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HEALTH TECHNOLOGIES AND PHARMACEUTICALS PROGRAMME

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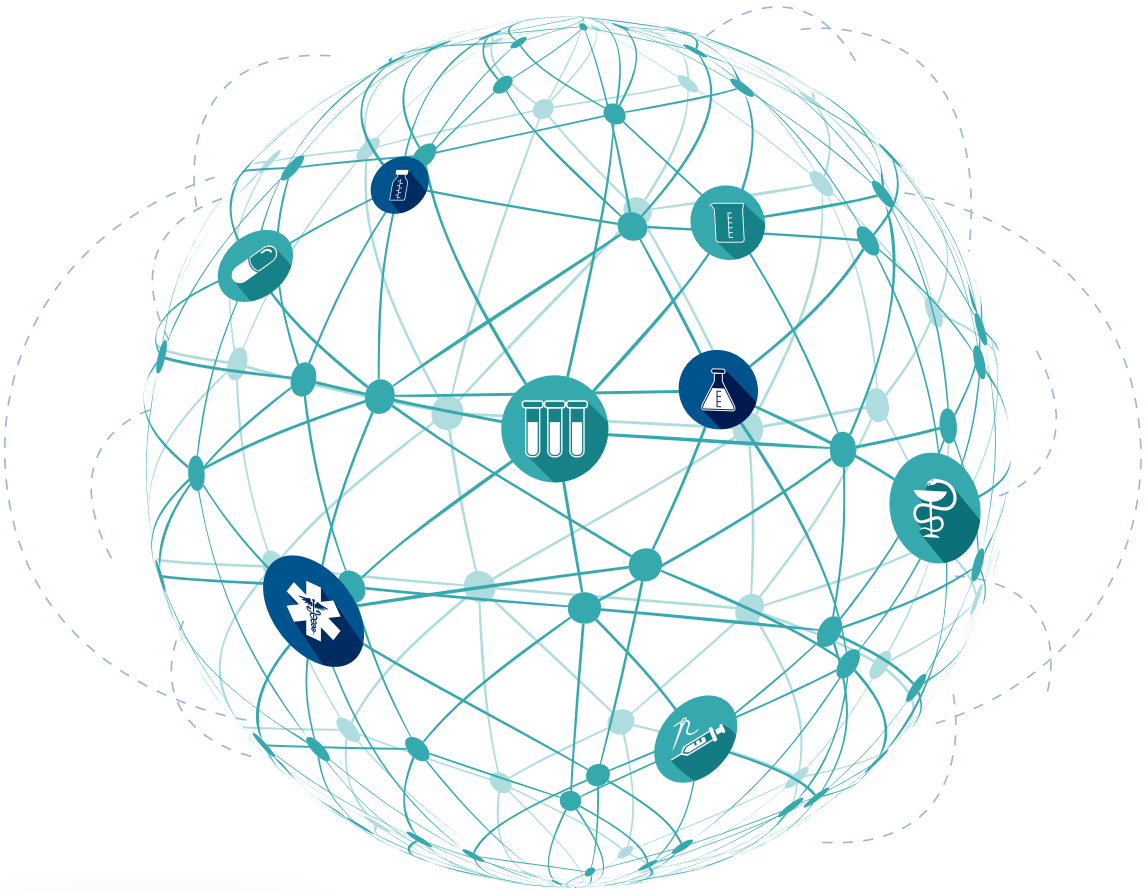

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Abbreviations

AMC	Antimicrobial Medicines Consumption [Network]
CIS	Commonwealth of Independent States
EU	European Union
HTA	Health Technology Assessment
HTP	Health Technologies and Pharmaceuticals [Programme]
PPRI	Pharmaceutical Pricing and Reimbursement Information [Network]
SBP	Similar Biotherapeutic Product
SDG	Sustainable Development Goals
UHC	Universal Health Coverage
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund


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The Health Technologies and Pharmaceuticals (HTP) Programme: 2017 in review

About the HTP Programme

The WHO European Region includes 53 Member States, of which 28 are members of the European Union. 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 products.

In addition to WHO resources, in 2017 the HTP Programme received voluntary donations to conduct activities (financial or technical staff support) from the Ministry of Health, Welfare and Sport in the Netherlands, the German Collaboration Programme, the Government of Norway, the Ministry of Foreign Affairs of Japan and Unitaid.

Partners of the Programme

- Clinical Pharmacology, Department of Laboratory Medicine, Karolinska University Hospital, Sweden
- European Centre for Disease Prevention and Control, Sweden
- Department of Pharmacy, University of Copenhagen, Denmark
- Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies), Austria
- London School of Economics and Political Science (WHO Collaborating Centre for Health Policy and Pharmaceutical Economics), 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: The Global Fund to Fight AIDS, Tuberculosis and Malaria; Organisation for Economic Co-operation and Development, Unitaid, United Nations Children's Fund (UNICEF)

Key achievements

HTP Programme key achievements in 2017 included providing technical assistance to countries related to analysis, evidence creation and policy action, as well as training linked to access to medicines and universal health coverage (UHC). Pharmaceuticals represent large budget components for health systems, and pharmaceutical cost containment is in focus in many countries. WHO has organized consultations and training in the use of methodologies, policies and regulation, fostering access to quality-assured affordable medicines and medical devices among countries in the Region. The HTP Programme's work helps to shape policy reform at the national and subregional levels. In 2017, major activities included the following (for further details see the calendar of activities in Annex).

In-country technical assistance

Estonia

- Review of the reimbursement system and recommendations on reimbursement schemes for vulnerable populations

Greece

- Review of the draft law establishing a new reimbursement committee
- Technical and legal support in formulating the proposed legislative framework, initiating the implementation phase of a viable health technology assessment (HTA) process
- Discussion of short- and medium-term targets to create the necessary operational environment for establishment of sustainable HTA processes and mechanisms

Kazakhstan
- Participation in technical workshop and country coordination meeting on quality of care
- Follow-up on the recommendations of the assessment visit to Kazakhstan in November 2015 to assess progress with development of a national action plan on antimicrobial resistance

Kyrgyzstan
- Review of policy options to reduce out-of-pocket payments for medicines
- Support for drafting and adoption of a new medicine law and for elaboration of corresponding bylaws
- Follow-up on antimicrobial consumption activity and work around the adoption of a national action plan on antimicrobial resistance
- Initiation of self-evaluation of the national regulatory authority for medicines

Lithuania
- Review of the 2017 medicines policy framework
- Policy dialogue on generic policies and access to medicines at the Lithuanian Parliament

Montenegro
- Visit to assess the hospital/primary health care interface and pharmaceutical utilization

Republic of Moldova
- Provision of technical support for revision of the list of reimbursed medicines and to discuss options for savings in the national health insurance fund medicines budget
- Assessment of the patent situation for a selection of medicines and training in intellectual property rights regulation
- Policy dialogue on access to medicines with the Moldovan Parliament's health committee and stakeholders

Ukraine
- Support for elaboration of the outpatient medicines reimbursement pilot scheme
- Follow-up on the adoption of national medicines policies
- Consultations on creating a systematic approach to monitoring antimicrobial consumption
- Assessment of patent situation for a selection of medicines and training in intellectual property rights regulation

Intercountry collaboration

- Creation of a subregional division of the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network for Russian-speaking countries
- Provision of support to developing the Malta European Union (EU) presidency policy brief on access to medicines
- Adoption of a decision during the 67th session of the Regional Committee for Europe on strengthening Member State collaboration on improving access to medicines in the WHO European Region
- Review and analysis of reimbursement models and policies for access to medicines, with a report to be published in 2018
- Preparation of a report on antimicrobial medicines consumption in the WHO European Region and organization of a meeting of the WHO Antimicrobial Medicines Consumption (AMC) Network
- Co-facilitation of PPRI Network meetings
- Participation in the Fair Pricing Forum steering committee

Building capacity through training

- Providing health systems training for delegates from the Transnistria region of the Republic of Moldova
- Arranging a study tour to Amgros, the Danish public procurement agency of hospital medicines, for delegates from the Republic of Moldova
- Providing prequalification assessment training for 10 Russian-speaking countries
- Offering medical device regulation technical consultation with participation from six Member States
- Providing capacity-building/training in pricing and reimbursement of medicines for Russian-speaking countries
- Arranging a study tour to Estonia for members of parliament from Kyrgyzstan to promote good governance in the pharmaceutical sector
- Organizing a meeting and providing technical support for the AMC Network
- Arranging a seminar on biotherapeutic regulation, including a focus on biosimilars
- Co-convening the second Summer School on Pharmaceutical Pricing and Reimbursement Policies with the Austrian Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies)
- Organizing a joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostics, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector-control products
- Arranging a strategic procurement workshop, with a focus on price negotiations
- Organizing a subregional workshop on medical device regulation for Armenia, Georgia, Kyrgyzstan and Ukraine in Yerevan, Armenia
- Providing training on intellectual property rights issues for the Republic of Moldova and Ukraine
- Contributing to the development of the WHO Fair Pricing Forum

Introduction

The WHO Regional Office for Europe, through the HTP Programme, supports its 53 Member States in 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[1]. It is aligned with the Tallinn Charter[2] and Health 2020 policy framework[3] at the regional level, and with the global 2030 Agenda for Sustainable Development,[4] 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 2017 the HTP Programme's programme of work contributed to strengthening countries' pharmaceutical sector systems through:

- technical advice on selection and responsible use of medicines;
- support to national regulatory authorities;

[1] Towards Access 2030 EMP Strategic Framework, 2017 (http://www.who.int/medicines/publications/towards_access2030/en/)

[2] 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 2017).

[3] 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 2017).

[4] 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 2017).

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- development or revision of national pharmaceutical policies;
- expanding the use of HTA;
- developing medicine pricing policies; and
- discussions on new directions in procurement and supply chain management.

The HTP Programme helps countries to become more efficient and thereby better prepared to provide sustainable access to quality-assured medical products through the sharing of country experiences and best practices.

This annual report summarizes the 2017 contribution of the HTP Programme to improving health in the WHO European Region by supporting improved access to essential, affordable, quality-assured pharmaceuticals and medical products.

Medicines, health products and the 2030 Agenda for Sustainable Development

The Sustainable Development Goals (SDGs) represent a shift of focus from specific diseases and population targets to a more comprehensive approach to health. SDG 3 emphasizes the promotion of health throughout the life-course and UHC. With the rise in epidemic-prone pathogens, there is an increasing need for resilient health systems. This new agenda 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 and a sharper focus on a number of emerging 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 SDG 3. 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 currently pay for medicines out-of-pocket, often leading to financial hardship. With the rise in noncommunicable diseases – 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. It will be increasingly important to focus research efforts on diseases that affect developing countries disproportionately, to ensure that no one is left behind.

Medicines regulation and quality

The HTP Programme supports countries 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 also provides specific technical assistance and training to manufacturers and regulators to help them achieve internationally recognized quality standards.

Assessment of national medicine regulation systems

WHO has developed a data collection tool to facilitate the review of national medicine regulatory systems.[5] WHO works in collaboration with local officials to assess the national regulatory situation, review the existing legal framework and identify specific needs for technical support and training.

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. Prequalification 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. Of the 5 products prequalified by WHO in 2017, three finished pharmaceutical products were produced by manufacturers in the Region.

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

Advocating WHO prequalification

In September 2017 the Regional Office, together with UNICEF and UNFPA, 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.[6] More than 350 participants attended daily, with 17 parallel streams of one-on-one meetings with stakeholders.

[6] 2017 UNICEF–UNFPA–WHO meeting. Copenhagen, Denmark – 18–21 September 2017 [website]. Geneva: World Health Organization (https://extranet.who.int/prequal/events/next-joint-unicef%E2%80%93unfpa%E2%80%93who-meeting-18-september-2017-0, accessed 23 October 2017).

Training on prequalification assessment

WHO prequalification programme has held annual assessment workshops in Copenhagen since 2009. These provide training in the practical aspects of quality and bioequivalence assessment – an area in which structured and practical training is lacking or generally unavailable. The workshops have been well attended by an international audience of regulators and very well received; in the past, however, they have been limited to English-speaking participants.

Interest was expressed in a dedicated workshop for Russian-speaking attendees, so WHO organized a Russian-language workshop in Copenhagen, Denmark, on 19–20 May 2017. Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan and Ukraine participated. The workshop's objectives were to:

- provide an overview of prequalification of medicines: the WHO prequalification team, its role and the guidelines and practices it applies;
- deliver presentations covering the fundamental areas of quality and bioequivalence assessment by senior experts in these fields;
- give an opportunity to increase knowledge about the important aspects of assessment of both the active pharmaceutical ingredient and finished pharmaceutical product;
- provide practical approaches and tips for assessment practices;
- offer a forum with experts for questions and answers related to the presentation topics and beyond, open to all questions related to the assessment process; and
- gain an understanding of the needs and preferences of the participants for possible future workshops.

The participants were regulators involved in practical assessment of quality (or bioequivalence), who had the capacity, interest and authority to communicate what they learned further in their respective organizations. Management staff of national regulatory authorities from some countries also participated to better understand the role of assessment and its place in regulatory framework.

Seminar on biotherapeutics including biosimilars in Russian-speaking countries

WHO guidelines on evaluation of similar biotherapeutic products (SBPs) were adopted by the WHO Expert Committee for Biological Standardization in 2009; these provide a set of globally accepted principles regarding regulatory evaluation of SBPs.[7] It was recognized, however, that the guidelines do not by themselves resolve all issues, so in 2010 the International Conference of Drug Regulatory Authorities recommended that WHO supplement its guidance by providing up-to-date guidelines for the evaluation of biotherapeutic products in general. In response, the Expert Committee developed and adopted WHO guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology in 2013.[8] Furthermore, the Sixty-seventh World Health Assembly in 2014 adopted a resolution on critical needs in the biotherapeutics area (including SBPs) in order to promote access to these products, as well as to ensure their quality, safety and efficacy. Resolution WHA67.21 requests that WHO support national regulatory authorities in developing national regulatory frameworks to meet current international regulatory expectations.

The first implementation workshop for Russian-speaking countries in the Region on WHO guidelines for biotherapeutics and SBPs was carried out in July in Copenhagen, Denmark, as a step towards implementation of the principles in both sets of WHO guidelines. The workshop was designed to:

[7] Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs). Geneva: World Health Organization; 2013 (http://apps.who.int/medicinedocs/en/m/abstract/Js19941en/, accessed 16 October 2017).

[8] Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology. Geneva: World Health Organization; 2014 (http://www.who.int/biologicals/biotherapeutics/biotherapeutic-products/en/, accessed 16 October 2017).

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- facilitate implementation of WHO guidelines for biotherapeutics into countries' regulatory practices;
- discuss key regulatory issues relevant to assurance of quality, safety and efficacy of biotherapeutics with regulators;
- provide a forum with experts for questions and answers related to the topic; and
- gain an understanding of the needs and desires of the participants for possible technical support in the field.

Experts with knowledge and experience of reviewing dossiers on quality, nonclinical or clinical evaluation of biotherapeutics for licensing from 12 Member States participated in the workshop to learn and discuss the key principles for evaluating biotherapeutic products including SBPs. A survey was conducted before the workshop to develop better understanding of the country situation and identify regulatory issues and needs. The course was organized in collaboration with the Essential Medicines and Health Products Programme at WHO headquarters and was completed by 30 participants representing Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan and Ukraine.

Regulation of medical devices

Medical devices are products used for the diagnosis, prevention, relief or treatment of a disease, disability, injury or similar; they include a wide range of products. Without medical devices, common medical procedures would not be possible. They are used in many different settings – from remote clinics to advanced medical facilities – and there are currently an estimated 2 million different kinds of medical devices on the world market.

Countries in the WHO European Region are at different stages in medical device regulation. Regulation and management to ensure access to and responsible use of safe and affordable products could be improved in many countries. In 2017 WHO developed a WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic devices.[9] This presents a two-step approach to regulate the quality and safety of medical devices, guiding each step of the regulatory chain.

The Model was introduced during a two-day workshop on 9–10 May 2017 in Geneva, Switzerland, during which countries developed roadmaps for implementation. Five countries from the WHO European Region attended the workshop (Armenia, Georgia, Kazakhstan, Kyrgyzstan and Ukraine). As a follow-up, the WHO Regional Office for Europe organized a three-day subregional workshop that focused on implementation of the Model in the five countries. Participants were trained on how to implement the existing tools and guidelines to ensure access to affordable and safe medical devices. They also received technical support and practical advice to help them further develop regulation for medical devices.

[9] Who Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017 (http://apps.who.int/medicinedocs/en/d/Js23213en/, accessed 16 October 2017).


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Strategic procurement

The high prices of new medicines continue to pose problems for the health care budgets of all countries. Achieving fair pricing and ensuring long-term sustainability of health care systems and access for patients is one of the biggest challenges for health care and pharmaceutical systems in Europe and worldwide.

There is growing interest in the strategic procurement of medicines across the WHO European Region. Indeed, greater collaboration on procurement activities between countries – including countries with smaller populations and limited power to negotiate effectively with industry – may facilitate access to new medicines, promote transparency and encourage the sharing of best practices. Recently a number of country collaboration initiatives have 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[10]. The HTP Programme of the WHO Regional Office for Europe has created opportunities for sharing knowledge and experiences between these subregional collaboration initiatives.

[10] In March 2017 Ministers of Health of Poland, Slovakia and Hungary together with Croatia and Lithuania (within Polish Presidency in 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 works Slovenia joined the initiative.

Sharing experiences in procurement

A technical meeting was organized in February 2017 as a follow-up to the 22–23 September 2016 meeting on challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region organized by the HTP Programme. This aimed to gauge countries' interest and willingness to initiate voluntary collaboration in joint horizon scanning;[11] to explore options to develop a medicines procurement practitioners' forum for the Region; and to define with participating countries the Region's contribution to strategic procurement activities, including networking and technical assistance.

During the consultation countries presented their models for horizon scanning. Participants expressed widespread interest and desire to develop a workshop and forum to improve negotiation capacity and provide a setting for sharing of experiences and best practices. Several subregional initiatives exist in the Region and are working on joint procurement. The BeneluxA countries met and finalized a joint horizon scanning agreement in April 2017; the Nordic Medicines Forum countries also have joint horizon scan-

[11] Horizon scanning is a method of identifying new and emerging health technologies likely to have a significant impact on health care.

ning as part of their collaboration. As there is a strong focus on joint horizon scanning pilots at the subregional level through these new initiatives, the HTP Programme will follow these developments and provide input where needed.

Negotiation training

In response to the February technical meeting, the Regional Office and the London School of Economics and Political Science (WHO Collaborating Centre for Health Policy and Pharmaceutical Economics) developed a training workshop for public procurement experts involved in negotiations linked to the introduction of new medicines. Its aim was to improve the negotiation capacity of key national stakeholders involved in public procurement of health technologies, thereby supporting Member States in improving access to quality-assured and affordable medicines. The ability to structure and conduct effective negotiations with the pharmaceutical industry over the product lifecycle through transparent public procurement practices is an important skillset. Further, the course aimed to frame medicines negotiations within the broader context of a country's health/pharmaceutical policies, as well as health financing goals.

The 2.5-day course took place on 27–29 October in Copenhagen, Denmark, and representatives of public medicines procurement agencies from 16 countries participated. The workshop combined negotiation theory, practical exercises and case studies based on products/therapy areas of concern to the countries involved to enable participants to build on and apply their negotiations knowledge.

The WHO Regional Office for Europe is in discussion with the London School of Economics and Political Science to conduct a similar workshop in 2018 for countries that could not attend this session because of the limited number of spaces available for the workshop.

The objectives of this training were to:

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

Malta's EU presidency

Interest is growing in further developing cross-border voluntary collaboration in the field of health, at both a bilateral and a multilateral level. EU legislation and directives outline options for EU Member State collaboration; one example is the Joint Procurement Agreement adopted by the Commission on 10 April 2014.[12]

During the Maltese presidency of the EU (January to July 2017), a policy brief was presented on voluntary cross-border collaboration in public procurement to improve access to health technologies. The Regional Office participated in revision of the policy brief, which was presented during a technical workshop in March 2017 in Malta, where further opportunities for structured cooperation to enhance access to medicines were discussed. The outcomes of the workshop contributed to a ministerial meeting on 20 March 2017 to set out the political direction for drafting European Council conclusions on this topic.

[12] Joint Procurement Agreement to procure medical countermeasures. Brussels: European Commission; 2010 (https://ec.europa.eu/health/preparedness_response/joint_procurement_en, accessed 16 October 2017).

Study visit to Amgros, the Danish pharmaceutical procurement agency

A delegation from the Ministry of Health of the Republic of Moldova and related special agencies visited the Danish pharmaceutical procurement agency, Amgros, to learn from the Danish experience in the supply of hospital pharmaceuticals. The two-day study tour, on 3–4 May 2017, was organized at the request of the national health authorities to strengthen the capacities and internal processes of a recently created Moldovan National Agency for Centralized Procurement in the Health Sector.

During the visit the delegates learned about various aspects of the procurement process undertaken by Amgros, such as:

- quantification and needs assessment
- the negotiation process and obtaining discounts
- managing supplier contracts
- information systems in place within Amgros.

Representatives from the Republic of Moldova took part in a workshop that covered various topics and shared the Danish experience in centralized procurement of pharmaceuticals, best practices promoting strategic procurement, understanding obstacles during negotiations and managing supplier performance.

The delegates from Moldovan national authorities identified and discussed the regulatory and organizational implications for the new National Agency; these will be translated into action and reform of the national pharmaceutical procurement system.

The study visit and capacity-building activity were organized as part of a broader WHO technical assistance programme to strengthen the pharmaceutical system in the Republic of Moldova, to harmonize the pharmaceutical legal framework with EU law and to make the current procurement system more efficient, transparent and sustainable.

HTA

HTA survey

In 2015 all Member States were invited to participate in a global survey on the use of HTA in advance of the Sixty-eighth World Health Assembly and a report on the findings was published.[13] The HTP Programme updated the survey in 2017, collecting data from the countries of the Commonwealth of Independent States (CIS) using the same methodology. Understanding the current status, development and use of HTA in these countries means that WHO is better able to provide technical support to strengthen national capacity for HTA and its supporting mechanisms.

The survey was circulated to 11 CIS countries between 1 May and 30 June 2017. Responses from the 2015 and 2017 surveys were consolidated and used to assess any reported changes in the use of HTA; eight countries were included in the analysis. Progressive realization of HTA capacity is a long-term investment for Member States, for which practical experience is imperative. The survey results suggest that countries are at varying stages of development in their HTA capacity, but have reported prioritizing the cost–effectiveness of medicines and the cost and clinical effectiveness, safety and ethical considerations surrounding vaccines.

Input to the WHO legal and regulatory guidance document for HTA

A meeting was convened in Rome with HTP Programme participation to draft chapters of a WHO legal and regulatory guidance document for HTA. Several lawyers were part of the group discussions to further develop the legal chapter of the guidance document. The group used WHO's draft "Good regulatory practices: guidelines for national regulatory authorities for medical products" as a basis for discussions, and sought to make a clear distinction between the legal framework for HTA and the decision-making process using this legal framework. The legal framework is to be developed on a robust scientific and legal basis. As many countries currently include HTA reviews in their decision-making related to the introduction of new technologies in health systems, the WHO guidance document may assist them in clarifying the role and function of HTA. This should inform political decisions taken on the basis of HTA reviews.

Greece takes a step towards the use of HTA in decision-making

The WHO Regional Office for Europe, through its HTP Programme, provided technical support to the Greek authorities in their revision of the functioning of the national medicine reimbursement committee. As part of the general reform of the health care sector in Greece, it was suggested that the authorities increase accountability and transparency in the medicines reimbursement process. The introduction of HTA principles in the decision-making process is seen as helping to achieve this objective. The work was conducted in collaboration with the Portuguese HTA agency, INFARMED, which shared experiences and practices in the use of HTA in a similar national context.

[13] 2015 Global Survey on Health Technology Assessment by National Authorities: main findings. Geneva: World Health Organization; 2015 (http://apps.who.int/medicinedocs/en/d/Js22174en/, accessed 16 October 2017).

Pricing and reimbursement

Initiation meeting of the first network of competent authorities on pharmaceutical pricing and reimbursement policies in the CIS

The HTP Programme, in collaboration with the Austrian Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies), convened the first meeting of the subregional division of the PPRI Network for countries of the CIS. This is the first such network created to allow representatives of CIS countries to share similar challenges in enhancing financial access to medicines.

The event took place on 13–14 June 2017 and representatives of Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Ukraine and Uzbekistan gathered in Chisinau, Republic of Moldova, to participate. The meeting provided representatives of competent authorities with information on pricing and reimbursement policies, using specific country examples from other countries in Europe. Participants reflected on their national systems and the difficulties they faced in ensuring the accessibility and affordability of medicines.

Participants agreed that the CIS PPRI Network should carry on with WHO support, but set a medium-term objective that participating countries should take responsibility for its direct management. A WHO report on the pricing and reimbursement system in CIS countries is in preparation, based on the information gathered during this meeting and a survey undertaken in the Region.

Intellectual property rights of medicines

Governments in the Region have sought the support of WHO on issues related to the impact of intellectual property on affordability of medicines. It is broadly acknowledged that national stakeholders often lack expertise in issues related to intellectual property and lack knowledge of the legal options available to increase access to medicines. In this context, the WHO Regional Office for Europe, in collaboration with WHO headquarters, designed and delivered specific training for Ukrainian and Moldovan officials on the interconnections between intellectual property rights and access to medicines, in which the World Intellectual Property Organization and United Nations Development Programme took part.

The objective of the two-day training session was to explore potential options for these countries to increase access to lower-priced medicines, drawing on lessons from other countries and international devel-

opments in this area. The seminar aimed to give to policy-makers core information about legal options under international and national intellectual property law that can be used to access affordable essential medicines. It provided practical guidance on the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights and discussed relevant regulatory issues for marketing authorization of generic medicines. Specific medicines case studies were used to illustrate possible obstacles to making generic medicines available and to discuss legal and practical options to overcome them. The seminar primarily focused on increasing access to essential medicines to treat HIV, hepatitis C and cancer.

Summer School on Pharmaceutical Pricing and Reimbursement Policies

In collaboration with the Austrian Institute of Public Health (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies), the HTP Programme offered a second five-day training course for professionals of competent authorities and public institutions working in the field of pricing and reimbursement of medicines. The event brought together 40 participants from 22 countries. International scientific experts and experienced national policy-makers were provided with insights into pharmaceutical policies related to medicine pricing and reimbursement. Topics discussed included methodology of external reference pricing, best procurement practices, general pharmaceutical economics concepts and intellectual property rights of medicines. The Summer School provided lectures, hands-on training sessions, a panel discussion with distinguished experts and case studies on implementation and optimization of pharmaceutical policies. Study visits to relevant institutions in Austria were also part of the programme.

In association with the Summer School, a high-level panel discussion on access to high-priced medicines in Europe was organized at the Austrian Ministry of Health. This discussion highlighted the difficulties in reconciling the views on financial aspects of access to medicines between the public and private sectors.

© PPRI Summer school/Austrian Health Institute

Responsible use of medicines

WHO estimates that more than half of all medicines worldwide are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take medicines correctly. Overuse, underuse and misuse result in wastage of scarce resources, continued health problems or adverse reactions to drugs.

The Regional Office provides direct support to countries, organizes training and helps build capacity among health professionals and relevant stakeholders to improve prescribing. It helps identify successful strategies to improve the use of medicines through medicine and therapeutic committees, formularies and clinical guidelines, feedback on medicine use data and policies on medicine promotion.

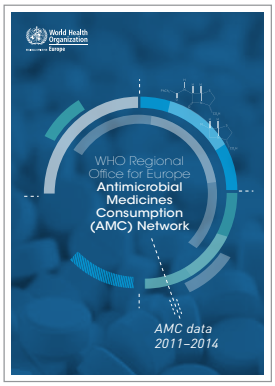
AMC Network

In 2015 WHO Member States adopted the Global Action Plan on antimicrobial resistance.[14] 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 Member States in setting up or strengthening national surveillance. 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 (in accordance with United Nations Security Council resolution 1244 (1999)), are currently engaged in the Network. National monitoring of consumption helps provide centralized data to ensure that strategies to address antimicrobial consumption and resistance are effective. Efforts are closely coordinated with the European Centre for Disease Prevention and Control so that data are comparable and can provide a pan-European overview of trends.

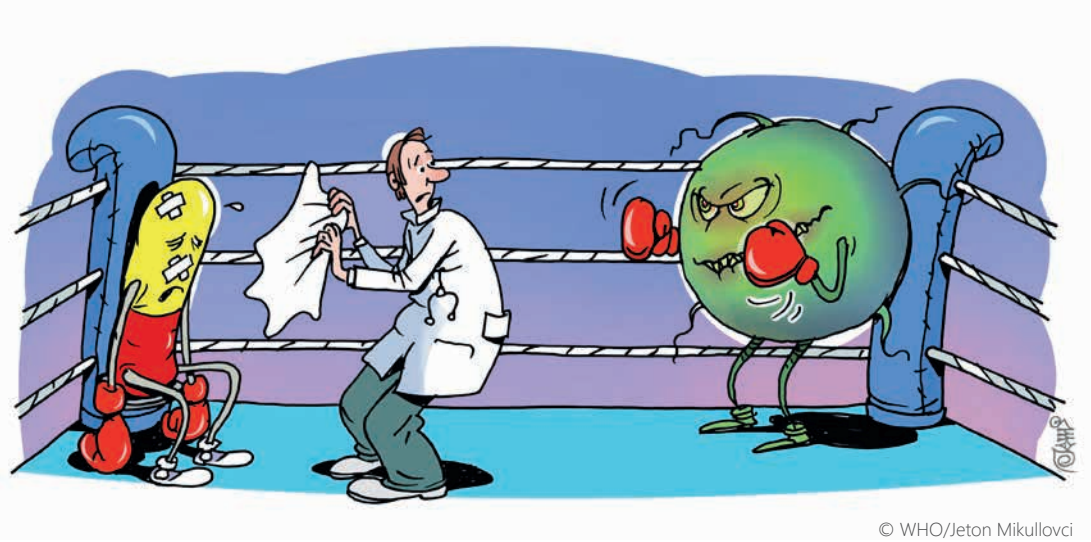
Report of data from the AMC Network

In May 2017 WHO published a report on antimicrobial consumption data collected in 11 non-EU countries and Kosovo (in accordance with United Nations Security Council resolution 1244 (1999)) during 2011–2014, gathered through the AMC Network.[15] The



[14] 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).

[15] Antimicrobial Medicines Consumption (AMC) Network: AMC data 2011–2014. Copenhagen: WHO Regional Office for Europe 2017 (http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2017/antimicrobial-medicines-consumption-amc-network.-amc-data-20112014-2017, accessed 16 October 2017).



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data were collected by national focal points from sources including import and customs records, sales records and estimates of local manufacturing. The report indicates that consumption across the countries surveyed varies widely and that this variation is unlikely to be explained by population health problems alone.

Quantitative data on consumption provide a starting-point for better understanding of the use of antibacterials in clinical practice; they should be supported by further quantitative and qualitative studies in the primary care and hospital sectors. Trends in consumption data must be interpreted with an understanding of local contexts, such as changes in regulations over time (including enforcement of prescription-only status), data sources used to generate consumption estimates, local resistance patterns and the potential impact of interventions directed at health care professionals and consumers to change practices.

Database of antimicrobial consumption data

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

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

Annual meeting of the AMC Network

The annual AMC Network meeting was held on 3–4 July 2017 in Copenhagen, bringing together national antimicrobial consumption focal points and national and international clinical experts in antimicrobial medicines use. In addition to reviewing the 2015 data, the meeting's discussions centred on encouraging countries to utilize their data to promote responsible use of antimicrobials.

Areas of particular focus were communicating data to clinicians, with examples of national- and local-level activities undertaken in England and Slovenia, and how to align work on consumption of medicines with national action plans on antimicrobial resistance. Participants were also updated on important changes to the antibacterials section of the WHO Model List of Essential Medicines in 2017 and the creation of the classification of Access, Watch and Reserve groups of antibiotics.[16]

[16] WHO Model Lists of Essential Medicines [website]. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/essentialmedicines/en/, accessed 16 October 2017).


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WHO Regional Committee for Europe

On 13 September 2017, at the 67th session of the WHO Regional Committee for Europe held in Budapest, Hungary, Member States adopted a decision to strengthen collaboration to improve access to quality, affordable medicines. A film featuring Josef Probst, Director-General of the Main Association of Austrian Social Security Institutions, opened the session and provided a payer's perspective on the topic, highlighting the increasing costs to the national budget from pharmaceuticals.[17] The HTP Programme background document was presented and followed by a dialogue on the challenges faced by countries relating to access to medicines.

During discussions, delegates highlighted the enormous challenges of providing medicines at a financially sustainable price; the lack of transparency in the real cost of medicine development and production; and the complexities of intellectual property rights and trade agreements. Austria emphasized that the issue is not so much technical as political, and noted that it is up to policy-makers to frame the market in which the pharmaceutical industry works; Norway reaffirmed that providing access to certain medicines is a challenge even for high-income countries; and the Netherlands expressed its objection to value-based pricing of medicines.

Member States agreed on the importance of collaborating to share best practices on pricing and reimbursement and strategic procurement to improve access to medicines. They noted that political will and mutual trust are essential for this. Countries also acknowledged WHO's role in providing technical support and fostering collaboration. In a statement, the World Heart Federation reiterated that all stakeholders, including the pharmaceutical industry, must work together to achieve fair pricing; that is, medicine prices that are affordable for health systems and patients, and at the same time provide sufficient market incentive for industry to invest in innovation and the production of medicines. In this context, fairness implies positive incentives and/or benefits for all stakeholders, including purchasers and those involved in the research and development and manufacture of medicines. Various civil society organizations acknowledged the discussion as a valuable one.

[17] Josef Probst, Director-General of the Main Association of Austrian Social Security Institutions, Austria [video]. Copenhagen: WHO Regional Office for Europe; 2017 (http://www.euro.who.int/en/about-us/governance/regional-committee-for-europe/67th-session/multimedia/voices-of-the-region/josef-probst,-director-general-of-the-main-association-of-austrian-social-security-institutions,-austria, accessed 16 October 2017).

Individual support to countries in the Region

KYRGYZSTAN: support for modernization of pharmaceutical legislation

On 28 February 2017 the WHO Country Office in Kyrgyzstan held a policy dialogue on new laws under discussion to regulate the pricing and procurement of medicines and health technologies in the country. Minister of Health, Dr Talantbek Batyraliev, chaired the meeting which gathered stakeholders representing the pharmaceutical industry, patients, prescribers, authorities and parliamentarians. Participants adopted a formal statement summarizing the discussions, and stressed the importance of having the laws adopted as soon as possible.

The WHO Regional Office for Europe and WHO Country Office supported the Kyrgyz Ministry of Health in developing a new health technology regulatory framework. The existing law needed to be updated for harmonization with requirements of Eurasian Economic Union accession. Three draft laws under discussion dealt with medicines, medical devices and transversal legal changes, and were developed by a multidisciplinary working group under the authority of the Kyrgyz Government.

The new legislation was formally adopted by the Minister of Health in June 2017 and promulgated thereafter by the President. WHO continued its support to the authorities during the drafting of corresponding bylaws, which will translate the legislation into national regulatory activities.

The passing of this legislation was a turning point for strengthening the health care sector in Kyrgyzstan. The availability and affordability of quality medicines is a pillar of UHC and will have positive consequences for the Kyrgyz population: registration and monitoring of medicines and medical devices will be strengthened; quality and circulation of health products will be better regulated; control and inspection activities will be improved, contributing to the elimination of smuggling and falsified and counterfeit medicines; and the pharmaceutical sector will be more transparent, predictable and accountable. These activities are part of the Regional Office's support through its biennial collaborative agreement for 2016–2017 with the Ministry of Health of Kyrgyzstan.

GREECE: a step towards use of HTA in decision-making

A WHO Regional Office for Europe HTA visit took place in Greece on 31 May – 2 June 2017, for:

- a rapid assessment of the actions taken since the previous HTA visit in May 2016;
- technical and legal support to the authorities on the proposed new legislative framework that initiates a reform of the medicine reimbursement process;
- identification of short- and medium-term objectives that will allow the creation of an environment where HTA is used in decision-making in Greece.

The visit agenda included discussions with the leadership of the Ministry of Health, members of the HTA Working Group and its legal team, the director of the National Organization for Medicines, members of the Negotiating Committee and the current Positive List Committee, and the director of the Institute of Pharmaceutical Research and Technology. The WHO team included experts from Portugal's HTA agency, INFARMED, who provided technical support and inputs to the discussions and development of the legal framework. A joint meeting with representatives of the Ministry of Health and of the European Commission also took place on 1 June, to discuss the current actions of the authorities with regard to Greece's commitments under the memorandum of understanding.

The Greek Ministry of Health organized a final briefing meeting on 2 June to discuss findings and preliminary recommendations. Minister Andreas Xanthos expressed his personal appreciation for the support provided by WHO and the Portuguese partners and renewed the Greek Government's commitment to achieving a transformation of the medicines reimbursement system, not only to cope with short-term reform imperatives but also as part of the country's movement towards UHC. The parties agreed on future steps in HTA policy implementation, related mainly to developing national capacities in HTA.

The visit was organized under the Strengthening Capacity for Universal Coverage initiative, carried out with funding from the EU through a grant agreement between the European Commission and WHO Regional Office for Europe. The general objective of the initiative is to contribute to improving health and health equity in Greece, especially among the most vulnerable in the crisis-stricken population, by helping the Greek authorities move towards universal coverage and strengthening the effectiveness, efficiency and resilience of the health system.

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REPUBLIC OF MOLDOVA:

Comprehensive assessment of pharmaceutical policies and strategies

The Government of the Republic of Moldova is taking relevant steps to harmonize its national legislation with the principles and standards of EU legislation (*acquis communautaires*) in the pharmaceutical sector. WHO has supported the process technically and provided expertise during 2016 at the request of the Ministry of Health. In 2017 WHO set up a framework for strategic advice and guidance to health authorities when implementing policies and strategies to strengthen the pharmaceutical sector. This was arranged under the guidance of the HTP Programme of the WHO Regional Office for Europe and was conducted by a highly experienced consultant in pharmaceutical systems within the European Region and globally. WHO's support for this work is part of the biennial collaborative agreement 2016–2017 with the Moldovan Ministry of Health. The initiative is financially supported by WHO and the Swiss Agency for Development and Cooperation.

Expanding access to treatment

While new antiviral medicines can cure most people infected with hepatitis C, they are often prohibitively expensive. The Republic of Moldova is one country that has made great progress in improving access to these medicines. In 2016 WHO updated its hepatitis C treatment and care guidelines, which strongly recommend direct-acting antivirals. Following this update, the Centre for Centralized Procurements in Health in the Republic of Moldova worked with WHO to identify ways to make medicines to treat hepatitis C more affordable, resulting in a procurement procedure for the introduction of generics. Prior to the introduction of this procedure, around 7000 people were registered and waiting for treatment, and approximately 300–400 people were treated every year. Since 2016, 3000 people have been treated with the new direct-acting antivirals and a second wave of patients will soon begin treatment.[18]

[18] Improving access to hepatitis C medicines [video]. Geneva: World Health Organization; 2017 (http://www.who.int/hepatitis/news-events/improving-access-to-hepatitis-c-medicines-moldova/en/, accessed 16 October 2017).

Annex. Calendar of activities

DATE	TOPIC	LOCATION
January 2017		
9	EU Austrian Presidency meeting: access to medicines brainstorming session	Brussels, Belgium
27	Malta workshop on small countries and access to medicines	Valletta, Malta
February 2017		
13–14	WHO workshop on antimicrobial consumption methodology training	Geneva, Switzerland
21–25	AMC Network-related consultation	Chisinau, Republic of Moldova
22–23	Follow-up meeting on strategic procurement and horizon scanning country collaboration	Copenhagen, Denmark
27–7 March	Kyrgyzstan regulation and policy consultation (follow-up visit to develop the action plan for regulation of pharmaceutical pricing)	Bishkek, Kyrgyzstan
28–2 March	Médecins Sans Frontières conference on access to medicines and technologies	Minsk, Belarus
28–5 March	EU Maltese presidency technical workshop on structured cooperation between health systems: enhancing access to novel highly specialized services, medicines and technologies	Sliema, Malta
March 2017		
13–17	Barcelona health financing course	Barcelona, Spain
24–25	Noncommunicable disease medicines consultation	Helsinki, Finland
27–1 April	Expert Committee on Selection of Essential Medicines	Geneva, Switzerland
April 2017		
1–6	Country visit and consultation on PHC and drug utilisation	Almaty, Kazakhstan
3–6	Joint visit with the EU to support development of the national medicines policy in Ukraine	Kiev, Ukraine
4–15	Participation in assessment of the Den Sooluk National Health Reform Program in Kyrgyzstan	Bishkek, Kyrgyzstan
26	European Commission-hosted procurement training on health commodities	Brussels, Belgium
27–28	PPRI Network meeting	Stockholm, Sweden

DATE	TOPIC	LOCATION
May 2017		
1–5	Health systems training for Transnistria, Republic of Moldova	Copenhagen, Denmark
2–3	Stakeholder consultation on access to, and use of, single biotherapeutic products (SBPs)	Geneva, Switzerland
3–4	Republic of Moldova study tour to Regional Office and Amgros, Denmark, on procurement of medicines	Copenhagen, Denmark
8–14	Joint AMC, AMR mission to assist in the development of the Kyrgyzstan national action plan on antimicrobial resistance	Bishkek, Kyrgyzstan
9–10	Medical device regulation technical consultation	Geneva, Switzerland
10–11	Third WHO Global Forum on Medical Devices	Geneva, Switzerland
10–12	Fair Pricing Forum	Amsterdam, the Netherlands
19–20	Training for Russian-speaking regulators	Copenhagen, Denmark
31–2 June	Review of the HTA system in Greece	Athens, Greece
June 2017		
7–10	Kyrgyz follow-up visit	Bishkek, Kyrgyzstan
12–15	First meeting of the CIS PPRI Network	Chisinau, Republic of Moldova
17–21	HTA international meeting; EuroScan workshop	Rome, Italy
18–23	Kyrgyz study tour to Estonia on medicines regulation	Tallinn, Estonia
27	BeneluxA country cooperation on horizon scanning meeting	Brussels, Belgium
July 2017		
3–4	AMC Network meeting	Copenhagen, Denmark,
5–7	Technical consultation on biotherapeutic regulation	Copenhagen, Denmark
9–14	Kyrgyzstan National Regulatory Authority benchmarking training	Bishkek, Kyrgyzstan
11–12	European Centre for Disease Prevention and Control meeting	Stockholm, Sweden
16–19	Visit to assess the hospital/primary health care interface and regulatory issues in the pharmaceutical sector	Podgorica, Montenegro
28	World Hepatitis Day/Access to hepatitis medicines in the Republic of Moldova	
August 2017		
28–1 September	Summer School on Pharmaceutical Pricing and Reimbursement Policies	Vienna, Austria

DATE	TOPIC	LOCATION
September 2017		
11–14	67th session of the Regional Committee for Europe	Budapest, Hungary
18–21	Joint UNICEF, UNFPA and WHO manufacturers' meeting	Copenhagen, Denmark
21–23	Policy dialogue at the Lithuanian Parliament on access to medicines	Vilnius, Lithuania
26	One-day conference on access to medicines at the Dutch Cancer Society (Chair of the European Cancer Leagues Task Force on Access) and the Danish Cancer Society (Co-chair of the European Cancer Leagues)	Copenhagen, Denmark
26–28	Strategic procurement and negotiations workshop	Copenhagen, Denmark
28	High-level briefing session on intellectual property rights for the Ministry of Health and stakeholders	Chisinau, Republic of Moldova
October 2017		
2–6	Country training on medical device regulation for five CIS countries	Yerevan, Armenia
5–6	State Expert Centre anniversary	Kiev, Ukraine
10	Study tour to Regional Office for Europe, Copenhagen University, Department of Pharmacy	Copenhagen, Denmark
12–13	Pharmaceutical Congress	Lisbon, Portugal
25	High-level briefing session on intellectual property rights for Ministry of Health and stakeholders	Kiev, Ukraine
26–27	Training on intellectual property rights issues for the Republic of Moldova and Ukraine with the World Intellectual Property Organization and United Nations Development Programme	Kiev, Ukraine
November 2017		
9–10	Preparatory expert and Member State meeting on health system responses to noncommunicable diseases: experience of the European Region	Madrid, Spain
12–13	PPRI Network meeting	Athens, Greece
15–17	Consultation with programme managers and Regional Advisers from the WHO Essential Medicines and Health Products Programme	Geneva, Switzerland
15–17	EuroDURG conference participation	Glasgow, United Kingdom
22-24	AMC mission to Uzbekistan	Tashkent, Uzbekistan
25–1 December	Technical assistance for finalizing bylaws after the pharmaceutical legislation was updated in August 2017 and adopted by the parliament	Bishkek, Kyrgyzstan
December 2017		
11-12	Technical assistance with development of antibiotic protocols for primary health care in Greece	Athens, Greece

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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