

ACCESS TO MEDICINES AND HEALTH PRODUCTS PROGRAMME **ANNUAL REPORT 2020**



Abstract

The WHO Regional Office for Europe supports Member States in providing people with sustainable access to essential and affordable high-quality medicines and medical products. The Access to Medicines and Health Products (AMP) programme focuses on health system strengthening, supporting the development, revision and implementation of comprehensive pharmaceutical sector policies covering regulation of medicines and medical devices, pharmacovigilance, selection and responsible use of medicines, expanding the use of health technology assessment, and developing medicine pricing and reimbursement policies. The programme also has an important convening role, bringing together international experts to promote cross-country/area dialogue and share country/area experiences. The COVID-19 pandemic has focused attention on weaknesses and vulnerabilities in health-care systems. These weaknesses have reinforced the importance of health system strengthening to provide safe, quality, affordable medicines and health-care products. The 2020 annual report of the Access to Medicines and Health Products (AMP) programme highlights some of the work done by the Regional Office in collaboration with agencies and partners.

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The AMP programme thanks its network of collaborating centres, other nongovernmental organizations in official relations with WHO, and WHO headquarters for their technical expertise and support in improving pharmaceutical policies and systems in the WHO European Region.

The contribution of national ministries of health, public health authorities, national regulatory and public procurement agencies through their collaboration and willingness to share their experiences in the pharmaceutical sector is gratefully acknowledged.

AMP programme partners

AMP programme partners are:

- Gesundheit Österreich GmbH (Austrian Public Health Institute)
- Department of Pharmacy, University of Copenhagen, Denmark
- Institute of Public Health, Norway
- LSE Health, London School of Economics and Political Science, United Kingdom
- Norwegian Institute of Public Health
- Amgros I/S, Denmark
- Uppsala Monitoring Centre, Sweden
- Utrecht Institute for Pharmaceutical Sciences, the Netherlands
- European Centre for Disease Prevention and Control
- the Global Fund to Fight AIDS, Tuberculosis and Malaria
- the Bill and Melinda Gates Foundation
- Organisation for Economic Co-operation and Development
- United Nations Children's Fund
- United Nations Development Programme
- International Pharmaceutical Federation
- International Network of Agencies for Health Technology Assessment
- Health Technology Assessment International.

Message from the Director

The COVID-19 pandemic inevitably affected planned work in 2020, with many country/area-based activities, workshops and opportunities for information-sharing cancelled or postponed. COVID-19 also focused attention on weaknesses and vulnerabilities in health-care systems. These weaknesses have reinforced the importance of health system strengthening to build robust, resilient and evidence-informed systems.

The European Programme of Work, 2020–2025 “United Action for Better Health in Europe” (EPW), recognizes health system strengthening as being central to moving towards universal health coverage, protecting against health emergencies, and promoting health and well-being for all. Affordable access to medicines and health products for all is a priority under the EPW. Out-of-pocket costs of medicines and health products are of concern in Europe, acting as a barrier to access, generating unmet health needs and leading to financial hardship for many. Addressing medicine costs, including transparency in medicines pricing, is important in tackling access to medicines.

Work undertaken in conjunction with European experts in 2020 provides a strong platform for our ongoing efforts. The Oslo Medicines Initiative, supported by the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency, will provide a platform for the public and private sectors jointly to outline a vision for equitable

and sustainable access to effective, innovative and affordable medicines. The WHO Regional Office for Europe will have an important leadership role in this initiative.

I welcome this report of the work of the Access to Medicines and Health Products (AMP) programme team in 2020. With its technical expertise and practical experiences in pharmaceutical regulation, procurement and supply, prescribing, dispensing and appropriate use of medicines, the AMP team is well placed to support the agenda of health system strengthening and assisting Member States in strengthening their pharmaceutical systems.

Collaborations across and beyond WHO are critical to delivering our programmes. We look forward to ongoing and effective partnerships with Member States, United Nations agencies and nongovernmental organizations as we address diverse challenges in the pharmaceutical sector, from improving access to high-priced medicines, to reducing out-of-pocket costs, limiting the circulation of substandard and falsified products, and promoting the responsible use of antibiotics. Our aim is to ensure that high-quality and affordable medicines and health technologies are available to all citizens of the WHO European Region.

Dr Natasha Azzopardi-Muscat

Director of the Division of Country
Health Policies and Systems
WHO Regional Office for Europe



Introducing the Director

Dr Natasha Azzopardi-Muscat was appointed Director of the Division of Country Health Policies and Systems, which includes the Access to Medicines and Health Products (AMP) programme, in 2020. Dr Azzopardi-Muscat brings a background in maternal and child health, mental health and primary care and an understanding of the challenges of small states in developing and sustaining robust health-care systems. She recognizes the importance of good governance and strong public health services to efficient and effective health-care systems and is a passionate advocate for activities that promote health and access to health care in communities.

Abbreviations

AMC	antimicrobial medicines consumption
AMP	Access to Medicines and Health Products (programme)
AT	assistive technologies
AWaRe	Access, Watch and Reserve (classification of antibiotics)
CPA	Central Procurement Agency (Ukraine)
CRP	collaborative registration procedure
DDD	defined daily dose
DU75%	drug utilization 75%
EECA	eastern Europe and central Asia
EPW	(WHO) European Programme of Work, 2020–2025
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
EU	European Union
GSMS	(WHO) Global Surveillance and Monitoring System
HREC	(WHO) Human Research Ethics Committee
HTA	health technology assessment
HTP	Health Technologies and Pharmaceutical (programme)
NRA	national regulatory authority
PPE	personal protective equipment
PPRI	pharmaceutical pricing and reimbursement information
PSM	procurement and supply management
SF	substandard and falsified (products)
UHC	universal health coverage
UNICEF	United Nations Children's Fund



Introduction

The WHO Regional Director for Europe, Dr Hans Henri P. Kluge, took office in February 2020, launching the strategic directions for the WHO Regional Office for Europe and the European Programme of Work, 2020–2025 – “United Action for Better Health in Europe” (EPW) (1). This led to a reorganization of units within the Regional Office to align with the EPW.

The former Health Technologies and Pharmaceutical (HTP) programme was renamed the Access to Medicines and Health Products (AMP) programme and is part of the Division of Country Health Policies and Systems. The director of the division is Dr Natasha Azzopardi Muscat.

Access to Medicines and Health Products (AMP) programme

AMP realizes the objectives of the EPW by focusing on health system strengthening through:

- supporting the development, revision and implementation of comprehensive pharmaceutical sector policies covering the regulation of medicines and medical devices;
- promoting the judicious selection and responsible use of medicines;
- expanding the use of health technology assessment (HTA); and
- developing medicine pricing and reimbursement policies.

The AMP undertakes a mix of country/area-specific, subregional and regional initiatives.

Where appropriate, AMP plays a convening role, bringing together national and international experts and colleagues to promote cross-country/area dialogue and share country/area experiences.

The EPW establishes the following thematic priorities for AMP:

- ensuring access for all to medicines, vaccines and health products;
- improving governance and stewardship in the pharmaceutical sector;
- supporting country/area preparedness and response capacity for medicines and health products in emergency situations;
- improving patient safety and tackling antimicrobial resistance; and
- supporting EPW flagship initiatives.

Impact of the COVID-19 pandemic

The COVID-19 pandemic necessitated changes to planned face-to-face country activities, regional meetings and workshops in 2020. AMP support to countries/areas in the European Region continued, with resources and activities directed towards supporting emergency responses and strengthening country/area capacity for access to essential medicines and health products in the face of disrupted supply chains, shortages of some medicines and demands for specific medicines and health technologies.

About the AMP programme

WHO describes the value chain of a medicine, identifying steps along the pathway from identification of a new chemical entity to its use in clinical practice (Fig. 1). Access to medicines and health products requires attention at all steps along this path.

Through the AMP and other programmes, the Regional Office supports countries/areas in their development of policies and guidance for selection and use of medicines and medical products. AMP provides direct technical assistance to countries/areas and supports networking and collaboration between them to improve access to quality, affordable essential medicines and promote their responsible use.

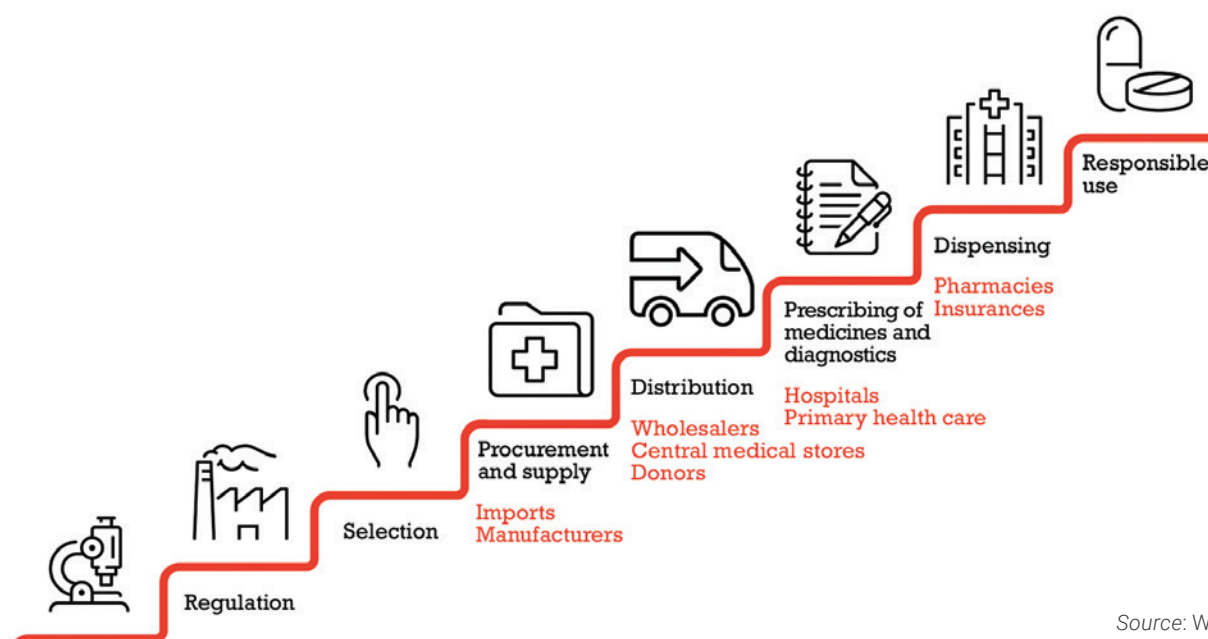
The aims and objectives of the AMP programme cover three strategic areas:

1. policies and regulation to ensure the quality, safety and efficacy of health products;
2. medicines and health products selection that will improve equitable and affordable access; and
3. data and information to understand and improve the responsible use of medicines and health technologies.

Under the umbrella of health system strengthening, AMP focuses on the development, revision and implementation of comprehensive pharmaceutical sector policies covering:

- regulation of medicines and medical devices;
- good governance in the pharmaceutical sector;
- efficient procurement and supply-chain management to ensure the quality of medicines and health technologies in circulation;
- pharmacovigilance;
- evidence-based selection of medicines and fair and affordable pricing;
- expanded use of HTA;
- medicine pricing and reimbursement policies; and
- data analysis on medicines consumption and use to promote the responsible use of antimicrobial medicines.

Fig. 1. Value chain of a medicine



Source: WHO (2).



The EPW

The EPW, approved by Member States in 2020, sets out regional health priorities and the framework for Regional Office activities (1). EPW core priorities are:

1. moving towards universal health coverage (UHC)
2. protecting against health emergencies
3. promoting health and well-being.

Supporting Member State efforts to ensure access for all to medicines, vaccines and health products will involve identifying and supporting the correction of vulnerabilities in regulatory procedures, production, procurement and supply chains.

Implementing the EPW requires a reconsideration of current interactions through which patients, health systems and governments can access affordable pharmaceuticals that meet their needs, while investors and the pharmaceutical industry are rewarded sufficiently for developing or manufacturing those medicines. WHO will have an important role in convening stakeholders to discuss their roles and responsibilities.

The high costs of medicines pose a significant barrier to access, cause inequities within and among Member States, and lead to unacceptable levels of out-of-pocket expenditure in countries/ areas across all income levels. In May 2019, Member States endorsed World Health Assembly resolution WHA72.8 on improving the transparency of markets for medicines, vaccines and other health products (3). The EPW recognizes the importance of accelerating implementation of WHA72.8 to improve access to high-priced innovative medicines and vaccines. This will be done by strengthening information systems, expanding voluntary intercountry/area collaborative platforms and supranational procurement groups, and developing technical options for fair pricing.

The Regional Office has worked with stakeholders to discuss challenges in access to innovative, high-value medicines in Europe and form proposals for the Regional Office's contribution to implementation of resolution WHA72.8. Experts from health ministries, insurance institutions and academia from Austria, Belgium, Malta, Norway, Switzerland and the United Kingdom, as well as European experts from a range of institutional backgrounds and representatives from the

Regional Office and WHO headquarters, convened to discuss potential actions (4).

Participants to this consultation agreed that the focus of the work must be on equity and leaving no one behind. Three key themes were identified:

- achieving greater solidarity between stakeholders on solutions to resolve critical access issues;
- understanding how transparency could be used to build trust and support access; and
- ensuring sustainability in both industry and health-care systems.

Concerns about high-cost medicines in Europe has given rise to the Oslo Medicines Initiative (5).

The Oslo Medicines Initiative: better access to effective, novel, high-priced medicines

The Oslo Medicines Initiative was developed by the Regional Office in conjunction with the Norwegian Ministry of Health and Care Services and the Norwegian

Medicines Agency (5). It aims to provide a platform for the public and private sectors jointly to outline a vision for equitable and sustainable access to effective, innovative and affordable medicines. The challenge is to ensure wider access to affordable medicines while maintaining commercial viability for medicine producers. Achieving this will require greater solidarity, transparency and coherence between the public and private sectors and a commitment to sustainability.

The constraints of the COVID-19 pandemic have affected the consultation process. Planned activities include:

- virtual consultations with WHO Member States, followed by non-state actors;
- a series of webinars and technical sessions with invited keynote speakers and panellists drawn from stakeholder groups across the WHO European Region;
- commissioned background documents related to the themes of solidarity, transparency and sustainability; and
- an in-person meeting, planned for spring 2022, to outline the new vision for collaboration to improve access to novel medicines in the WHO European Region.

COVID-19-related activities

AMP supported the development of several technical documents providing guidance to national agencies related to the COVID-19 pandemic. AMP staff were co-opted to the WHO Health Emergencies Response team.

Supply management

The COVID-19 Supply Chain System was established to streamline procurement and increase efficiencies in the distribution of 58 critical products (6). A technical document was developed to support national authorities facing interrupted supplies of medicines and health technologies during the COVID-19 pandemic (7). AMP supported several Member States in local procurement of personal protective equipment (PPE), diagnostics and medical equipment.

Minimum criteria for procurement were developed for procurement and supply management (PSM) agencies. Guidance focused on prioritization, legislation, registration and marketing authorization, procurement, distribution and management of shortages. WHO headquarters, the Regional Office and the United Nations Children's Fund (UNICEF) are codeveloping a module on the resilience of PSM systems in cases of emergency.

Preparedness to deploy COVID-19 vaccines

Guidance on deployment and vaccination planning supports countries/areas in developing their plans for the introduction of COVID-19 vaccines (8). WHO is working to ensure that national regulatory authorities (NRAs) have procedures and pathways for emergency approvals, and can facilitate importation of vaccines, expedite lot release of COVID-19

vaccines and make provision for traceability of vaccines in their health-care systems.

Use of experimental medicines

Technical advice was developed to address questions from Member States regarding the use of experimental medicines in the treatment of COVID-19 patients (9). The document provides WHO recommendations for the treatment of COVID-19 patients, and information on the ethical and legal requirements for the clinical-trial use of experimental medicines and donated medicines.

Pharmacy services

Pharmacists are likely to have had an enhanced role during the COVID-19 pandemic, with people who are unwell visiting pharmacies first for professional advice on symptom management and treatments for existing conditions. Technical guidance was developed to support pharmacists to provide safe, high-quality services in community pharmacy settings (10).



Examples of country support

Azerbaijan

At the request of the First Vice-President of Azerbaijan, WHO sent a team of experts to provide recommendations and support response-planning for the COVID-19 pandemic. AMP supported this mission, focusing on activities to ensure access to medicines and health products for the prevention and treatment of COVID-19 infection.

Georgia

AMP participated in a high-level advocacy meeting to discuss planned reforms in the pharmaceutical sector to address issues that included gaps in health insurance coverage and high out-of-pocket costs. Mapping of the pharmaceutical system and institutions was undertaken. Challenges in the reform process were discussed and measures to address concerns identified.

Romania

A review of procurement of tuberculosis medicines and diagnostics identified problems with the licensing of medicines, no centralized stock of medicines or forecasting mechanism, and high prices. Procurement legislation was reviewed. A PSM consultant developed a simple stock-management tool, provided training on its use and supported its implementation in six regions.

Tajikistan

Tajikistan does not have a system for monitoring medicine prices at any level of the health-care system. A MedMon (11) survey was conducted in response to concerns about access to essential

medicines amid the COVID-19 crisis. A customized MedMon platform was developed and training of data collectors undertaken in 2020, with data collection in community pharmacies carried out in early 2021.

Turkey

A mission was undertaken to review progress in the development of the NRA self-benchmarking report and the institutional development plan. The review showed good progress in the implementation of planned improvements to the NRA. Formal benchmarking, planned for 14–18 September, was postponed due to the epidemiological situation.

Turkmenistan

Poor management of noncommunicable diseases contributes to high premature mortality rates. AMP is supporting the Ministry of Health to revise the national medicines policy, review the National Essential Medicines List and its concordance with WHO Model Lists and alignment with approved clinical protocols and guidelines, and evaluate quantification mechanisms to ensure adequate procurement of medicines for noncommunicable diseases.

Uzbekistan

WHO has been working with the Ministry of Health to analyse data from a pilot site (Syrdarya region) on current spending on medicines. A customized MedMon survey has been developed to provide baseline data on availability and prices of essential medicines in community pharmacies. Training for data collectors and data collection are planned for early 2021.

Enhanced support to countries

AMP has been able to support specialist national professional officers in some countries who provide continuous and enhanced engagement on medicines and health products.

Kyrgyzstan

- A series of online capacity-building activities was conducted for NRA staff.
- Peer-learning training was provided by the Swiss regulatory agency, SwissMedic, on performance effectiveness, quality, reliability and regulatory agency accountability.
- Support was given for training on the common technical documents and regulation of medicines and medical devices within the Eurasian Economic Union.
- Work was undertaken on implementing the institutional development plan developed in accordance with the WHO benchmarking tool for regulatory agencies.
- Technical assistance was provided to pilot a new government decree on price controls for medicines included in the health insurance package.
- Support was given for local procurement of PPE and medical equipment for the COVID-19 response.

Republic of Moldova

- Rapid assessment of the national procurement and supply management system for essential medicine was organized, in accordance with the UNICEF supply-chain maturity model (12).
- Contributions were made to the new national health 2030 strategy and to the development of a new draft of the law on pharmacy.

- A review of the National Essential Medicines List and a new methodology for inclusion/exclusion based on the WHO National Essential Medicines List were organized.
- Capacity-building activities were facilitated for the NRA and emergency-use approval for COVID-19 vaccines developed.
- A national survey of antimicrobials supplied in community pharmacies in the Republic of Moldova following the COVID-19 pandemic was prepared, to be implemented in 2021.
- A national availability, price and affordability survey of essential medicines in community pharmacies was designed, to be implemented in 2021.

Ukraine

- A series of workshops was conducted for the Central Procurement Agency (CPA), focusing on WHO standards for procurement agencies and best procurement practices.
- PSM assessment of the CPA was facilitated and an institutional development plan to ensure procurement of safe, quality-assured medicinal products was developed.
- Contributions were made to technical discussions on HTA and medicine-selection procedures.
- Facilitation was provided for the analysis and preparation of a draft report of an availability, price and affordability survey of essential medicines in outpatient settings.
- Support was provided to the CPA, Ministry of Health and the HTA Department of State Expert Centre of the Ministry of Health through advice on procurement, clinical-trial protocols and regulatory matters to enhance the pandemic response.
- Support was given to local manufacturers to improve quality-management systems.

Medicine regulation and quality

Regulation primarily is concerned with enabling patient access to quality, safe and effective medicines and medical devices. A strong regulatory system builds confidence in the quality of products in circulation and protects from exposure to substandard and falsified (SF) products. Some countries in the WHO European Region are governed by European Union (EU) rules on the regulation of medicines and health products, while smaller countries and areas outside the EU use a mix of national regulatory procedures and reliance on regulatory assessments conducted by other Member States.

Regulatory system strengthening

- AMP has supported countries/areas in the Region undertaking self-benchmarking as part of formal assessment of their regulatory systems using the WHO Global Benchmarking Tool. Several have formulated an institutional development plan to build on strengths and address gaps identified in their systems.
- The prequalification team's virtual online medicines quality-assessment training focused on the assessment of a generic product dossier (active pharmaceutical ingredients and finished products) and covered the topics of bioequivalence and biowaivers. The training targeted regulators from NRAs in emerging markets and quality assessors.
- The eighth annual meeting on the collaborative registration procedure (CRP) was conducted online in 2020. Participants from Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Ukraine and Uzbekistan presented their achievements and challenges regarding the CRP and addressed questions from those yet formally to join the CRP process.
- Updated WHO guidelines on good storage and distribution practices for medical products were published in 2020 (13). The term good storage and distribution practices replaces the previously used good distribution practices. The guidelines assist in ensuring the quality and identity of health products during all aspects of the distribution process, including procurement, purchasing, storage, transportation, repackaging, relabelling, documentation and record-keeping.
- AMP and the Regional Office participated in a virtual meeting with coordinators of national tuberculosis programmes to share information about the WHO CRP for medicines and experiences in the application of CRP for tuberculosis in Kyrgyzstan and Ukraine.
- A WHO examination training course was conducted on strengthening country/area-adapted active tuberculosis drug-safety monitoring and management systems and their alignment with national pharmacovigilance. The course covered the concepts of pharmacovigilance, and adverse drug reactions and adverse events following immunization, with analysis of the clinical management of cases of each. Participants were drawn from the tuberculosis, HIV, hepatitis and immunization programmes and NRAs in Azerbaijan, Tajikistan, Turkmenistan and Uzbekistan.



Substandard and falsified (SF) products

Substandard products (also called out of specification) are authorized medical products that fail to meet either their quality standards or specifications, or both. *Falsified medical products* are those that deliberately/fraudulently misrepresent their identity, composition or source.

SF medical products pose an unacceptable risk to public health, are in circulation in every region of the world and affect products of all types, including generic and innovator brands, vaccines and diagnostics. The COVID-19 pandemic has exacerbated problems, with seizures of SF products occurring as countries/areas compete for access to medicines, vaccines and PPE globally (14). The need to address SF has been highlighted in the EPW.

The WHO European Region is bordered by several countries that are major manufacturers of pharmaceuticals and known-source countries of SF medical products (15). The key component to preventing, detecting and responding to SF is a transparent NRA that is appropriately resourced in terms of finance, staff and equipment.

The WHO Global Surveillance and Monitoring System (GSMS) is a structured reporting system that allows a fast response to emergencies and the issuing of global/regional alerts in the most serious cases of SF products. The GSMS is only as good as the reports it receives and is best supported by regional networks. While EU countries actively participate, non-EU countries/areas in the European Region report SF medical products only sporadically to the GSMS.

In response, AMP commissioned a review and action plan to advance the agenda on SF products, particularly in the non-EU part of the European Region. Specifically, AMP will initiate work in selected WHO Member States to increase government and public awareness of the problems of SF products. The countries/areas involved will be encouraged to participate in the Member State Mechanism, fostering international cooperation and information exchange on, for example, good

manufacturing practices (and good storage and distribution practices) inspection reports. A limited medicine-quality survey conducted in accordance with established guidelines is a proven method of establishing a benchmark against which to measure progress. Opportunities for a subregional network for non-EU countries/areas will be explored.

Blood products

In 2020, WHO launched its action framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 (16), with six key objectives:

- appropriately structured, well coordinated and sustainably resourced national blood systems;
- regulatory capacity to ensure the quality and safety of blood;
- functioning and efficiently managed blood services;
- effective implementation of patient blood management to optimize transfusion practices;
- effective surveillance, haemovigilance and pharmacovigilance, supported by comprehensive and accurate data-collection systems; and
- partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

Some European countries, mainly EU and other high-income states, have been assessed as meeting the standards of the WHO Global Benchmarking Tool + Blood. In other cases, there is a lack of regulation and coordination of blood services, with significant proportions of donations collected from family replacement

and/or paid donors and private blood banks. This can lead to high levels of wastage of donations during collection, processing and testing, and due to expiry. Even the status of blood varies: it is classed as a medicine in some countries/areas and specifically excluded from classification as a medicines or medicines product in others.

In 2020, AMP commissioned a review and action plan to consider the global action framework in the context of the European Region and support its implementation. AMP will work to increase awareness of the WHO Global Benchmarking Tool + Blood and WHO action framework on blood products and, where appropriate, support Member States to develop the regulatory framework for a national blood service.



AMP will enhance opportunities for collaboration between Member States in sharing information and expertise to advance universal access to safe, effective and quality-assured blood products.

Procurement and supply management

Ensuring access for all to medicines, vaccines and health products is identified as a priority in the EPW. Efficient PSM facilitates the purchase of quality products at best prices, ensures adequate and timely supply and minimizes stockouts and shortages.

PSM strengthening for transitioning countries/areas

Global Fund systems using international procurement procedures have facilitated access to quality-assured medicines for the treatment of HIV and tuberculosis in low- and middle-income countries/areas globally. The transition of several middle-income countries/areas in the European Region from Global Fund to national procurement has focused attention on the need to upgrade national PSM systems to avoid disruptions to service delivery and ensure access to treatment. This may require changes to laws, regulations and procedures, capacity-building for agencies, and allocation of sufficient funds for purchases of medicines and health products.

AMP works with other WHO teams to support transition efforts through the CRP, strengthening of national regulatory agencies, prequalification of medicines and health products, promotion of good manufacturing practices and support for pricing and reimbursement policies.

Assessing PSM systems in the European Region

In 2020, AMP worked with UNICEF to assess PSM systems in Azerbaijan, Georgia, Kazakhstan, the Republic of Moldova and Uzbekistan, with the support of a grant from the Global Fund for Access to Medicines and Health Products. The UNICEF supply-chain maturity model measures performance

and capability of national supply chains for essential medicines or any other health commodity across a maturity framework that ranges from level 1 (minimum development and performance) to level 5 (fully developed, integrated and excellent performance) (12). These assessments identify gaps and priorities across the supply chain and allow tracking of progress as countries reform, develop recommendations and improve their systems.

A separate assessment of the CPA in Ukraine was undertaken by the WHO Country Office in Ukraine using the WHO Model Quality Assurance System for Procurement Agencies. The tool assesses the quality-assurance requirements for procurement across six domains – general requirements, prequalification, purchasing, reception and storage, distribution and reassessment. A preliminary report outlines findings across some domains. A capacity improvement plan has been drafted to address key gaps.

Assistive technologies for hearing, mobility and vision

Tajikistan developed its first list of essential assistive products for older people and people with disabilities in 2018. The list of 30 products was based on the WHO Priority Assistive Products List and was the result of a consultative, consensus-driven process involving representatives from the Ministry of Health





and Social Protection and stakeholders that included the Government, donor agencies, nongovernmental organizations, disabled people's organizations and users of assistive technologies (AT). The three main barriers to access to ATs in Tajikistan were found to be affordability, lack of awareness and lack of availability at community level (17).

To support WHO's work to improve access and affordability of ATs for hearing, mobility and vision, an intern with the AMP programme conducted a mapping of AT manufacturers and wholesalers in nine countries of the WHO European Region and in Kosovo.¹ The desk review collated information on sources of hearing aids, wheelchairs, spectacles and prosthetics in four low-middle-income countries (Azerbaijan, Georgia, Tajikistan and Ukraine) and in Kosovo,¹ and in five high-income countries (Denmark, France, Germany, Malta and the United Kingdom).

Most of the high-income countries maintained national databases with information on companies supplying ATs, typically manufacturing companies. In contrast, it was often difficult to find information on suppliers in low-middle-income countries and in Kosovo;¹ these mostly were local distributors or retailers of imported products rather than local manufacturers. In total, the review identified 429 companies across the nine countries and Kosovo,¹ primarily wheelchair and prosthetic companies.

The results of the mapping exercise will be used by UNICEF and WHO to inform a joint UNICEF–WHO tender for ATs and an international joint meeting for global AT companies. Placing priority ATs in UNICEF and WHO supply catalogues will facilitate Member States' procurement of affordable and high-quality products for their populations. The first joint UNICEF–WHO tender, to be launched in the first quarter 2021, will focus on hearing aids and wheelchairs.

¹ All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Access to medicines and health products

Evidence-based selection and efficient introduction of medical products into country/area health-care systems are key to controlling public pharmaceutical expenditure and balancing spending in public health while remaining aware of neglected and orphan diseases.

Electronic WHO Model Lists of Essential Medicines

Essential medicines are those that satisfy the priority health-care needs of the population and should be selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines of assured quality should always be available in a functioning health system at prices individuals and the community can afford.

AMP has made available Russian-language summaries of key changes to the 2019 WHO Model Lists, including the 2019 update of the Access, Watch and Reserve (AWaRe) classification of antibiotics. A Russian-language version of WHO guidance on selection of essential medicines at country level has also been published (18). Support is provided to Member States on revisions to national lists.

A digital version of the WHO Model List of Essential Medicines was launched in 2020, allowing computer and smartphone access to a comprehensive online database of information on essential medicines. The electronic WHO Model List of Essential Medicines can be adopted or adapted for national lists.

WHO MedMon

The WHO MedMon tool is used to rapidly collect and analyse data on the availability and prices of medicines in health facilities and procurement

centres. In collaboration with the WHO Health Emergencies Programme, it was adapted in 2020 to rapidly assess access to priority medicines and health products needed for the COVID-19 pandemic.

In Tajikistan, the MedMon app was customized for a community pharmacy survey conducted to respond to the public's concern about access to essential medicines amid the COVID-19 crisis.

A MedMon survey is being used to provide baseline data of availability and prices of essential medicines in community pharmacies in Uzbekistan and results will complement the situation analysis being done for the State Health Insurance project. MedMon offers a regular monitoring tool for availability and prices of medicines in both Tajikistan and Uzbekistan.

Cross-country collaborations to improve access to medicines and vaccines in the European Region

An analysis of five government-led, voluntary, cross-country initiatives – the Baltic Procurement Initiative, the Beneluxa Initiative, Fair and Affordable Pricing, the Nordic Pharmaceutical Forum and the Valletta Declaration – has been conducted (19). Joint activities focused on information-sharing, HTA, horizon-scanning, joint pricing/reimbursement negotiations and joint procurement of medicines. Challenges to successful collaboration included the resources required, different languages, dissimilar organizational and legal frameworks, and industry reluctance to engage in joint negotiations. Facilitating factors included political support, trust within the collaboration, commitment of the technical experts involved, similarities between health-care systems and the leadership of a dedicated person. A checklist of prerequisites for successful cross-country collaborations has been developed.

Pricing and reimbursement

Pharmaceuticals remain the most important component of out-of-pocket payments for health in countries/areas in the WHO European Region (20). Affordable and fair pricing and effective financing schemes are integral to the achievement of UHC and the Sustainable Development Goals, and are in line with the EPW priority to ensure access for all to medicines, vaccines and health products.

Pharmaceutical pricing and reimbursement information (PPRI) eastern Europe and central Asia (EECA) network

A relaunch of the PPRI EECA network Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan was conducted online in 2020 with support from the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. The network is an information-sharing initiative on pharmaceutical policies related to pricing and reimbursement from a public health perspective. The meeting introduced the network and included an update on previous and ongoing work. Challenges to pharmaceutical policies during the COVID-19 pandemic and measures to address the challenges were discussed. Several PPRI EECA indicators were presented for consideration by network members.

WHO guideline on country pharmaceutical pricing policies

A revised WHO pharmaceutical pricing policies guideline (2020) has updated the literature, evidence and incorporated country experiences on managing

the prices of pharmaceutical products (21). The guideline identifies eight overarching principles for pricing policies and provides specific recommendations for 10 policies countries/areas may choose and adapt according to the objectives and structure of their health systems.

While most recommendations are defined as “conditional”, reflecting a limited evidence base, a “strong” recommendation is made in favour of promoting the use of quality-assured generic and biosimilar medicines. There is a “conditional” recommendation for promoting price transparency through clear description of pricing approaches and their technical requirements. Mechanisms for increasing transparency include:

- sharing the net transaction prices of pharmaceutical products with relevant stakeholders;
- disclosing prices along the supply and distribution chain;
- reporting research and development contributions from all sources; and
- communicating pricing and reimbursement decisions to the public.

Price regulation in Kyrgyzstan

Facilitated by the national professional officer, WHO provided technical assistance to the Ministry of Health on piloting a new government decree that introduced price controls for selected medicines included in the universal benefits package. The pilot exposed weaknesses in regulation and problems in collecting reliable information from manufacturers and distributors. In response, WHO convened policy dialogues with stakeholders to try to find consensus on mechanisms to improve the sharing of price data. This process informed amendments to the regulation that are pending approval. Ownership of,



and commitment to, the next round of piloting by the Ministry of Health will be critical to the successful implementation of the pricing regulation.

Health technology assessment

HTA refers to the systematic evaluation of properties, effects and/or impacts of a health technology. The HTA approach informs decisions by making the trade-offs between benefits and costs more explicit, and aids decisions on how best to allocate limited funds to health interventions and technologies. In high-income countries, HTA is used to support subsidization decisions for expensive medicines. HTA principles, such as transparency and conflict of interest management, are also important for decisions on selecting medicines for inclusion in nascent health insurance benefits packages in low- and middle-income countries/areas.

HTA meeting for Balkan countries and Kosovo²

A workshop for seven Balkan countries (Albania, Croatia, Bosnia and Herzegovina, Montenegro, North Macedonia, Serbia and Slovenia) as well as

for Kosovo² was conducted to share experiences of the use of HTA to support decision-making. International groups working in HTA and WHO headquarters supported the workshop. HTAs that had been conducted generally were limited to assessments of clinical evidence. Barriers to HTA use were identified as a lack of qualified staff, no HTA agency, no legislation supporting the use of HTA and limited budgets for HTA assessments (22). Ongoing discussions with HTA experts will inform programme development for further workshops and identify opportunities for regional collaboration.

HTA procedure approved in Ukraine

The Cabinet of Ministers of Ukraine approved the state HTA procedure in December 2020 (through Decree No. 1300). The decree mandates HTA assessments of all medicines for public coverage with the conclusions of the assessments shared as advice with the Ministry of Health.

Annexes to the decree include application forms for HTA, HTA dossier requirements for submissions, and requirements for HTA reports to provide clear, structured and transparent processes for all HTA stakeholders. An agency to conduct the HTAs will be created in Ukraine.



² All references to Kosovo in this document should be understood to be in the context of United Nations Security Council resolution 1244 (1999).

WHO Europe Antimicrobial Medicines Consumption Network

AMP continues to support the WHO Europe Antimicrobial Medicines Consumption (AMC) Network in data collection and analysis. As well as disseminating the findings of quantitative analyses, countries/areas are undertaking studies to better understand how antibiotics are used in practice.

Joint publication of the European Centre for Disease Prevention and Control and the WHO Regional Office for Europe

A joint publication comparing European Surveillance of Antibiotic Consumption network (ESAC-Net) and Regional Office AMC data for 2014–2018 was submitted for publication in December 2020. Analyses apply key metrics of consumption and the 2019 updates to defined daily doses (DDDs) and the WHO AWaRe classification. While total consumption was similar in the two networks, the composition of agents varied substantially, underlining the importance of a set of measures to better understand how antibiotics are consumed. The findings can facilitate development of Europe-wide strategies to improve the use of antibiotics and address antimicrobial resistance.

Third report of the AMC Network: AMC data 2014–2018

This report analyses AMC data for 18 participating countries and for Kosovo³ in which the ministries of health and/or public health authorities approved data-sharing and publication. National, cross-national and area analyses include trends over time (2014–2018) for key metrics of antibacterial consumption, the WHO national monitoring target of at least 60% of total consumption being Access

agents, and the drug utilization 75% (DU75%), which represents the antibacterial substances accounting for 75% of the consumption measured in DDD.

Antimicrobials supplied in community pharmacies

A master protocol was developed by AMP for a study to assess patterns of supply of antiviral and antibacterial agents in community pharmacies during the COVID-19 pandemic. For one week, pharmacists from a random sample of pharmacies in countries'/areas' capital cities and in up to five regions were asked to record information on patients' ages and genders, antimicrobials supplied, formulation (oral, injectable) and, where possible, reason(s) for supply. The protocol was approved by the WHO Human Research Ethics Committee (HREC) and adapted for use in nine AMC Network countries and in Kosovo³. National and cross-national and area reports are being prepared.

Access to antibiotics without prescription

AMP developed a study protocol that used simulated patients with concealed identities to assess the proportion of over-the-counter antibiotic requests or consultations for advice from community pharmacists that result in the sale of an antibiotic without a prescription from a medical practitioner. In addition to finding out which antibiotics are sold, the study sought information on whether the client was advised on how to take the medicine and whether possible side-effects were discussed. Two members of the AMC network, Armenia and Kosovo³, undertook studies using the WHO HREC-approved protocol and reported results in 2020. Country/area summary reports are being prepared.

³ All references to Kosovo in this document should be understood to be in the context of United Nations Security Council resolution 1244 (1999).

AMP 2020 reports and publications

Reports

Current status of health intervention and technology assessment in the Balkan region (22) provides an overview of developments in HTA in Balkan countries and in Kosovo⁴ using information shared at a subregional workshop, supplemented with a literature review and a survey of professionals working on HTA.

Assessing the magnitude and nature of shortages of essential medicines and vaccines: focus on the WHO European Region (23) reports the results of a survey commissioned to support WHO's work on addressing the global shortage of medicines and vaccines.

Expert meeting on market transparency to improve access to high-priced innovative medicines (4) summarizes meeting discussions and considers opportunities for the Regional Office to support work on improving the market transparency for medicines, vaccines and other health products.

Cross-country collaborations to improve access to medicines and vaccines in the WHO European Region (19) assesses five government-led, voluntary, cross-country collaborations in the WHO European Region that aim to improve access to essential medicines through joint activities.

WHO Regional Office for Europe Antimicrobial Medicines Consumption (AMC) Network. AMC data 2011–2017 (24) analyses trends over time for key metrics of antibiotic consumption and considers new metrics to inform the responsible use of antibiotics.

Peer-reviewed publications

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Rechel B, Moldoisaeva S. Improving maternal and newborn health in Kyrgyzstan. *Lancet Glob Health* 9(3):e237–8. doi:10.1016/S2214-109X(20)30511-8.



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Annex 1. Calendar of activities

Country-based activities in 2020 were curtailed by the COVID-19 pandemic.

DATE	TOPIC	LOCATION
January 2020		
15–18	NRA self-benchmarking, technical support visit	Ankara, Turkey
27	Meeting of MEDEV	Brussels, Belgium
28–31	Scoping meeting on medicines reform	Tbilisi, Georgia
February 2020		
11–13	HTA workshop for Balkan countries/areas	Ljubljana, Slovenia
18	Meeting on market transparency to improve access to high-value medicines	Brussels, Belgium
20	Amgros I/S lead team meeting	Copenhagen, Denmark
24–25	Meeting with regional advisers on the implementation of WHO global goods	Geneva, Switzerland
26–28	Meeting of guideline development group on pricing of pharmaceuticals	Geneva, Switzerland
March 2020		
8–14	COVID-19 emergency mission	Baku, Azerbaijan
April 2020		
28	First meeting, WHO Regulatory Update on COVID-19	Virtual meeting
May 2019		
13	PPRI online meeting: working in times of COVID-19. Special topic: medicines shortages	Virtual meeting
September/October 2020		
28–1	Prequalification team medicines quality assessment training	Virtual meeting
November 2020		
11	Second meeting, WHO Regulatory Update on COVID-19	Virtual meeting
16	PPRI EECA network meeting	Virtual meeting
23–27	Eighth annual meeting on (CRP)	Virtual meeting

DATE	TOPIC	LOCATION
December 2020		
2	Intercountry practitioners' network – CRP for tuberculosis medicines	Virtual meeting
7–11	Aligning active tuberculosis drug safety monitoring and management systems with national pharmacovigilance programmes	Virtual meeting

NRA: national regulatory authority.

HTA: health technology assessment.

MEDEV: Medicine Evaluation Committee.

PPRI: pharmaceutical pricing and reimbursement information.

EECA: eastern Europe and central Asia.

CRP: collaborative registration procedure.

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	Lithuania
Andorra	Luxembourg
Armenia	Malta
Austria	Monaco
Azerbaijan	Montenegro
Belarus	Netherlands
Belgium	North Macedonia
Bosnia and Herzegovina	Norway
Bulgaria	Poland
Croatia	Portugal
Cyprus	Republic of Moldova
Czechia	Romania
Denmark	Russian Federation
Estonia	San Marino
Finland	Serbi
France	Slovakia
Georgia	Slovenia
Germany	Spain
Greece	Sweden
Hungary	Switzerland
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