World Health Organization
REGIONAL OFFICE FOR Europe

HEALTH TECHNOLOGIES AND PHARMACEUTICALS PROGRAMME

ANNUAL REPORT 2019

Division of Health Systems and Public Health,
WHO Regional Office for Europe

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

Publications
WHO Regional Office for Europe
UN City, Marmorvej 51
DK-2100 Copenhagen Ø, Denmark

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

Contents

Message from the Director

As we consolidate activities in the WHO Regional Office for Europe in support of WHO's global programme of work, it is extremely useful to reflect on the work and achievements of the Health Technologies and Pharmaceuticals (HTP) Programme in 2019. HTP work takes place within a health systems approach that has the underlying goal of improving health outcomes. Strong health care systems underpinned by effective pharmaceutical and medical technology policies are central to ensuring affordable and equitable access to the medicines and health technologies that are needed to lead a healthy and productive life. It is critical that the Regional Office's vision for united action for better health is aligned with the needs and the expectations of the governments to which we are accountable.

The pharmaceutical sector is complex, involving many actors in the public and private sectors, national and regional regulatory authorities, United Nations agencies, the World Bank, philanthropic groups, academic institutions, researchers, those implementing practical policies on the ground and more. WHO recognizes the importance of ensuring that these collaborations are effective, focusing on how WHO can support, complement and add value to the vital work being undertaken in the Region.

This report illustrates several important ways that the HTP Programme is working in the Region with the provision of specific technical support to individual countries, capacity-building through regional and subregional training and workshops, providing mechanisms for information-sharing on issues including the pricing and reimbursement of medicines, encouraging data collection and local dissemination of findings to inform decision-making by policy-makers and clinicians, and exploring new ways of working within and between countries to ensure effective procurement and supply of quality-assured medicines and health products. Work is being undertaken in collaboration with the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the Global Fund to Fight AIDS, Tuberculosis and Malaria and several WHO collaborating centres in the Region.

As this annual report goes to print, countries around the world, and particularly in the WHO European Region, are grappling with the human, health and economic costs of dealing with the COVID-19 pandemic. The needs of countries in the Region to embed robust and sustainable health care systems have never been greater.

WHO commits to working with all countries in the Region to deal with the immediate health crisis and to assist in the long recovery that will follow. The requirements for support will vary enormously across the Region, and we will respond to the diversity of demands made on us. The work of the Regional Office for Europe and our partners will be critical in supporting country systems to better manage the economic impacts of the crisis and to ensure that high-quality and affordable medicines and health technologies are available to all citizens in the Region.

Dr Santino Severoni,
Division of Health Systems and Public Health

Acknowledgements

The work of the Health Technologies and Pharmaceuticals (HTP) Programme, Division of Health Systems and Public Health of the WHO Regional Office for Europe, would not be possible without the generous voluntary financial assistance provided by Unitaid, the Ministry of Health, Welfare and Sport in the Netherlands, the German Collaboration Programme and the Ministry of Foreign Affairs of Japan.

The significant support of Unitaid for the regional activities of the WHO Prequalification of Medicines Programme is also acknowledged.

The HTP Programme is grateful to its network of collaborating centres, other nongovernmental organizations in official relations with WHO, and WHO headquarters, Geneva, for technical expertise and support in improving pharmaceutical policies and systems in the European Region.

Further thanks go to representatives of national ministries of health and regulatory and public procurement agencies for their collaboration and willingness to share their experiences in the pharmaceutical sector.

The boundaries and names shown and the designations used on this site do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Abbreviations

3S	Smart Safety Surveillance [Project]
AMC	Antimicrobial Medicines Consumption [Network]
AMR	antimicrobial resistance
AT	assistive device or technology
AWaRe	Access, Watch and Reserve [WHO classification of antibiotics]
CRP	collaborative registration procedure [of WHO]
EAEU	Eurasian Economic Union
EECA PPRI	Eastern Europe and central Asia Pharmaceutical Pricing and Reimbursement Information [Network]
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
GBT	WHO Global Benchmarking Tool
GDP	good distribution practice
GMP	good manufacturing practice
HTA	health technology assessment
HTP	Health Technologies and Pharmaceuticals [Programme]
IDP	institutional development plan
NRA	national regulatory authority
PPRI	Pharmaceutical Pricing and Reimbursement Information [Network]
QMS	quality management system
SDG	Sustainable Development Goal
TB	tuberculosis
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund

©Tifenn Humbert

The Health Technologies and Pharmaceuticals (HTP) Programme: 2019 in review

About the HTP Programme

The WHO European Regional Office for Europe supports Member States in providing people with sustainable access to essential and affordable high-quality medicines and medical products. The work of the HTP Programme focuses on health system strengthening, supporting the development, revision and implementation of comprehensive pharmaceutical sector policies covering:

- regulation of medicines and medical devices
- pharmacovigilance
- selection and responsible use of medicines
- expanding the use of health technology assessment
- developing medicine pricing and reimbursement policies.

In addition, the Programme has an important convening role, bringing together national and international experts and national colleagues to promote cross-country dialogue and to share country experiences.

Partners of the Programme

- Austrian Institute of Public Health
- Department of Pharmacy, University of Copenhagen, Denmark
- European Centre for Disease Prevention and Control, Stockholm, Sweden
- Institute of Public Health, Norway
- International Pharmaceutical Federation
- LSE Health, London School of Economics and Political Science, United Kingdom
- Norwegian Institute of Public Health, Norway
- Organisation for Economic Co-operation
- Pharmakon, Denmark
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Unitaid
- United Nations Children's Fund (UNICEF)
- United Nations Development Programme (UNDP)
- Uppsala Monitoring Centre, Sweden
- Utrecht Institute for Pharmaceutical Sciences, the Netherlands

Highlights

A few highlights of the technical and policy support provided to Member States are listed below.

In 2019 the HTP Programme:

- supported the ministry of health in Kyrgyzstan with the reform of pricing regulation for medicines reimbursed at the primary health care level;
- introduced and supported the use of the WHO Global Benchmarking Tool for evaluation of national regulatory systems in nine countries and Kosovo;[1]
- conducted workshops for 12 Russian-speaking countries to introduce the WHO collaborative registration procedure for accelerated registration of finished pharmaceutical products that have received approval from a stringent regulatory authority;
- co-sponsored the second Medicine Procurement Practitioners Exchange Forum, conducted in collaboration with the UNICEF Supply Division, UNDP and Global Fund to Fight AIDS, Tuberculosis and Malaria;
- provided training in good manufacturing practice and on the WHO guidelines on the implementation of quality management system for national regulatory authorities in two countries;
- coordinated the third eastern Europe and central Asia Pharmaceutical Pricing and Reimbursement Information (EECA PPRI) Network meeting and Winter School on pharmaceutical pricing and reimbursement policies, involving nine countries in the WHO European Region;
- supported development of national pharmacovigilance centres in Armenia;
- conducted a two-day capacity-building workshop on health technology assessment for medical devices in Baltic countries;
- supported revision of clinical protocols for common infections in primary care in Kyrgyzstan and Uzbekistan;
- facilitated peer learning study visits to the Norwegian Medicines Agency (Oslo, Norway), SwissMedic (Geneva, Switzerland) and Amgros, the Danish medicines procurement agency (Copenhagen, Denmark).

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

Introduction – focus of work

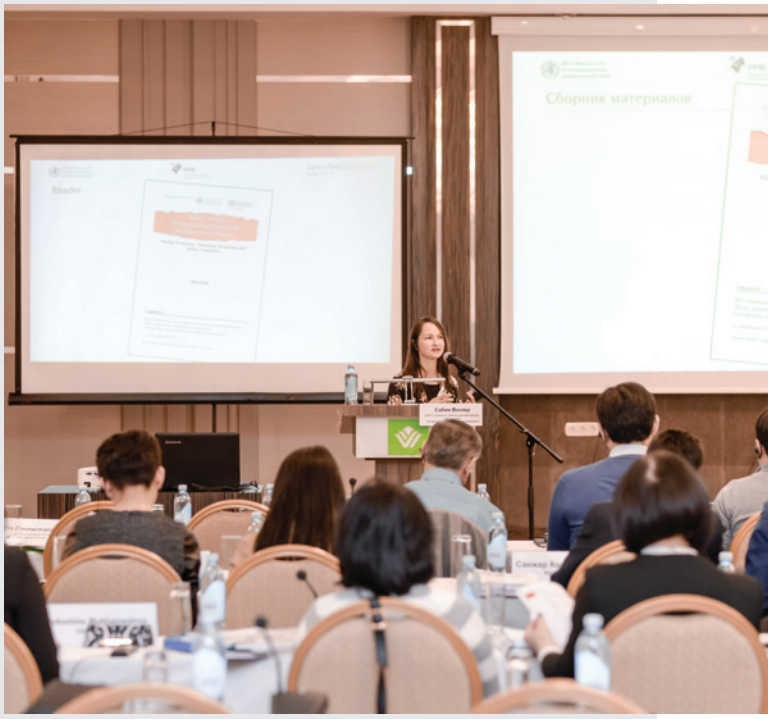
The HTP Programme of the WHO Regional Office for Europe supports Member States in providing people with sustainable access to essential and affordable high-quality medicines and medical products. Equitable access to health products is a global priority that needs to be addressed to achieve the Sustainable Development Goals – in particular, Target 3.8:

> *Achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all.*

The HTP Programme provides highly specialized policy dialogue, strategic support and direct technical assistance to Member States across all the steps required to ensure access to medicines and health products.

The Programme works across all levels and programmes of WHO, with activities related to such access. Its programme of work includes:

- support to WHO headquarters for the development of WHO global norms and standards on the quality, safety and effectiveness of medicines and related health products, including medical devices and assistive technologies;
- support to Member States for development and implementation of national medicines policies, national essential medicines and in-vitro diagnostic lists, reimbursed medicines lists and standards using WHO global lists and guidelines, including prequalification;
- support to Member States to improve access to medicines and health products and affordability for patients and health care systems through developments including health technology assessment (HTA), pricing, strategic procurement, supply chain management and reimbursement, including out-of-pocket payments;
- support to Member States to improve access to medicines and health products through market assessments and interventions to address shortages and challenges related to specific products;
- regulatory system strengthening, including of laboratories and inspection capacity;
- activities related to antimicrobial resistance (AMR), including capacity-building for collection and analysis of data on consumption of antimicrobial medicines, promoting evidence-based prescribing practices and responsible use of antibiotics;
- definition, coordination and delivery of research;
- coordination of regional and subregional meetings and workshops to share information and experiences in various aspects of the pharmaceutical and health products sector and to support capacity-building.



© WHO

Focus on country and area work

The HTP Programme worked on a variety of projects in countries and areas in the WHO European Region in 2019, including the following (for further details see the calendar of activities in Annex 1).

Country work

Albania

- Self-assessment benchmarking of the national regulatory authority (NRA)
- Direct technical assistance based on an institutional development plan (IDP) for the NRA
- WHO workshop on implementation of European Union (EU) guidelines on good distribution practice (GDP)

Armenia

- Phase III pilot of Smart Safety Surveillance (3S) Project (pharmacovigilance for tuberculosis (TB) medicines) completed
- Development of mobile phone application for reporting adverse drug events
- Direct technical assistance based on the IDP for the NRA
- Peer learning site visit to the Norwegian Medicines Agency
- Preliminary visit to agree next steps on NRA benchmarking
- Advanced GDP training for the national pharmaceutical inspectorate

Azerbaijan

- Advanced good manufacturing practice (GMP) training completed (three modules)
- Registration for the WHO collaborative registration procedure (CRP) commenced
- Advanced GDP training for national pharmaceutical inspectorate

Belarus

- Registration for the CRP commenced
- Peer learning site visit to Amgros, the Danish procurement agency
- Advanced GDP training for national pharmaceutical inspectorate

Bosnia and Herzegovina

- Self-assessment benchmarking of the NRA
- Direct technical assistance based on the IDP for the NRA
- WHO workshop on implementation of EU guidelines on GDP

Georgia

- Peer learning site visit to the Norwegian Medicines Agency
- Direct technical assistance based on the IDP for the NRA
- Registration for the CRP commenced
- Advanced GDP training for national pharmaceutical inspectorate

Kazakhstan

- Advanced GMP training completed (three modules)
- Direct technical assistance based on the IDP for the NRA
- Registration for the CRP commenced
- Advanced GDP training for national pharmaceutical inspectorate

Kyrgyzstan

- A new mechanism on pricing regulation for medicines reimbursed at the primary health care level developed and approved
- Revision of clinical guidelines for respiratory tract infection and urinary tract infection ongoing
- Regulations for medicines and medical devices revised; bylaws developed and adopted
- NRA self-benchmarking completed and IDP implemented, with the introduction of quality management system (QMS) and establishment of a GDP/GMP inspectorate

© WHO

- Analysis of procurement of medicines by hospitals
- Advanced GMP training completed (three modules)
- GMP/GDP sensitization workshop
- Advanced GDP training for national pharmaceutical inspectorate

Montenegro

- Self-benchmarking assessment of the NRA
- Legal support for drafting a law on operations of retail pharmacy outlets
- WHO workshop on implementation of EU guidelines on GDP

North Macedonia

- Self-assessment benchmarking of the NRA
- Direct technical assistance based on the IDP for the NRA

Republic of Moldova

- Medicines availability and pricing survey conducted using the WHO MedMon tool
- Advanced GMP training completed
- Advanced GDP training for national pharmaceutical inspectorate

Romania

- Support for access to TB medicines

Russian Federation

- WHO NRA follow-up visit

Serbia

- Benchmarking of the NRA finalized

Tajikistan

- Implementation of regulations on export of medicines
- Revising and updating pharmaceutical legislation
- Advanced GDP training for national pharmaceutical inspectorate

Turkey

- National action plan for AMR developed
- NRA self-assessment benchmarking completed, and IDP prepared
- Technical support for transition process to the WHO Global Benchmarking Tool Revision VI

Turkmenistan

- National action plan for AMR developed
- Advanced GDP training for national pharmaceutical inspectorate

Ukraine

- Report evaluating the Affordable Medicines Programme published
- Medicines availability and pricing survey conducted using the WHO MedMon tool
- Assessment of processes for development and revision of the national essential medicines list
- Advanced GDP training for national pharmaceutical inspectorate

Uzbekistan

- Revising clinical guidelines for paediatric infections (pneumonia, otitis media)
- Country consultation on moving to prescription-only status for antibiotics

© WHO

- Advanced GMP training completed (three modules)
- GMP/GDP sensitization workshop
- Advanced GDP training for national pharmaceutical inspectorate

Area work

Kosovo[2]

- Revisions to the national essential medicines list completed
- WHO Access, Watch and Reserve (AWaRe) categorization of antibiotics adopted
- Self-assessment benchmarking of the NRA
- Direct technical assistance based on the IDP for the NRA
- WHO workshop on implementation of EU guidelines on GDP

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

Intercountry meetings and workshops

During 2019 several meetings and workshops were conducted to encourage sharing of information and experiences, and to support capacity-building efforts in the Region.

- Training workshop on GMP with a theoretical module in Copenhagen, Denmark, and two practical in-country modules involving mock-up inspections of manufacturers (Azerbaijan, Kazakhstan, Kyrgyzstan, Republic of Moldova and Uzbekistan)
- GDP workshop in Kiev, Ukraine, for Russian-speaking countries (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan)
- GDP workshop in Podgorica, Montenegro, for Balkan countries (Albania, Bosnia and Herzegovina, Montenegro and Serbia) and Kosovo[3]
- Subregional workshop in Chisinau, Republic of Moldova, for Russian-speaking countries on introduction of the CRP (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan)
- Peer learning site visits, including to the Norwegian Medicines Agency (Armenia and Georgia), SwissMedic (Armenia and Kazakhstan) and Amgros, the Danish procurement agency (Belarus)
- Implementation workshop in Istanbul, Turkey, of the WHO guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkey and Turkmenistan)
- In-country workshops in Bishkek, Kyrgyzstan, to ensure QMS establishment, implementation and maintenance to strengthen NRA in accordance with international standards
- Sub regional self-benchmarking workshop in Skopje, North Macedonia (Albania and Bosnia and Herzegovina, Montenegro and North Macedonia, as well as Kosovo[3])
- Second Medicine Procurement Practitioners Exchange Forum in Copenhagen, Denmark, conducted in collaboration with the UNICEF Supply Division, UNDP, Global Fund to Fight AIDS, Tuberculosis and Malaria and United Nations Population Fund
- EECA PPRI Network meeting in Astana, Kazakhstan, in conjunction with the Austrian Institute of Public Health
- Annual meeting of the WHO Regional Office for Europe's Antimicrobial Medicines Consumption (AMC) Network in Copenhagen, Denmark
- Workshop on the CRP in Chisinau, Republic of Moldova (12 eastern European and central Asian countries)
- Joint United Nations Population Fund, UNICEF and WHO meeting with manufacturers and suppliers of essential medical products in Copenhagen, Denmark
- Capacity-building workshop in Riga, Latvia, on HTA for medical devices for Baltic countries (Estonia, Latvia and Lithuania)

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

WHO resources

Key WHO resources were developed or modified in 2019, with revisions to the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) (Box 1), AWaRe classification for antibiotics (Box 2) and pilot testing of a medicines monitoring tool (Box 3).

Box 1. Revisions to WHO EML and EMLc

EML Model List of Essential Medicines

Evidence-based selection of medicines to guide choices for national essential medicines lists, reimbursed medicines lists and medicines formularies

The WHO EML and EMLc wereupdated, with:

- 28 new medicines added to the EML
- 23 new medicines added to the EMLc
- new formulations for 16 medicines
- additional indications for use of 26 currently listed medicines
- major revisions to the cancer sections for adults and children
- revision to the AWaRe classification of antibacterials

Box 2. Revision of the AWaRe classification of antibiotics

AWaRe

Inappropriate use of antibiotics favours the emergence and spread of antibiotic resistance, amplifying the natural ability of bacteria to resist.

The Expert Committee on the Selection and Use of Essential Medicines updated its 2017 classification of antibiotics into Access (widely available), Watch (used selectively) and Reserve (last-resort) groups.

The AWaRe classification was updated and expanded to cover 177 of the most commonly used agents globally.

A new target indicator based on the AWaRe classification was adopted, specifying a country-level target that at least 60% of overall antibiotic consumption should be from the Access group.

Box 3. Medicines monitoring tool (MedMon)

WHO MedMon App
MEASURING PRICE AND AVAILABILITY OF HEALTH PRODUCTS

WHO has developed the MedMon tool to allow rapid collection and analysis of data on the price and availability of medicines in health facilities and procurement centres.

In 2019 the tool was translated into Russian and is being used in the field in Kyrgyzstan, the Republic of Moldova and Ukraine to improve understanding of the challenges to affordable access to essential medicines.

The system allows data collection online and offline, has GPS tracking capability to locate the facility surveyed and has built-in analytics.

Work of national professional officers

The HTP Programme has three country-based national professional officers who provide technical assistance and guidance to the ministry of health on planning, development, implementation and monitoring of key activities in relation to national medicines policy, essential drugs and medicines, intellectual property rights and the trade of medical products and technologies.

Kyrgyzstan (Saltanat Moldoisaeva)

In 2019 significant progress was made in aligning subsidiary acts and related documents with the new legislative framework for medicines approved by parliament in 2017. Modernization of legislation is critical to ensure a smooth transition to a common market for medicines and medical devices within the Eurasian Economic Union (EAEU) at the end of 2020.

The new framework resulted in the introduction of good regulatory practices, separation of regulation of medicines and medical devices, and differentiated approaches for marketing authorization. Implementation of EAEU rules and regulatory controls for medical devices is ongoing. With WHO encouragement, the NRA engaged with international regulatory networks, resulting in membership of the Asian Harmonization Working Party. WHO supported the development and implementation of the IDP for the NRA. A GMP/GDP inspectorate has been established and introduction of a QMS is ongoing.

© WHO

Supported by WHO, an interministerial working group developed a mechanism for pricing regulation of essential medicines, beginning with the 58 international nonproprietary names reimbursed at the primary health care level.

In parallel with the monitoring of antimicrobial medicine consumption, WHO supported a revision of clinical guidelines for common diseases in primary care and introduced the WHO AWaRe categorization of antibiotics.

The introduction of new TB medicines accelerated strengthening of pharmacovigilance. Activities included capacity-building of staff of the TB programme and the NRA, awareness-raising among health care professionals and the public, and training on monitoring tools (VigiFlow and VigiLyze).

Republic of Moldova (Zinaida Bezverhni and Tatiana Zloi-Cazacu)

In 2019 work in the Republic of Moldova focused on capacity-building of the Medicines and Medical Devices Agency, supporting harmonization of regulatory rules to align with EU standards, provision of strategic policy advice, support for improving access to medicines and pricing reforms for the health insurance agency.

An institutional assessment of the Medicines and Medical Devices Agency was carried out and a draft strategic plan for improvements developed. Alignment of regulatory processes with those used in the EU necessitated development of new medicine laws and drafting of bylaws on clinical trials for medical devices and in vitro diagnostics.

WHO provided technical guidance on processes to revise the national essential medicines list and

© WHO

to combine the selection processes for medicines needed for outpatients, inpatients and national health programmes so that decisions are taken by a single expert committee.

An assessment of the pharmaceutical reimbursement system was conducted, including an analysis of consumption data for reimbursed medicines. A review of the current pricing methodology for medicines was undertaken and proposals for process improvements and greater transparency in determining prices paid by patients and the health insurance fund were developed. Publication of maximum consumer prices on the website of the Medicines and Medical Devices Agency is proposed.

The national procurement agency undertakes centralized procurement of medicines and medical products for hospitals, health clinics and national health programmes. WHO is providing technical support to the Agency to improve and streamline its procurement strategy and processes.

Ukraine (Svitlana Pakhnutova)

In 2019 WHO supported the review and implementation of a national action plan on AMR, facilitated data approvals for a regional AMC Network report and initiated a WHO tool to monitor Sustainable Development Goal (SDG) Indicator 3.b.3 (the proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis) to improve access and to monitor strategic information on availability and affordability of health products. WHO is assisting the ministry of health in developing a digital communication strategy for 2020, promoting rational use of antibiotics by the public.

WHO has coordinated capacity-building activities in support of regulatory system strengthening for the National Medicines Regulatory Authority, State Expert Centre and State Service on Medicines and Drug Control. This included workshops and training on GMP/GDP practices, CRP, biotherapeutics assessments, quality assessment training from the WHO prequalification team and the annual meeting of representatives of national pharmacovigilance centres.

WHO supported capacity-building for the national central procurement agency through participation in international forums and study visits and information exchange on e-procurement systems between the central procurement agencies of Ukraine and Kazakhstan.

Access to affordable medicines is a priority topic. WHO facilitated discussions on medicines and health technologies included in the state-guaranteed benefits packages and supported efforts to promote the uptake of generics and biosimilar products. Ukrainian experts participated in PPRI Network meetings and the Winter School on pharmaceutical pricing and reimbursement. The WHO MedMon tool is being used to collect data on availability and affordability of essential medicines.

© WHO

Medicines regulation and quality

Effective regulatory systems are an essential component of health systems. Helping NRAs fulfil their mandates in an effective, efficient, predictable and transparent manner is critically important in ensuring the quality, safety and efficacy of health products, especially in an increasingly complex global environment.

Emer Cooke, WHO Headquarters

Capacity-building

Progress towards enhancing practices related to medicines quality around the world is supported by the HTP Programme through course development initiatives dedicated to improving the professional knowledge and skills of NRA staff and other professionals through a series of innovative learning opportunities. In 2019 activities focused on benchmarking of NRAs (Box 4), introduction of the CRP (Box 5) and country support for implementation of IDPs.

Box 4. WHO Global Benchmarking Tool (GBT)

The GBT represents the primary means by which WHO objectively evaluates regulatory systems, as mandated by World Health Assembly Resolution WHA67.20 on regulatory system strengthening for medical products. The GBT is supported by a computerized platform to facilitate the benchmarking. The methodology has the following steps:

- preliminary visit
- self-benchmarking
- benchmarking
- follow-up and monitoring.

The tool and benchmarking methodology enable WHO and regulatory authorities to:

- identify strengths and areas for improvement
- facilitate the formulation of an IDP to build on strengths and address the gaps identified
- prioritize IDP interventions
- monitor progress and achievements.

The GBT incorporates the concept of maturity levels, allowing WHO and regulatory authorities to assess the overall maturity of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).

Serbia was the first country in the WHO European Region to achieve maturity level 3 for its vaccine regulatory system, commensurate with a stable, well-functioning and integrated regulatory system, effective from 2 August 2019. This major achievement is a result of investment by the government in strengthening the regulatory system and a longstanding collaboration with WHO since the establishment of the NRA in 2010.

WHO, the Medicines and Medical Devices Agency of Serbia (ALIMS) and other regulatory institutions had been in contact since the benchmarking visit in July 2017 to address outstanding issues. During a follow-up visit by experts from the regulatory system strengthening team, WHO Regional Office for Europe and WHO country office on 27–28 November 2018, it was confirmed that ALIMS and the related regulatory institutions had implemented most of the recommendations provided in the IDP. Between November 2018 and August 2019, a series of discussions took place between WHO and NRA experts to review and resolve the few minor outstanding items in the IDP.

Box 5. Collaborative procedure for accelerated registration

In response to delays in registration of pharmaceuticals that can occur at the country level, WHO introduced a CRP to facilitate assessment and accelerated national registration of WHO-prequalified pharmaceutical products. It also applies to finished innovator and generic pharmaceutical products that have received approval from a stringent regulatory authority.

In 2019 the WHO Regional Office for Europe introduced the CRP for products already approved from a stringent regulatory authority to Russian-speaking Commonwealth of Independent States countries. The main purpose of the CRP approach is to ensure that needed medicines reach patients more quickly. In addition, the approach facilitates capacity-building and regulatory harmonization. The success of the procedure relies on the ability and willingness of pharmaceutical companies (the applicants), regulatory authorities and WHO to work together.

In practice, a pharmaceutical company submits a finished innovator and a generic pharmaceutical product dossier for registration to a participating NRA, which is the same as that submitted to the stringent regulatory authority that approved the product. A uniform technical document format is used to facilitate this process. The stringent regulatory authority agrees to share the full assessment and inspection reports for the product with the participating NRAs.

The HTP Programme held a workshop for Russian-speaking countries to introduce the CRP, with participants from 12 countries.

Procurement and supply chain management

Efficient procurement and supply chain management are critical for sustained access to high-quality medicines and health products. Good procurement practices facilitate product purchases at the best prices, ensure adequate and timely supply, and minimize stockouts and shortages.

Affordable access to key medicines like insulin has been an important topic regionally and globally (Box 6). Improving access to assistive devices and technologies has been a focus of WHO's work (Box 7), along with a greater focus on the importance of pharmacists to support medicines supply and appropriate use of medicines (Box 8).

In 2019 the HTP Programme initiated research to explore the potential for cross-country collaboration on joint procurement. This involved reviews of published and unpublished literature on this topic and stakeholder interviews with representatives of five cross-country collaborations – the Baltic Procurement Initiative, Beneluxa Initiative, Nordic Pharmaceutical Forum, Valletta Declaration and Fair and Affordable Pricing initiative. This work was undertaken in collaboration with the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Austrian Institute of Public Health.

Box 6. Improving access to insulin

A two-day regional workshop was held in Bishkek, Kyrgyzstan, to discuss the challenges countries face in making insulin available to patients needing this life-saving medicine. Participants were drawn from eight non-EU countries in the WHO European Region and represented ministries of health, medicine procurement personnel, staff of national medicines regulatory authorities, leading clinicians and representatives from national diabetes associations.

The scope of work of the Addressing the Challenge and Constraints of Insulin Sources and Supply study was discussed. Evidence gathered on the insulin market was presented, along with identified barriers and enablers to insulin access. Tools developed by the study were shared during the workshop.

Participants shared their experiences and challenges related to the registration of insulin products, as well as forecasting needs, procurement and distribution of insulin products for both type 1 and type 2 diabetes. They were encouraged to develop country-specific responses to the challenges identified.

Perceptions of biosimilar insulin products and barriers to their use in clinical practice were debated. The more complex requirements for the registration of biosimilar products were discussed and WHO was asked to include insulin in its prequalification programme.

The workshop was conducted by Health Action International, with the support of the Health Policy Analysis Centre in Kyrgyzstan. The Addressing the Challenge and Constraints of Insulin Sources and Supply study is supported by the Leona and Harry B Helmsley Charitable Trust in the United Kingdom.

Box 7. Assistive technologies

© WHO

WHO estimates that over one billion people need an assistive device or technology (AT), yet over 900 million people (90%) do not have access to the wheelchairs, eyeglasses, hearing aids, prosthetics and other life-changing ATs they need. Lack of access to ATs leads to a risk of social isolation for individuals and exclusion from education, work, family and community life, as well as increased costs of care, more limited employment prospects and poorer health outcomes. To improve access to ATs, increasing awareness of AT needs is required among politicians and policy-makers, along with commitment to address these needs.

Any assistive products procured must be appropriate and of high quality; they should also meet international quality standards. Development of the sector requires interventions aimed at reducing barriers to the use of assistive products, to maximize benefits for both users and society.

WHO is contributing to the global collaborative effort to increase access to assistive products by developing normative guidelines; organizing regional and country workshops, meetings and seminars to promote and facilitate access to ATs; aiding the development of national policies and programmes on ATs and creating a database on availability of appropriate ATs.

In addition to coordinating the Global Cooperation on Assistive Technology (GATE) programme, WHO is working with the UNICEF Supply Division to develop a guide for public procurement of assistive products, accessories, spare parts and related services. Member States are requested to collect data on access to ATs to report to the World Health Assembly in 2021.

During a three-month WHO internship, Rana Al-Tayar, a biomedical engineering student from the Technical University of Denmark, surveyed the current state of ATs in Armenia, Denmark, Spain and Ukraine. From WHO's priority assistive product list, 15 products were selected, covering the areas of mobility, vision and hearing. Aspects surveyed included the selection and provision of products, their regulation, existence of service facilities, recycling procedures, procurement procedures and supply and distribution. The objective of the online survey was to qualitatively assess a country's capacity to procure and provide the assistive products to end-users.

Rana found that the 15 priority assistive products selected for the survey were available at the primary health care level in all four countries. It was reportedly difficult to collate information on the AT needs of the populations in Armenia and Ukraine, however, which may reflect a lack of planning for ATs in these settings. There is a need to ensure comprehensive service provision of quality AT that is regulated by adequate standards for products procured both in the public and private sectors for all, irre spective of the registered status as a person with a disability. Rana's work was presented at the consultation on the global report on effective access to AT in Geneva, Switzerland, in August 2019.

Source: Improving access to assistive technology: report by the Director-General. Geneva: World Health Organization; 2017 (EB142/21; https://apps.who.int/iris/handle/10665/274140, accessed 9 March 2020).

Box 8. The role of the pharmacist

© WHO

The theme for World Pharmacists' Day (25 September 2019) was "Safe and effective medicines for all", with a focus on promoting the role of the pharmacist in safeguarding patient safety by improving medicines use and reducing medication errors. Pharmacists have a key role in ensuring access to medicines and their appropriate use, improving adherence.Increasingly, they are involved in coordinating care transitions between the community, hospitals and care facilities for older people.

In support of global activities, the WHO Regional Office for Europe prepared a short video showcasing Gilles Bonnefond, a pharmacist in Montélimar, France, for more than 25 years. Gilles noted the changing roles of the pharmacist over time, from supplier of medicines to ensuring access, providing advice and following up with patients to ensure optimal use of medicines, including for prevention and control of chronic noncommunicable diseases. Electronic record systems are increasingly important in maintaining a patient's medication history, assisting in monitoring potential adverse drug reactions and reducing prescription errors.

Pharmacists can advise on treatments for minor illness and recommend referrals for more serious health issues. In some settings, they can provide adult vaccinations and monitor blood pressure. They can contribute to addressing the challenges of AMR by complying with the prescription-only status of antibiotics and encouraging responsible use of these products.

The diversity of services offered by pharmacists in the European Region is described in the WHO report *The legal and regulatory framework for community pharmacies in the WHO European Region*. Core services that should be provided in all countries include dispensing of over-the-counter and prescription-only medicines, pharmaceutical consulting, pharmacovigilance and health promotion. In settings with high implementation of pharmaceutical care, core services also include compounding of medicines, medication management (unit dose packaging, new medicines service, medicine use review), emergency care (including emergency contraception) and minor ailment management.

This second group of services, sometimes referred to as advanced professional pharmacy services, is not obligatory for all pharmacies and additional certification or training may be required to provide it. Services can also include chronic disease management, early screening and testing, vaccination, smoking cessation advice and measurement of blood pressure, cholesterol and glucose.

Many countries have adopted national Good Pharmacy Practice standards to define the activities and services provided in community pharmacies. The report describes some of the differences in scope of practice between settings, along with the variety of legal and regulatory measures used in countries to regulate ownership and operation of community pharmacies.

Source: The legal and regulatory framework for community pharmacies in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2019 (http://www.euro.who.int/en/publications/abstracts/the-legal-and-regulatory-framework-for-community-pharmacies-in-the-who-european-region-2019, accessed 9 March 2020).

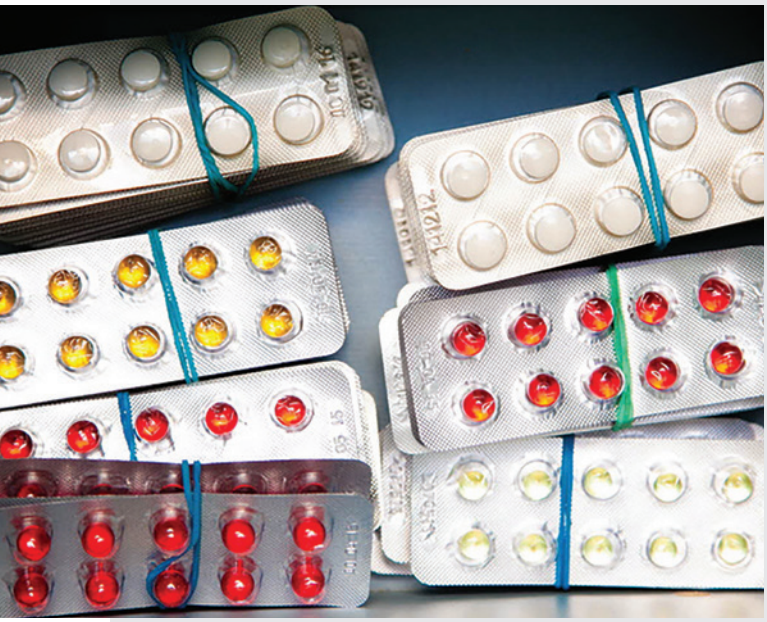
Medicines selection, pricing and reimbursement

Poor selection of essential medicines, insufficient public financing, and inefficiencies in procurement and distribution are the major causes of lack of universal access to affordable medicines. The free market will not resolve this, and strong government action is the only way forward.

Hans Hogerzeil, Professor of Global Health, Groningen University

Access to medicines indicators

While the United Nations-approved SDG indicator 3.b.3 will measure the proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis, more detailed information is required to guide policy actions at the country level. The HTP Programme contributed to an expert panel that identified 22 indicators covering the dimensions of pricing and reimbursement, selection, procurement, supply chains and distribution, market authorization, licensing, market surveillance and control and pharmacovigilance for further refinement.[4]



© WHO

Evidence-based selection of medicines for national essential medicines and medicines reimbursement lists

Adoption or expansion of national essential medicines or diagnostics lists requires the capacity and competency at the national level to translate findings from evidence to local contexts, and to use the findings for decision-making. The HTP Programme supported revisions to the laws in Kyrgyzstan governing processes for selection of essential medicines, engaged with counterparts in Ukraine regarding medicines selection for national essential medicines and reimbursed medicines lists, and discussed processes and procedures for prioritizing medicines for reimbursement in Albania.

Monitoring access and affordability of medicines – MedMon

The MedMon tool has been developed by WHO to facilitate data collection on availability and affordability of medicines.[5] The tool uses a mobile

4 Monitoring the components and predictors of access to medicines. Geneva: World Health Organization; 2019 (https://www.who.int/medicines/areas/policy/monitoring/monitoring-components-predictors-of-access-to-medicines/en/, accessed 9 March 2020).

5 MedMon – WHO essential medicines and health products price and availability monitoring mobile application. In: World Health Organization [website]. Geneva: World Health Organization; 2020 (http://origin.who.int/medicines/areas/policy/monitoring/empmedmon/en/, accessed 9 March 2020).

phone- or tablet-based application that reduces the burden of paper-based systems and has built-in analytical capabilities to produce summary data rapidly that can be used by health facilities to support improved medicines access. Standard analyses allow reporting on the SDG medicines indicator, but the tool can be adapted to include more medicines, target specific regions or address specific medicine issues of interest.

MedMon was used in a pilot study conducted in the Republic of Moldova in 2019. This included medicines and some diagnostics and covered 60 settings in community pharmacies and primary health care centres, in rural and urban areas, and in private and public pharmacies. Seven regions and two municipalities were surveyed. MedMon studies were also conducted in Ukraine and are being planned in Kyrgyzstan.

The HTP Programme will continue to support countries in the Region to measure progress against the SDG medicines indicator and to conduct other studies of medicines availability and affordability to address particular areas of concern where poor availability and/or high prices are compromising access to needed therapies.

The EECA PPRI Network provides an important mechanism for information-sharing related to medicines pricing and reimbursement (Box 9).

Box 9. PPRI Network for countries in eastern Europe and central Asia

© WHO

A regional subnetwork of the PPRI Network for countries of the former Soviet Union has been established, coordinated by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Information at the Austrian Institute of Public Health and the WHO Regional Office for Europe.

Members of the EECA PPRI Network are representatives of public authorities in the field of medicines (particularly related to pricing, procurement and funding) in the central Asian countries in the WHO European Region. The purpose of the network is to provide a platform for peer learning and information exchange on current challenges and emerging issues in pharmaceutical pricing and reimbursement systems.

Nine countries and 40 delegates participated in the third Winter School for the network, held in Astana, Kazakhstan. This focused on pricing and reimbursement policy developments related to diabetes. Network members also participated in the PPRI Network meeting for EU countries held in Tallinn, Estonia. The focus of the meeting was the Estonian health care system and challenges faced with price agreements, managed entry agreements and the availability of medicines in small markets.

HTA for medical devices

Medical device: an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.[6]

In recent years, the rapid rate of technological and scientific development in medical devices has necessitated greater regulation of these products to ensure a high level of health and safety and to protect patients. This has been supported by a risk classification system and strengthening of post-market surveillance requirements for manufacturers. In parallel, increasing costs of medical devices and limited health budgets have focused attention on the need for more rigorous assessment of the value for money of the new devices. The principles of HTA that have been applied to assessments of medicines for some decades are increasingly being applied to assessment of medical devices.

A workshop for Baltic countries on HTA for medical devices was held in Riga, Latvia, in March 2019. Participants from Estonia, Latvia and Lithuania shared their experiences and discussed the challenges of decision-making around medical devices and their use of HTA to date. Under guidance from the Norwegian Institute of Public Health, participants learnt more about EU experiences of the use of HTA for medical devices, including identification and prioritization of devices for formal HTA, decision-making processes and horizon scanning to anticipate future demands on health care systems.

© WHO

6 Definitions. In: World Health Organization [website]. Geneva: World Health Organization; 2012 (https://www.who.int/medical_devices/definitions/en/, accessed 2 April 2020).

Responsible use of medicines and the AMC Network

The HTP Programme continues to support the WHO Regional Office for Europe's AMC Network in capacity-building for data collection and analysis. Equally important to the quantitative estimates of consumption are the steps taken at the country level to disseminate the findings of the analyses and to identify targets for further intervention to improve how antibiotics are used in practice.

Supporting countries to collect antibiotic consumption data is critical for them to be able to understand prescribing patterns, make interventions and monitor changes over time. Bringing the leads together creates a network of learning and support.

Danilo Lo Fo Wong, Programme Manager, Control of AMR, WHO Europe

AMC Network meeting

Given that most antimicrobial medicines are consumed in community and outpatient settings, the annual meeting of the AMC Network focused on antibiotics and primary care and opportunities to improve antibiotic use. Moving beyond aggregated AMC data, methods for measuring consumption in the community were discussed. Experiences from Spain and Sweden in measuring consumption and changing health care professional and public behaviours were shared. Examples of studies using different data sources were presented from AMC Network countries, along with experiences from a similar network of countries in southern and eastern Africa (the MURIA Network). In workshops, participants identified activities and interventions to address several prescribing challenges in primary care and considered methods for assessing the impact of the interventions.

Second report of the AMC Network: AMC data 2011–2017

This report[7] sets out and analyses AMC data for 16 of the participating countries and Kosovo,[8] in which the ministry of health and public health authorities approved data-sharing and publication. The report analyses trends over time (2011–2017) for key metrics of antibacterial consumption, applies the 2017 WHO AWaRe classification of antibiotics and examines the impact of proposed changes to defined daily doses in 2019 for some commonly used antibiotics. The results are compared with the European Centre for Disease Prevention and Control's European Surveillance of Antimicrobial Consumption Network (ESAC-Net) quality indicator estimates for 2017. Analyses are presented for each AMC Network country and area separately, with comparisons across the Network for selected metrics.

AWaRe classification of antibiotics

In 2017 WHO experts grouped antibiotics into three categories – Access, Watch and Reserve – known as the AWaRe classification.[9] Access group antibiotics should be available at all times as treatments for a wide range of common infections; the Watch group includes antibiotics that are recommended as first- or second-choice treatments for a small number of infections; while the Reserve group includes antibiotics that should be considered last-resort options and used only in the most severe circumstances when all alternatives have failed.

7 WHO Regional Office for Europe Antimicrobial Medicines Consumption (AMC) Network: AMC data 2011–2017. Copenhagen: WHO Regional Office for Europe; 2020 (http://www.euro.who.int/en/publications/abstracts/who-regional-office-for-europe-antimicrobial-medicines-consumption-amc-network.-amc-data-20112017-2020, accessed 9 March 2020).

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

9 AWaRe [website]. Geneva: World Health Organization; 2020 (https://adoptaware.org/, accessed 10 March 2020).

In 2019 the WHO Expert Committee on the Selection and Use of Essential Medicines restructured section 6.2 of the WHO EML and EMLc to align with the AWaRe classification. To better support stewardship and quality improvement activities, the classification was extended to include 177 commonly used antibiotics. In addition, a new indicator specifying a country-level target of at least 60% of overall antibiotic consumption from the Access group was proposed. The overall goal is to reduce the use of Watch group and Reserve group antibiotics and to increase the use of Access antibiotics where availability is low. AMC Network analyses are being modified to incorporate the revised AWaRe classification and target indicator.

Based on the WHO 2017 recommendations on antibiotic choice, two countries – Kyrgyzstan and Uzebekistan – initiated reviews or development of clinical protocols for common infections in primary care in 2019 (Box 10).

Prescription-only access to antibiotics

Following the 16-country consultation in Almaty, Kazakhstan, in November 2018,[10] a paper was published outlining the literature evidence on the impact of activities undertaken to enforce prescription-only access to antibiotics.[11] The review concluded that comprehensive multifaceted interventions targeting all stakeholders with regular reinforcement of messages are most likely to be effective.

© WHO

Since that meeting, two members of the AMC Network undertook mystery client surveys to determine the proportion of antibiotic sales occurring without prescription. These data can provide a baseline from which to measure improvements as authorities enforce policies and laws prohibiting over-the-counter sales. In Uzbekistan a regulation was amended in September 2019 to enforce the law on sales of prescription-only medicines, including antibiotics. Stakeholders met to discuss their roles and develop a roadmap for implementation of the new regulation.

Box 10. Clinical algorithms for common infections in primary care in Kyrgyzstan

In Kyrgyzstan a working group was established to review the existing clinical guidelines for common infections in primary care. Two clinical guidelines for respiratory tract infections and urinary tract infections were revised based on recommendations by WHO and international clinical guidelines on first and second choices of antibiotics.

Along with an international expert, AMR and HTP teams from the WHO Regional Office for Europe visited Kyrgyzstan to support a working group with further review of the revised guidelines. A meeting to discuss the revised guidelines with wider stakeholders was also conducted. The revised guidelines have been submitted to the ministry of health for approval.

Recognizing the issue that existing clinical guidelines have not been utilized well in practice, the working group is currently planning implementation of the revised clinical guidelines, including training for primary health care doctors.

10 Iwamoto K, Pedersen HB, Tello JE, Lo Fo Wong D, Robertson J. Cross-programmatic consultation on the role of primary care in the responsible use of medicines and the reduction of antimicrobial resistance. Expert Rev Anti Infect Ther. 2019;17:2:75–8. doi:10.1080/14787210.2018.1563482.

11 Jacobs TG, Robertson J, van den Ham HA, Iwamoto K, Bak Pedersen H, Mantel-Teeuwisse AK. Assessing the impact of law enforcement to reduce over-the-counter (OTC) sales of antibiotics in low- and middle-income countries; a systematic literature review. BMC Health Serv Res. 2019;19:536. doi:10.1186/s12913-019-4359-8.

HTP reports and peer-reviewed publications

Reports

Assessing non-prescription and inappropriate use of antibiotics[12] reports the results of an 18-country survey and identifies priority actions for improving antibiotic use, including greater enforcement of prescription-only access, education of health care professionals, greater use of standard treatment guidelines and improving public awareness on rational use of antibiotics.

Evaluation of the Affordable Medicines Programme in Ukraine[13] concludes that the programme has contributed to a significant increase in access to needed outpatient medicines, although uptake across regions has been uneven. It also proposes options to support the sustainability and expansion of the programme.

The legal and regulatory framework for community pharmacies in the WHO European Region[14] provides an overview of the regulatory provisions for community pharmacies and their activities in Europe, addressing issues including licensing, location and ownership of pharmacies.

The second report of the AMC Network,[15] which covers data for 2011–2017, includes chapters for each of the members of the Network, separately along with selected cross-national and area comparisons for key metrics of antibiotic consumption.

Peer-reviewed publications

Beran D, Bak Pedersen H, Robertson J. Noncommunicable diseases, access to essential medicines and universal health coverage. Glob Health Action. 2019;12(1):1670014. doi:10.1080/16549716.2019.1670014.

Ferrario A, Dedet G, Humbert T, Vogler S, Suleman F, Bak Pedersen H. Achieving fair pricing of medicines: strategies to achieve fairer prices for generic and biosimilar medicines. BMJ. 2020;368:l5444. doi:10.1136/bmj.l5444.

Iwamoto K, Pedersen HB, Tello JE, Lo Fo Wong D, Robertson J. Cross-programmatic consultation on the role of primary care in the responsible use of medicines and the reduction of antimicrobial resistance. Expert Rev Anti Infect Ther. 2019; 17:2:75–8. doi:10.1080/14787210.2018.1563482.

Jacobs TG, Robertson J, van den Ham HA, Iwamoto K, Bak Pedersen H, Mantel-Teeuwisse AK. Assessing the impact of law enforcement to reduce over-the-counter (OTC) sales of antibiotics in low- and middle-income countries; a systematic literature review. BMC Health Serv Res. 2019;19:536. doi:10.1186/s12913-019-4359-8.

Robertson J, Iwamoto K, Hoxha I, Ghazaryan L, Abilova V, Cvijanovic A et al. Antimicrobial medicines consumption in eastern Europe and central Asia – an updated cross-national study and assessment of quantitative metrics for policy action. Front Pharmacol. 2019;9:1156. doi:10.3389/fphar.2018.01156.

12 Assessing non-prescription and inappropriate use of antibiotics. Copenhagen: WHO Regional Office for Europe; 2019 (http://www.euro.who.int/en/publications/abstracts/assessing-non-prescription-and-inappropriate-use-of-antibiotics-2019, accessed 10 March 2020).

13 Evaluation of the Affordable Medicines Programme in Ukraine. Copenhagen: WHO Regional Office for Europe; 2019 (http://www.euro.who.int/en/publications/abstracts/evaluation-of-the-affordable-medicines-programme-in-ukraine-2019, accessed 10 March 2020).

14 The legal and regulatory framework for community pharmacies in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2019 (http://www.euro.who.int/en/publications/abstracts/the-legal-and-regulatory-framework-for-community-pharmacies-in-the-who-european-region-2019, accessed 9 March 2020).

15 WHO Regional Office for Europe Antimicrobial Medicines Consumption (AMC) Network: AMC data 2011–2017. Copenhagen: WHO Regional Office for Europe; 2020 (http://www.euro.who.int/en/publications/abstracts/who-regional-office-for-europe-antimicrobial-medicines-consumption-amc-network.-amc-data-20112017-2020, accessed 9 March 2020).

Annex 1. Calendar of activities

Date	Topic	Location
January 2019		
8–17	Training workshop: GMP module 2	Tashkent, Uzbekistan
14–18	Development of national action plan on AMR and working group meeting revision of clinical guidelines	Bishkek, Kyrgyzstan
15–18	Study visit (peer learning) tour to Norwegian Medicines Agency	Oslo, Norway
21–22	Technical meeting on selection of health products	Geneva, Switzerland
29–31	Meeting of working group for the development of national action plan on AMR	Sofia, Bulgaria
29–31	WHO benchmarking self-assessment workshop for Balkan countries and areas	Skopje, North Macedonia
February 2019		
7–8	Meeting of the WHO Global Cooperation on Assistive Technology (GATE-WHO) consortium and European Assistive Technology Information Network	Geneva, Switzerland
18–22	EECA PPRI Network Winter School	Astana, Kazakhstan
19–21	Introduction of new WHO TB guidelines on treatment of multidrug- and extensively drug-resistant TB for European countries with a high burden of drug-resistant TB	Vienna, Austria
25–27	Updated self-benchmarking report developed by the NRA	Bishkek, Kyrgyzstan
26–28	Workshop – monitoring the components and predictors of access to medicines: taking stock and moving forward	Bangkok, Thailand
27 February – 1 March	Meeting on strengthening vaccine procurement performance and access to vaccines in South-Eastern Europe Health Network countries	Tirana, Albania
March 2019		
11–12	Antimicrobial Resistance and Healthcare-associated Infections (ARHAI) Programme Meeting of the Disease Network Coordination Committees	Stockholm, Sweden
19–20	Training on CRP	Chisinau, Republic of Moldova

(Continued)

Date	Topic	Location
24–26	WHO advocacy and consensus-building workshop	Tbilisi, Georgia
27–28	Workshop on HTA for medical devices, for Baltic countries	Riga, Latvia
27 March – 3 April	Intercountry GMP inspectors training	Tashkent, Uzbekistan
April 2019		
2–4	Intercountry GMP inspectors training	
11–13	Fair Pricing Forum	Capetown, South Africa
15	Follow-up visit to the NRA	Moscow, Russian Federation
26–27	Stakeholder meeting, revision of clinical guidelines for common infections in primary care	Bishkek, Kyrgyzstan
30 April – 2 May	Pandemic Influenza Preparedness Framework vaccine deployment workshop	Dushanbe, Tajikistan
May 2019		
7–9	Training: GMP Module 2	Kiev, Ukraine
13–15	Meeting on access to TB medicines under the Global Fund to Fight AIDS, Tuberculosis and Malaria grants	Bucharest, Romania
20–22	Meeting of PPRI Network	Tallinn, Estonia
20–24	Technical support for transition process to GBT Revision VI	Ankara, Turkey
21–23	Training: GMP Module 3	Shymkent, Kazakhstan
27–29	Annual meeting of the WHO Regional Office for Europe's AMC Network	Copenhagen, Denmark
June 2019		
3–5	WHO international consultation meeting for the development of the guideline on the implementation of QMSs for NRAs	Geneva, Switzerland
4–6	Training: GMP Module 3	Odessa, Ukraine
4–7	Country visit to support revision of the national essential medicines list and HTA	Kiev, Ukraine

Date	Topic	Location
13–14	Data managers meeting for ESAC-Net (European Centre for Disease Prevention and Control)	Stockholm, Sweden
18–20	Training: GMP Module 3	Chisinau, Republic of Moldova
18–20	Working group meeting for revision of clinical guidelines for common infections in paediatrics	Tashkent, Uzbekistan
24	Study tour to Amgros	Copenhagen, Denmark
25–27	Medicines Procurement Practitioners Forum	Copenhagen, Denmark
July 2019		
8–12	In-country GMP/GDP sensitization workshop and QMS for the GMP/GDP inspectorate	Bishkek, Kyrgyzstan
17	Utrecht University Summer School on pharmaceutical policies	Utrecht, Netherlands
30 July – 1 August	Implementation workshop on regulatory preparedness for marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries	Istanbul, Turkey
August 2019		
4–7	Promoting the role of the community pharmacist in primary health care – promotional video	Montélimar, France
22–23	Consultation on the global report on effective access to assistive technology	Geneva, Switzerland
26–30	In-country GMP/GDP sensitization workshop and QMS for the GMP/GDP inspectorate	Tashkent, Uzbekistan
September 2019		
12–13	Stakeholder meeting for development of roadmap for rational use of medicines	Tashkent, Uzbekistan
23–27	International course on implementation of GDP	Kiev, Ukraine
26–27	Closing of 3S Pharmacovigilance project: next steps	Yerevan, Armenia
October 2019		
4–5	Workshop on hospital procurement	Brussels, Belgium
7–10	Visit to support revisions to medicines law	Dushanbe, Tajikistan

(Continued)

Date	Topic	Location
13–15	Workshop on improving access to insulin	Bishkek, Kyrgyzstan
14–18	Meeting of 54th Expert Committee on Specifications for Pharmaceutical Preparations	Geneva, Switzerland
15–17	Visit to support revisions to the national reimbursed medicines list	Tirana, Albania
16–17	Workshop to support hospital procurement, pharmacovigilance activities and review of legislation	Bishkek, Kyrgyzstan
23–25	Fourth PPRI conference: "Medicines access challenge – The value of pricing and reimbursement policies"	Vienna, Austria
23–25	International Pharmaceutical Federation regional conference: Europe	Ankara, Turkey
28 October – 1 November	Joint AMR visit, support for implementation of the national action plan on AMR	Ashgabat, Turkmenistan
30–31	Follow-up country visit to support revisions to national reimbursed medicines list	Tirana, Albania
November 2019		
11–13	Planning meeting for access to assistive technology data collection	Geneva, Switzerland
11–14	Regulatory training course at Swissmedic – a peer learning event	Berne, Switzerland
11–22	Pricing and reimbursement; supporting implementation of QMS in the NRA	Bishkek, Kyrgyzstan
12–13	Effective combat of counterfeiting – WHO's work on substandard and falsified medical products	Yerevan, Armenia
12–15	Thematic week on quality of care: policy dialogue	Bishkek, Kyrgyzstan
18–20	Workshop on QMS for the NRA	Bishkek, Kyrgyzstan
20–22	Workshop on procurement of ATs	Dushanbe, Tajikistan
26–28	Training in GDP for Balkan countries	Podgorica, Montenegro
December 2019		
2–3	Global Vaccine Safety Summit	Geneva, Switzerland
2–6	Prequalification joint meeting	Copenhagen, Denmark

THE WHO REGIONAL OFFICE FOR EUROPE

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

MEMBER STATES

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

World Health Organization
Regional Office for Europe
UN City, Marmorvej 51,
DK-2100 Copenhagen Ø, Denmark
Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01
Email: eurocontact@who.int
Website: www.euro.who.int