

Annual Report 2016

Health Technologies and Pharmaceuticals



Division of Health Systems
and Public Health

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We offer our special thanks to representatives of national ministries of health, regulatory agencies, public procurement agencies and WHO country offices with whom we worked and collaborated during the year. We would like to recognize the significant support of UNITAID to the regional activities of the WHO Prequalification of Medicines Programme.

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2016 in review

Our region: The WHO Regional Office for Europe includes 53 Member States, of which 27 are members of the European Union.

Our mission: To support Member States in providing people with sustainable access to essential and affordable quality medicines and medical products.

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Our website: www.euro.who.int/en/health-technologies-and-medicines

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Our partners:

Clinical Pharmacology, Department of Laboratory Medicine, Karolinska Institutet, Stockholm, Sweden,

Clinical Research & Drug Assessment Unit, Pharmaceutical Department, Local Health Authority, Veneto Region, Italy

European Centre for Disease Prevention and Control (ECDC)

European Commission: Directorate General for Health and Food Safety (DG Santé), DG for Internal Market and DG for Growth

EUROSCAN

Faculty of Health and Medical Sciences, Department of Pharmacy, University of Copenhagen, Denmark

Fundacio Institut Català de Farmacologia, Spain (Collaborating Centre for Pharmacoepidemiology)

Gesundheit Österreich GmbH, Austria (Collaborating centre for pharmaceutical pricing and reimbursement policies)

I.M. Sechenov First Moscow State Medical University, Moscow, Russian Federation

London School of Economics and Political Science (LSE Health), UK (Collaborating Centre for Health Policy and Pharmaceutical Economics)

Norwegian Institute of Public Health, Norway (Collaborating centre for Drug Statistics Methodology)

Pharmakon, Denmark (Collaborating center for drug policy and pharmacy practice)

Uppsala Monitoring Centre, Sweden, (Collaborating centre for Pharmacovigilance)

Utrecht Institute for Pharmaceutical Sciences (The Netherlands)

International organizations and agencies: GFATM, OECD, UNICEF, UNITAID

In 2016, our major activities included:

Providing direct technical and policy support to countries

- Support to the development of an outpatient medical devices reimbursement scheme in Albania
- Technical report and policy dialogue to identify possible barriers to increase the availability of medicines in Estonia and to suggest options to overcome them
- Technical assistance towards the development of health technology assessment (HTA) capacity in Greece
- Technical report and policy dialogue on the pricing and reimbursement reform of outpatient medicines in Kyrgyzstan
- Support for the revision of National Essential Medicines List in Kyrgyzstan
- Strengthening of the legal framework of the pharmaceutical sector in Moldova
- Technical report and country consultation on the strategic procurement of pharmaceuticals
- Support for national regulatory agency assessment in the Russian Federation
- Technical assistance to the National Medicine Regulatory Authority on implementation of the WHO Certification scheme on the quality of pharmaceutical products in Tajikistan and Turkmenistan
- Support for the development of the national medicines policy in Ukraine

Biannual collaboration agreements with 19 countries providing support for a range of activities in the pharmaceutical sector

Building capacity through training

- Co-convening of the first Summer School on Pharmaceutical Pricing and Reimbursement Policies
- Co-convening of the course on the Interface Management of Pharmacotherapy
- Training on Good Distribution Practices
- Training of pharmaceutical inspectors in the Russian Federation
- Training on Good Manufacturing Practice in Turkmenistan and Tajikistan

Facilitating networks and workshops on pharmaceutical policies

- Meeting and technical support of the WHO Antimicrobial Medicines Consumption (AMC) network
- Technical Briefing on “Access to high-priced medicines: challenges and opportunities” at the 66th session of the WHO Regional Committee for Europe
- Contribution to the development of the WHO “Fair Pricing Initiative”
- Co-facilitating the Pharmaceutical Pricing and Reimbursement Policy Information (PPRI) network meetings



Introduction

The WHO Regional Office for Europe, through the Health Technology and Pharmaceuticals (HTP) programme, supports its 53 Member States in providing people with sustainable access to essential and affordable quality medicines and medical products.

The work of the HTP programme is in line with the strategies developed by the WHO Essential Medicines and Health Products programme (EMP) at WHO headquarters in Geneva. It is aligned with the Tallinn Charter¹ and Health 2020² policy framework at the regional level, and with the global 2030 Agenda for Sustainable Development Goals (SDGs), striving for a world where every child, man and woman can afford and has access to the quality 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

quality pharmaceuticals along with their pricing and reimbursement and responsible use. In 2016, the HTP 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, the development or revision of national pharmaceutical policies, expanding the use of Health Technology Assessment (HTA), developing medicine pricing policies, and in new directions in procurement and supply chain management. HTP programme is assisting countries to become more efficient and thereby better prepared to provide sustainable access to quality products through the sharing of country experiences and best practices.

This report summarizes the 2016 contribution of the HTP programme to improving health in the WHO European Region, by supporting improved access to essential, affordable, quality pharmaceuticals and medical products.

¹ The Tallinn Charter : <http://www.euro.who.int/en/publications/policy-documents/tallinn-charter-health-systems-for-health-and-wealth>

² Health 2020: <http://www.euro.who.int/en/health-topics/health-policy/health-2020-the-european-policy-for-health-and-well-being>

Medicines, health products and the 2030 Agenda for Sustainable Development

The Sustainable Development Goals (SDG) represent a shift of focus from specific diseases and population targets to a more comprehensive approach to health. SDG 3 emphasises the promotion of health throughout the life course and universal health coverage (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, and also the opportunity to drive change through a more integrated structure and 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 3b) and more broadly in at least seven other targets under SDG3. Access to health products will be a key indicator for countries' progress to 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 universal health coverage.
- Currently, the majority of people in low- and middle-income countries pay for medicines out of pocket, often leading to financial hardship. With the rise in non-communicable 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 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 under-served by markets and R&D. 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. The HTP programme also provides specific technical assistance and training to manufacturers and regulators to help them achieve internationally recognized quality standards¹.

Assessment of national medicine regulation systems

WHO has developed a data collection tool to facilitate the review of national medicine regulatory systems². WHO works in collaboration with local officials to assess the national situation, review the existing legal framework and to identify specific needs for technical support and training.

^{1,2} http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/

Since 2015, the HTP programme in collaboration with WHO headquarters in Geneva has been engaged in assessing the functions of the national medicines regulatory authority in the Russian Federation. A roadmap for further improvements has been developed and is to be endorsed by the Russian authorities.

During the assessment, a number of trainings were delivered to authorities in Quality Management System development and maintenance, Good Manufacturing Practice, Pharmacovigilance and Adverse Events Following Immunization monitoring and surveillance.

Prequalification of health products

WHO prequalification of medicines is a service provided 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 medicines for bulk purchase.

The Regional Office continues to provide technical assistance and advice on preparing application dossiers to support manufacturers on prequalification of their products. Of the 26 products prequalified by WHO in 2016, three finished pharmaceutical products and three active pharmaceutical ingredients were produced by manufacturers in the WHO European Region. Additionally, two quality control laboratories were prequalified and two laboratories were re-qualified in the Region.

Advocating for WHO prequalification

In November 2016, the Regional Office participated in a ministerial meeting organized by the Global Fund, UNAIDS and the Stop TB Partnership to discuss the problems of poor access to quality medicines for the treatment of tuberculosis and HIV. The twelve countries represented at the meeting (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), have the highest burden of multi-drug resistant tuberculosis (MDR-TB) and HIV in the Region. WHO has advocated for manufacturers in the Region to apply for WHO prequalification of anti-tuberculosis medicines

and antiretrovirals to help improve access and affordability of these medicines.

Training on Good Distribution Practices

Good Distribution Practices (GDP) aim to build well-regulated distribution and supply chains and help protect patients from unsafe medical products. They are a fundamental component in ensuring access to quality, safe and effective medical products.

A four-day workshop conducted in June 2016 trained 16 participants from seven countries in risk-based assessment of the supply chain and good distribution practices of medical products. Inspectors from Albania, Armenia, Bosnia and Herzegovina, Serbia, Turkey and Ukraine attended the event, which was organized in collaboration with EMP, WHO Geneva, Pharmakon², the Danish Medicines Agency, the inspectorate of the Medicines and Healthcare products Regulatory Agency of United Kingdom, and the UNICEF Supply Division.

The training aimed to enhance understanding and compliance with GDP, based on the most recent guidelines from the European Union³. The workshop included hands-on training in inspection of wholesale facilities.

² Pharmakon, Denmark: WHO Collaborating Centre for drug policy and pharmacy practice development

³ http://ec.europa.eu/health/human-use/good_distribution_practice/developments_en



Strategic procurement

The high prices for new medicines are posing problems for the health care budgets of all countries and denying patients access to important medicines that may prolong life or improve the quality of life. 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 Europe. 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.

Gathering evidence on pharmaceutical procurement

A Regional Office online survey gathered information on public procurement methods in Europe, with a specific focus on tendering for medicines. Most of the 39 Member States who responded to the survey reported procuring medicines through public tenders. Twenty-five countries reported using international calls for tenders, two reported national tenders and ten posted tenders at both levels. Typically, tenders cover medical products for both hospital and ambulatory care sectors. Twenty-five countries

reported publishing their tender results in the public domain.

Procurement modalities vary in the Region. A majority of countries have mechanisms to centralize the procurement of high-priced medicines, where orders are merged at the national level, regional level or through joint procurement with other jurisdictions. There are also some examples of initiatives in the Region where countries aggregate purchase volumes in order to obtain a better price.

Sharing experiences in procurement

The evidence gathered from the online survey on public procurement methods provided discussion points for a country consultation on improving access to medicines by enhancing the efficiency of procurement systems in Europe. At the event, organized on 22-23 September 2016 in Copenhagen, Denmark, representatives of public medicine procurement agencies from 42 countries and key partners reviewed national experiences and discussed a number of recent collaborative procurement initiatives.

Analysis of hospital spending on medicines, transparency in pricing, informed purchasing and collaborative procurement were discussed at the consultation. Experiences of collaboration in the Region, such as that of the Benelux^A (Belgium, the Netherlands, Luxembourg and Austria), the Nordic country collaboration (Denmark, Norway, Sweden and Iceland) and the Central Europe Collaboration¹, illustrated the challenges of collaborative arrangements and helped identify opportunities for future collaborations.



WHO report on improving access to medicines through strategic procurement

The report *Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region*², published in November 2016, presents findings of the survey and outlines future directions based on the conclusions of the country

consultation.

The report examines the effects of different public procurement practices on supply security and prices for pharmaceuticals, and concludes that collaboration on procurement within and across countries could improve the availability of affordable medicines for patients in the Region.

A two day follow-up workshop is planned for February 2017 to discuss next steps and how WHO can facilitate country collaboration and efficient knowledge sharing in the Region.

Relevance to European and global priorities

Increasing collaboration between health systems in Europe is also a priority in the European Union agenda. During the Maltese presidency of the EU (January to July 2017), there will be a technical workshop in March 2017 to further discuss opportunities for structured cooperation. The outcomes of this workshop will feed into a ministerial meeting on 20 March 2017, which will set out the political direction for drafting Council conclusions on this topic.

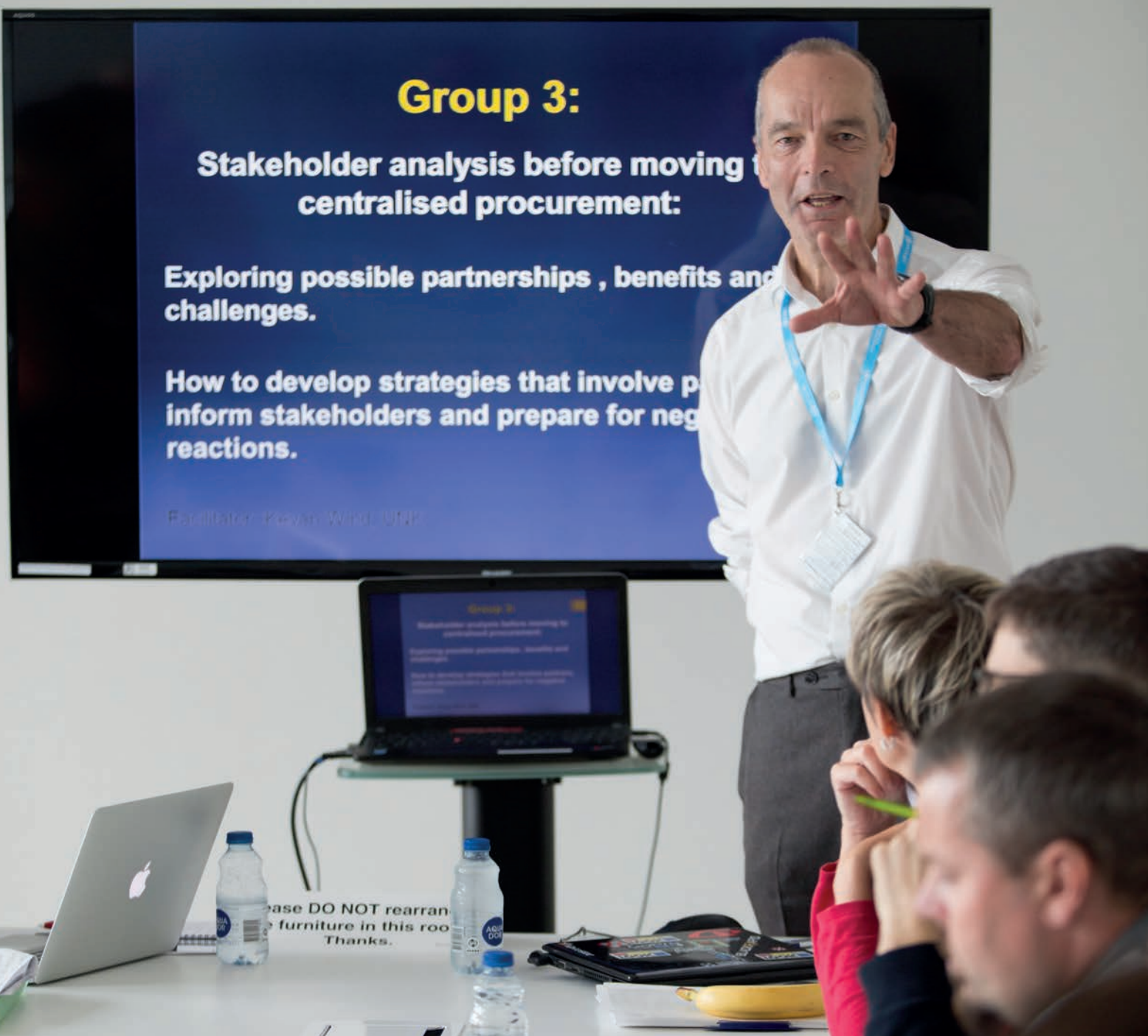
“Malta being an island, we would benefit from inter-country collaboration. The only way to set up a sustainable system is by collaboration.”

Karl Farrugia, CEO, Central Procurement and Supplies Unit, Department of Health, Malta

The topic of improving access to medicines in the European Region is also on the agenda for the 67th session of the WHO Regional Committee for Europe, to be held in September 2017 in Budapest, Hungary.

¹ Bulgaria, Croatia, Estonia, Hungary, Latvia, Romania, Serbia, Slovakia, Slovenia and the former Yugoslav Republic of Macedonia

² http://www.euro.who.int/en/2016/efficient_procurement_of_medicines



Support to improve availability of pharmaceuticals

Procurement and supply chain management systems should ensure that the right product is available from the right source, in the right quantity, at the right place, at the right price and at the right time. Many countries in the Region face shortages of some health products, including medicines and rapid diagnostic tests, due to limited coordination between technical experts and those in charge of procurement and supply management systems.

Furthermore, typically a large amount of a national health programme's budget is devoted to the procurement and management of health commodities in countries. A WHO study conducted in 2015 in Ukraine reported that as

much as 40% of the health care budget was spent in procurement of pharmaceuticals³. It is therefore important that procurement takes into consideration existing national treatment guidelines as well as international/WHO guidance for specific diseases.

Availability of medicines is crucial in all health programmes, however, it is even more important when the non-compliance with treatment regimens could increase the development of drug resistance and risk of treatment failure. Poor availability of recommended medicines for HIV and TB, for example, can lead to incomplete

³ Konduri Niranjana, Lebeaga Oksana. How Public Funds Were Spent on Procurement of Medicines in Ukraine's Hospitals? Interim Analysis for the Ministry of Health, Ukraine. Technical Brief # 1. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services Program. Arlington, VA: Management Sciences for Health; June 2015. <http://apps.who.int/medicinedocs/en/d/Js22167en/>



courses of treatment, switches to medicines that are available or treatment abandonment in some cases.

In an effort to facilitate better coordination, the HTP programme of WHO Regional Office for Europe presented foundations of procurement and supply chain management to technical experts from 12 eastern European and Central Asian countries at a regional consultation in Minsk on the dissemination of the new WHO guidelines on HIV and viral hepatitis. The information helped participants gain an overview of the importance of a functional national procurement and supply management system in increasing the availability of quality health products.

How the increased use of biosimilars in Norway has freed up funds to treat more patients

In Norway, the drug procurement agency *Legemiddelinnkjøpssamarbeid* (LIS) is the entity responsible for the procurement of medicines for hospitals. LIS provides procurement support from developing specifications for tenders to conducting negotiations with suppliers. The procurement process is centralized and the prices obtained are shared with all hospitals in Norway ensuring that all hospitals pay the same negotiated price for the medicines.

To ensure that efforts to improve efficiency in procurement fit the overall objective of developing and maintaining a healthy market that recognizes the needs of patients, clinicians and industry, LIS organizes regular seminars with medical staff, pharmaceutical industry, patients and media.

Since January 2014, LIS has been procuring the patented version of infliximab (Remicade) to treat rheumatoid arthritis. A biosimilar version of infliximab – Inflectra – was also available but was not procured until February 2016.

A clinical study¹, sponsored by the Norwegian government, found that efficacy and safety were comparable between patients switched to the biosimilar version of infliximab and those who remained on the originator product. Based on these results, the tenders issued by LIS now include the procurement of the originator and the biosimilar version. The biosimilar product is now available in Norwegian governmental hospitals, and doctors are expected to switch all patients currently on the originator to the biosimilar.

This successful switch to a biosimilar, achieved by working closely with clinicians and patients, has led to substantial savings on total expenditure on the medicine and to more patients having access to treatment within the fixed budget of the public health system.

¹ Moe L (2016) Nor-Switch: – Safe switch to biosimilar. In: Dagens Medisin. <http://www.dagensmedisin.no/artikler/2016/10/17/nor-switch--safe-switch-to-biosimilar/>



Pricing and reimbursement

The high prices for new medicines are also an important challenge for countries of the Region. Achieving fair pricing and ensuring long-term sustainability of health care systems and access to medicines remains critical.

The WHO Regional Office for Europe supports countries in developing and implementing strategies to contain and regulate medicine costs. The HTP programme also supports countries in the management of their lists of reimbursed medicines through legislation, selection process, and updating.

Building regional capacity on developing medicine pricing policies

The HTP programme co-organized a five-day summer school on pharmaceutical pricing and reimbursement policies, with the Austrian Institute of Public Health (Gesundheit Österreich GmbH) the designated WHO Collaborating Centre on pharmaceutical pricing and reimbursement. The school offered training to pharmaceutical experts and policy makers in the European Region in developing and implementing medicine pricing policies. The school provided a training

“We need to completely change the rules of the game because the pharma business model is outdated.”

- Josef Probst, Main Association of the Austrian Social Security Institutions

GmbH) the designated WHO Collaborating Centre on pharmaceutical pricing and reimbursement. The school offered training to pharmaceutical experts and policy makers in the European Region in developing and implementing medicine pricing policies. The school provided a training



opportunity for participants from Eastern Europe in particular, and was conducted in English with simultaneous Russian translation.

The event brought together 33 participants from 20 countries (13 participants from 9 EU countries and 20 participants from 10 non-EU countries).

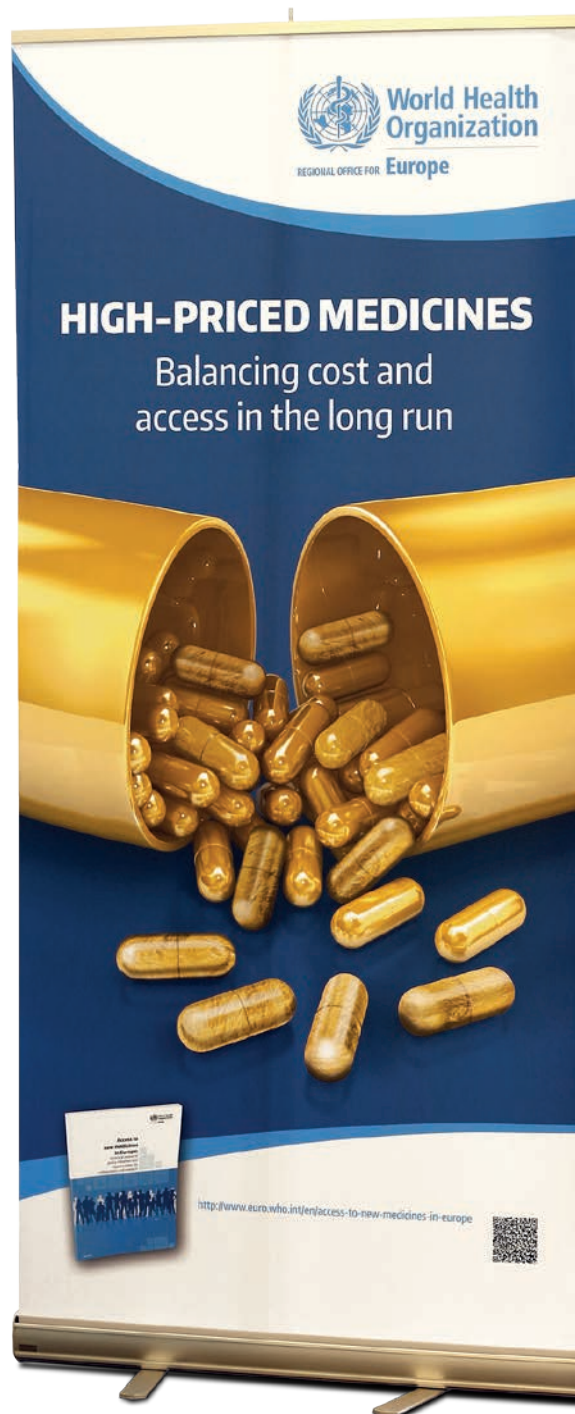
In association with the summer school, a high-level panel discussion on access to high-priced medicines in Europe was organized at the Austrian Ministry of Health.

“As a policymaker, my main challenge is to overcome fragmentation of national pharmaceutical markets.”

- Clemens Auer, Austrian Ministry of Health

Briefing of WHO Member States on high-priced medicines

The issue of high-priced medicines was discussed at a technical briefing on 13 September 2016, during the 66th session of the WHO Regional Committee for Europe, which gathered together representatives from Member States, academics and representatives from the pharmaceutical industry. Experts and panel members at the event debated recent trends in the pharmaceutical market and discussed possible ways forward for the development of strategies for national action and collaboration between countries to increase access to new high-priced medicines in the WHO European Region.



The main recommendation from the technical briefing was for WHO to take an active role in facilitating country collaboration, in generating evidence and in developing meaningful policy dialogue to further access to medicines and to act as a forum to debate good practices. Suggestions of specific areas to initiate international collaboration included horizon scanning and strategic procurement.



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 correctly¹. 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 medicines and therapeutic committees, formularies and clinical guidelines, feedback of medicine use data, and policies on medicine promotion.

Antimicrobial Medicines Consumption (AMC) Network

Following a pilot data collection project in 2011 involving the University of Antwerp, the WHO Regional Office for Europe set up the WHO Antimicrobial Medicines Consumption (AMC) network to assist countries in setting up or strengthening national AMC surveillance and to contribute to Region-wide AMC surveillance.

Efforts are closely coordinated with the European Centre for Disease Prevention and Control (ECDC) to ensure that data are compatible and comparable and are able to provide a pan-European overview of trends in antimicrobial medicines consumption.

A national approach to monitoring and evaluation serves to provide centralized data to ensure that policies and strategies to address antimicrobial resistance and consumption are effective. Furthermore, as recognized by the WHO Global Action Plan on antimicrobial resistance, collecting and analyzing data on antibiotic use is a means of identifying potential over-use, under-use and inappropriate use of antimicrobial medicines and is a basis for developing interventions to address inappropriate practices.

Seventeen non-EU countries in the European Region and Kosovo (in accordance with Security Council resolution 1244 (1999)) are part of the AMC network, which has met annually since its inception. A highlight was the 2016 meeting held in Copenhagen in September that aimed to encourage countries to move from data collection to data analysis. Modelled after an interactive workshop, the meeting included exercises for participants to analyze gathered data, discussions

¹ The pursuit of responsible use of medicines: sharing and learning from country experiences. 2012. Geneva: WHO (http://www.who.int/medicines/publications/responsible_use/en/)



on how to share results with stakeholders and engage with Ministries of Health to facilitate the use of data on antimicrobial consumption within countries.

The Regional Office has supported the development of new software that will facilitate and simplify data analysis for future years of antimicrobial consumption data. A report of consumption data from 2011 to 2014 is being prepared and is intended to illustrate the value of national surveillance and will help stimulate the sharing of data both within and between countries.

Based on its experience of the antimicrobial consumption network, the Regional Office is working with the WHO headquarters in Geneva to develop global guidance on collecting antimicrobial consumption data.



Using community pharmacists to enhance responsible use of medicines

The HTP programme collaborates with the Pharmaceutical Group of the European Union (PGEU) that represents national associations and professional bodies of community pharmacists in 32 European countries. The aim of this partnership is to support community pharmacists in their public health role and to promote their greater engagement in issues related to the responsible use of medicines.

At the group's 2016 meeting in November, "State of Health in EU: Community Pharmacy Contribution", the HTP programme presented on the topic of potential expanded roles for community pharmacists in addressing topics including adherence to guidelines on antibiotic use, increasing collaboration with other health professionals for responsible use for medicines, promoting chronic disease prevention, in the delivery of vaccination programmes and in the screening and treatment of minor ailments.

Support to countries in the region



Estonia

There has been continued support from the programme to Estonia for several years and in 2016 a study identified possible barriers to increasing the availability of medicines in Estonia and suggested options to overcome them. The

analysis included a review of relevant national and EU legislation regulating the marketing of pharmaceuticals, and local practices relating to pricing, reimbursement and procurement. In addition, further development of the clinical guideline process was supported.



Republic of Moldova
Strengthening the legal
framework of the
pharmaceutical sector
in Moldova

Upon the request of the Ministry of Health of the Republic of Moldova, the WHO Regional Office for Europe is supporting the country's move to align its pharmaceutical legislation and practice with respective EU *acquis communautaire*. The government of the Republic of Moldova has expressed strong political desire to achieve EU membership, necessitating such alignment process.

The HTP programme supported the WHO country office and organized a series of three seminars on key aspects of pharmaceutical regulation in the EU, aimed at increasing the capacity of staff

“The seminars are insightful, useful and timely, considering the current ongoing work on harmonization of national legislation in the pharmaceutical sector with EU legislation – work that is strongly supported by WHO”.

– Maria Lapteanu, head of the pharmaceutical department at the Ministry of Health, Republic of Moldova

of the Ministry of Health, Agency for Medicines and Medical Devices, National Health Insurance Company, State Medical and Pharmaceutical University to support the necessary legislative changes.

The HTP programme has also supported the Republic of Moldova in increasing access to new hepatitis C medicines. In collaboration with WHO headquarters in Geneva, the HTP programme conducted a rapid assessment of the patent status for hepatitis C medicines in the country, concluding that

the patent rules allowed the import and use of generic versions of these medicines. In 2016, the HTP programme also facilitated contact with a manufacturer of generic medicines for hepatitis C, to foster import of those medicines to Moldova.



Ukraine

Support to developing Ukraine's national medicine policy

The pharmaceutical reform in Ukraine, a pillar of the general reform of the country's health sector, aims at increasing access to essential quality medicines and reducing out-of-pocket expenditures for pharmaceuticals. In the last two years, WHO and partners have consulted with the Ministry of Health on revising the processes and systems for the selection, financing, procurement and use of medicines in Ukraine.

In January 2016, the Ministry of Health circulated the terms of reference for nine working groups that would contribute to developing the national medicines policy. Each group focused on an aspect of the pharmaceutical sector such as regulation, reimbursement, financing and responsible use. The HTP programme supported and advised the working groups during their discussions and contributions were compiled into a draft policy.

The new policy is expected to be endorsed by the government in 2017.

Emergency pharmaceutical support

Ongoing political conflict in Eastern Ukraine has led to the internal displacement of more than one million people and around five million people in need of humanitarian aid¹. To address the urgent needs of internally displaced people WHO implemented an emergency relief network, with 37 mobile emergency primary care units in six regions of eastern Ukraine.

The HTP programme provided technical support to the Country Office on increasing transparency and accountability in the supply chain and on promoting the rational use of medicines and medical supplies. The Programme also provided hands-on training and mentoring on good storage of medicines and handling practice for staff of mobile units.

¹ <http://www.usip.org/olivebranch/2015/11/23/ukraines-invisible-crisis-15-million-who-fled-war-russia>

Kyrgyzstan

Pricing and reimbursement of outpatient medicines in Kyrgyzstan

WHO has been working with the Kyrgyz Ministry of Health to help in the reform and regulation of their national pharmaceutical sector.

A country analysis, commissioned by the WHO Regional Office for Europe in 2016, examined the causes of high out-of-pocket payments for prescription medicines in Kyrgyzstan, and presented options to address the problem through policy reform.

The report reviewed current reimbursement mechanisms, assessed their ability to protect the Kyrgyz population from high out-of-pocket payments, analyzed reimbursement and import data and interviewed relevant stakeholders in the country.

The report proposed a number of recommendations to control and reduce high out-of-pocket payments, including putting in place price regulation for medicines publically reimbursed by the Kyrgyz health insurance fund, regulating retail sector margins, updating legislation on the criteria and processes for adding or removing medicines from the list of reimbursed medicines, and improving data collection on reimbursement prices. These policy options were presented and discussed with the Kyrgyz authorities and other partners in September 2016 in Bishkek during a thematic week on health financing and universal health coverage.

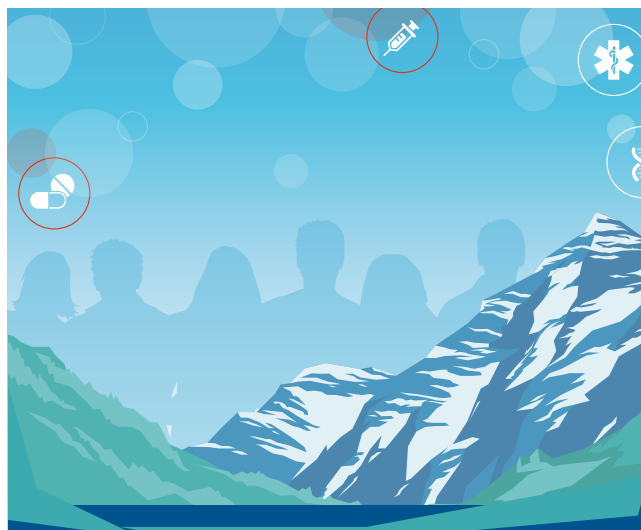
Review of National Essential Medicines List

The HTP programme in collaboration with WHO headquarters in Geneva provided technical assistance to the Ministry of Health of Kyrgyzstan towards updating the National Essential Medicines List (NEML).

A two-stage proposal was suggested to address both the need to have a revised NEML by the end of 2016 and the development of a sustainable platform for future revisions to the NEML. A Ministerial Decree was issued to revise the NEML in 2016. The HTP programme worked with members of the national expert group appointed to conduct this review. The expert group reviewed discrepancies between the 2015 WHO Model List



Pharmaceutical pricing and reimbursement reform in Kyrgyzstan



“This year, the Ministry of Health, with technical support from WHO, started working on pharmaceutical pricing policies. We are confident that this, together with the revision of the Essential Medicines List, will contribute to increase access to medicines and to achieve universal health coverage”.

Dr. Samat Toimatov, head of medical service delivery and medicine policy reform, Ministry of Health, Kyrgyzstan

of Essential Medicines and the 2012 Kyrgyzstan NEML and suggested revisions for consideration by the Minister of Health.

CALENDAR OF ACTIVITIES

Date	Topic	Country
January		
25	Participation in OECD workshop on high-cost medicines	France
27	Participation in European Master in Health Economics and Management Winter School	Austria
27-28	Presentation on pharmaceutical policy during a Policy dialogue	Estonia
February		
1	Presentation at seminar on national and international health systems	Norway
9-11	Mission to support the pharmaceutical policy reform	Ukraine
10-11	Participation in ministerial conference on antimicrobial resistance	Netherlands
16	Mission to support pharmaceutical policy development	Republic of Moldova
17-18	Subregional training in collection of antimicrobial consumption data	Republic of Moldova
15-26	Training in GMP for Russian Federation	Denmark
24-26	Participation in workshop on adverse events following immunization (AEFI)	Russian Federation
24-26	Mission to support pharmaceutical policy reform	Ukraine
March		
1-2	Participation in workshop on European Surveillance of Veterinary Antimicrobial Consumption	UK
1-2	Participation in ministerial conference on affordable and innovative medicines	Netherlands
3-4	Presentation at WHO drug utilization workshop	Switzerland
8-9	Presentation at London School of Economics Summit (Advance HTA)	UK
15-17	WHO subregional workshop on national antimicrobial resistance action plans	Turkey
16-22	Training workshop related to assessment of National Regulatory Authority	Russian Federation
22	Participation in OECD workshop on new health technologies	France
29-1 Apr	Presentation at WHO meeting on methodologies for surveillance of anti-microbial medicines consumption	Switzerland
April		
8	Presentation at OECD workshop on pharmaceutical procurement	France
13-15	Mission to support pharmaceutical policy reform	Ukraine
14-18	Mission to support pharmaceutical sector reform	Kyrgyzstan
16-22	Mission to support National Regulatory Authority assessment	Russian Federation
19-20	Participation in meeting on WHO Global Patient Safety Challenge - Medication Safety	Switzerland
27	Participation in EuroScan consortium meeting	Portugal
28-29	Presentation at the meeting of the PPRI network	Portugal
May		
5-6	Training workshop on collection of antimicrobial consumption data	Uzbekistan
9-13	Training on Good Manufacturing Practice	Denmark
12	Presentation at the WHO technical briefing seminar on pharmaceutical policies	Switzerland
16-19	Mission to support assessment of Health Technology Assessment (HTA)	Greece
19	Participation in meeting of <i>Nordisk kontaktpunkt for prioritering</i>	Norway
30-1 Jun	Presentation at the meeting of the MEDEV group	Netherlands
30-2 Jun	Mission to support pharmaceutical sector reform (procurement and pricing)	Kyrgyzstan
31-1 Jun	Presentation at ESAC-Net meeting	Sweden
June		
6-8	Mission in support of improved access to medical devices	Albania
6-10	Training on Good Manufacturing Practice	Denmark
9-10	Presentation at training on Anatomical Therapeutic Chemical Classification System	Norway
13	Presentation at Nordic Pharmaceutical Forum	Denmark
14-16	Training in Good Manufacturing Practice for pharmaceutical industry in the Eurasian Economic Union (EEU)	Russian Federation
16-19	Presentation at the People's meeting <i>Folkemødet</i>	Denmark

Date	Topic	Country
July		
6-8	Study tour of Greek delegation to Portugal related to HTA	Portugal
13-15	Participation in WHO HTA meeting	Switzerland
15-17	Presentation at Utrecht University summer school	Netherlands
August		
22	Presentation at University of Copenhagen summer school	Denmark
22-24	Participation in meeting on WHO Global Patient Safety Challenge - Medication Safety	Switzerland
25-28	Participation in International Conference on Pharmacoepidemiology	Ireland
29-2 Sep	Co-convenor of summer school on pharmaceutical pricing and reimbursement policies	Austria
30-2 Sep	Participation in Global Vaccine Quality Control Laboratories Networking Meeting	Netherlands
September		
6-7	Mission in support of revision of National Essential Medicines List	Kyrgyzstan
13	Convenor of technical briefing on access to high-priced medicines at the 66th session of the WHO Regional Committee for Europe	Denmark
19-20	Convenor of Antimicrobial Medicines Consumption (AMC) network meeting	Denmark
22-23	Convenor of workshop on strategic procurement	Denmark
25-30	Presentation at WHO workshop on new guidelines for management of HIV and viral hepatitis	Belarus
26-2 Oct	Mission to support pharmaceutical sector reform (health financing)	Kyrgyzstan
October		
3-5	Participation in workshop on methodologies for surveys on antimicrobial consumption	Switzerland
10-11	Mission to support monitoring of antimicrobial resistance and consumption	Kazakhstan
11-12	Presentation at meeting on pharmacovigilance	Ukraine
20	Presentation at the WHO technical briefing seminar on pharmaceutical policies	Switzerland
17-19	Co-convenor of course on interface management of pharmacotherapy	Spain
17-18	Participation in discussions on structured cooperation between health systems	Malta
20-21	Participation in ESAC-Net meeting	Sweden
November		
2-3	Presentation on expanding access to affordable quality medicines	Belarus
1-4	Mission to support pharmaceutical policy reform	Ukraine
14-17	Participation in meeting of the WHO pharmacovigilance global network	Oman
14-18	Mission on surveillance of antimicrobial resistance and consumption and presentation on World Antibiotic Awareness Day	Turkey
15	Presentation at the Pharmaceutical Group of the European Union (PGEU)	Belgium
17-18	Presentation at the meeting of the PPRI network	Finland
17-20	Technical assistance to the National Medicine Regulatory Authority	Turkmenistan
21-24	Training of pharmaceutical inspectors	Russian Federation
21-25	Presentation at WHO workshop on pharmacovigilance for vaccines	Montenegro
22-14	Presentation at WHO Fair Pricing forum	Switzerland
26-3	Participation in International Conference of Drug Regulatory Authorities	Republic of South Africa
28-1 Dec	Mission to support pharmaceutical sector reform (pricing and Essential Medicines List)	Kyrgyzstan
December		
7-8	Participation in EU meeting relating to Pharmaceutical Care Resolution	France
12-15	Technical support to the National Medicine Regulatory Authority	Tajikistan
13-16	Participation in WHO meeting of collaborating centres related to Global Antimicrobial Resistance Surveillance System (GLASS)	Switzerland

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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