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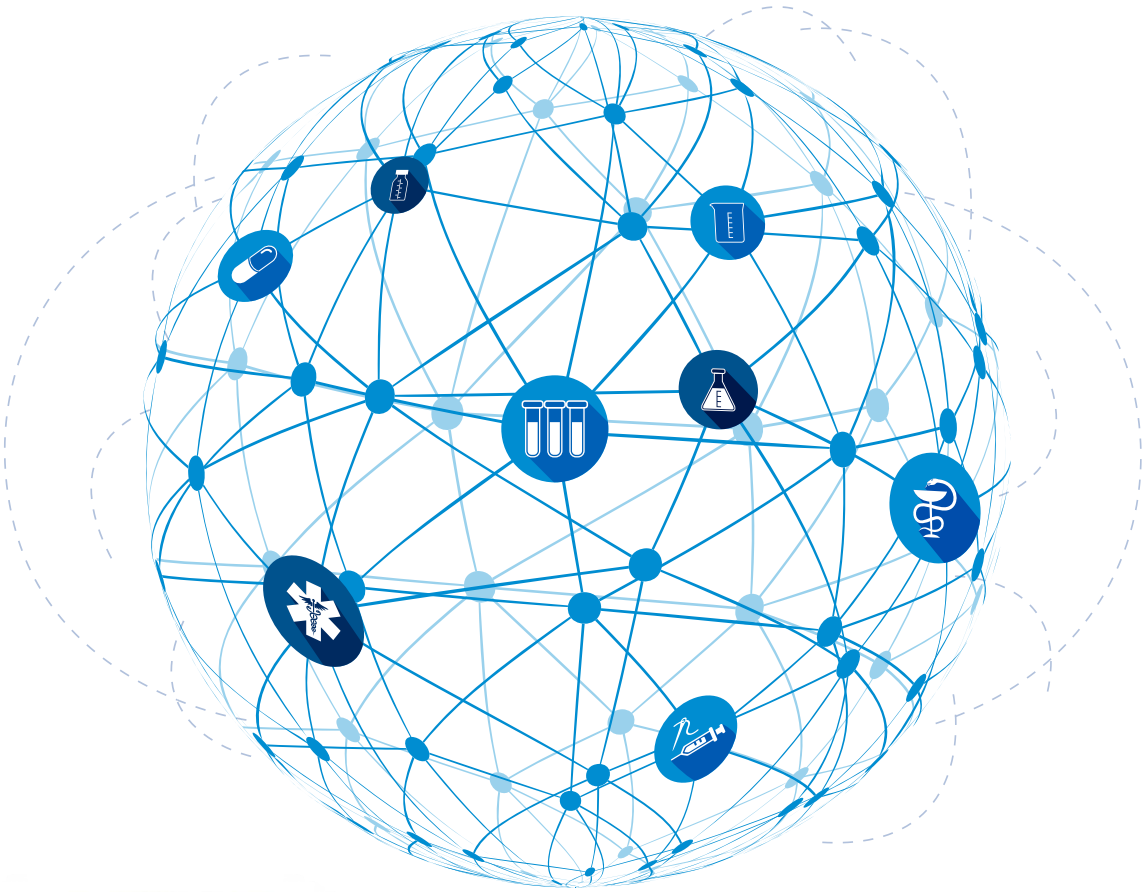
REGIONAL OFFICE FOR Europe

HEALTH TECHNOLOGIES AND PHARMACEUTICALS PROGRAMME
ANNUAL REPORT 2018



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Further thanks go to technical partners, including the WHO country offices, WHO headquarters and WHO collaborating centres in the European Region, for their valuable assistance with activities and support for this area of work in 2018.

Abbreviations

3S	Smart Safety Surveillance [Project]
AMC	Antimicrobial Medicines Consumption [Network]
AMP	Affordable Medicines Programme (of Ukraine)
AMR	antimicrobial resistance
ATC	Anatomical Therapeutic Chemical [classification system]
CIS	Commonwealth of Independent States
DDD	defined daily dose – a measuring unit used in international drug utilization monitoring and research
ECDC	European Centre for Disease Prevention and Control
EML	WHO Model List of Essential Medicines
EMLc	WHO Model List of Essential Medicines for children
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
EU	European Union
GMP	good manufacturing practices
HTA	health technology assessment
HTP	Health Technologies and Pharmaceuticals [Programme]
LMICs	low- and middle-income countries
MDR-TB	multidrug-resistant tuberculosis
NCD	noncommunicable disease
NRA	national regulatory authority
PPRI	Pharmaceutical Pricing and Reimbursement Information [Network]
PSM	procurement and supply management
SDG	Sustainable Development Goal
TB	tuberculosis
UHC	universal health coverage
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund

The Health Technologies and Pharmaceuticals (HTP) Programme: 2018 in review

About the HTP Programme

The WHO European Region includes 53 Member States, of which 28 are members of the European Union (EU). The HTP Programme's mission is to support Member States in providing people with sustainable access to essential and affordable quality-assured medicines and medical devices.

In addition to WHO resources, in 2018 the HTP Programme received voluntary donations for activities (financial or technical staff support) from the Ministry of Health, Welfare and Sport in the Netherlands, the German Collaboration Programme, the Ministry of Foreign Affairs of Japan and Unitaid.

Partners of the Programme

- Department of Pharmacy, University of Copenhagen (WHO Collaborating Centre for research and training in the patient perspective on medicines use), Denmark
- Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies), Austria
- LSE Health, London School of Economics and Political Science, United Kingdom
- Norwegian Institute of Public Health (WHO Collaborating Centre for Drug Statistics Methodology), Norway
- Pharmakon, Denmark
- Uppsala Monitoring Centre (WHO Collaborating Centre for Pharmacovigilance), Sweden
- Utrecht Institute for Pharmaceutical Sciences (WHO Collaborating Centre for Pharmaceutical Policy and Regulation), the Netherlands
- International organizations and agencies: European Centre for Disease Prevention and Control (ECDC), Sweden, the Global Fund to Fight AIDS, Tuberculosis and Malaria; Organisation for Economic Cooperation and Development, Unitaid, United Nations Children's Fund (UNICEF), United Nations Development Programme

Highlights

In 2018 the HTP Programme carried out situation analysis and provided technical guidance to countries and areas on how to increase and sustain access to medicines, including reform of their pharmaceutical sectors, gathered evidence for policy action and helped to build national/area capacity. The Programme focused on increasing access to quality-assured affordable medicines and medical devices, responsible use of medicines – giving special attention to antibiotics – and pharmaceutical policy development for progress towards universal health coverage (UHC). HTP works closely with other health system programmes in the Division of Health Systems and Public Health and with other divisions at the WHO European Regional Office, where it is part of the antimicrobial resistance (AMR) interdivisional team.

Pharmaceuticals represent large budget components for publicly funded health systems, but out-of-pocket payments are also high in many countries and areas in the WHO European Region; this is a major challenge in moving towards UHC.

WHO has organized cross-country/area consultations and training in the use of methodologies, policies and regulation, fostering access to quality-assured affordable medicines and medical devices among countries and areas in the Region and facilitating cross-border collaboration where relevant and feasible. The HTP Programme's work helps to shape policy reform at the national and subregional levels. Major activities in 2018 included the following (for further details see the calendar of activities in Annex 1).

In-country technical assistance and training

Albania

- Technical advice on procurement and supply management to enhance access to tuberculosis (TB) medicines and medical devices
- Technical guidance and consultation related to the monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR

Armenia

- Introduction of the Smart Safety Surveillance Project, supporting collaboration between the pharmacovigilance programme and TB programme of the national regulatory authority (NRA) in monitoring adverse events relating to the use of new TB medicines (such as bedaquiline)

Azerbaijan

- Organization of the Commonwealth of Independent States (CIS) subregional meeting of the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network
- Consultation and sharing experiences with the Kyrgyz authorities about the introduction of medicines price regulation
- Training in good manufacturing practices (GMP) inspection

Belarus

- Technical input to and collaboration with partners on the Second Regional Consultation on Expanding Access to Affordable and Quality Assured Medicines and Diagnostic Technologies in Eastern Europe and Central Asia in Minsk
- Technical guidance and consultation related to monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR

Georgia

- Technical guidance in shaping the national regulatory inspection function and competency-based training of five pharmaceutical inspectors
- Review and technical advice in relation to the government's revision of medicines legislation
- Development of a quality management system for the NRA
- Basic training to strengthen national pharmacovigilance monitoring and analysis

Greece

- Technical guidance to the Ministry of Health on the introduction of health technology assessment (HTA) as part of the decision-making process for inclusion of new medicines for reimbursement
- Technical guidance to the Ministry of Health in drafting an action plan for implementation of the legislation on HTA

Kazakhstan

- Technical guidance and facilitation of several workshops to improve efficiency in regulating pharmaceuticals
- Benchmarking of the NRA functions; technical guidance and training related to implementation of the NRA institutional development plan
- Technical guidance and consultation related to monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR
- Training in GMP inspection

Kyrgyzstan

- Technical guidance to the Ministry of Health and related government bodies and institutions to improve access to quality medicines and medical devices, including:
  - technical guidance on the drafting of new pharmaceutical bylaws and their adoption
  - workshops and policy dialogues on efficiency in regulation of quality and safety, as well as pricing policies for national actors and stakeholders
  - technical guidance linked to the introduction of regulation of medical devices
  - support to the task force responsible for development of medicines price regulation
  - ATC DDD course participation at the Nor-

wegian Institute of Public Health (WHO Collaborating Centre for Drug Statistics Methodology), Norway
- introduction of a Unitaid project supporting collaboration between the NRA pharmacovigilance programme and TB programme in monitoring adverse events relating to the use of new TB medicines (such as bedaquiline)
- follow-up on antimicrobial consumption monitoring activities and work on adoption of a national action plan on AMR, anti-infective treatment guidance development and responsible use of medicines, in collaboration with Control of Antimicrobial Resistance Unit, WHO Regional Office for Europe
- training in GMP inspection for NRA staff

Lithuania

- Participation, along with several EU Member States, in a Ministry of Health-organized consultation on the regulation of pharmacy practice, linked to pharmaceutical sector reform activities in the country

- Leading up to this consultation, carrying out a review of regulation of pharmacy practice in the Region (a WHO report will be published in 2019) to gather evidence for sharing during the national consultation

Montenegro

- Technical guidance to the Ministry of Health in developing a law governing the activities of the retail pharmacy sector and participation in a national consultation on the topic

- Technical guidance on the selection and use of medicines, including monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR

Republic of Moldova

- Technical guidance to the Ministry of Health and related government bodies and institutions to improve access to quality medicines and medical devices, including:
  - consultations on access to medicines with the government's health committee and stakeholders
  - technical guidance on the selection and use of medicines, including monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR
  - initiation of a medicines price survey
  - initiation of high-level policy dialogue on the revised draft law on medicines
  - gap analysis of the pharmacovigilance system and creation of a follow-up plan
  - introductory workshop on systematic reviews and use of HTA methods
  - training in GMP inspection

Poland

- Review and technical guidance to the Ministry of Health on development of the national pharmaceutical policy

Portugal

- Co-organization of the Infarmed conference "Facing the Challenges: Equity, Sustainability and Access"

Serbia

- Technical support, including workshops, to improve efficiency in regulation of pharmaceuticals

- Benchmarking of the NRA functions with a focus on vaccines, technical guidance and training related to implementation of the NRA institutional development plan

- Technical guidance and consultation on the monitoring of antimicrobial consumption and follow-up action linked to a national action plan on AMR

Tajikistan

- Technical guidance and consultation on monitoring antimicrobial consumption and follow-up

action linked to a national action plan on AMR, including training of a new national focal point

- Training in GMP inspection

The former Yugoslav Republic of Macedonia

- Support to strengthen the pharmaceutical system, focusing on regulatory issues as part of the EU accession process
- Revision of legal documents reforming the selection and pricing of medicines

Turkey

- Technical workshop for the NRA on self-assessment of the national regulatory functions for medicines

Turkmenistan

- Discussions with the Ministry of Health on registration of medicine products to advance the agenda on access to medicine

Ukraine

- Review and assessment of the outpatient reimbursement scheme – the Affordable Medicines Programme – after its first year and prior to expansion
- Participation in a Ministry of Health policy dialogue with stakeholders to present and discuss results and recommendations from the assessment
- Support in revising patent laws and regulation of intellectual property rights of medicines
- Technical guidance and consultation on monitoring antimicrobial consumption and follow-up action linked to a national action plan on AMR, including training of a new national focal point
- Introduction of a Unitaid project supporting collaboration between the NRA pharmacovigilance programme and TB programme in monitoring adverse events relating to the use of new TB medicines (such as bedaquiline)

Uzbekistan

- Technical guidance and support to the Ministry of Health and related government bodies and institutions in relation to a major reform of the pharmaceutical regulation initiated by the president
- Training in GMP inspection
- Technical guidance and consultation on monitoring antimicrobial consumption and follow-up action linked to a national action plan on AMR

In-area technical assistance and training

Kosovo[1]

- Technical guidance to the public health authorities to improve access to essential medicines linked to the planned introduction of a Kosovo health insurance fund, including guidance on revision of the Kosovo

[1] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

essential medicines list and processes for evidence-based selection of medicines for the list and the health insurance fund

- Technical revision of the administrative instruction for creating a pharmaceutical pricing committee
- Technical guidance and consultation on monitoring antimicrobial consumption and follow-up action linked to a Kosovo action plan on AMR

Intercountry/area meetings and workshops for building technical capacity in Member States

- Co-organization of the Medicine Procurement Practitioners Exchange Forum, in collaboration with the UNICEF Supply Division, the United Nations Development Programme and the Global Fund to Fight AIDS, Tuberculosis and Malaria
- Organization of strategic procurement negotiations workshops for procurement practitioners from countries and areas in the Region, in collaboration with LSE Health
- Introduction of the Smart Safety Surveillance Project, supporting collaboration on pharmacovigilance between NRAs and TB programmes in Armenia, Kyrgyzstan and Ukraine
- Training of pharmaceutical inspectors in Azerbaijan, Georgia, Kyrgyzstan, Kazakhstan, the Republic of Moldova and Uzbekistan
- Co-organization of the second meeting of the CIS PPRI Network
- Co-organization of the Joint Meeting of the Antimicrobial Resistance, Antimicrobial Consumption and Healthcare-associated Infections Networks, with joint sessions for the ECDC's European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and WHO Regional Office for Europe's Antimicrobial Medicines Consumption (AMC) Network
- Organization of the annual meeting of the AMC Network, with a focus on antimicrobial stewardship activities
- Desk review of country and area regulation of community pharmacy practices in the Region (WHO will publish a report in 2019)
- Co-organization of post-market surveillance of in vitro diagnostic tests for providers and regulators in the WHO European Region
- Co-convening the third Summer School on Pharmaceutical Pricing and Reimbursement Policies with the Austrian Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies)
- Administrating a joint United Nations Population Fund (UNFPA)–UNICEF–WHO meeting with manufacturers and suppliers of essential medical products
- Provision of continuous regional support to the WHO Prequalification Programme
- Undertaking subregional cross-programmatic consultation on the role of primary care in the responsible use of medicines and reduction of AMR

Introduction

The WHO Regional Office for Europe, through the HTP Programme, supports its 53 Member States with technical guidance related to providing people with sustainable access to essential and affordable quality-assured medicines and medical products. The work of the HTP Programme is in line with the strategies developed by the Essential Medicines and Health Products Programme at WHO headquarters in Geneva.[2] It is aligned with the Tallinn Charter,[3] whose values were re-affirmed by WHO Member States at its 10th anniversary in June 2018; the Declaration of Alma-Ata of 1978, which was reaffirmed through the 2018 Declaration of Astana on primary health care in October 2018;[4] the Health 2020 policy framework at the regional level;[5] and the global 2030 Agenda for Sustainable Development,[6] which strives for a world where every child, man and woman can afford and has access to the quality-assured medicines and health products they need to lead a healthy and productive life.

Member States are increasingly seeking WHO support and guidance in best practices for regulating, selecting, procuring and distributing pharmaceuticals, along with their pricing and reimbursement and responsible use. In 2018 the HTP Programme's work contributed to increasing access to medical products by strengthening countries and areas' pharmaceutical sector systems via:

- technical guidance on selection and responsible use of medicines, with a particular focus on antibiotics;
- support to NRAs with self-assessment of their functions and development of institutional development plans to work towards efficient regulatory practices;
- development or revision of national pharmaceutical policies, including pricing and reimbursement policies;
- promoting transparency and evidence-based decision-making in the pharmaceutical sector, including use of HTA, when relevant;
- facilitation of discussions on new directions and collaboration in procurement and supply chain management.

In addition, the HTP Programme provides countries and areas with opportunities to share experiences and inspiring practices and offers a platform for intercountry/area collaboration on increasing access to medical products.

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[2] Towards access 2030: WHO Medicines and Health Products Programme Strategic Framework 2016–2030. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/towards_access2030/en/, accessed 7 December 2018).

[3] The Tallinn Charter: Health Systems for Health and Wealth. Copenhagen: WHO Regional Office for Europe; 2008 (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies/publications2/2008/tallinn-charter-health-systems-for-health-and-wealth-2008, accessed 13 October 2018).

[4] Declaration of Astana. Geneva: World Health Organization; 2018 (http://www.euro.who.int/en/health-topics/Health-systems/primary-health-care/news/news/2018/10/new-global-commitment-to-primary-health-care-for-all-at-astana-conference, accessed 22 November 2018).

[5] Health 2020: a European policy framework supporting action across government and society for health and well-being. Copenhagen: WHO Regional Office for Europe; 2013 (http://www.euro.who.int/en/publications/abstracts/health-2020-a-european-policy-framework-supporting-action-across-government-and-society-for-health-and-well-being, accessed 13 October 2018).

[6] Transforming our world: the 2030 Agenda for Sustainable Development. In: Sustainable Development Knowledge Platform [website]. New York: United Nations; 2016 (https://sustainabledevelopment.un.org/post2015/transformingourworld, accessed 16 October 2018).

This annual report summarizes the 2018 contribution of the HTP Programme to progress towards UHC in the WHO European Region by supporting improved access to essential, affordable, quality-assured pharmaceuticals and medical products.

Pharmaceuticals, the 2030 Agenda for Sustainable Development and WHO's Thirteenth Global Programme of Work 2019–2023

The Sustainable Development Goals (SDGs) represent a shift of focus from specific diseases and population targets to a more comprehensive approach to health. SDG3 emphasizes the promotion of health throughout the life-course and UHC, and there is an increasing need for resilient health systems that can respond to the rise in epidemic-prone pathogens. The 2030 Agenda for Sustainable Development provides a clear case for WHO to scale up its work on strengthening pharmaceutical systems, taking into account the growing need for a wider range of health technologies. It also opens the opportunity to drive change through a more integrated structure to support access and a sharper focus on a number of emerging points and trends:

- The need to expand access to medicines and health products is highlighted in the SDGs, specifically in two targets (3.8 and 3.b) and more broadly in at least seven other targets under SDG3. Access to health products will be a key indicator for countries' progress towards UHC.

- Medicines and health products often make up the largest portion of countries' (and households') health spending: their impact on health financing places them in a central position in all discussions, strategies and plans for UHC.

- The majority of people in low- and middle-income countries (LMICs) currently pay for medicines out of pocket, often leading to financial hardship. With the rise in noncommunicable

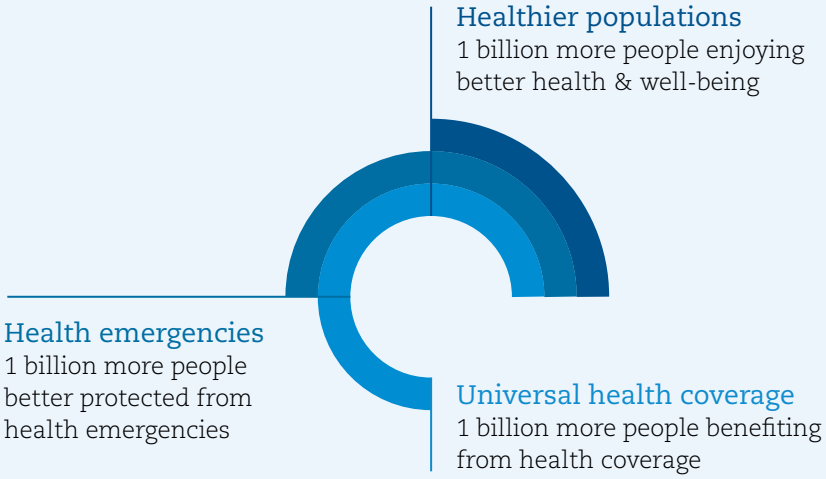
Fig. 1 SDG3, target 3.8

SDG3:
"Ensure healthy lives and promote well-being for all at all ages"

UHC addresses dimensions of equity and solidarity in public policy. UHC is not just about health systems, it enables WHO to work collectively across the three levels of the organization, as well as horizontally across diverse programmes and health topics. Health system strengthening and UHC are the backbone to improved health service delivery.

Source: WHO (2018).

Fig. 2 **Illustration of the WHO five-year strategic plan (2019–2023), with its "triple billion" target**



Source: WHO (2018).

diseases (NCDs) – many of which are chronic conditions that require long-term treatment – the financial burden will become even greater, and so will the need to accelerate progress towards effective and comprehensive UHC.

- Ensuring that quality-assured essential medicines and health products are available in sufficient quantities and affordable to the population requires functioning regulatory and procurement systems, as well as legal provisions for UHC, governance and efficient management of resources. WHO is working with countries to promote and strengthen these functions.

- Finally, many public health needs in developing countries remain underserved by markets and current research and development. To ensure that no one is left behind, it will be increasingly important to focus research efforts on diseases that affect developing countries disproportionately.

WHO has two strategic roles to increase access, which are complementary in addressing cross-cutting challenges such as AMR and medical product shortages:

- a **facilitator** role, supporting needs-based innovation and reinforcing health product selection, use, procurement and supply systems to increase access;

- a **guardian** role, strengthening regulatory capacity and practices to ensure the quality, safety and efficacy of products and improve the efficiency of regulatory systems to secure health gains.

WHO's Thirteenth General Programme of Work 2019–2023 was adopted by the Seventy-first World Health Assembly in May 2018. It provides strategic direction for the work of the Organization for the next five years and identifies three missions for WHO: to promote health, to keep

the world safe and to serve the vulnerable. The goals linked to these three objectives are identified as the "triple billion" to be achieved by 2030: 1 billion more people enjoying better health and well-being, 1 billion more people protected from health emergencies and 1 billion more people benefiting from UHC.

Strategic plans for implementation of the Thirteenth General Programme of Work 2019–2023 were prepared in 2018 by WHO headquarters, with input at the regional and country levels. In the area of health technologies and pharmaceuticals, these plans focus on the efficient regulation of medical products and continuous supply of quality, safe, effective and affordable medicines, medical devices and vaccines.

Access to essential medical products is crucial for the highest attainable level of health as envisaged by the WHO Constitution: it is one of the building blocks of every well functioning health system and is integral to the attainment of the SDGs and indispensable for responding to outbreaks and health emergencies. Addressing out-of-pocket payments for medical products will be crucial. Prioritizing regulatory initiatives to help advance UHC is another important element, as in 2018 too many countries and areas in the WHO European Region still have weak regulation of medical products. People in many countries and areas in the Region face an unnecessary and additional barrier to access the essential medicines and health products they need to lead healthy lives. Solutions have to be tailored to the diverse needs of countries and areas: a country/area that imports all its essential medicines and tests will have different regulatory needs from a country/area with significant manufacturing capacity and export potential.

In 2018 the HTP Programme began strengthening collaboration with countries and areas in these important areas, along with continuing work on the responsible selection and use of medical products.

Medicines regulation and quality

The HTP Programme has intensified its support to countries and areas in 2018 in building effective medicine regulation systems to ensure that standards of quality, safety and efficacy are met at every stage of pharmaceutical manufacture, supply and use. It has also provided specific technical guidance and training to manufacturers and regulators to help them achieve internationally recognized quality standards.

Assessment of medicine regulation systems

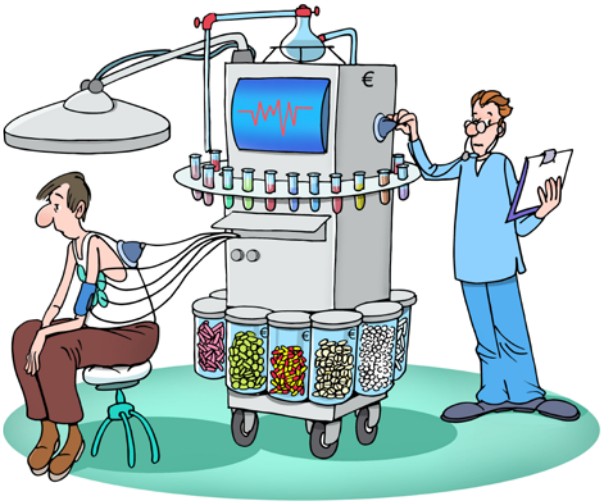
WHO has developed a data collection tool to facilitate the review of medicine regulatory systems in countries and areas.[7] The Organization works in collaboration with local officials to assess the regulatory situation, review the existing legal framework and identify specific needs for technical support and training. In 2018 support and guidance was provided to Armenia, Georgia, Kazakhstan, Kyrgyzstan, Serbia and Turkey. This work will continue and will be expanded in 2019.

Peer learning is an important aspect of increasing regulatory efficiency and is exemplified by very close collaboration with NRAs in the Region, which are already performing in an efficient manner. The HTP Programme is very grateful for their support and plans to continue and expand this collaboration. Visits and placement training were undertaken to the NRAs of Estonia, Germany, Italy and Norway; these have been of very high value to countries and areas currently working to improve their efficiency in regulation of medicines and vaccines. The Programme hopes to expand peer learning opportunities in 2019 in collaboration with already well functioning NRAs in the Region.

Prequalification of health products

Prequalification of medicines is a service WHO provides to assess the quality, safety and efficacy of medicinal products for a number of priority diseases.[8] It is intended to give international procurement agencies the choice of a wide range of quality-assured medicines for bulk purchase.

The WHO Regional Office for Europe continues to provide technical assistance and advice on preparing application dossiers to support manufacturers on prequalification of their products.



[7] Assessing national medicines regulatory systems. In: Essential medicines and health products [website]. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/, accessed 16 October 2018).

[8] Prequalification. In: World Health Organization [website]. Geneva: World Health Organization; 2018 (https://www.who.int/topics/prequalification/en/, accessed 12 December 2018).

Box 1 Procurement and supply management (PSM) visit to Albania

The National TB Programme for Albania is focused on diagnosis of TB patients and the linkage of diagnosis to treatment, as well as on establishment of MDR-TB care in Albania.

The Ministry of Health and Social Protection signed a memorandum of understanding for technical assistance with the WHO Regional Office for Europe.

The latest PSM reports highlighted some potential challenges that might affect the availability of TB medicines in the country in 2019:

- weak forecasting procedures for TB medicines and laboratory TB diagnostics;
- TB drugs not offered by local suppliers and lack of interest by foreign manufacturers/suppliers, making procurement challenging;
- long internal procurement processes;
- lack of trained staff to perform PSM activities;
- procurement from international agencies (such as the Global Drug Facility of the Stop TB partnership) not finalized due to incompatibility of payment terms with Albanian procurement law;
- procurement of TB laboratory reagents for culture and susceptibility drug tests insufficient due to budget availability;
- national TB treatment guidelines yet to be updated.

The main aims of the technical visit by the HTP Programme to Albania were:

- to review existing reports on PSM for TB medicines;
- to analyse national procurement of TB medicines and identify the need for technical assistance and creation of a procurement working group;
- to develop a PSM workplan, with details of activities and timeline for TB medicines;
- to review the different options available for procurement of TB medicines;
- to support the Ministry of Health and Social Protection in developing standard operating procedures for procurement (including identification of potential suppliers) and forecasting of TB medicines and TB lab supplies;
- to provide technical assistance and facilitate the working group on developing guidelines for managing medicines.

At present, around 650 adult patients per year are enrolled in first-line treatment. This includes around 10 children with sufficient body weight to be treated with adult drug formulations. In addition, around 10 infants and younger children require a lower dose, but child-friendly formulations have not yet been procured by the National TB Programme. It is expected that the number of cases diagnosed and treated will increase over the coming years, especially considering the anticipated introduction of GeneXpert technology.

The burden of MDR-TB is low, at around two or three cases diagnosed annually. All MDR-TB cases are treated in Peja Hospital in Kosovo.[9] Collaboration between Kosovo and Albania is very good; in 2017, due to stock-out of first-line medicines in Albania, around 72 patients from Albania received first-line medicines from health institutions in Kosovo.

[9] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

Of the 40 products prequalified by WHO in 2018, seven finished pharmaceutical products were produced by manufacturers in the Region. A number of applications by manufacturers from the Region are in the prequalification assessment process.

Advocating WHO prequalification

In September 2018 the Regional Office, together with UNFPA and UNICEF, brought together a wide range of stakeholders – manufacturers; quality, safety and efficacy experts; procurement agencies; and international donors – whose combined efforts bring needed health products to vulnerable populations. The meeting covered in vitro diagnostic devices, vaccines, finished pharmaceutical products, active pharmaceutical ingredients and contraceptive devices, as well as vector-control products. [10] More than 350 participants attended, and several parallel streams allowed one-on-one meetings with all stakeholders.

Enhancing pharmacovigilance in LMICs

With the urgent need for novel treatments for diseases such as TB, malaria and HIV, more and more medicinal products are expected to be released on an accelerated fast-track basis, but there has not been a proportional improvement in pharmacovigilance.[11] This is of great concern, as effective monitoring systems are essential to learn about the safety of novel treatments, manage adverse effects and minimize risks. In addition, the lack of a functional pharmacovigilance system is a barrier to access, as many new products require safety monitoring as a condition for authorization of a license for use.

The Smart Safety Surveillance (3S) Project was launched in 2016 to help LMICs identify, assess and adequately manage the risks associated with new medicines and vaccines. The 3S approach supports the introduction of new health products through identification, assessment and management of any risks associated with them.

The activities include piloting a set of key pharmacovigilance principles using selected new products, in selected countries and areas, to establish the proof of concept for strategies aimed at building or strengthening LMIC pharmacovigilance systems. The strategies include improving the qualitative and quantitative aspects of pharmacovigilance data and information – and the capacity to analyse the information collected – to support evidence-based therapeutic and regulatory decisions. Piloting of these principles in the first phase of the project will complement ongoing initiatives and create synergy and enhance pharmacovigilance impact. If proven, the concept and principles will be extended to additional countries and regions.

In the WHO European Region, Armenia, Kyrgyzstan and Ukraine have been selected as pilot countries for the project due to their high burden of multidrug-resistant TB (MDR-TB) and the use of bedaquiline. They are among the 18 high-priority countries for TB in the WHO European Region.

In March 2018 the HTP Programme visited TB clinics and national pharmacovigilance centres in Armenia and Kyrgyzstan to gain insight into existing pharmacovigilance systems and to

[10] 2018 Joint UNICEF–UNFPA–WHO Meeting with Manufacturers and Suppliers. In: Essential medicines and health products [website]. Geneva: World Health Organization; 2018 (https://extranet.who.int/prequal/events/Joint-2018-unicef-unfpa-who-meeting, accessed 7 December 2018).

[11] Safety and vigilance. In: Essential medicines and health products [website]. Geneva: World Health Organization; 2018 (https://www.who.int/medicines/regulation/safety-vigilance/en/, accessed 12 December 2018).

explore how the 3S principles could be applied to strengthen existing systems. A similar assessment was conducted in Ukraine in June 2018.

Through various meetings and discussions the HTP Programme gained an understanding of structural components such as legislation, existence of guidelines and standard operating procedures, human resources and access to data, as well as information gaps, in these countries. The team also developed insights into the processes of reporting, analysis and decision-making at various levels. Meetings with several nongovernmental agencies, including Médecins sans Frontières and KNCV Tuberculosis Foundation, were organized to clarify roles, activities and future plans under the scope of pharmacovigilance. The team gathered information on areas that require support, so that countries are prepared for the safety monitoring of new medicinal products, and developed and implemented workplans with associated activities. WHO will continue support to these countries so that the NRAs and their partners follow up on the pharmacovigilance activities planned.

Russian-language guidance on in vitro diagnostics surveillance

A Russian translation of the 2015 publication *Post-market surveillance of in vitro diagnostics* is now available.[12] This outlines the objectives and processes of post-market surveillance of the in vitro diagnostics prequalified by WHO. It describes what should be done to ensure that WHO-prequalified in vitro diagnostics continue to meet requirements for safety, quality and performance after they are placed on the market, and manufacturers, users and regulators are encouraged to follow this guidance. It is hoped that making the document available in Russian will greatly increase the number of people able to access and implement the guidance.

In vitro diagnostics are medical devices and accessories used to perform tests on samples – for example, blood or urine – in order to detect infection, establish a diagnosis and prevent disease. WHO prequalifies in vitro diagnostics by undertaking a comprehensive assessment through standard procedures. Products that meet all the prequalification requirements are recommended by WHO to be bought for use by Member States.

Protecting individual and public health surveillance of in vitro diagnostics continues once they are sold on the market after prequalification. They are monitored to ensure safety, quality and performance; this monitoring also ensures that manufacturers can be made aware of any adverse events. If such an event occurs – for example, a problem with the accuracy of a blood test – manufacturers have an obligation to assess risks and take action immediately to ensure individual and public health are protected.

[12] Post-market surveillance of in vitro diagnostics. Copenhagen: WHO Regional Office for Europe; 2018 [Russian version] (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2015/post-market-surveillance-of-in-vitro-diagnostics, accessed 7 December 2018).

Pharmaceutical pricing and reimbursement policies

Strengthening collaboration for affordable medicines in countries and areas in eastern Europe and central Asia

Countries and areas in eastern Europe and central Asia, including countries of the CIS, have further strengthened their collaboration on affordable medicines by agreeing to develop a subregional division of the PPRI Network called the CIS PPRI Network.

A meeting of the CIS PPRI Network in Baku, Azerbaijan, on 15–16 May 2018 was organized by the WHO Regional Office for Europe in collaboration with the Austrian Public Health Institute. It was attended by 36 representatives from 10 countries and areas. The event was a platform for participants to share and compare their experiences and reflect on challenges ahead. Pricing and reimbursement of medicines was the main focus, and the agenda covered topics such as financial coverage for HIV, TB and hepatitis medicines in situations where funding is making the transition from donor-funded programmes to domestic resources. Another topic of interest was the management of intellectual property rights for medicines and how countries and areas can make the most of existing agreements to foster generic competition and get the best prices for medicines.

Financial access to medicines is a priority in the health system strengthening agenda of countries and areas in the WHO European Region. Out-of-pocket expenditure on medicines is regularly reported to account for the highest burden on households' private expenditure for health. This issue must be addressed by governments in order to progress towards UHC, and the CIS PPRI Network will play a key role in this.

Third Summer School on Pharmaceutical Pricing and Reimbursement Policies

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Austrian Public Health Institute in Vienna, with the HTP Programme, offered a third five-day training course on policies for pricing and reimbursement of medicines. International scientific experts and experienced national policy-makers provided insights into pharmaceutical policies related to medicine pricing and reimbursement – at the time of launching new medicines, before and after the launch.

The Summer School included lectures, hands-on training sessions and case studies on implementation and optimization of pharmaceutical policies. Study visits to relevant institutions in Austria were also offered. Participants included representatives of competent authorities in the field of pricing and reimbursement of medicines (policy-makers, technical staff) and payers in the health care system (such as health insurance institutions/sickness funds, ministries, medicines agencies and private health insurance institutions), as well as researchers involved in offering policy advice to public institutions and not-for-profit stakeholders (such as consumer/patient organizations).

Box 2 Negotiation training in Greece

The Greek Ministry of Health is taking the next steps towards the use of HTA in decision-making. An HTA-related law regarding evaluation and reimbursement of medicines for human use was approved in January 2018, establishing a committee tasked with evaluation of medicines that have received authorization for marketing in the country.

The HTP Programme, with the support of the Medical Technology Research Group of the London School of Economics, organized a two-day workshop in Athens in March to support implementation of this law, based on future institutionalization of HTA. The workshop explained the HTA process using various country examples and models. Participants assessed their HTA readiness through group discussions and exercises structured around overall HTA strategy, activity coordination, finance and resourcing; they also defined the governance, capabilities, processes, data and tools required to support HTA implementation. Outputs include identification of several HTA priority areas to explore, based on the newly introduced law and supporting ministerial decrees.

Participants included professionals working in fields related to the HTA strategy and implementation: representatives from the Ministry of Health, National Organization of Medicines, National Organization for the Provision of Health Care Services, Social Insurance E-Governance Organization, Negotiations Committee, Protocols Committee, Positive List Committee, universities and the National School of Public Health.

WHO report reviews policies that improve access to medicines

The WHO report *Medicines reimbursement policies in Europe*[13] examines the various policies that increase access to affordable medicines. The HTP Programme prepared the report in collaboration with the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in Vienna, Austria, affiliated with the Austrian Public Health Institute. Based on direct data collected from 45 of the 53 countries in the WHO European Region, it showcases diverse national practices and aims to identify key aspects of policy frameworks that protect vulnerable groups from unaffordable out-of-pocket payments for medicines.

Ensuring that people have fair access to essential medicines at affordable prices is a fundamental part of the human right to health, and is crucial for advancing UHC. Until now, however, Europe has lacked good evidence to identify which reimbursement systems and policies represent best practice. WHO's new report aims to fill this information gap.

[13] Medicines reimbursement policies in Europe. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/publications/abstracts/medicines-reimbursement-policies-in-europe, accessed 7 December 2018).

Medicines reimbursement policies that work

To meet the goal of affordable, equitable and sustainable access to quality-assured medicines, policy-makers must work to implement a balanced mix of pharmaceutical policy options. High out-of-pocket payments for medicines, including co-payments, create the risk of lower treatment adherence and lower medicine consumption. This has an obvious negative impact on population health – particularly for the most vulnerable members of society.

Decision-makers should therefore take the needs and specificities of these groups into consideration. The analysis in the report shows that any medicines reimbursement policy should be accompanied by specific elements of protection for people on a low income or at a social disadvantage; otherwise, poorer people with chronic conditions could suffer disproportionately. At the same time, co-payment policy schemes, if designed properly, may improve efficiency without lowering equity, in particular with reference to the off-patent market.

Highlighting best practice

The study shows that one size does not fit all – there is no formally defined, ideal reimbursement policy model. Nevertheless, it identifies the following principles that support policy frameworks to increase affordable access and protect vulnerable groups from excessive out-of-pocket payments.

- Prioritization is essential. There are tough choices to make, and it will never be possible to fund the full cost of all medicines.

- Basing decisions on the best available evidence is a fundamental requirement. However, the tools required to do this are resource-intensive and require highly qualified staff, which can be a challenge for lower-income and small countries and areas. One solution is to adapt assessments from other countries to local contexts so that evidence and data can be shared.

- Processes should be transparent and smooth; reimbursement decisions and the rationale behind them should be publicly available. Membership of reimbursement committees should be disclosed, along with declarations of potential conflicts of interest.

- Vulnerable population groups must be identified, and co-payment policies must pay specific attention to them. Socioeconomic factors such as low or irregular income, unemployment or responsibility for several dependents lead to vulnerability.

- Price regulation and/or competition bring prices down and help patients as well as the public institutions that pay for medicines. Most European countries and areas regulate the prices of reimbursable medicines or use competition to drive product prices down.

- When using lower-priced medicines such as generics, it is important to conduct awareness-raising activities to ensure trust in their quality.

- Encouraging patient involvement can have beneficial results. Few countries and areas include patients in consultations, but those that do demonstrate that it can be helpful in public debate when communicating sensitive decisions, such as non-funding of medicines with limited added therapeutic benefit.

- Evaluations, monitoring and adjustments are crucial for policy-makers to assess the effectiveness of measures and decide whether changes should be made.

- Finally, decision-makers must consider the implications of the policies they develop and make sure that they are compatible with their overall public health priorities. They have to balance affordable access, protection of patients from

Box 3 Supporting the development of a community pharmacies law in Montenegro

A consultation was organized in Podgorica, Montenegro, to support the Ministry of Health in development of a new law on community pharmacies. Montenegro faces many challenges in the overall distribution of community pharmacies in its territory and the activities they conduct: their number is rising in some locations, while in some rural areas pharmaceutical services are not available.

During the consultation the ministries of health of Malta and Slovenia presented their own experiences in regulating community pharmacies, sharing challenges and successes. International organizations representing pharmacists in the WHO European Region and globally (including the Pharmaceutical Group of the EU and International Pharmaceutical Federation) also shared best practices and provided a summary of approaches used elsewhere to regulate numbers and locations. In addition, they shared experiences relating to expanding the role of the community pharmacy and pharmaceutical services. In many countries the role of community pharmacies in primary health care has been consolidated, and they now provide a series of health services to the community, such as prevention, screening and pharmaceutical management of NCDs; medicines use reviews; improvement of adherence to treatment; point of care testing; triage of patients; vaccination for adults; and collection of expired or unused medicines. The new law will include relevant new practices and tasks to be conducted by pharmacists in community pharmacies.

out-of-pocket payments and the constraints of the system – for example, budget limitations.

Co-organization of the Infarmed–WHO Conference: "Facing the Challenges: Equity, Sustainability and Access"

During a conference on 29–30 November 2018 in Lisbon, Portugal,[14] the challenges of balancing political priorities with access in the management of health systems were presented and discussed, along with multinational collaboration through a debate on strategic thinking to promote transparency of prices and equitable, sustainable access to innovative medicines. The focus was on challenges in planning and prioritization of investment; budgetary constraints and the need for new payment models; preventing increases in out-of-pocket payments; and creating essential synergies between the regulatory system, HTA and financing.

The benefits of country collaboration were highlighted; these include building a favourable environment for collective processes, strengthening capacity to negotiate fair prices and providing

[14] International Conference "Facing the Challenges: Equity, Sustainability and Access" [website]. Lisbon: Infarmed; 2018 (http://www.infarmed.pt/web/infarmed/25-anos/eventos/international-conference-facing-the-challenges-equity-sustainability-and-access, accessed 7 December 2018).

efficient ways of sharing information linked to the introduction and reimbursement of new medicines. The conference brought together a large number of public sector policy-makers and technical experts from EU Member States along with the European Commission, Organisation for Economic Cooperation and Development and WHO staff.

Revisions to the WHO Model List of Essential Medicines now available in Russian

Following key updates to the WHO Model List of Essential Medicines (EML) and WHO Model List of Essential Medicines for Children (EMLc), in 2018 the HTP Programme developed three publications to highlight and summarize the revisions, available in English and Russian.[15]. Their objective is to communicate EML and EMLc changes to national counterparts involved in the evidence-based selection of medicines for inclusion in national essential medicines list, medicines for inclusion in reimbursement programmes and medicine formularies for use in primary, secondary and tertiary care.

The publications address the following areas:

- changes to the 2017 EML and EMLc
- consideration of antibacterial medicines (section 6.2) within the revisions to the 2017 EML and EMLc
- consideration of diabetes medicines (section 18.5) within the revisions to the 2017 EML and EMLc.

The summary publications do not replace the 2017 report of the WHO Expert Committee on the Selection and Use of Essential Medicines but should be read in conjunction with the full report.[16] The updates were the result of the 21st meeting of the WHO Expert Committee, which took place in Geneva, Switzerland, on 27–31 March 2017. The goal of the meeting was to review and update the 19th EML and the 5th EMLc. The Expert Committee considered 92 applications, including proposals to add 41 new medicines and extend the indications for six existing listed medicines and five applications to delete medicines from the lists, as well as a comprehensive review of the antibacterials listed in sections 6.2.1 and 6.2.2 and their use in the treatment of 21 common, priority infectious syndromes, five paediatric infectious diseases and three sexually transmitted infections. In accordance with approved procedures, the Expert Committee evaluated the scientific evidence for the comparative effectiveness, safety and cost–effectiveness of the medicines.

[15] Resources. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/policy-areas/resources#355765, accessed 11 February 2019).

[16] The selection and use of essential medicines: report of the WHO Expert Committee, 2017. Geneva: World Health Organization; 2017 ((WHO technical report series no. 1006; https://www.who.int/medicines/publications/essentialmedicines/trs-1006-2017/en/, accessed 7 December 2018).

New report highlights the value of an aligned health system response to NCDs

The HTP Programme provided input to a WHO report entitled *Health systems respond to NCDs: time for ambition*.[17] The report provides pragmatic and actionable policy responses and demonstrates the case for holistic transformation and systems thinking. It sets out 38 key policy messages and 160 potential policy responses, over nine policy areas considered particularly relevant for addressing NCDs. The key messages to promote improved access to NCD medicines are:

- priority NCD medicines should align with agreed clinical guidelines and protocols, and their selection should be evidence-based;
- priority NCD medicines should be available to all patients who need them, including those in rural and remote communities;
- priority NCD medicines in evidence-based treatment protocols should be included in public sector procurement or in coverage policies, with no or minimal out-of-pocket payments;
- acceptance of and use of generic medicines, which increase access to affordable medicines for patients and contain costs for health care systems, should be promoted through coordinated supply- and demand-side policies;
- adherence to long-term treatments for NCDs should be promoted through improved communication between patients and health care providers on the rationale for the treatment, discussions on possible side-effects and simplified treatment regimens.

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[17] Health systems respond to noncommunicable diseases: time for ambition. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/time4ambition, accessed 7 December 2018).

Strategic procurement

Interest in the strategic procurement of medicines is growing across the WHO European Region. Greater collaboration on procurement activities between countries and areas – including countries and areas with smaller populations and limited power to negotiate effectively with industry – may facilitate access to new medicines, promote transparency and encourage sharing of best practices. A number of country/area collaboration initiatives have recently been established. Examples include the Baltic Partnership Agreement (Estonia, Latvia, Lithuania), BeneluxA (Belgium, Netherlands, Luxembourg and Austria), the Bulgaria and Romania collaboration, the Nordic Medicines Forum (Denmark, Finland, Iceland, Norway and Sweden), the Valetta Declaration (Cyprus, Greece, Italy, Ireland, Malta, Portugal, Romania, Slovakia and Spain) and the Visegrad Plus project.[18] The HTP Programme has created opportunities for sharing knowledge and experiences between these subregional collaboration initiatives.

Getting the best deal for patients: building country/area capacity in procurement and negotiations

Good pricing and availability of medicines and health products is central to any health system. Indeed, medicines and health products account for the lion's share of health spending for both households and countries/areas, and this has a direct effect on health financing and UHC. To facilitate there are enough affordable quality medicines and health products a health system needs:

- a well functioning procurement system
- legal provision for UHC
- good governance
- efficient management of resources.

To help Member States maintain sustainable access to affordable pharmaceuticals and medical devices, the HTP Programme organized two important training events in January and February 2018, both in Copenhagen, Denmark.

Improving procurement system performance

The first ever Medicine Procurement Practitioners Exchange Forum was organized in collaboration with UNICEF Supply Division in January 2018. The Forum was part of the Issue-based Coalition on Health initiative, which was established in 2016 as a means of cross-sectoral cooperation on health to achieve the SDGs and get closer to UHC.

The Forum brought together health supply chain experts and government delegates from 11 Member States in the WHO European and Eastern Mediterranean regions (Albania, Armenia, Belarus, Kazakhstan, Kyrgyzstan, Libya, Republic of Moldova, Sudan, Tajikistan, Turkey and Ukraine) alongside UNICEF, UNDP, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Medicines Patent Pool. Together they looked at ways to improve the performance of their national medicines procurement systems to expand access to treatment for their populations. The focus was on medicines and medical devices related to HIV, hepatitis C virus and NCDs.

[18] In March 2017 ministers of health of Hungary, Poland and Slovakia, together with Croatia and Lithuania (within the Polish Presidency of the Visegrad Group 2016–2017) signed a memorandum of understanding in Warsaw on ensuring fair and affordable prices of medicinal products. In the course of further work Slovenia joined the initiative.

Learning to negotiate for good procurement

Following the success of the Forum in January, the second training event in February focused on capacity-building for negotiation in the procurement of medicines. It was the second strategic procurement workshop held by the HTP Programme focusing on negotiations, bringing to 27 the number of WHO Member States whose representatives have been trained in this field. It was organized in collaboration with the Medical Technology Research Group of the London School of Economics.

As the demand for innovative medicines in Europe grows, so do the expectations of patients. This, combined with demographic changes, threatens the fiscal sustainability of health systems and intensifying budgetary pressures. With topics ranging from budget planning and horizon scanning to practical case studies and sharing of national negotiations practices, Member States reinforced the importance of discussing different approaches and challenges to medicines procurement, to collectively identify options and develop potential solutions.

The objectives of the 2.5-day workshop were to support participants to:

- build practical skills in preparing and conducting negotiations, with a refresher on negotiation concepts;
- understand obstacles faced by countries when planning and conducting negotiations to access new health products, maintain a competitive supply environment and/or manage entry of generics/biosimilars; and
- integrate key learning from the workshop into daily work.

Participants included national public procurement and negotiation experts involved in the planning, forecasting and/or procurement of medicines in their respective countries.

Box 4 WHO technical assistance to strengthen access to medicines in the former Yugoslav Republic of Macedonia

As part of the 2018–19 biennial collaborative agreement with the former Yugoslav Republic of Macedonia, the WHO Regional Office for Europe organized a fact-finding visit to Skopje in June 2018, with a focus on pharmaceutical regulatory and financial access issues. The objective was to identify possible areas of collaboration between the authorities and the Regional Office. This visit was an opportunity to meet with key national stakeholders – such as the Ministry of Health, the Agency for Medicine and Medical Devices, the health insurance fund, the Macedonian Association of Pharmacists and the Macedonian Chamber of Pharmacists – to take stock of the current situation.

A series of potential areas of work were identified, including strengthening the regulatory agency's functions (in the context of alignment with the EU's "*acquis communautaire*": the accumulated body of EU law and obligations) and developing national capacity to engage in pricing negotiations with manufacturers. These actions will contribute to increasing access to safe, affordable and efficacious medicines in the former Yugoslav Republic of Macedonia and are a pillar of advancing UHC and the health-related SDGs.

Addressing responsible use of antibiotics while ensuring access

AMR is a global health challenge, mainly driven by poor regulation of medicines and their production standards in certain settings, overuse of antibiotics, uncontrolled over-the-counter sales and self-prescription. AMR complicates the treatment of infections, jeopardizes the ability to perform complex medical interventions and may lead to longer hospital stays and increased mortality.

Overuse of antibiotics is a global issue; however, more people die due to lack of access to antibiotics. By 2050, 28 million people – mostly in developing countries – may be pushed into poverty by the cost of second- or third-line antibiotics. Thus, while the HTP Programme seeks to reduce the excess use of antibiotics, it also works to ensure access to them when needed.

HTP is part of the WHO Regional Office for Europe's interdivisional AMR team and responsible for activities linked to selection, monitoring and responsible use of antimicrobial medicines including awareness creation and stewardship. HTP contributes to the technical guidance provided to countries and areas for their development AMR strategic action plans and implementation of these.

The AMC Network

In 2015 WHO Member States adopted the Global action plan on AMR.[19] Its objectives include strengthening surveillance and optimizing the use of antimicrobial medicines. Monitoring consumption of antimicrobial medicines forms part of effective antimicrobial stewardship programmes that promote access to necessary antibiotics and support their appropriate prescribing and responsible use.

The AMC Network was established in 2011 to assist non-EU countries and areas in setting up or strengthening surveillance at country/area level. Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyzstan, Montenegro, the Republic of Moldova, the Russian Federation, Serbia, Tajikistan, the former Yugoslav Republic of Macedonia, Turkey, Ukraine and Uzbekistan, as well as Kosovo,[20] are currently engaged in the Network. Monitoring of consumption at country/area level helps provide centralized data to ensure that strategies to address antimicrobial consumption and resistance are effective. Efforts are closely coordinated with ECDC so that data are comparable and can provide a pan-European overview of trends.

The WHO Regional Office for Europe also participated in a number of joint country visits on AMR to reinforce the importance of integrated monitoring of consumption, resistance and effective stewardship.

Report of data from the AMC Network

An article outlining 2015 AMC Network data was accepted for publication in the *Frontiers in Phar-*

[19] Global action plan on antimicrobial resistance. Geneva: World Health Organization; 2015 (http://www.who.int/antimicrobial-resistance/publications/global-action-plan/en/, accessed 16 October 2017).

[20] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

macology journal in October 2018.[21] Data from the AMC Network were also shared with WHO headquarters in Geneva and included in the first global antimicrobial consumption report, published during World Antibiotic Awareness Week in November 2018.[22]

In addition to the quantitative analyses undertaken by the AMC Network, several countries and areas have worked on qualitative studies with the Social and Clinical Pharmacy group of the Faculty of Health and Medical Sciences at the University of Copenhagen, Denmark, to improve understanding of the reasons behind the use of antibiotics. Semi-structured interviews have been conducted with patients (receiving antibiotics both with and without prescriptions), general practitioners and pharmacists. A pilot study was undertaken in Albania and Turkey, as well as in Kosovo;[20] based on these experiences, a few amendments were made to the research protocol and the study was initiated. In total, 13 members of the Network have carried out around 12–20 interviews in their countries and areas, including Albania, Armenia, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Serbia, Tajikistan, the former Yugoslav Republic of Macedonia, Turkey and Uzbekistan, as well as Kosovo.[20]

Annual meeting of the AMC Network

The 2018 AMC Network meeting was held on 11–12 June 2018 in Copenhagen, Denmark. Network members discussed analyses of their antimicrobial consumption data and activities to support the appropriate use of antibiotics. In addition, the meeting introduced the concepts of antimicrobial stewardship programmes, with invited experts from the European Society of Clinical Microbiology and Infectious Diseases Study Group for Antimicrobial Stewardship. The experts spoke about the "what, how and who" of antimicrobial stewardship, with special emphasis on the importance of strategies for behaviour change, and presented some practical examples of hospital-based stewardship programmes. Experiences with antimicrobial stewardship activities in AMC Network countries were also shared. Network members were especially keen to learn how others have addressed enforcement of laws restricting over-the-counter sales of antibiotics, recognizing this as a common concern.

This year's AMC Network meeting was followed by the Joint Meeting of the Antimicrobial Resistance, Antimicrobial Consumption and Healthcare-associated Infections Networks, jointly held by ECDC and the WHO Regional Office for Europe, on 13–15 June 2018. This meeting brought together all European surveillance networks to share experiences and good practices, and to discuss future collaboration and joint activities across the WHO European Region. The AMC Network and ESAC-Net had joint sessions for the first time. It was a great opportunity to share information about challenges in data collection and analysis and best practices in antimicrobial consumption surveillance.

Important discussions took place about which consumption indicators to use for antimicrobial stewardship purposes. Indicators from the EU-funded Defining and implementing responsible antibiotic use project were discussed, along with the metrics used by ESAC-Net and the AMC Network. Indicators for antimicrobial consumption monitoring in the animal sector were also presented. Both networks will continue collaboration, sharing of data and methods, to provide a Europe-wide perspective on antimicrobial consumption.

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[21] Antimicrobial medicines consumption in eastern Europe and central Asia – an updated cross-national study and assessment of quantitative metrics for policy action. Front Pharmacol. [in press]. doi: 10.3389/fphar.2018.01156.

[22] WHO report on surveillance of antibiotic consumption: 2016–2018 early implementation. Geneva: World Health Organization; 2018 (http://www.who.int/medicines/areas/rational_use/oms-amr-amc-report-2016-2018/en/, accessed 7 December 2018).

Database of antimicrobial consumption data

The Regional Office has continued development and maintenance of the database that will simplify analysis for future years of antimicrobial consumption data and facilitate timely utilization of data collected within countries and areas. Based on the experience of the AMC Network, a collaboration for analysis of consumption data has been established with the WHO South-East Asia Region.

Online survey of AMC Network countries and areas

An online survey was conducted among AMC Network members. Its aims were:

- to find out more about the situation in countries and areas;
- to assess current AMR and medicines consumption-related activities and structures, existing surveillance systems, the existence and enforcement of policies and legal frameworks (such as national and subnational laws) on the use of antimicrobial agents in human health; and
- to understand what types of activity are being undertaken to moderate the use of antibiotics in both the community and hospital settings.

Responses were received from 45 participants from the 18 members of the AMC Network. In the cases of Tajikistan and Turkey, a single response represented the results of local consultation with several relevant experts. Respondents were predominantly from ministries of health, national public health institutes, public health authorities and professional organizations.

The survey results suggest that a legislative framework already exists that governs the marketing authorization of antimicrobial agents, their distribution, assessment of the quality of products in circulation and their prescription and dispensing in all 18 participating countries and areas. Respondents commented that legislation and regulations are mostly enforced. Almost all countries and areas reported a pharmacovigilance programme for reporting adverse events and adverse drug reactions to antimicrobials, although the descriptive accounts provided suggest that the extent to which of these reporting systems are used varies widely across countries and areas.

Respondents reported a wide range of activities in support of appropriate use of antimicrobials that targeted the general public, doctors and pharmacists. Many, but not all, reported the existence of endorsed clinical guidelines or treatment protocols for some common infections in hospitals and for primary health care, although the extent of acceptance and use of the guidelines in practice was less clear.

Survey respondents were asked to nominate priority actions to improve the appropriate use of antibiotics. Those most commonly nominated were enforcing and improving legislation on the prescribing and dispensing of antibiotics; educating health professionals; improving public awareness on rational use of antibiotics; and implementing standard clinical protocols. A full report of the study findings will be published on the HTP Programme website.[23]

Call to enhance the responsible use of medicines to reduce AMR

Experts called for the responsible use of medicines and the reduction of AMR during a con-

[23] Health technologies and medicines. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2018 (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines, accessed 10 December 2018).

Box 5 Kosovo[24] visits focusing on selection and procurement of essential medicines

In 2018 the HTP Programme visited Kosovo several times to support the pharmaceutical reform processes started by the public health authorities to increase access to quality-assured, affordable medicines and medical devices in the area. The objectives of these visits were:

- to assess the key issues linked to access to medicines;
- to provide input to the process for updating Kosovo's essential medicines list; and
- to undertake an initial review of the current public procurement process for medicines.

The HTP Programme met with relevant stakeholders including the public health authorities, the Kosovo Medicines Agency, the Central Pharmacy – University Clinical Centre of Kosovo, the health insurance fund and the Pharmaceutical Chamber of Kosovo to better understand the processes in place and the existing challenges in increasing access to medicines and medical devices. Suggestions to make the system more efficient were presented to the public health authorities and have been followed up since.

The HTP Programme, in collaboration with the WHO EML Secretariat, also provided hands-on training to the newly appointed Kosovo essential medicines list committee in October 2018. The objective of this workshop was to provide committee members with training on how best to adapt WHO's methodology and experience to their revision of the Kosovo essential medicines list. This three-day tailored workshop gathered more than 40 participants and presented very practical approaches for the committee to initiate its endeavour.

[24] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

sultation held in Almaty, Kazakhstan, from 30 October to 1 November 2018. Focusing on the role of primary health care in this area, the event gathered participants from 15 countries. They included managers involved in primary health care reforms, officers in charge of pharmaceuticals and promoting the responsible use of medicines, experts on medicine safety and other professionals currently or potentially promoting prescription-only dispensing of antibiotics.

Highlighting the critical role of primary health care in addressing AMR

The recently adopted Declaration of Astana[25] calls for continuous, comprehensive, coordinated, community-oriented and people-centred primary health care with appropriately prioritized disease prevention and health promotion. Yet primary health care is not always viewed

[25] Declaration of Astana. Geneva: World Health Organization; 2018 (http://www.euro.who.int/en/health-topics/Health-systems/primary-health-care/news/news/2018/10/new-global-commitment-to-primary-health-care-for-all-at-astana-conference, accessed 22 November 2018).

and supported as a key area in the response to AMR in health systems. One of the aims of the cross-programmatic consultation in Almaty was to emphasize and explore its crucial role in tackling AMR.

Most antimicrobial medicines are consumed in community and outpatient settings – that is, outside hospitals – and about 90% of all antibiotic prescriptions are issued by general practitioners in primary health care. For this reason, only an approach rooted in communities and focused on engaging patients, parents and public and professional associations can succeed in improving the responsible use of antibiotics.

Trust in and utilization of primary health care services can be improved by ensuring there are sufficient, appropriately skilled health workers and reliable supplies of quality-assured medicines and diagnostics, including first-line antimicrobials. AMR must be tackled in tandem with the continuing evolution of health systems to deliver quality primary health care to all those in need.

Responses to AMR should include enforcement of policies prohibiting over-the-counter sales of antibiotics, effective regulatory measures, expansion of the role of pharmacists and the use of simple yet effective tools such as:

- flowcharts for clinical guidelines and protocols;
- a simple table to record actions;
- classification of pharmaceuticals;
- use of valid, rapid point of care tests; and
- promotion of delayed antibiotic prescribing strategies.

Alongside these measures, the communication skills of general practitioners and nurses and public awareness campaigns should also be developed.

"One Health" approach needed

Experts highlighted the need to keep working on aligning clinical guidelines and protocols with essential medicines lists; developing a closely monitored procurement and production system; and building the competencies of prescribers. Tackling AMR requires a whole-of-government approach and investments that will yield returns many years from now. It also requires a focus on the many causes and drivers of AMR that lie outside the health sector. For example, antimicrobials are widely used to treat livestock. The EU recently approved restrictions on the use of antibiotics for healthy farm animals, starting in 2022.

A multifaceted approach is needed, covering education, training and guidelines. Professional organizations have an important role to play – not only governments. The HTP Programme and the Health Services Delivery Programme of the WHO Regional Office for Europe's Division of Health Systems and Public Health jointly organized the meeting in Almaty, which was hosted by the WHO European Centre for Primary Health Care.

Box 6 Introducing price regulation in Kyrgyzstan

As part of its 2018 partnership with the HTP Programme, the Government of Kyrgyzstan prioritized implementation of pharmaceutical price regulation, and a dedicated interministerial task force was appointed to design, implement and follow up on the introduction of outpatient medicines price regulation. The group received extensive training and capacity-building from the WHO Regional Office for Europe. As part of this collaboration, a study visit was organized to Azerbaijan, which had engaged in such reforms some years ago and was able to share its policy experience. Members of the task force also participated in a two-day policy lab at the WHO Collaborating Centre on Pricing and Reimbursement Policies in Vienna, Austria, to help in the development of their plan.

On 14 September 2018, in a policy dialogue, the authorities reviewed progress and presented and discussed the preliminary findings and policy options developed by the task force. As a first step, the working group proposed introducing regulation of distribution chain margins for the medicines covered by the health insurance fund. Preliminary estimates suggest that such reform would immediately reduce expenditure on reimbursed medicines by around 8%, providing extra budget to cover more patients under the state-guaranteed package or to broaden the benefit package. The effort showcases how concrete health reforms can benefit people and move towards UHC.

All stakeholders of the pharmaceutical sector were involved during this policy dialogue, including representatives of the private sector, and broad consensus was reached that such reform was both needed and acceptable. The importance of communication was highlighted as a key enabler. The Kyrgyz authorities committed to create the necessary legislative framework to allow enforcement of margin regulation for medicines covered by the health insurance fund before the end of 2018. Control of ex-factory prices will be initiated as another pillar of the reform in 2019.

Ensuring population access to safe and affordable medicines remains especially challenging for newly independent states in the WHO European Region. Recent evidence shows that outpatient medicines constitute the main driver of health-related catastrophic expenditure in Kyrgyzstan. Over the past two years the Regional Office has actively supported the Kyrgyz health authorities on medicine financing issues. An exhaustive report was published in 2016, analysing the current status in the country and recommending the introduction of outpatient medicines price regulation as a means to increase patients' financial access while preserving fiscal sustainability for the health system. Further, throughout 2017 WHO supported the revision of the entire pharmaceutical legal framework in the country including to facilitate the introduction of medicines price controls. The policy has benefited from wide discussions under the current Den Sooluk health programme and is further prioritized in the fourth-generation health programme "Healthy Person – Prosperous Country" to deliver results towards achieving the SDGs by 2030.

Country/area collaboration on access to medicines: identifying opportunities to improve performance

The HTP Programme provided several topic-specific opportunities for countries and areas to meet and both discuss their challenges and pursue opportunities for new collaborations. In cooperation with partners, the Programme also investigated opportunities for collaboration in more detail. Increasingly, country governments are challenged to provide sustainable access, in particular to high-priced medicines for diseases such as cancer, hepatitis C and rare conditions. Main barriers to access to medicines are financing, affordability, product quality, use and development of new medicines.

To improve access to medicines, public authorities have collaborated or are starting to collaborate in a variety of areas, using different mechanisms such as horizon scanning, HTA, price negotiations and procurement. Collaboration on high-priced medicines access has increased in recent years due to political interest, uncertainties over the cost–effectiveness of some new medicines coming to market, increased demand for these medicines and limited financial resources, among other factors.


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With a view to learning from successful country/area collaborations – and failures – the HTP Programme investigated how cross-border collaboration can promote increased effectiveness and efficiencies in introducing medicines. The objectives of the investigation were to:

- describe existing country/area collaborations, including their intent and objectives;
- understand the results of country/area collaborations;
- analyse facilitating and challenging factors for country/area collaborations;
- identify gaps where country/area collaborations could provide an important opportunity to promote equitable access to affordable new medicines;
- recommend strategies to strengthen existing collaborations to increase their effectiveness and efficiency.

The results of the investigation will be published in 2019.

Project partners on investigating cross-border collaboration

- WHO Collaborating Centre for Pharmaceutical Policy and Regulation (Faculty of Sciences, Utrecht Centre for Pharmacoepidemiology and Pharmaceutical Policy Analysis, Division of Phamacoepidemiology and Pharmacotherapy, Department of Pharmaceutical Sciences, Utrecht, Netherlands)
- WHO Collaborating Centre in Pharmaceutical Policy (Boston University School of Public Health, Boston, Massachusetts, United States of America)
- WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (Austrian Public Health Institute, Vienna, Austria)

Box 7 Review of the Affordable Medicines Programme in Ukraine

In April 2018 the WHO Regional Office for Europe was asked to support the Ukrainian authorities with an evaluation of the Affordable Medicines Programme (AMP), which was introduced in April 2017. The state budget allocated to the AMP in 2017 was 700 million Ukrainian hryvnya (21.8 million euros); this was increased to 1 billion hryvnya (31 million euros) in 2018.

The evaluation assessed whether the AMP had succeeded in fulfilling its objective to provide more patients with affordable medicines for selected chronic diseases (cardiovascular diseases, type 2 diabetes and bronchial asthma), irrespective of their place of residence, age or previous reimbursement eligibility (for example, as a war veteran). It also analysed policy actions to be considered to ensure the medium-term sustainability of the AMP.

WHO engaged a team of international and national experts to undertake the evaluation. The United States Agency for International Development project Safe, Affordable, and Effective Medicines for Ukrainians and the Ministry of Health of Ukraine provided significant technical support and shared an important proportion of the information necessary for the evaluation. Since no formal procedure for evaluation of such a public policy intervention was found, the team developed a context-relevant analytical framework that relied on a combination of quantitative and qualitative analysis. Four specific components were appraised: efficiency of the programme (organizational aspects); access to medicines (availability and affordability); acceptance of the system; and perceived quality and outcomes.

An in-depth analysis of the AMP confirmed that it had contributed to a significant increase in access to needed outpatient medicines, and all stakeholders agreed that it was both timely and needed. It was also noted that, although the implementation was successful overall, uptake of the AMP across regions was uneven. Some explanatory factors were identified, constituting possible directions for reform. The efficiency of the AMP could also be improved further by dissemination of best practices. The findings, along with short- and medium-term recommendations, offer guidance to decision-makers to further expand/integrate the AMP; they were discussed at a national policy dialogue in October in Kiev and will be disseminated via an official public report to be published early 2019.

Annex. Calendar of activities

DATE	TOPIC	LOCATION
January 2018		
15–18	Technical assistance visit to Kosovo[26] institutions responsible for procurement and supply chain management to improve access to essential medicines	Pristina, Kosovo
22–24	Joint UNICEF–WHO meeting: Medicines Procurement Practitioners Forum	Copenhagen, Denmark
29–3 February	Consultation on surveillance of antimicrobial consumption: methodological transfer from international experiences to national level – a side meeting within the Prince Mahidol Award Conference "Making the World Safe from the Threats of Emerging Infectious Diseases"	Bangkok, Thailand
February 2018		
11–14	Follow-up visit to discuss revisions to the essential medicines list and processes for evidence-based selection of medicines for the national essential medicines list and health insurance fund	Pristina, Kosovo
20–22	Strategic procurement of medicines: negotiation training workshop for public sector medicines procurement specialists	Copenhagen, Denmark
March 2018		
6	Presentation on drug shortages under the EU presidency	Sofia, Bulgaria
10–20	Introducing the 3S Project, supporting collaboration between pharmacovigilance and TB programmes in Armenia and Kyrgyzstan	Yerevan, Armenia, and Bishkek, Kyrgyzstan
19–23	GMP sensitization workshop	Tbilisi, Georgia
19–23	Visit to consult on the bylaws of the newly adopted medicines regulation	Bishkek, Kyrgyzstan
29–30	Negotiations workshop, using practical examples to further build skills, extending the negotiations workshop held in Copenhagen in February	Athens, Greece
April 2018		
4–6	Meeting of the WHO Advisory Group on the Availability and Affordability of Cancer Medicines	Geneva, Switzerland

[26] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

DATE	TOPIC	LOCATION
16–18	Aligned Health Systems for NCD good practice – high-level meeting linked to the launch of the WHO report *Health systems respond to noncommunicable diseases: time for ambition*	Sitges, Spain
23–25	Medicine Evaluation Committee and Piperska group meetings	Athens, Greece
24	French-speaking technical briefing seminar on essential medicines and health products	Geneva, Switzerland
26–27	PPRI Network meeting	Dublin, Ireland
May 2018		
3–4	Stakeholder consultation meeting on the 3S Project	Geneva, Switzerland
15–16	Consultation on the law on community pharmacies	Podgorica, Montenegro
15–16	Second meeting of the CIS PPRI Network	Baku, Azerbaijan
17	Kyrgyzstan and Azerbaijan consultations on the introduction of pharmaceutical price regulation	Baku, Azerbaijan
June 2018		
11–15	AMC Network annual meeting and Joint Meeting of the Antimicrobial Resistance, Antimicrobial Consumption and Healthcare-associated Infections Networks	Copenhagen, Denmark
13–14	WHO high-level regional meeting on health systems for prosperity and solidarity, celebrating the 10th anniversary of the Tallinn Charter	Tallinn, Estonia
13–15	Preliminary visit for evaluation of the medicines reimbursement pilot project	Kiev, Ukraine
18–22	Country assessment of regulatory issues as part of the EU accession and fact-finding visit on assessing and strengthening the pharmaceutical system	Skopje, the former Yugoslav Republic of Macedonia
18–19	WHO meeting on antibiotic stewardship programmes in hospitals in LMICs	Geneva, Switzerland
18–29	Training of Georgian GMP inspectors	Hilleroed, Denmark
20–22	WHO Regional programme advisors meeting	Geneva, Switzerland
July 2018		
1–5	Pharmaceutical policies review	Belgrade, Serbia
2-7	NRA benchmarking visit	Bishkek, Kyrgyzstan
4–5	Post-market surveillance of in vitro diagnostics meeting	Minsk, Belarus
6	High-level meeting on revised draft law on medicines	Chisinau, Republic of Moldova
7–14	Support to the NRA in relation to ongoing reform of regulation of medical products	Tashkent, Uzbekistan
9–10	Policy lab on the introduction of price regulation for the Kyrgyzstan interministerial task force	Vienna, Austria

DATE	TOPIC	LOCATION
9–13	Ministry of health meetings on pharmaceutical sector reform	Ashgabat, Turkmenistan
15–20	Quality management system development for the NRA	Tbilisi, Georgia
23–26	Quality management system development for the NRA in Georgia pharmacovigilance gap analysis	Chisinau, Republic of Moldova
23–27	Third Summer School on Pharmaceutical Pricing and Reimbursement Policies	Vienna, Austria
23–27	Sensitization workshop on GMP/good distribution practices implementation	Astana, Kazakhstan
August 2018		
1–3	WHO Prequalification Programme advocacy work	Cairo, Egypt
20–25	Benchmarking of NRA	Astana, Kazakhstan
20–25	Pharmacovigilance training	Tbilisi, Georgia
September 2018		
3–7	International Conference of Drug Regulatory Authorities	Dublin, Ireland
4–6	Workshop on introduction to systematic reviews and HTA	Chisinau, Republic of Moldova
11–13	NRA assessment visit	Ankara, Turkey
11–15	Preparation of and participation in the high-level policy dialogue on the introduction of pharmaceutical price regulation	Bishkek, Kyrgyzstan
17–20	Joint visit with AMR team to support implementation of national action plan	Bishkek, Kyrgyzstan
25–26	Meeting of the Network of Competent Authorities on Pricing and Reimbursement, organized by the EU presidency	Vienna, Austria
October 2018		
1–2	Second Member States consultation on the Global Development and Stewardship Framework to Combat Antimicrobial Resistance	Geneva, Switzerland
8–12	Training of Georgian GMP inspectors	Tbilisi, Georgia
9–11	PSM visit	Tirana, Albania
10–12	Essential medicines list committee workshop	Pristina, Kosovo[27]
15	Technical meeting to support development of the pharmacy practice in Lithuania	Vilnius, Lithuania
17–19	Global Fund to Fight AIDS, Tuberculosis and Malaria cross-cutting workshop on pharmacovigilance	Tbilisi, Georgia
16–18	Senior policy dialogue to present results and recommendations of joint Ministry of Health–WHO assessment of the AMP	Kiev, Ukraine

[27] All references to "Kosovo" should be understood as "Kosovo (in accordance with Security Council resolution 1244 (1999))".

DATE	TOPIC	LOCATION
19–26	Training and capacity development for the NRA In Kyrgyzstan, including in quality management systems	Bishkek, Kyrgyzstan
30–1 November	Subregional cross-programmatic consultation on the role of primary care in the responsible use of medicines and reduction of AMR	Almaty, Kazakhstan
November 2018		
5–8	40th annual meeting of representatives of national pharmacovigilance centres participating in the WHO Programme for International Drug Monitoring	Geneva, Switzerland
12	Opening Symposium of WHO CC at Copenhagen University	Copenhagen, Denmark
15–16	PPRI Network meeting	Ljubljana, Slovenia
20–22	Second Regional Consultation on Expanding Access to Affordable and Quality Assured Medicines and Diagnostic Technologies in Eastern Europe and Central Asia	Minsk, Belarus
22–23	Expert consultation to develop guidance to countries on implementing the WHO Global Patient Safety Challenge: Medication Without Harm	Geneva, Switzerland
29–30	25th anniversary of Infarmed Conference on access to medicines: "Facing the Challenges: Equity, Sustainability and Access"	Lisbon, Portugal
December 2018		
3–14	Intercountry GMP inspectors' training	Hilleroed, Denmark
10–11	Antibiotic shortages consultation	Oslo, Norway

The WHO Regional Office for Europe

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

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