

Health Technologies and Pharmaceuticals (HTP) Programme

Division of Health Systems and Public Health

ANNUAL REPORT 2015



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Introduction

The Health Technology and Pharmaceuticals (HTP) Programme of the WHO Regional Office for Europe (WHO/Europe) has the overarching goal of supporting access to essential, quality health technologies including medicines. The current report summarizes the 2015 work of the HTP team of WHO/Europe in supporting its Member States and contributing to health in the WHO European Region, in line with the Tallinn Charter and Health 2020 policy framework.

Equity in public health depends on access to essential, high-quality and affordable medical technologies, and improving access to medical products is central to the achievement of universal health coverage (UHC). Indeed, increasing access to medical products is one of six WHO global leadership priorities, and the HTP programme has divided its work into specific themes in line with the WHO 12th General Programme of Work¹.

We support countries to formulate evidence-based policies and ensure good practice and good governance throughout the health technologies supply chain, from selecting the right products to using them correctly. We address access to medicines and medical devices for current and emerging health priorities, such as anti-microbial resistance (AMR) and non-communicable diseases (NCD), and develop tools to assess situations and monitor and measure progress on access to quality health products.

Guidance in medical product regulation continues to be a crucial element of HTP's work. HTP aids countries to strengthen regulation, including post-marketing surveillance, and to eliminate substandard and falsified medicines. Convergence in regulation of medical products is desirable, and HTP provides country specific support as

well as support to the WHO Prequalification Programme², where European medicines manufacturers can facilitate their regulatory affairs work through participation in the initiative.

In terms of responsible use of medicines, the current focus is on use of antimicrobial medicine and supporting countries in setting up medicines registers that allow for monitoring of use of medicines. Along with policy considerations of antimicrobial use in human and animal health, AMR global surveillance, and considerations of the economic consequences of AMR, there is a need to focus on aspects of medicines policies and practices that influence the extent and appropriateness of use of antimicrobial medicines. A number of Member States already have comprehensive action plans to address AMR and extensive experience in the development of programmes focused on the responsible access and use of antimicrobial medicines. Such programmes require appropriate policy settings supported by regulations, evidence-based guidelines to promote optimal use of antimicrobials, and the engagement of civil society as well as health care professionals. Attention to appropriate use of medicines requires urgent follow up and action in Member States. HTP has spearheaded efforts in this regard,

1 http://www.who.int/about/resources_planning/twelfth-gpw/en/

2 <http://apps.who.int/prequal/>

along with efforts to analyze drug utilization in general, also to support and improve access to relevant NCD medicines.

During 2015 our work in and with countries continued on the basis of best practices and has been taking into consideration the potential of both the eastern and the western parts of the Region. Below are selected highlights of our work.



Increasing access to medicines through national policy development

Lack of pharmaceutical policies and inefficient use of medicines is one of the top sources of inefficiency in health systems. As the number of new medicines introduced in Europe rises, governments are finding it increasingly difficult to afford them. Governments across Europe face similar problems, but the challenge is even greater in countries facing financial pressures. Pharmaceuticals are the main contributor to out-of-pocket health payments in the Region and, consequently, in some settings lead to catastrophic and impoverishing medical expenditures.

The challenges for national health systems have been illustrated in the 2015 WHO/Europe HTP publication, *Access to new medicines in Europe: technical review of policy initiatives, opportunities for collaboration and research*³. Potential policy directions and choices that may help governments manage or reduce high prices when introducing new drugs are outlined in this publication, and a number of case-studies around specific disease areas are provided. The report suggests that countries need to strengthen cooperation and share their experiences if better transparency in pricing is to be achieved, and differential pricing policies are to be addressed. HTP works both on bringing countries together to debate and discuss possible ways forward as well as to provide country specific support.

Examining the evidence base across Europe, this 2015 report reviews policies that affect medicines throughout their lifecycle (from research and development to disinvestment). While many European countries have not traditionally required active priority-setting for access to medicines, appraising new medicines using pharmacoeconomics is increasingly seen as critical in order to improve efficiency in spending while maintaining an

appropriate balance between access and cost-effectiveness. The report includes findings from 27 countries and explores different ways that health authorities in European countries are dealing with high spending on new medicines, including methods such as restrictive treatment guidelines, target levels for use of generics, and limitations on the use of particularly expensive drugs. It also outlines possible policy directions and choices that may help governments to reduce high prices when introducing new drugs. During 2015 the report and its findings were shared in several fora, and follow up country consultations were held to facilitate policy action at national and sub-regional levels.

³ See: <http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015>

Improving the managed introduction of new medicines: sharing experiences to aid health and medicines authorities across Europe (Warsaw, Poland)

The 3-day course on the managed introduction of new drugs was organized in collaboration with the Piperska group (Rational Prescribing) and the Polish Agency for Health Technology Assessment and Tariff System. It aimed to share experiences and case histories among health authority and health insurance personnel and academics from across Europe on potential ways to optimize the managed entry of new medicines. This process starts before product launch with horizon scanning and budgeting, includes the peri-launch period, including critical drug evaluation, and finally the post-launch period, which includes monitoring prescribing of new medicines against agreed guidance and indicators. The course included discussions on practical implementation of Health Technology Assessment (HTA), issues regarding managed entry schemes and procurement strategies including for biosimilars.





Celebrating 10 years of Good Governance, September 2015 (Copenhagen, Denmark)

World Health Organization Resolution WHA67.22 on access to essential medicines recognizes that the effective implementation of the WHO medicines strategy, as set out in the twelfth general programme of Work 2014-2019, is of critical importance to progressing towards Universal Health Coverage (UHC) and the health-related Millennium Development Goals. A regional meeting took place in September 2015 to review and share effective governance practices and strategies for improving access to medicines and to address the implementation of the resolution. This one day meeting aimed at advocating for recognition of the importance of effective national medicines policies and their implementation under good governance, and to recognize the importance of transparency and management of conflict of interest in decision making. During the meeting, countries from across the European Region shared their views and experiences on these issues, and workshops on how to improve accountability, transparency and manage conflict of interest in the public sector pharmaceutical system were undertaken with WHO expert consultants. The meeting supported participants in better understanding of the importance of effective national medicines policies, and their implementation under good governance.



Health Technology Assessment (HTA) and selection of medicines

Health Technology Assessment refers to the systematic evaluation of properties, effects and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision-making.

The definition of health technology is the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life.

Understanding the importance of Health Intervention and Technology Assessment in support of universal health coverage, a resolution (WHA67.23) was approved during the Sixty-seventh World Health Assembly. And while many advances have been made in the recent years in Europe regarding the implementation of HTA, in many Member States, particularly in South and Eastern Europe, HTA is still in a nascent phase and much can be done to inform local decision-makers about uses of HTA in different setups.

Advance Health Technology Assessment (HTA) workshop (London, England)

AdvanceHTA
Rethinking the future of Health Technology Assessment

ADVANCE-HTA - a research project funded by the European Commission's Research Framework Programme (FP7) - comprises several complementary streams of research that aim to advance and strengthen the



methodological tools and practices relating to the application and implementation of HTA. It is a partnership of 13 Consortium Members led by the LSE Health (London School of Economics). WHO participated in and contributed to the Advance-HTA workshop held in September 2015 in Warsaw, Poland and well as the November 2015 Advance-HTA Final Conference in London, England.

Tailor-made to the needs of countries in the European Region, the workshop was an opportunity to build HTA capacity, outline the options available for decision-makers and debate the actions required. Various topics were discussed, including Multiple Criteria Decision Analysis, HTA in the orphan drugs context, HTA and medical devices and potential collaboration in this area. The workshop was attended by participants from various European countries (Bulgaria, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Republic of Moldova, Poland, Russia, Ukraine, United Kingdom), mainly policy makers working in public institutions such as Ministries of Health, Health Insurance Funds, National Health Services and HTA Agencies.

Workshop on pharmacoeconomics for Russian speaking countries (Chisinau, Republic of Moldova)

A workshop with I.M. Sechenov First Moscow State Medical University, and with support from WHO/Europe, was held in Chisinau to provide countries with the updates on current requirements for pharmacoeconomics studies. The aim of the workshop was to increase participants' understanding in the basics of applied health economics and to facilitate application of health economics into practice at national level.

Participants included representatives from drug agencies, Ministries of Health, health insurance funds and academia from the Republic of Moldova and Ukraine. The theoretical part of the workshop was supported by practical exercises where participants were able to implement pharmacoeconomics modelling as a tool for decision making and explore the basic principles of Health Technology Assessment.

Workshop on how to organize/structure Horizon Scanning and Health Technology Assessment activities (Verona, Italy)

A workshop was conducted for the Russian Federation in collaboration with the Pharmaceutical Department of the Veneto Region Local Health Authority, Italy on practical implementation of horizon scanning and HTA activities in decision making. Several Italian regional health agencies shared their experiences on the structures and processes of their work linked to introducing new medicines and medical devices into health care services. The workshop was useful linked to current plans for establishment of national and regional HTA agencies in the Russian Federation.

Pricing and Reimbursement

WHO supports countries in developing and implementing strategies to contain costs and optimize the use of medical products. In the countries in transition, this means helping them set up and support regulation, Health Technology Assessment, pricing and reimbursement systems, as well as other relevant supply related matters.

WHO collaborates with European Union (EU) initiated networks and projects, including mapping out national medicine reimbursement policies in the EU countries (Pharmaceutical Pricing and Reimbursement Information⁴) and enhancing the exchange of information and experiences on medicine pricing and reimbursement.

WHO also supports the authorities in the transition countries in building capacity for evaluating medicines to include in their essential medicines list and reimbursement system.

Country decisions on procurement, pricing and reimbursement must be informed by accurate and up-to-date information on prices to ensure value for money. WHO/Europe supports countries in gaining access to price information from other countries, as well as in monitoring prices within their own markets. Several of the transition countries have started applying the standard WHO methodology for measuring and monitoring drug prices. This includes ATC/DDD and the WHO/Health Action International (HAI) tool⁵ for measuring prices and availability of medicines.

4 <http://whocc.goeg.at/Networks/Organisation>

5 <http://haiweb.org/what-we-do/price-availability-affordability/price-availability-data/>





Pharmaceutical Pricing and Reimbursement information (PPRI) network meeting (Prague, Czech Republic)

Pharmaceutical Pricing and Reimbursement information (PPRI), is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network consists of more than 60 members, mainly competent authorities and third party payers from more than 40 countries. The PPRI network includes representatives from all 28 EU Member States plus the following countries from the WHO European Region: Albania, Armenia, Belarus, Iceland, Israel, Kazakhstan, Kyrgyzstan, the Former Yugoslav Republic of Macedonia, Norway, Russian Federation, Serbia, Switzerland, Turkey and Ukraine. Additionally, European and international institutions (European Medicines Agency, the Organisation for Economic Co-operation and Development (OECD), World Bank) have been involved in the PPRI project. During this meeting, WHO/Europe had the opportunity to present the report on high price medicines. Issues related to horizon scanning and external price referencing were also discussed, based on countries experience (United Kingdom, Norway, etc.).



Access to new medicines consultation (Copenhagen, Denmark)

A country consultation on access to new medicines in Europe was held 8 September 2015 at the WHO/Europe offices in Copenhagen, Denmark gathering 74 participants from 25 countries, along with participants from WHO Headquarters. The purpose of the consultation was to share the WHO/Europe report on Access to New Medicines in Europe, and encourage policy dialogue between governments and experts on how WHO/Europe can facilitate country collaboration in the 2016-17 WHO HTP work programme.

Through a mix of presentations from different perspectives involving country representatives, the consultation covered the need for increasing awareness of senior decision-makers and key national stakeholders about medicines policy issues linked to high-priced medicines. This consultation provided opportunity to identify areas of prioritization linked to access to new medical products, and specifically how WHO can support this work. It was agreed that it would be important to have HTP facilitate collaboration between countries on horizon-scanning and strategic procurement, and it was suggested that the programme set up two working groups in 2016.





Pharmaceutical Pricing and Reimbursement (PPRI) conference and meeting of WHO collaborating centres (Vienna, Austria)

The international PPRI conference was held in October 2015 and gathered more than 300 persons. It was an important networking opportunity for experts and stakeholders involved, or with an interest, in the pricing and reimbursement of pharmaceuticals. HTP was part of the organizing committee and the programme reflected key issues and current challenges around pricing and reimbursement across the world. Representatives from most European countries took part, along with a number from Asia and Africa. Future additional collaboration on medicines prices was discussed informally with various potential partners, including the OECD, LSE Health and European Brands Association (AIM).



A meeting of representatives from WHO, eight WHO collaborating centres (WHO CCs) working in the field of pharmaceutical policies, and four research institutes in this area was held at the Austrian Public Health Institute after the conference. The meeting aimed to promote an exchange of information and knowledge between the WHO CCs about their activities and opportunities for cooperation, as well as between WHO and the WHO CCs. The meeting discussed future projects and collaboration, and it shed light on the fact that WHO/Europe needs to maintain its collaboration with WHO CCs in a flexi-team approach also linked to country work in the Region.

European Health Forum Gastein 2015 (Gastein, Austria)

Over the past decade the European Health Forum Gastein has developed into an important institution in the scope of European health policy. It has had a critical role in all the cross-border exchange of experience, information and cooperation. About 600 leading experts participated in the annual conference held in the Gastein Valley in Austria in October 2015.

HTP organized a session around the complexity of the challenges in improving access to new medicines in Europe, with a particular focus on new cancer medicines. The session did not aim to propose solutions but rather discussed a number of options, including: Greater use of public/private partnerships in the development of new medicines, greater use of horizon scanning to facilitate planning for introduction of new medicines, more focus on value based pricing, more monitoring of the appropriate use of medicines in practice following marketing and after reimbursement decisions. Practice variability was suggested to be a significant contributor to health system inefficiencies.



Country specific support

Estonia

A study on availability of medicines in Estonia was carried out. The relatively limited selection of available medicines in Estonia – in terms of different formulations and number of generics on the market in comparison with other European Union (EU) countries – was highlighted both in the draft medicine policy and by the National Audit Office (NAO) in its 2012. In response, the former government coalition (April 2014 to March 2015) asked the Ministry of Social Affairs (MoSA) to develop a proposal to improve the situation. The study collected and analyzed evidence to inform such a proposal. It also 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 examined local practices relating to pricing, reimbursement and procurement. The study findings and recommendations will be discussed in a policy dialogue meeting with the Ministry of Health in early 2016.

Turkmenistan

In the context of WHO support to strengthen the health system in Turkmenistan, the HTP programme has been involved in providing specialized advice related to the pharmaceutical sector since 2014.

- Consultations with the Ministry of Health and Medical Production (MoH&MP) have identified a number of areas where national policies and practices required

strengthening, most notably relating to access and appropriate use of medicines related to non-communicable diseases (NCD) and the prudent use of antibiotics. The establishment of the Working Group for the Development of the National Strategy on Combating Antimicrobial Resistance has led a draft consensus document, which has now been submitted for approval.

- In close collaboration with local partners, law-makers and the Parliament (Medjlis), HTP provided assistance in developing the national law on pharmaceuticals, which has now been authorized by the President. The Turkmenistan Law on Pharmaceuticals Provision includes compliance to WHO Good Practice Standards and use of the Anatomic Therapeutic Classification/Daily Defined Doses (ACT/DDD) methodology; a clause prohibiting the sale of antimicrobials and other medicines labeled as “prescription only” without prescription; a ban on the commercial advertisement of antimicrobials; and a requirement to use clinical standards (protocols) for prescriptions in general practice in line with the National Medicines Formulary.

Baltic policy Dialogue

As most other Central European Member States of the European Union, the Baltic states are spending a relatively larger share of their health budgets on pharmaceuticals (between 24 and 32%). With the introduction of new expensive medicines the pressure on governments is increasing to ensure access to these new innovative products while keeping control over public pharmaceutical expenditure. High price levels are not sufficiently reflecting national income or the therapeutic value of the

products. As countries are still recovering from the recent economic recession, cost containment remains a prime objective for their health systems. Drug pricing and reimbursement policies are important levers for guaranteeing the timely availability of valuable new medicines to the population. However they need to be embedded within broader strategies that also review the status of older products and improve rational use of medicines. Although the specific design of pharmaceutical policies differs from country to country, there is a great deal to learn and share about what combination of mechanisms and strategies is more or less effective than others. Additionally, through increased cooperation and transparency countries may strengthen their position as purchasers. HTP coordinated the organization of this 12th edition of the Baltic policy dialogue series, hosted by the Latvian Ministry of Health, focused on ways to strengthen national medicines policies and to foster collaboration among the Baltic countries. In particular the meeting covered:

- An analysis of the challenges the Baltic states currently face with respect to ensuring access to medicines, especially in the context of new expensive drugs entering the market;
- Review of the potential and limitations of pricing and reimbursement policies applied in the Baltics and elsewhere in the EU;
- Exploration of alternative options and policies that can help to achieve policy objectives, including strategies for improving responsible use of medicines; and
- Discussion of the options for closer collaboration between countries in the procurement of high price medicines.





The 2010 Baltic policy dialogue addressed options and strategies for ensuring access to medicines in the context of the economic crisis in Europe. The 2015 meeting was an occasion to see how the recent policies have influenced and shaped access to and use of medicines in the Baltic States. Meeting recommendations are followed up through collaboration in 2016-17.

Ukrainian policy dialogue

Ukraine is undergoing a major pharmaceutical sector reform moving towards increasing access to essential quality medicines and reducing out of pocket payments. This process includes a large number of changes to the legislation and regulation as well as improved enforcement. Furthermore, sustainable financing for the pharmaceutical reform is required. HTP has provided support to the reform process for several years including assistance to up-date legislation and regulation; advise on the selection of medicines; support in the development of a pricing and reimbursement model; and analysis of the procurement and supply management system. An overall pharmaceutical policy framework is being developed and several consultations with the Ministry of Health and stakeholders have been held.

In November 2015 a policy dialogue was undertaken, aimed at taking stock of current key policy developments in Ukraine and considering potential adjustments, as well as facilitating knowledge transfer and sharing of relevance experience from across Europe. The aim was to assist in bringing evidence to practice and further support ongoing step-wise reform in Ukraine. A series of meetings

with individual partners and stakeholders was held over three days, and was concluded by a joint meeting with all stakeholders to exchange views on next steps in the pharmaceutical policy reform.

Romania

The Ministry of Health (MoH) of Romania requested WHO technical support for pharmaceutical pricing policies. One of the priorities of the National Health Strategy 2014-2020 'Health for Prosperity' is related to the development of a National Pharmaceutical (Drug) Policy. One of the components is pricing policy, and the MoH has primary responsibility. HTP undertook a mission in April 2015, the aim of which was to discuss the pricing policy with a number of key stakeholders and experts nominated by the MoH and to make some recommendations for measures or policy changes.

Azerbaijan

At the request of the Azeri Ministry of Health, the HTP programme carried out a rapid assessment of the new pricing mechanism for medicines in Azerbaijan, and undertook initial consultations during a short mission from 5 to 10 October 2015. This mission provided feedback to the country stakeholders on areas related to over-the-counter (OTC) medicines pricing policies, and consolidation of the drug consumption monitoring system.



Medicines regulation and quality

WHO plays a vital role in the regulation of medical products. At global level, WHO works to develop internationally recognized norms, standards and guidelines for medicine quality, safety and efficacy. At country level, WHO provides guidance, technical assistance and training to enable countries to implement these guidelines in the context of their own specific regulatory environment and needs. At regional level, WHO supports countries in building effective medicines regulation systems that promote and protect public health by ensuring certain standards:

- Medicines are of the required quality, safety and efficacy.
- Medicines are appropriately manufactured, stored, distributed and dispensed.
- Illegal manufacturing and trade are detected and adequately sanctioned.
- Health professionals and patients have the necessary information to enable them to use medicines responsibly.
- Promotion and advertising are fair, balanced and aimed at responsible drug use.
- Unjustified regulatory work does not hinder access to medicines.

As a focal point for the United Nations Prequalification Programme, WHO also provides specific technical assistance and training to manufacturers and regulators in the WHO European Region to help them achieve internationally recognized quality standards. The intention is to give a better understanding of what is required and why, particularly for medicines for HIV/AIDS, tuberculosis and malaria, reproductive health products and neglected diseases. Since quality systems are built by manufacturers and assessed by national authorities, the quality of medicines and the capacities of both to safeguard patient safety should be developed equally.

Prequalification Programme: A United Nations Programme managed by WHO

In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme (PQP) aims to make quality priority medicines available for the benefit of those in need. This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of quality medicines.

The WHO Regional Office for Europe, through the HTP programme, continues to provide support to the programme. Out of 35 products prequalified by WHO in 2015, 10 products produced by European manufacturers (in Germany, Italy, Slovakia, Finland, Belgium) were prequalified. Technical assistance and advice was provided to a number of manufacturers preparing their dossiers for the submission to the PQP.

Two quality control laboratories were re-qualified in 2015, one received initial inspection and one was re-inspected to prove their consistence of good quality practices.



Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostic products, vaccines, finished pharmaceutical products, active pharmaceutical ingredients and contraceptive devices (Copenhagen, Denmark)

This UN meeting, held on 23–26 November 2015 at UN City Copenhagen, provided a forum at which manufacturers, quality, safety and efficacy experts, procurement agencies, and international donors working in public health, came together to discuss issues around the production and supply of quality in vitro diagnostics, essential medicines, vaccines and contraceptive devices needed for vulnerable populations.

Plenary sessions of the meeting covered product priorities for HIV/AIDS, TB, malaria, reproductive health and maternal/neonatal/child health, market demand for priority in vitro diagnostics, medicines, vaccines and contraceptive devices. The meeting agenda was focused on providing participants with technical updates on WHO's prequalification of diagnostics, finished pharmaceutical products, active pharmaceutical ingredients and vaccines, and WHO/UNFPA's prequalification of contraceptive devices. Regarding contraceptive devices, sessions addressed the different products i.e. male condoms, female condoms and Copper T 380A intrauterine devices, and included updates on ISO standards and specifications. Data integrity – a topic that was of great interest to manufacturers – was looked at from the point of view of a manufacturer, a regulator and the WHO prequalification team.

The session on product evaluation for urgently-needed products introduced the emergency evaluation mechanism developed by WHO as a result of the recent Ebola outbreak in West Africa. The session on processes for accelerating regulatory approval included updates on the Expert Review Panel for Diagnostics – successfully piloted in 2014 – and on WHO's procedure for collaborative registration, which is helping to get products to patients more quickly, as well as saving the resources of manufacturers and regulators alike.

Manufacturers looking for the detailed information regarding the procurement requirements and procedures of UNFPA and/or UNICEF and or the Global Drug Facility (GDF), had meetings with members of the procurement teams of these agencies.

The meeting was attended by more than 400 representatives from all WHO regions, with web streaming of all plenary sessions available to those unable to attend.

Throughout the meeting, the WHO Prequalification Team was available to meet with representatives of more than 65 individual manufacturers. Manufacturers were able to raise questions relating to current or proposed applications for WHO prequalification, and to seek further information regarding prequalification requirements.

Presentations from the annual consultation of UNFPA/UNICEF/WHO medical product manufacturer focusing on prequalification can be found here: http://apps.who.int/prequal/trainingresources/Meeting_Manufacturers2015.htm

Country specific support

First intercountry technical workshop on the Good Distribution Practices (GDP) of medical products in the WHO European region (Copenhagen, Denmark)

On 27-29 January 2015 the HTP programme organized a Good Distribution Practice (GDP) workshop in collaboration with the Danish Health and Medicines Authority and the WHO collaborating centre for drug policy and pharmacy practice development (Pharmakon).

GDP is a fundamental component in ensuring access to quality, safe and effective medical products and globalization of supply chains brings a number of challenges to the pharmaceutical manufacturing and distribution industries and the National Medicines Regulatory Authorities regulating them. Ensuring that no weak links exist in the supply chain is critical in protecting patients from unsafe medical products. The risks posed by substandard, falsified, stolen and diverted medical products are well documented. Non-compliance with GDP by just one distributor can lead to a disproportionately large negative impact on public health, including a loss of public confidence in our health systems, health products and healthcare professionals. A well regulated supply chain is the best way of minimizing the risks from these types of products.

The European Union updated the GDP guidelines in 2013, recognizing the need to regulate the distribution channels in a proportionate, consistent and risk based manner. The goal of the workshop was to enhance understanding and compliance to GDP of medical products in the WHO





European Region. This was undertaken through sharing of practical experiences on GDP guideline implementation, and the process for risk based inspection of the supply chain. The event was attended by GDP inspectors and lawyers from Albania, Bulgaria, Estonia, Romania and Turkey. Sessions included quality management, personnel, premises and equipment, documentation, operations, complaints, returns, suspected falsified medical products, recalls, outsourced activities, self-inspection, quality risk management and transportation.

Training workshop Regulation of medicines – introduction into good practices (Dushanbe, Tajikistan)

31 August-04 September 2015 the HTP programme organized a workshop on the regulation of medicines and introduction into good practices for the National Medicines Regulatory Authority in Tajikistan, along with representatives of pharmaceutical manufacturers and distributors. The workshop was attended by 30 experts from Tajikistan.

Participants were introduced into: The main principles of medicines regulation, including marketing authorization, licensing of manufacturers, distributors and their inspection; the main principles of good manufacturing and distribution practices; and requirements to the national pharmaceutical inspectorate and inspectors. Using a WHO Prequalification of Medicines Programme as a model for a regulatory agency, participants learned about the role and place of inspection within the national regulatory framework. The importance of the development, implementation and maintenance of the



quality management system was presented, along with the inspection methodology, planning, classification of observations and their categorization, activities related to the substandard, spurious, falsely labeled, falsified and counterfeit medicines.

Capacity building within the assessment of medicines regulatory functions in Russian Federation (Moscow, Russian Federation)

A WHO sensitization workshop on a Quality Management System for National Medicines Regulatory Authorities was conducted from 29 June to 01 July 2015 in Moscow at the Federal State Institution State Institute of Drugs and Good Practices. It was organized within the framework of WHO support to strengthen the regulatory system in the Russian Federation in accordance with the agreed plan of action.

The workshop focused on the establishing, implementing and maintenance of a quality management system in national medicines regulatory authorities, based on the ISO 9001:2008 norm and its newer version ISO 9001:2015. In total, 26 experts participated in the workshop: 4 from the Ministry of Health, 9 from the Federal Service for Surveillance in Healthcare (Roszdravnadzor), and 13 from the Ministry of Industry and Trade.

Additionally a sensitization workshop on Good Manufacturing Practices for the representatives of National Medicines Regulatory System of the Russian Federation was conducted 15 – 16 December 2015 at Roszdravnadzor, with participation of the Ministries of Health and Industry and Trade.

Interactive presentations were focused on WHO's constitutional role in setting international norms and standards with respect to food, biological, pharmaceutical and similar products and support in their implementation. Participants learned about the main principles of GMP their role in ensuring quality medical products, and the need for their consistent implementation. Challenges in the implementation of GMP in the national context – general and specific – were raised, and instruction on drafting an institutional development plan to strengthen medicinal products' regulation in Russian Federation was provided.

Additional information was presented on the WHO PQP, its structure and the role of inspection in the process, as well as findings and follow-up activities.

Participation in introduction of Good Distribution Practices (Yerevan, Armenia)

A project on implementation of Good Distribution Practices (GDP) was conducted by WHO Country office in Armenia with the support of the HTP programme. It included assessment of the current distribution chain and its function, audit of a number of distributors by external WHO consultant, and a consensus building workshop to consolidate all data generated during the project in order to present it to the public. All presentations during the workshop were followed by discussion with participants, leading to the acceptance of the GDP implementation in Armenia.

Responsible use of medicines



It is estimated that up to 50% of medicines are not taken as intended which raises awareness of the immense cost to patients' health, as well as to the health economy from suboptimal medicines adherence. There is a clear relationship between medication adherence and improved outcomes, and if adherence was improved better results could be achieved along with savings made. Increasing adherence is crucial for the future sustainability of European health systems, and pharmaceutical services can support this. Innovative interventions can help clinicians and patients get the best from medicines, and prescribing-related consultations and pharmaceutical services can make a significant contribution. The use of innovative and effective strategies include therapeutic committees, electronic formularies and clinical guidelines, feedback of data on medicine use, medicine information policies and evaluation of health outcomes. There are many good experiences in Europe which could be expanded to cover countries where appropriate use efforts need strengthening. This area of work continues to be a priority in the HTP programme.

Utrecht study tour on rational use of medicines (Utrecht, Netherlands)

From 8 to 12 June 2015 a WHO study tour on rational use of medicines took place in Utrecht, Netherlands. Representatives of 11 European countries (Azerbaijan, Kosovo, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Republika Srpska, Serbia, Tajikistan, Ukraine and Uzbekistan) attended this meeting hosted by the Dutch Institute for Health Services Research (NIVEL).

During the week a number of critical issues regarding the pharmaceutical sector were tackled, such as the implementation of prescription guidelines, the role of the pharmacist in pharmaceutical policies, the problem of falsified medicines and questions related to pricing mechanisms.

This meeting was also a great opportunity for countries to share and discuss the main challenges they are facing today in their respective pharmaceutical policies.



Antimicrobial resistance

Antimicrobial resistance (AMR) is recognized as one of the major health threats of our time. Addressing this complex public health problem requires action in all relevant sectors, including human health, veterinary health, agriculture, environment and education to preserve the effectiveness of antibiotics by discouraging their misuse and overuse, and by gathering data to track resistance and usage patterns. If we lack the ability to prevent or treat infections, we stand to lose all the progress we have made in modern medicine over the past 70 years. Although the development of resistance to treatment by pathogens is a natural phenomenon, the misuse and overuse of antimicrobials has greatly accelerated the rate at which it occurs and spreads around the world.

AMR is not a problem of any individual country and the successful control of AMR requires that all countries are involved. A common

understanding of the issues related to AMR is required, and every stakeholder needs to recognize their role and responsibility.

To facilitate this, the WHO Regional Office for Europe organized a multi country workshop on AMR held on 24–27 February 2015 at UN City in Copenhagen, Denmark. The set-up of the workshop reflected some of the complexity of AMR by bringing together colleagues from different countries, disciplines and sectors. This provided a unique opportunity for interaction between counterparts from different countries and between national colleagues who need to coordinate their activities to control AMR in a comprehensive manner. The workshop was attended by individuals from national AMR surveillance networks and medicines consumption focal points, microbiologists and clinicians from almost 20 countries in the Region. Seven countries sent additional colleagues who had received a grant to set up AMR awareness campaigns to share their experience.



Antimicrobial Medicines Consumption (AMC) Network

In the framework of the multicountry AMR event, February 2015, mentioned above, the HTP programme and the University of Copenhagen conducted an antimicrobial medicines use workshop. Delegations from 17 Member States participated. The aim was to provide capacity building in countries and covered important topics including:

- Research methodology for qualitative analysis of the use of antimicrobial medicine;
- Drug statistics methodology;
- Review of antimicrobial medicines consumption data from participating countries.

During the workshop, the HTP programme and representatives from the University of Copenhagen discussed a research proposal for investigating knowledge about, and behaviors and attitudes towards antibiotic use in a number of Eastern European countries that are part of the WHO/Europe AMC Network. This research will be carried out in 2015/2016 by the University of Copenhagen and will be an important element for countries in their development of policies and tools for prudent use of antibiotics. The work is part of the larger agenda linked to supporting countries with development of systems to facilitate appropriate use of medicines.

The 5th WHO/Europe AMC Network meeting, which also took place in February, discussed antimicrobial medicines consumption data from participating countries of the WHO/Europe AMC Network to identify trends and plan the next phase of collaboration.





Annual course in ATC/DDD methodology

The ATC/DDD methodology course was an opportunity to help strengthen national registries provided by the WHO Collaborating Centre on drug statistics methodology at the Norwegian Public Health Institute in Oslo.

The 2015 annual course in ATC/DDD Methodology was held 11-12 June at the WHO Collaborating Centre for Drug Statistics Methodology in Oslo. The course provided an introduction to the Anatomical Therapeutic Chemical (ATC) classification system and the technical unit of measurement, the Defined Daily Dose (DDD). Applications of the ATC/DDD methodology were also presented and discussed. The lectures covered the following topics:

- Background, overview and development of the ATC/DDD methodology
- The main principles for establishing new ATC codes and assigning DDIs
- Procedures for applications (ATC codes, DDIs and changes)

The second day focused on the application of the ATC/DDD methodology in drug consumption statistics, along with practical examples. The course will continue to be conducted in Oslo in June every year and is instrumental in facilitating country monitoring of drug utilization to support pharmaceutical policy implementation.

Training in qualitative research methodologies to investigate use of antimicrobial medicines

Workshops on qualitative research methodology took place in the Republic of Moldova, Serbia and Turkey to strengthen capacity in undertaking qualitative research in use of antimicrobial medicines. These workshops were conducted by Copenhagen University.



Estonia – appraisal of the national clinical guideline development process




Well-developed and high-quality guidelines provide the basis for promoting quality of care in a health system. If the guidelines are based on evidence, are accepted by local health professionals, and linked with performance indicators and implementation strategies, they can lead to improved quality of care and health outcomes. In fact, there is no viable alternative to evidence-based development of tools like guidelines that support decisions at a clinical, population or system level.

In August an appraisal of the Estonian national clinical guideline development process was conducted. The aim of the appraisal was to review the progress made with clinical guideline development in relation to the process, the outcomes, and gain an understanding of potential or actual impact on improvements in quality of care and the health care system as a whole.

In 2010, Estonia started revising its national clinical guideline development process as part of an overall programme of quality improvement in health care. WHO, the Estonian Health Insurance Fund (EHIF), the Medical Faculty at the University of Tartu, and selected national and international experts carried out a comprehensive assessment of guideline development in Estonia in an effort to streamline and harmonize the principles and processes of guideline development. As an outcome of a two-year preparation process, the Estonian handbook for guidelines development⁶ was developed. The handbook aimed to bring together the experience and internationally accepted methods for developing guidelines covering all aspects of guideline development, including a consistent approach.

The EHIF, with support from partners including WHO, has invested in the development of a clinical guideline development process since 2011 that has resulted in:

- Five completed high-quality clinical guidelines of international standard, and 10 in progress, which were developed with reference to the Estonian handbook for guideline development and with local ownership by health professionals participating in guideline panels and guideline development.
- Completion of patient guidelines on six topics.
- Over 200 health professionals in Estonia trained in evidence-based guideline development.
- Developments linking the new guidelines with effective and appropriate quality standards.
- Progress in transforming health professional workforce capabilities to practice evidence-based medicine using best practice internationally.
- Effective links between the Ministry of Social Affairs, the EHIF and academic institutions such as the University of Tartu and the National Institute for Health Development in Estonia.
- Changes to the reimbursement of some items and services funded by the EHIF to promote better quality of care.
- An operational framework to improve the quality of care delivered in Estonia, particularly by family medicine practitioners.

This is a model for many other countries aiming to develop similar programmes. Provided the guideline process is maintained and the linkage to quality improvement (especially clinical indicators and audit processes) and reimbursement continues to strengthen, we expect that over the next few years, there will be evidence of the cost-effectiveness of the guidelines, as well as data supporting the improvement in quality of care. In addition to the EHIF that has led this process, these developments are a tribute to the leaders driving the process, the staff involved, and the health professionals and societies who have participated and continue to do so. 

⁶ See: <http://www.euro.who.int/en/countries/estonia/news/news/2011/10/estonian-handbook-for-guidelines-development-launched>

Region-wide celebration of European Antibiotic Awareness Day

Antibiotic resistance affects the entire WHO European Region, driven by the overuse, underuse and misuse of antibiotics. Since 2008, the European Centre for Disease Prevention and Control (ECDC) and Member States in the European Region have celebrated European Antibiotic Awareness Day (EAAD) to raise awareness of this issue and emphasize every person's shared responsibility to help prevent it. In 2015 the Awareness Day became a global event.



National action plan for rational use of medicines in Montenegro



With support and technical assistance from the HTP programme, the government of Montenegro adopted the National Plan on Rational Use of Medicines. WHO provided technical assistance in the development of a detailed analysis of medicines consumption by ATC groups to indicate consumption trends in Montenegro, to then enable policy action follow up. In addition draft regulation was developed along capacity building.

According to the current legislation in Montenegro, Master Plan of Health Sector Development, National Plan for Rational Use of Medicines, and recently adopted MoH guidance for health care providers on conducting a regular analysis of medicines consumption, improvement in rational pharmacotherapy has been recognized as a priority task and prerequisite for improving population health, health care quality assurance and cost containment in the health sector.

Additionally, the Law on Medicines (Official Gazette of Montenegro No 56/11) bestowed authority on the Drugs Agency to collect and process data on distribution and consumption of medicines. The data are processed in accordance with the WHO recommendations and consumption monitoring methodology by ATC/DDD system.

As a result of the up to date health sector reform efforts in Montenegro an integrated health information system has been introduced at the PHC and hospital level, including/linking also Ministry of Health, Drug Agency, Health insurance fund, Institute of public health and Public Drugs Wholesaler with its network of public pharmacies. At this point in time the information system supports the exchange of data on medicines (procurement, supply, distribution between the different health care providers, consumption).

So far the Drug Agency was able to process data obtained only from the wholesalers. Health care workers do not report back on the medicines consumption and policy makers do not have complete data to use for policy making purposes.

As clearly recognized by the health policy makers further improvement in terms of making concerted efforts aimed at raising level of awareness and knowledge among health workers on irrational use of medicines and its complex far reaching implications is required.


To address the challenge the Ministry of Health has inter alia recently requested all health care providers to appoint focal points for rational use of medicines and focal points for pharmacovigilance.

Having reviewed the up-to-date practice and key challenges for rational use of medicines it proved that education of health workers at the primary health care and hospital level with its various approaches, has an important role to play in promoting the rational use of medicines. Continuous training is required, combined with monitoring, feedback and reinforcement.

Therefore, it is necessary to provide technical assistance to increase and sustain professional awareness, interest, refresh knowledge of rational use of medicines. In particular, it is very important that social and cultural factors that influence medication and prescribing behaviour are taken into consideration.

Support was provided in organizing two rounds of training:

- For designated focal points (for rational use and pharmacovigilance) across primary health care (PHC) and hospital level
- For all doctors at the PHC centers and hospitals

The purpose of this training was to ensure establishment of an institutional arrangement of focal points network that would be competent enough to monitor and report back on a regular basis on the medicines consumption in the respective health facilities using the WHO methodology and to raise level of awareness and knowledge among health workers on irrational use of medicines and its complex far reaching implications. 

Country specific support

AMR missions to countries

In the framework of strategic action plan on antibiotic resistance 2011, the WHO Regional Office for Europe and partners conducted a several missions in countries to increase the knowledge and awareness of different health care workers to address this public health threat. The following countries were visited: Turkmenistan, Tajikistan, Republic of Moldova, Kazakhstan, Armenia, and Ukraine. The objective of these missions were to gain understanding of the status of national and intersectoral coordination to implement actions to counteract AMR; assess the status of national AMR surveillance; and discuss technical requirements for joining an international network for AMR surveillance, and antibiotic susceptibility testing. As a result of the mission it is expected that all the involved stakeholders gain a better understanding of the roles and responsibilities of a national coordinating mechanism on AMR. The HTP unit has been involved in each of these missions preparation and reporting.



Seminar on rational use of medicines in Bulgaria

At the request of the Bulgarian Ministry of Health and in collaboration with the national medicines agency a seminar on responsible use of medicine in Bulgaria was organised by HTP and took place 17 September 2015 in Sofia with around 100 participants from the health and pharmaceutical sector. This one day seminar gathered stakeholders including physicians, hospital managers, hospital pharmacists on how to foster responsible use of medicines with a focus on principles of rational use of medicines, Monitoring and Evaluation (M&E), use of biosimilars and as well as antimicrobial medicines. Recommendations for follow up at national level were developed linked to the current focus on medicines policy development in the country and development of a coherent framework of action to increase access to medicines in Bulgaria.

Tajikistan

A study protocol on rational use of medicines in Tajikistan was developed. The objective is to investigate prescribing patterns at central district primary health care centres and central district hospitals in Tajikistan, and to compare prescribing practices between regions, districts implementing the basic benefit package (BBP) vs. non-implementing districts vs. Gorno-Badakhshan Autonomous Region (GBAO) and urban vs. rural areas. The study also aims to collect additional patient care and facility indicators for primary health care. A pilot study in two districts was conducted in 2015 and the data collection was finalized toward the year end. The pilot covered one district of Dushanbe and one district of Khatlon. The report from the pilot study will be available in 2016.



Republic of Moldova develops national capacity and tools to enhance rational use of medicines



On 10-13 February 2015 the HTP programme and the WHO Country Office in the Republic of Moldova jointly hosted a two-day seminar to finalize guidelines for rational use of medicines and selecting medicines for the positive list. The seminar marked the final session of the first phase of a technical assistance programme aimed at improving access to medicines related to noncommunicable diseases. In addition to facilitating broader prescription drug access, the first phase of the programme seeks to further build the capacities of national stakeholders in the rational use of medicines as part of the European Union and WHO joint initiative to support health policy dialogue and universal health coverage.

The discussion portion of the seminar highlighted the preliminary results of the assessment of rational use of antihypertensive medicines in the Republic of Moldova; experience from the provider level in monitoring and improving the rational use of medicines; and experience and the role of regulatory and purchasing institutions in monitoring and improving the rational use of medicines.

The practical portion of the seminar focused on rational selection of medicines in the Republic of Moldova; evidence from other countries regarding criteria for rational selection; and finalization of the proposed guideline for rational selection of medicines.

The seminar, which included both discussion and workshops, specifically targeted members of the medicines selection committee. A total of

35 clinicians and academics from the committee collaborated to finalize and jointly agree upon guidelines for selecting medicines for the positive list. Prior to the discussion, background documentation was prepared and distributed in accordance with international best practices and earlier experiences from the Republic of Moldova. The participants provided feedback and proposals for the guidelines governing the selection of medicines, which were taken into account in the final version.

The package of proposals for the final guidelines for listing medicines was submitted to the Ministry of Health. The document is meant to encourage rational selection of medicines, both to the positive list and to the hospital procurement list.

The first phase of the technical assistance programme to improve access to medicines has been working to lay a strong foundation that will enable the Republic of Moldova to effectively implement rational use of medicines. Activities have included initial assessment, building an action plan and recommendations, and building capacities in rational use and promotion of medicines, pharmacoeconomics and cost-effectiveness. The second phase of support to be provided in 2016 will focus on developing further capacities in selected areas including budget impact analysis, pricing and good pharmaceutical practices, and rational use of medicines. It will also include follow ups on the implementation of recommendations and tools developed as part of the first phase. <<<

Publications

Report on Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research

This report, with a focus on sustainable access to new medicines, reviews policies that affect medicines throughout their lifecycle (from research and development to disinvestment), examining the current evidence base across Europe. While many European countries have not traditionally required active priority-setting for access to medicines, appraising new medicines using pharmacoeconomics is increasingly seen as critical in order to improve efficiency in spending while maintaining an appropriate balance between access and cost-effectiveness. The study features findings from 27 countries and explores different ways that health authorities in European countries are dealing with high spending on new medicines, including methods such as restrictive treatment guidelines, target levels for use of generics, and limitations on the use of particularly expensive drugs. It also outlines possible policy directions and choices that may help governments to reduce high prices when introducing new drugs. The report is also available in Russian.

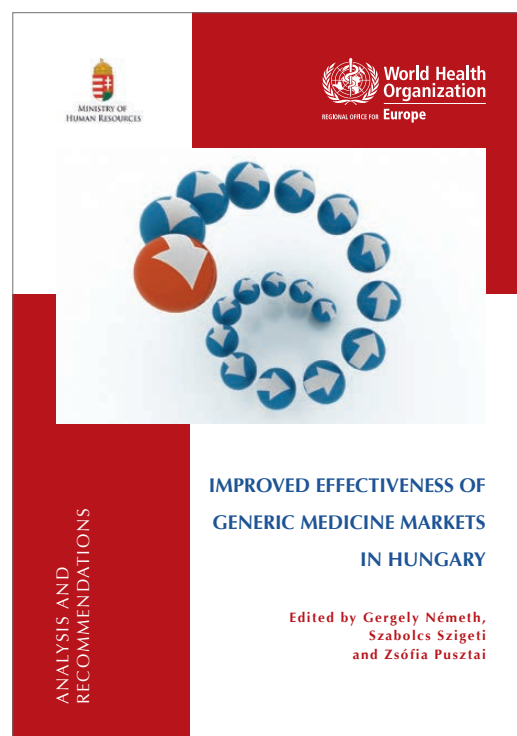


The report is available at:

<http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015>

Improved effectiveness of generic medicine markets in Hungary. Analysis and recommendations

This publication summarizes the findings of a series of technical reports by a number of key experts involved in assessing the effectiveness of pharmaceutical policy on generic essential medicines markets in the context of the Hungarian health system. Its primary objective is to provide an overview of the development of incentives to use generics in the Hungarian health system up to the end of 2011, focusing in particular on reference pricing system and assessing what impact these incentives have had in recent years. Within the framework of bilateral framework agreements, WHO provided technical advice in collaboration with local experts, and the report benefitted from involvement of several international consultants.



The report is available at:

http://www.euro.who.int/__data/assets/pdf_file/0011/278129/Improved-effectiveness-generic-medicines-Hungary-en.pdf?ua=1

Developing and implementing guidelines for health policy and clinical practice in Estonia: interim appraisal of progress

The Estonian Health Insurance Fund (EHIF), with support from partners including WHO, has invested in the development of a clinical guideline development process since 2011 that has resulted in:

- Five completed high-quality clinical guidelines, of international standard, and 10 in progress, which were developed with reference to the Estonian handbook for guideline development (3), and with local ownership by health professionals participating in guideline panels and guideline development.
- Completion of patient guidelines on six topics.
- Over 200 health professionals in Estonia trained in evidence-based guideline development.
- Developments linking the new guidelines with effective and appropriate quality standards.
- Progress in transforming health professional workforce capabilities to practice evidence-based medicine using best practice internationally.
- Effective links between the Ministry of Social Affairs, the EHIF and academic institutions such as the University of



Tartu and the National Institute for Health Development in Estonia.

- Changes to the reimbursement of some items and services funded by the EHIF to promote better quality of care.
- An operational framework to improve the quality of care delivered in Estonia, particularly by family medicine practitioners.



The report is available at:

<http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications>

New HTP website

In 2015, the HTP program decided to reshape its webpages. Previously two separate sites existed in parallel, one dedicated to pharmaceuticals and the other to health technologies. It has been decided to update and merge them.

All the information related to the unit's activities, publications and news can be accessed easily on these pages. The link to new web-site is <http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines>

The screenshot shows the WHO Europe website interface. At the top, there is the WHO logo and the text 'World Health Organization REGIONAL OFFICE FOR Europe'. To the right, there are language options: English, Français, Deutsch, and Русский. Below this is a search bar with a 'Search' button. A navigation menu includes 'Home', 'Health topics', 'Countries', 'Publications', 'Data and evidence', 'Media centre', and 'About us'. The main content area is titled 'Health technologies and medicines' and features a sidebar with a menu: News, Events, Health technologies, Medicines, Policy areas, Country work, Data and statistics, Publications, Partners, and Contact us. The main content includes a 'Health technologies and medicines' section with a brief description of WHO/Europe's support for countries in developing policies and guidance for responsible selection and use of medicines. Below this are three featured articles: 'Top story' about WHO/Europe partners with Austria and Belgium to address new, high-priced medicines in Europe; 'News' about a joint UNICEF-UNFPA-WHO meeting with pharmaceuticals and diagnostics manufacturers and suppliers; and 'Medicines' about WHO/Europe working with countries to help them ensure equitable access to affordable medicines. There are also sections for 'Health technologies' and 'Country work' with corresponding images.



The new website can be found at:

<http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines>

Calendar of activities

January

11–16 January 2015

Quality, efficacy and safety of medicines consultations, Geneva, Switzerland

19–21 January 2015

Fact finding mission on procurement of medicines, Kiev, Ukraine

20–23 January 2015

BCA implementation mission, Budapest, Hungary,

27–29 January 2015

GDP training, Denmark, Copenhagen

28–31 January 2015

AMC qualitative study workshop pilot, Ankara, Turkey

February

04–06 February 2015

PCNE working conference, Brussels, Belgium

09–14 February 2015

BCA implementation mission, Chisinau, Republic of Moldova

11–13 February 2015

Antimicrobial Resistance and Healthcare-associated Infections Programme (ARHAI), Stockholm, Sweden

16–18 February 2015

Coordination/integration of health services delivery (CIHSD), Istanbul, Turkey

18–20 February 2015

BCA implementation mission, Tallinn, Estonia

24–27 February 2015

AMR multicountry workshop, Copenhagen

25–27 February 2015

National regulatory system assessment, Moscow, Russian Federation

March

16–17 March 2015

Pharmacoeconomics conference, Ufa, Russian Federation

18–20 March 2015

Kyrgyz study tour on drug market development within the custom union, to Moscow, Russian Federation

18–20 March 2015

PPRI meeting, Prague, Czech Republic

20–22 March 2015

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (ALMBIH) Conference, Jahorina, Bosnia and Herzegovina

25–27 March 2015

Russian study on Horizon Scanning and Health Technology Assessment, Verona, Italy

30 March–01 April 2015

MEDEV and Piperska meetings, Brussels

April

12–16 April 2015

AMR country assessment mission, Dushanbe, Tajikistan

20–23 April 2015

Policy dialogue, Bucharest, Romania

20–24 April 2015

Selection and use of essential medicines expert committee, Geneva, Switzerland

21–23 April 2015

AMC Qualitative training for CCEE Member States, Belgrade, Serbia

27–30 April 2015

Biosimilars and Medical Devices for Cancer Management consultations, Geneva, Switzerland

May

11–13 May 2015

Piperska meeting, Warsaw, Poland

19–23 May 2015

AMC qualitative training, Chisinau, Republic of Moldova

June

8–12 June 2015

Rational use of medicines study tour, Utrecht, the Netherlands

24 June 2015

OECD meeting on high price medicines, Paris, France

25 June–2 July 2015

Capacity building for NRA, Moscow, Russian Federation

26 June 2015

PPRI conference scientific committee meeting in Vienna, Austria

28–30 June 2015

Meeting on current problems of drugs quality assurance and health care in Russia, Sochi, Russian Federation

29 June–01 July 2015

WHO sensitization workshop on Quality Management System for National Medicines Regulatory Authorities in Russian Federation, Moscow, Russian Federation

July

13–18 July 2015

National Regulatory Agency (NRA) self-assessment mission, Moscow, Russian Federation

20–21 July 2015

TBC - EMP HQ meeting on high price medicines, strategy consultation in Geneva, Switzerland

August

19-23 August 2015

Technical assistance in procurement of medical products, Kiev, Ukraine

23-28 August 2015

Appraisal of clinical guideline development process, Tallinn, Estonia

31 August – 04 September 2015

WHO workshop Regulation of medicines – introduction into good practices, Dushanbe, Tajikistan

September

01-11 September 2015

Procurement of medicines mission, Kiev, Ukraine

07-11 September 2015

Multi country consultation GGM, New Medicines and AMC, Copenhagen, Denmark

14-18 September 2015

Pharmaceutical policy seminar for French speaking experts, Geneva, Switzerland

17 September 2015

Rational Use of Medicines Seminar, Sofia, Bulgaria

24-25 September 2015

Participation to the advance HTA capacity building workshop, Warsaw, Poland

30 September – 2 October 2015

High prices medicine - access and sustainability session, Gastein, Austria

October

2 October 2015

Access to HCV treatment in Europe 53, Sitges, Spain

5-10 October 2015

Pharmaceutical pricing policy mission, Baku, Azerbaijan

12-14 October 2015

PPRI conference and meeting with WHO Collaboration Center, Vienna, Austria

26 October 2015

Consultation with DOH and NORAD, Oslo, Norway

28-29 October 2015

Baltic policy dialogue on Ensuring access to new medicines in the Baltics, Riga, Latvia

30 September-3 October 2015

Eurasia Congress of infectious diseases, Tbilisi, Georgia

November

03-07 November 2015

Pharmacoeconomics course, Chisinau, Republic of Moldova

16-20 November 2015

Pharmaceutical Policy Dialogue Week, Kiev, Ukraine

17-18 November 2015

Advance HTA Conference London, United Kingdom

23-25 November 2015

Meeting with OECD Health and the European Council, Paris, France

23-26 November 2015

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostic products, vaccines, finished pharmaceutical products, active pharmaceutical ingredients and contraceptive devices, Copenhagen, Denmark

23-27 November 2015

AMR country assessment, Kiev, Ukraine

30 November 2015

GDP implementation advocacy workshop, Yerevan, Armenia

December

02 December 2015

Seminar at Karolinska Institute: Access to new medicines in Europe, Stockholm, Sweden

02-04 December 2015

Second WHO international consultation on regulatory systems strengthening, Geneva, Switzerland

07-08 December 2015

International conference on Evidence based medicine achievements and barriers, Kazan, Russia

14-16 December 2015

WHO sensitization workshop on Good Manufacturing Practices for the representatives of National Medicines Regulatory System of Russian Federation, Moscow, Russian Federation

17-18 December 2015

Implementation of Health System Transformation, Madrid, Spain

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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**Health Technology and
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Annual Report 2015

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: contact@euro.who.int
Website: <http://www.euro.who.int/en/health-topics/Health-systems/medicines>