB care centres.
- TB treatments are procured via the Global Fund's Project Implementation Unit, using domestic funds for first-line treatments and Global Fund donations for second-line therapies.

2018

World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in Turkmenistan

HIV

- Treatment for HIV is provided through a specific programme. A national strategy is under development.
- ARV medicines are dispensed to patients free of charge in specialized care centres.
- The Ministry of Health and Medical Industry is in charge of procuring ARV medicines, using domestic funds.
- All ARV medicines procured have a valid market authorization.

Hepatitis

- Treatment for hepatitis is provided through a specific programme. A national strategy is under development.
- Medicines are dispensed free of charge to registered patients in primary health care facilities. The Ministry of Health and Medical Industry is in charge of procuring hepatitis medicines, using domestic funds.
- All hepatitis medicines procured have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme. A national strategy has been developed and approved (2016–2020).
- Medicines are dispensed free of charge in specialized TB care centres and at the primary health care level.
- TB treatments are procured by the national authorities for first-line treatments, using domestic funds. Second-line treatments are procured via the Global Fund's Project Implementation Unit and UNDP, using donations from the Global Fund (until 2019).
- All TB medicines procured have a valid market authorization.

2018

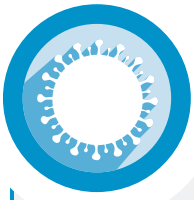
World Health Organization
REGIONAL OFFICE FOR Europe

Accesssto HIV, hepatitis and TB medicines

in Ukraine

HIV

- Treatment for HIV is provided through a specific programme. A national strategy has been developed for the period 2014–2018.
- ARV medicines are dispensed to patients free of charge through primary and secondary health care facilities and specialized AIDS centres.
- International organizations are in charge of procuring ARV medicines, using domestic funds (80% of the total budget) and Global Fund donations (20%).
- ARV medicines procured using domestic funds have a valid market authorization.



Hepatitis

- Treatment for hepatitis is not provided through a specific programme. A national strategy for the prevention and treatment of hepatitis B and C by 2030 is under development.
- Medicines are dispensed free of charge to patients in public health facilities but the quantities provided are very limited and do not cover the population's needs. To expand access to treatment, the country is focused on ensuring access to generic medicines that can be procured at a much lower price than originator medicines.
- Centralized procurement has been in place since 2014, using budgeted funds to provide medicines through the "Provision of medical measures of individual state programmes and complex measures of a programmatic nature" programme.
- International organizations are in charge of procuring hepatitis medicines, using budgeted domestic funds. Some quantities of direct-acting antivirals for hepatitis C treatment are also donated and dispensed by nongovernmental organizations such as Médecins Sans Frontières and the international charitable foundation Alliance for Public Health, which are involved in implementing treatment programmes among the most vulnerable groups.

TB

- Treatment for TB is provided through a specific programme. A national strategy has been developed and approved (covering the period 2018–2021).
- Medicines are dispensed free of charge in specialized TB care centres and at the primary health care level.
- TB treatments are procured by UNDP and financed using a combination of domestic funds and a Global Fund grant. Bedaquiline is available in Ukraine since 2018 using a free donation program.
- TB treatments procured using domestic funds have a valid market authorization.

2018

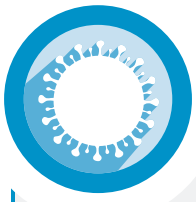
World Health Organization
REGIONAL OFFICE FOR Europe

Access to HIV, hepatitis and TB medicines

in Uzbekistan

HIV

- Treatment for HIV is provided through a specific programme. A national strategy has been developed and is currently enforced.
- ARV medicines are dispensed to patients free of charge through the National AIDS Centre and 14 regional AIDS centres.
- UNDP is in charge of procuring ARV medicines, using domestic funds for first-line treatment and the Global Fund for second-line treatment.
- Most ARV medicines procured do not have a valid market authorization.



Hepatitis

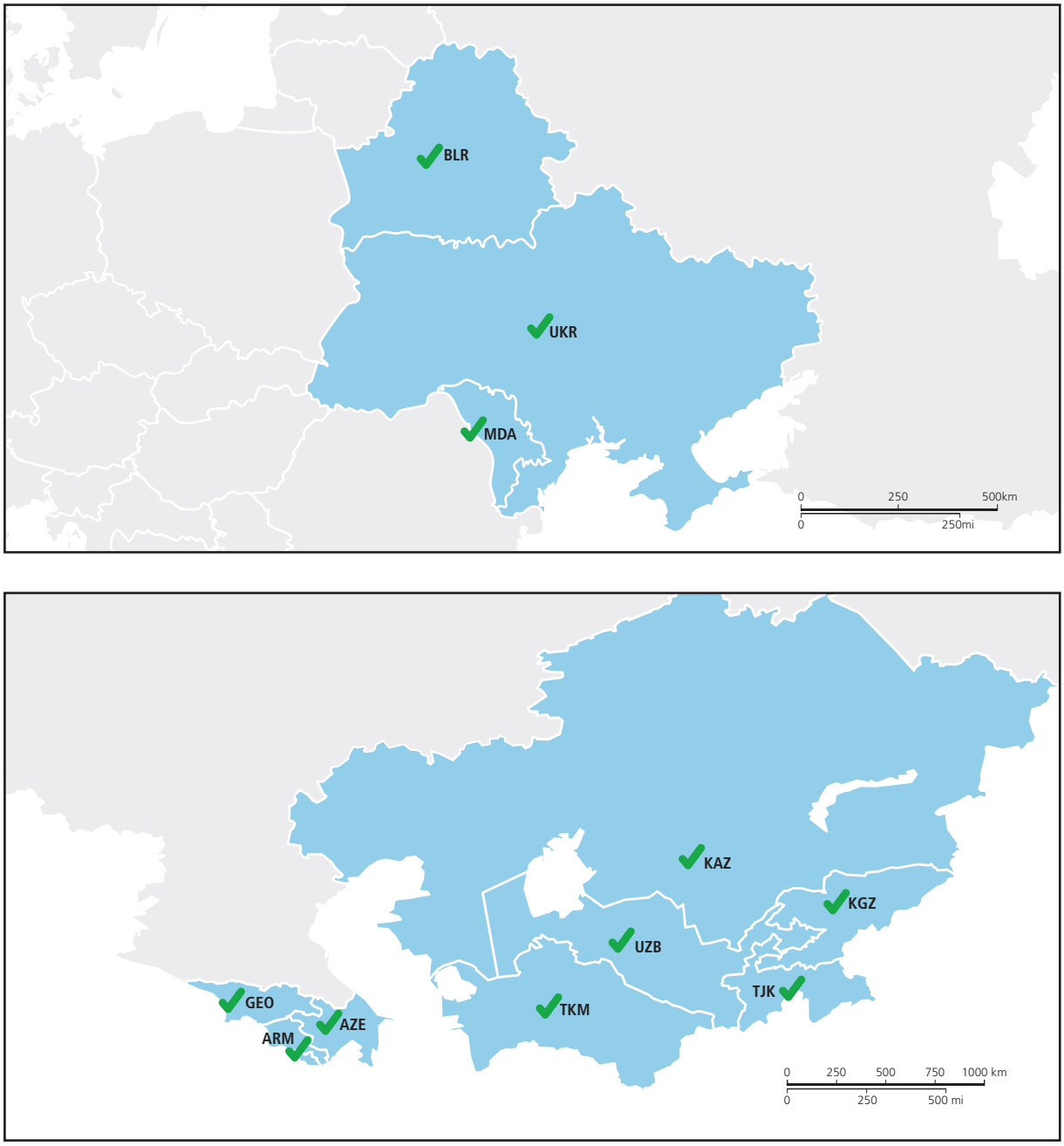
- Treatment for hepatitis is provided through a specific programme.
- A national strategy on hepatitis has been developed and is currently enforced.
- Medicines are not yet dispensed free of charge to patients, but this will change when the national programme is launched. Dispensing will be through specialized hepatological regional health care centres.
- It is expected that procurement will be undertaken by national authorities, using domestic funds.
- All hepatitis medicines used have a valid market authorization.

TB

- Treatment for TB is provided through a specific programme. A national strategy has been developed and approved (2016–2020).
- Medicines are dispensed free of charge in specialized TB care centres and at the primary health care level.
- TB treatments are procured by the national authorities for first-line treatment, using domestic funds, and via the National Centre for TB for second- and third-line treatments, using the Global Fund.
- Not all TB medicines used have a valid market authorization.

Intercountry comparisons

Map 1 | Access to HIV medicines in eastern Europe and central Asia



Countries with specific programme for HIV

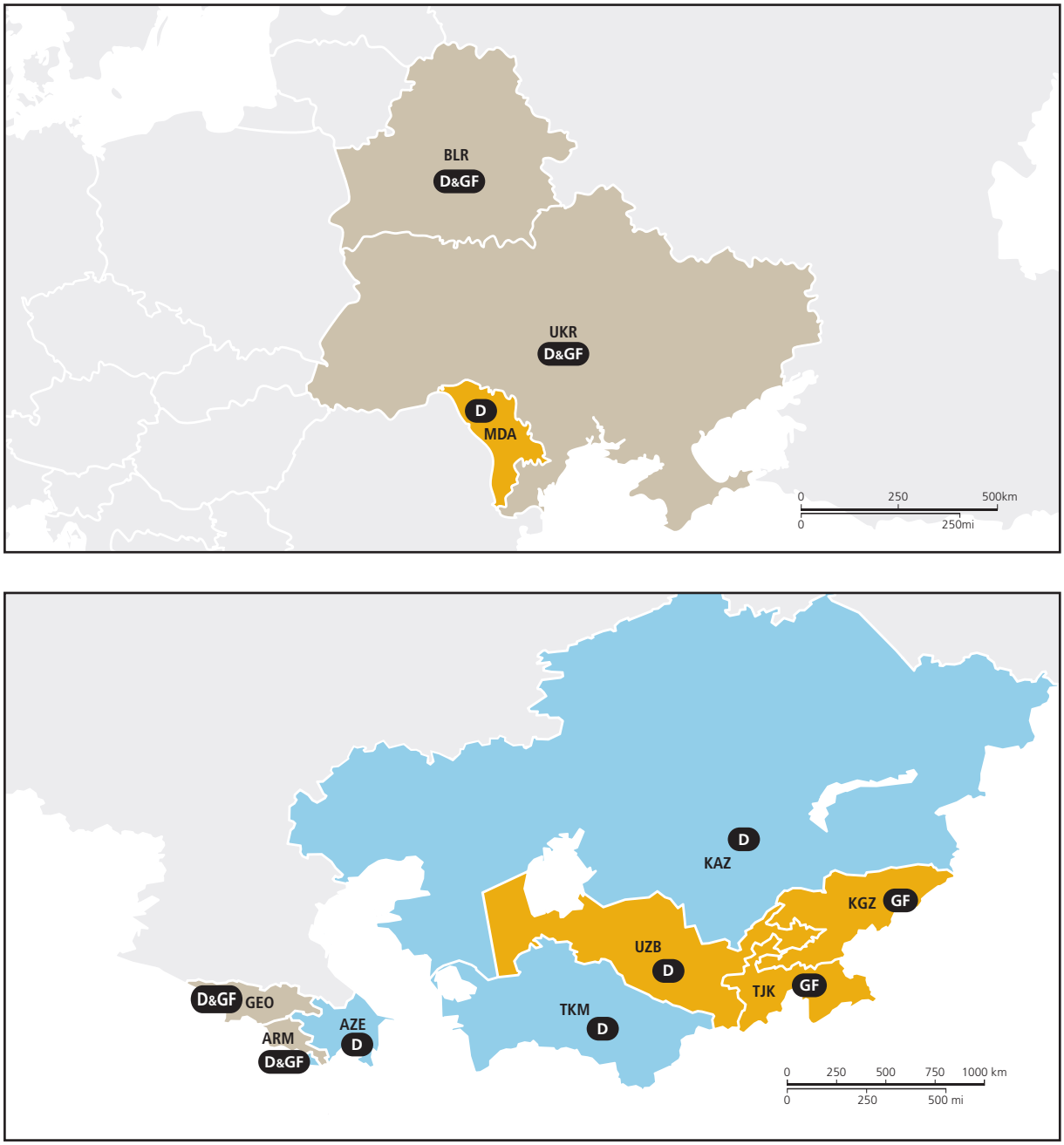
Countries with no dedicated programme for HIV

Countries with free access to ARV medicines

Countries with no free access to ARV medicines

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Map 2 | Procurement of HIV medicines in eastern Europe and central Asia



National authorities responsible for the procurement of ARV medicines

International partners responsible for the procurement of ARV medicines

Both national authorities and international partners responsible for the procurement of ARV medicines

D Domestic funds

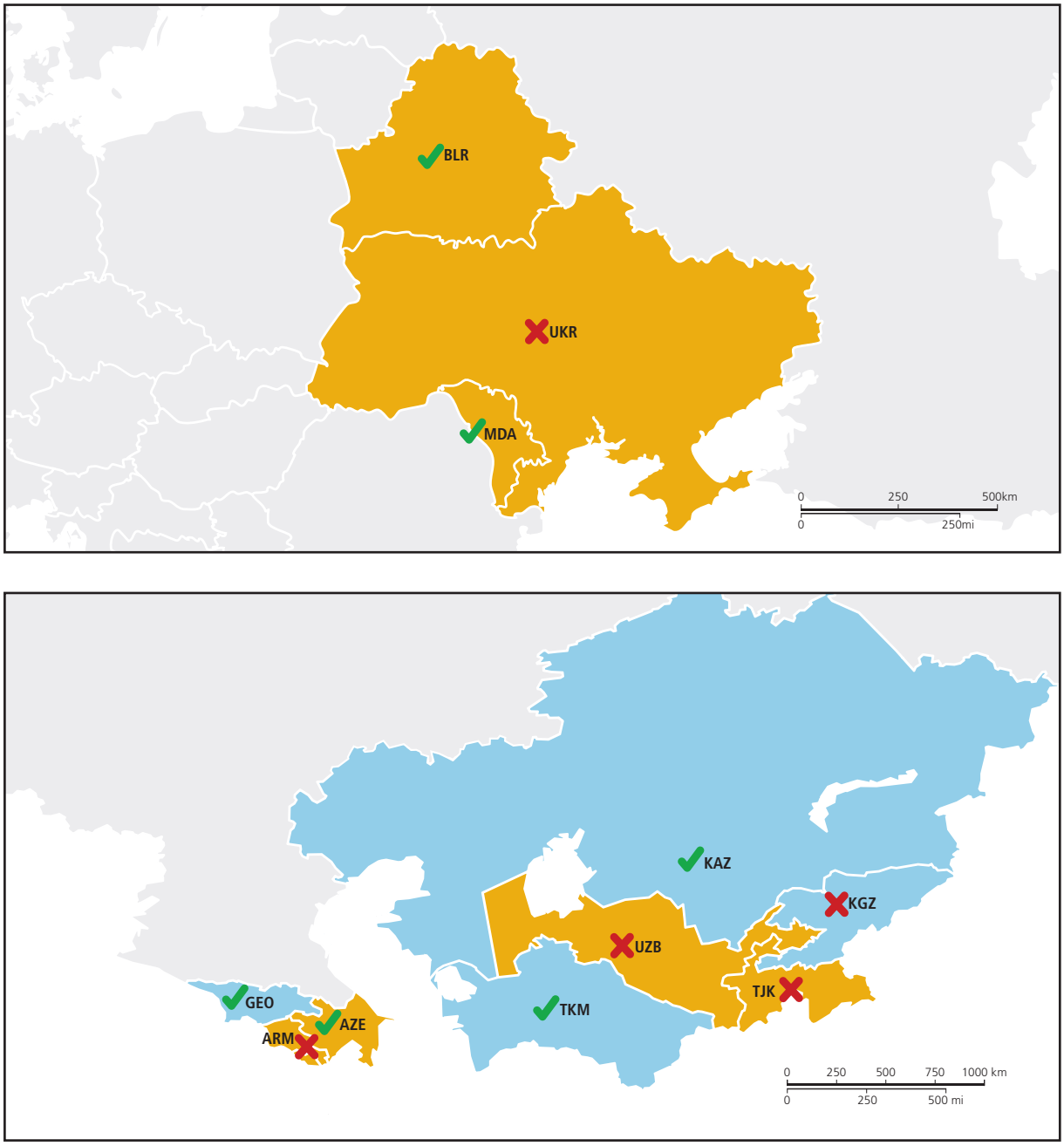
GF Global Fund donation

D&GF Domestic funds and Global Fund donation

Belarus: third-line therapies are procured by the Global Fund until 2021.
Georgia: domestic funds cover first-line treatment and 25% of second-line treatments.
Kyrgyzstan: UNDP is responsible for the procurement of ARV medicines using donations from the Global Fund.
Republic of Moldova: UNDP is in charge of procurement; the Global Fund provides funds for ARV medicines used in penitentiaries.
Ukraine: 80% of procurement is covered by domestic sources.
Uzbekistan: UNDP is in charge of procurement, using domestic funds.

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Map 3 | Access to hepatitis medicines in eastern Europe and central Asia



Countries with specific programme for hepatitis

Countries with no dedicated programme for hepatitis

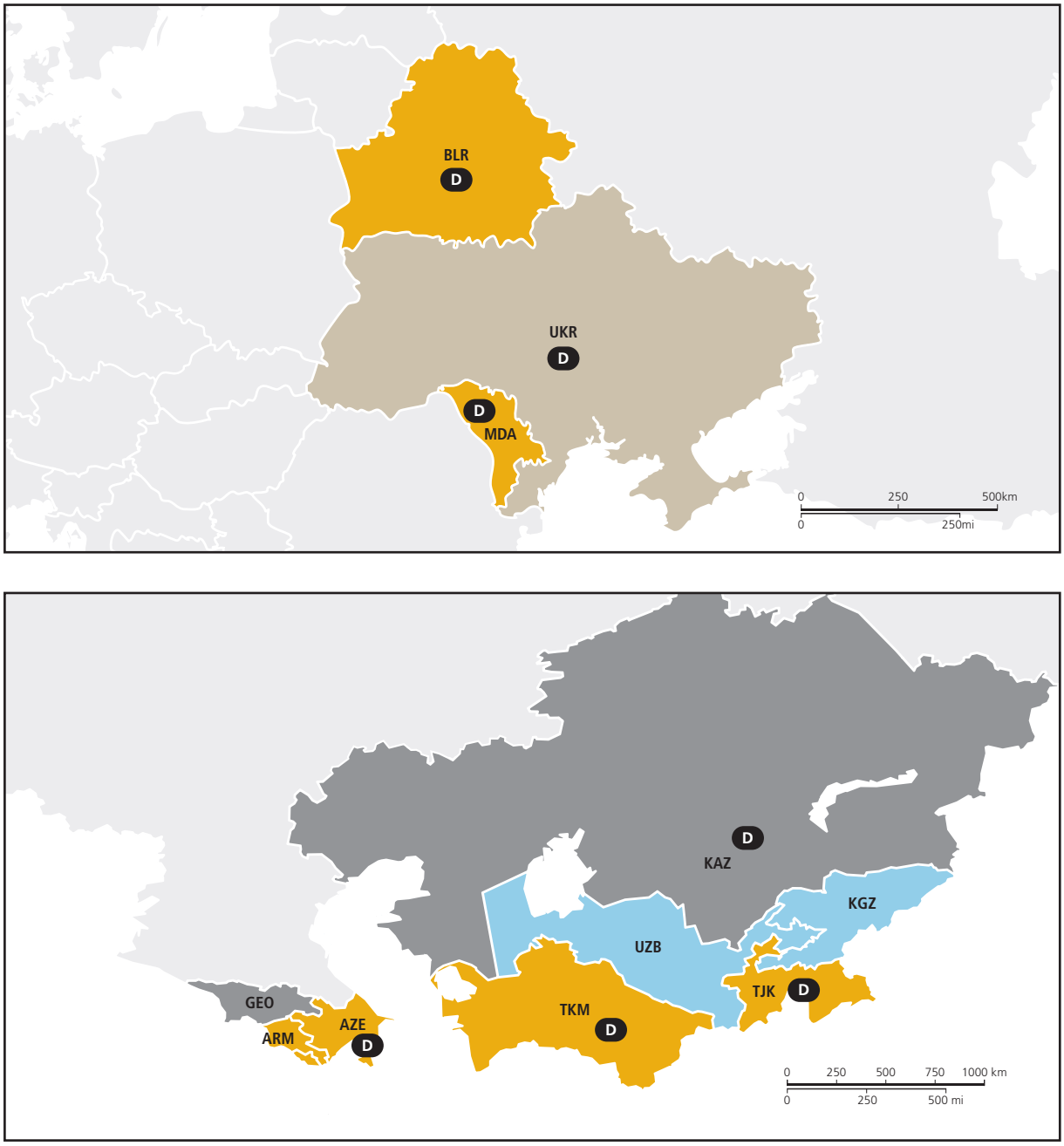
Countries with free access to hepatitis medicines

Countries with no free access to hepatitis medicines

Belarus: medicines are free for some specific categories of patients.
Tajikistan: medicines are partially covered through budgeted funds.
Kyrgyzstan: only HIV co-infected patients receive treatments free of charge.
Ukraine: quantities publicly supplied are very limited.
Uzbekistan: a national programme is under development.

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Map 4 | Procurement of hepatitis medicines in eastern Europe and central Asia



No national procurement for hepatitis medicines

National authorities responsible for the procurement of hepatitis medicines

International partners responsible for procurement of hepatitis medicines

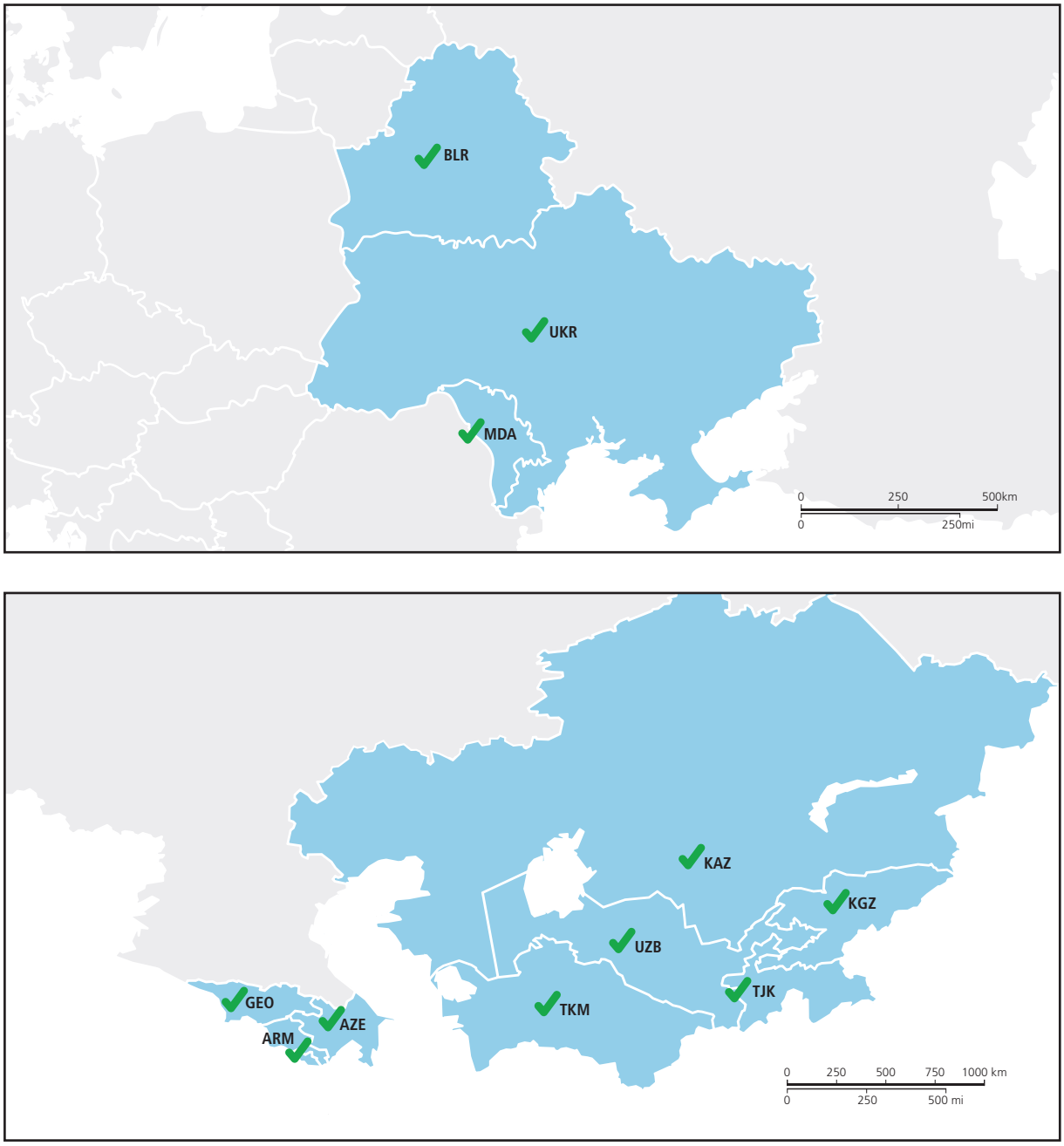
Donation from manufacturers

Both national authorities and international partners responsible for procurement of hepatitis medicines

D Domestic funds

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Map 5 | Access to TB medicines in eastern Europe and central Asia



Countries with specific programme for TB

Countries with no dedicated programme for TB

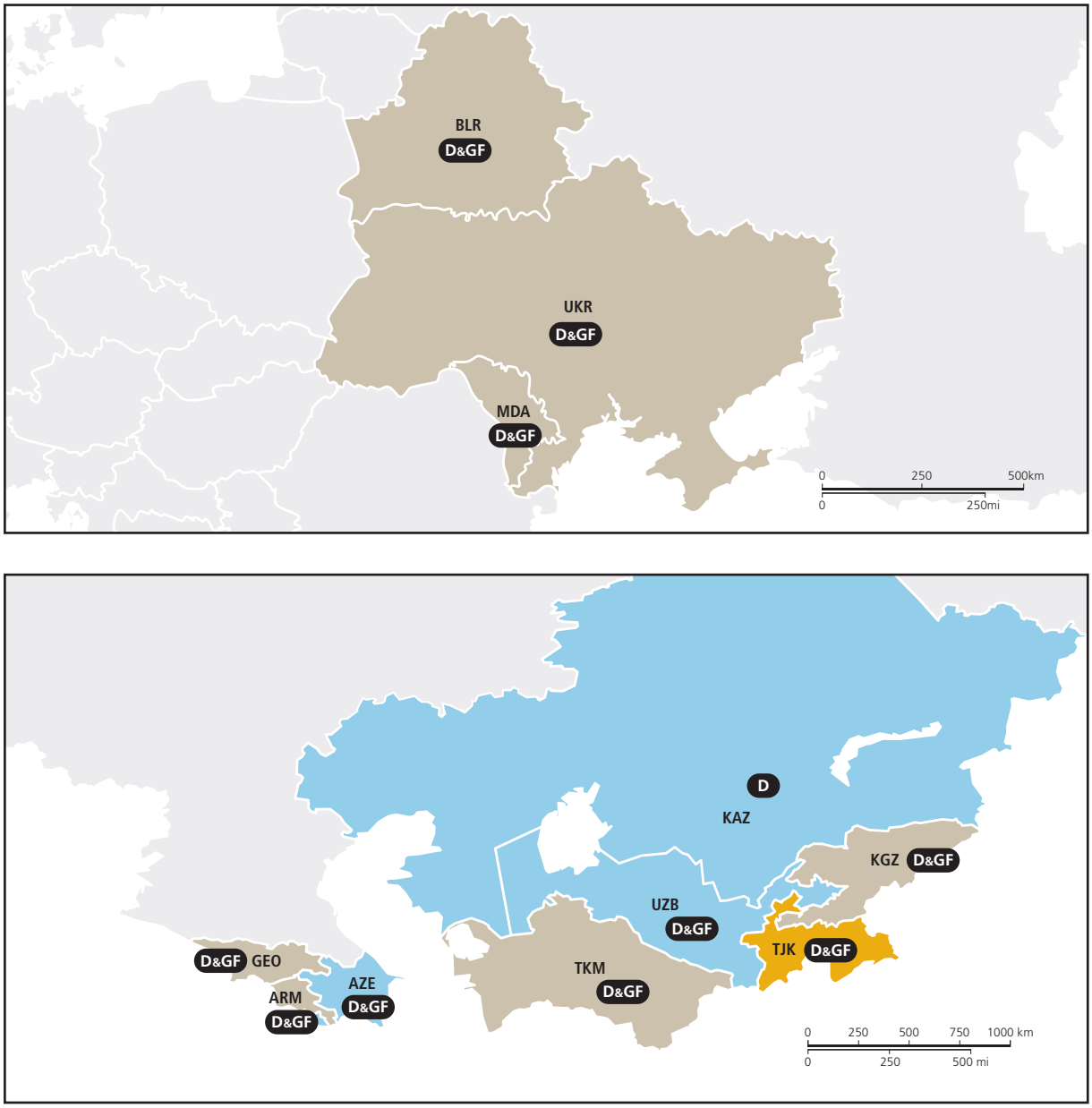
Countries with free access to TB medicines

Countries with no free access to TB medicines

Armenia: the programme exists only for inpatient TB care.

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Map 6 | Procurement of TB medicines in eastern Europe and central Asia



National authorities responsible for the procurement of TB medicines

International partners responsible for the procurement of TB medicines

Both national authorities and international partners responsible for the procurement of TB medicines

D Domestic funds

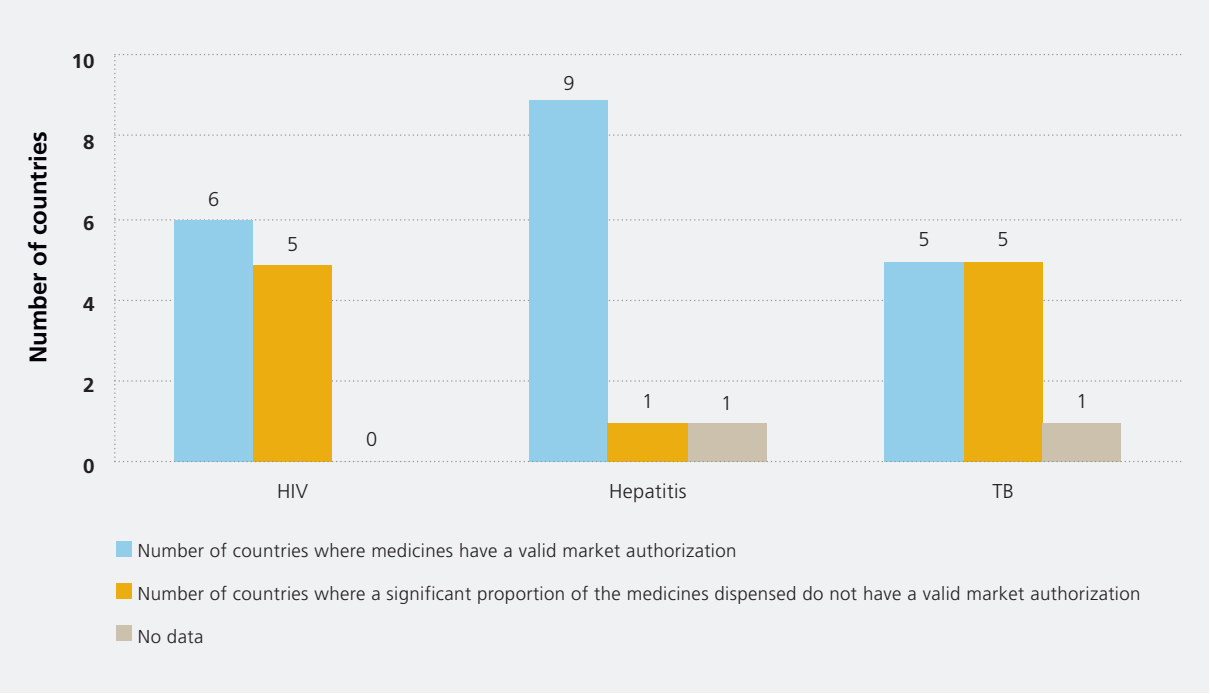
GF Global Fund donation

D&GF Domestic funds and Global Fund donation

Armenia: first-line treatments are procured using national funds; second-line therapies are procured by international organizations until 2021.
Belarus: first-line treatments are procured using domestic funds; second-line therapies are procured by international organizations until 2021.
Kyrgyzstan: first-line treatments are procured by the National TB Centre using domestic funds; second-line medicines are procured by the Global Fund using their own donations.
Republic of Moldova: procurement is done by UNDP for first-line treatments and the Unit for Coordination, Implementation and Monitoring of the Project on Health System Restructuring for second-line therapies.
Tajikistan: the Global Fund's Project Implementation Unit is in charge of procurement, first-line treatments are funded using domestic funds.
Turkmenistan: second-line treatments are procured and funded by international organizations until 2019.
Ukraine: TB treatments are procured by the national authorities for first-line treatment and by the Global Fund's Project Implementation Unit for the rest; for first-line treatment domestic funds are used and Global Fund donations for the rest.
Uzbekistan: national authorities are responsible for procurement of first-line treatment and via the National Centre for TB for second- and third-line treatments; funds come from domestic sources and the Global Fund for the second- and third-line therapies.

Map source: United Nations Geospatial Information Section.
Data source: World Health Organization.
Map production: WHO Regional Office for Europe, Division of Health Systems and Public Health.

Figure 1 | Status of medicines treating HIV, hepatitis and TB in eastern Europe and central Asia



Annex 2. Glossary

Access (accessibility)

The patient's ability to obtain medical care, including medicines, and a measure of the proportion of a population that reaches appropriate health services, including medication.

Ease of access is determined by such components as the availability of medical services and their acceptability to the patient, the location of health care facilities, transportation, hours of operation and cost of care.

Barriers to access can be financial (insufficient monetary resources), geographical (distance to providers), organizational (lack of available providers) and sociological (e.g. discrimination, language barriers).

Efforts to improve access often focus on providing/improving health coverage.

Anatomical, Therapeutic, Chemical (ATC) classification

A classification system of medicines where the active ingredients are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Medicines are divided into 14 main groups (first level – ATC 1), with pharmacological/therapeutic subgroups (second level – ATC 2). The third and fourth levels (ATC 3 and ATC 4) are chemical/pharmacological/therapeutic subgroups and the fifth level (ATC 5) is the chemical substance. The second, third and fourth levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

Claw-back

A funding element in a reimbursement system allowing third-party payers to recoup (part of the) discounts/rebates granted by various stakeholders, such as wholesalers and pharmacists.

Co-payment

A form of cost-sharing commonly applied in three variants of fixed co-payments, percentage co-payments and deductibles. It can be expressed as a percentage of the total cost of the service or as a fixed amount.

Coverage

A measure of the extent to which the services rendered cover the potential need for those services in the community.

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.

Discount

A price reduction granted to specified purchasers under specific conditions prior to purchase.

Dispensing fee

A type of remuneration to reward pharmacies for their service of filling prescriptions – normally a fixed fee that pharmacies are allowed to charge per prescribed item, independent of the price of the medicine.

Eligibility scheme

Prescription medicines coverage is provided to individuals in eligible groups, for whom the status and extent of reimbursement is defined according to different characteristics. In general, there are four types of eligibility scheme:

- product-specific reimbursement
- disease-specific reimbursement
- population-group-specific reimbursement
- consumption-based reimbursement.

Ex-factory price

The manufacturer's posted price.

Discounts or other incentives offered by manufacturers result in an actual price that is lower than the ex-factory price.

External price referencing (EPR, international price comparison, external reference pricing)

The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

Fixed co-payment

An out-of-pocket payment in the form of a fixed amount (like, for example, a prescription fee) to be paid for a service, a medicine or a medical device.

Free pricing

A pricing policy, in which pharmaceutical companies determine the price of the medicine they launch.

Generic substitution

The practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).

Generic substitution may be allowed (indicative generic substitution) or required (mandatory/obligatory generic substitution).

Health expenditure (total health expenditure)

The sum of expenditure on activities that – through application of medical, paramedical and nursing knowledge and technology – has the goals of:

- promoting health and preventing disease;
- curing illness and reducing premature mortality;
- caring for people affected by chronic illness who require nursing care;
- caring for people with health-related impairments, disabilities and handicaps who require nursing care;
- assisting patients to die with dignity;
- providing and administering public health;
- providing and administering health programmes, health insurance and other funding arrangements.

Health expenditure includes expenditure on:

- personal health (curative care, rehabilitative care, long-term nursing care, ancillary services to health care, medical goods dispensed to outpatients);
- collective health (prevention and public health, administration and insurance).

Health expenditure can be separated into:

- public expenditure: health expenditure incurred by public funds (state, regional and local government bodies and social security schemes);
- private expenditure: the privately funded part of total health expenditure – private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

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 (e.g. physicians) to prescribe medicines by 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).

Inpatient care

An inpatient is a patient formally admitted to an institution (or "hospitalized") for treatment and/or care who stays for a minimum of one night in the hospital or other institution providing inpatient care.

Inpatient care is mainly delivered in hospitals, but also in nursing and residential care facilities or in establishments that perform inpatient care as a secondary activity (classification based on focus of care by the ambulatory care industry).

Internal price referencing (IPR)

The practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutically equivalent treatment (not necessarily a medicine) in a country to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in the same country.

Joint procurement

The procurement of certain products or services done by a single purchasing body for several health care providers (e.g. hospitals, regions, countries).

List price

The selling price of the drug set by the manufacturer when sold to a wholesaler/non-wholesaler.

Depending on the country and/or the product, the list price may not include the full transaction cost (e.g. delivery charges, VAT and other indirect taxes on products, discounts/rebates, surcharges, service charges and voluntary gratuities).

Managed entry agreement

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.

Margin (distribution margin)

The percentage of the selling price that is profit.

In the case of pharmaceutical distribution, a wholesale or pharmacy margin is one type of remuneration awarded to distribution actors such as wholesalers and pharmacies for handling their services.

The wholesale margin is the gross profit of wholesalers, expressed as a percentage of the wholesale price (pharmacy purchasing price).

The pharmacy margin is the gross profit of pharmacies expressed as a percentage of the pharmacy retail price.

Mark-up (distribution mark-up)

A defined (linear or percentage) amount added to the cost of a good to create a profit (either linear or regressive at the wholesale and/or retail levels).

In the case of pharmaceutical distribution, it is one type of remuneration awarded to distribution actors such as wholesalers and pharmacies for handling their services.

The wholesale mark-up is the gross profit of wholesalers, expressed as a fixed or percentage add-on to the ex-factory price.

The pharmacy mark-up is the gross profit of pharmacies expressed as a fixed or percentage add-on to the wholesale price (or pharmacy purchasing price).

Marketing authorization (licensing)

A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.

National health service (NHS)

A system financed through general taxation (central or regional), usually covering all inhabitants/residents.

The scope of services rendered is identical for every person covered and most services are offered by public institutions. In some countries people may opt for a complementary voluntary health insurance for services that are not covered through the NHS.

Negative list

A list of medicines that cannot be prescribed at the expense of a third-party payer.

Out-of-pocket (OOP) **payment**

Payments made by a person at the time of service use that are not reimbursed by a third-party payer.

OOP payments include expenses for non-reimbursable medicines and any form of co-payment for reimbursable medicines.

Outpatient care (ambulatory care, community care)

This comprises medical and paramedical services delivered to outpatients.

Outpatient (ambulatory) care is provided in the outpatient sector, as opposed to hospital care and the hospital sector.

Over-the-counter medicine (non-prescription medicine)

Medicines which may be dispensed without a prescription.

In some countries these are available via self-service in pharmacies and/or other retail outlets (e.g. drugstores).

Selected over-the-counter medicines may be reimbursed for certain indications in some countries.

Pay-back

A financial mechanism that requires manufacturers, or other health care stakeholders, to refund part of their revenue to a (third-party) payer if sales exceed a previously determined or agreed target budget.

Pharmaceutical budget

These define ex ante the maximum amount of money to be spent on medicines during a period of time.

Pharmaceutical budgets may be addressed to payers, health care professionals (e.g. physicians) and companies. They may be designed in different forms and may include financial incentives or sanctions.

Pharmaceutical expenditure (total pharmaceutical expenditure)

Total expenditure on pharmaceutical and other medical nondurables.

This comprises medicinal preparations, branded and generic medicines, on-patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives.

Other medical nondurables include a wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.

Pharmaceutical expenditure can be separated into:

- public expenditure: pharmaceutical expenditure incurred by public funds (state, regional and local government bodies and social security schemes);
- private expenditure: privately funded part of total pharmaceutical expenditure – private sources of funds include OOP payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care;
- outpatient expenditure: pharmaceutical expenditure incurred in the outpatient (ambulatory setting) – due to data availability limitations in several countries, what is listed as total pharmaceutical expenditure only refers to the outpatient expenditure;
- inpatient expenditure: pharmaceutical expenditure incurred in the hospital setting.

Pharmaceutical service

All services rendered by pharmaceutical staff to support the provision of pharmaceutical care.

Beyond the supply of pharmaceutical products, pharmaceutical services include information, education and communication to promote public health, the provision of pharmaceutical information and counselling, regulatory services, education and training of staff.

Pharmacists

People who have completed studies in pharmacy at university level (granted by appropriate diploma) and who are licensed to practise pharmacy.

They may be either salaried or self-employed pharmacists delivering services, irrespective of the place of service provision.

Services provided by pharmacists include preparing and directing the preparation of medicines according to prescriptions of medical and dental practitioners or established formulae; checking prescriptions to ensure that recommended dosages are not exceeded and that instructions are understood by patients – or people administering the medicines – and advising on possible medicine incompatibility; dispensing medicines in hospitals or selling them in pharmacies.

Pharmacy retail price

The price charged by community pharmacies to the general public, including any pharmacy remuneration such a pharmacy mark-up or dispensing fee.

It can be a gross (including value-added tax/VAT) or a net pharmacy retail price (excluding VAT).

Positive list (formulary)

List of medicines that may be prescribed at the expense of a third-party payer – one form of a reimbursement list.

Prescription

An order mostly in written form (receipt) by a qualified health care professional to a pharmacist or other therapist for a medicine or treatment to be provided to their patients.

One prescription may contain several items. The maximum number of items on a prescription can be regulated.

Pricing policies

Regulations and processes used by government authorities to set the price of medicine as part of exercising price control (e.g. statutory pricing, price negotiation).

If other stakeholders are allowed to set medicine prices, their strategies can be also considered pricing policies (e.g. free pricing by pharmaceutical companies).

Reference price system

A reimbursement policy in which identical medicines (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).

Rebate

A payment made to the purchaser after the transaction has occurred.

Purchasers (either hospitals or pharmacies) receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler or manufacturer over a particular period of time.

Reimbursement

Coverage of the cost of reimbursable medicines by a public payer (such as social health insurance/NHS).

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.

Social health insurance (SHI)

A system of financing health care often funded through insurance contributions by employers and employees as well as state subsidies.

Many countries have obligatory schemes for (employed) people whose income does not exceed a certain amount/limit (an insurance obligation). 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 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.

Wholesale

All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and people authorized or entitled to supply medicines to the public in the country concerned.

Wholesalers may have a "public service obligation": the obligation to guarantee permanently an adequate range of medicines to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of that area.

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.

Member States

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands
North Macedonia
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Turkey
Turkmenistan
Ukraine
United Kingdom
Uzbekistan

World Health Organization
Regional Office for Europe

UN City, Marmorvej 51
DK-2100 Copenhagen Ø, Denmark

Tel: +45 4533 7000
Fax: +45 4533 7001
Email: euwhocontact@who.int
Website: www.euro.who.int