World Health Organization
REGIONAL OFFICE FOR Europe

Health Technologies and Pharmaceuticals (HTP) Programme

DIVISION OF HEALTH SYSTEMS AND PUBLIC HEALTH

Annual Report 2014

DIVISION OF HEALTH SYSTEMS AND PUBLIC HEALTH

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At the heart of the Health Technology and Pharmaceuticals Programme (HTP) strategies is the goal of access to essential, quality health technologies including medicines and medical devices

Introduction

At the heart of the Health Technology and Pharmaceuticals Programme (HTP) strategies is the goal of access to essential, quality health technologies including medicines and medical devices - this is a fundamental part of every person's right to health. National health systems must ensure access and the appropriate and ethical use for individual and community well-being.

The current report summarizes the 2014 work of the HTP team of WHO Regional Office for Europe in supporting Member States and contributing to health in the WHO European Region in line with the Tallinn Charter and Health 2020.

Our work in and with countries in 2014 continued on the basis of best practices and considered the potential of both the eastern and the western parts of the region. Pharmaceutical policies are embedded in a framework with many stakeholders, a dynamic environment and variations across the region in terms of the political and social context to consider. Generally speaking, resources are always limited but related to pharmaceutical expenditure and given the resource constraints which many countries are facing, it is important to prioritize and obtain best value for money both in terms of public and individual health. Adjustments to pharmaceutical policies have been many but a major expression of commitment was reflected in the reviews of policy and strategies used in countries to increase and sustain access to new medicines in Europe. A WHO technical review of country policy initiatives and opportunities for collaboration and research brought together several WHO collaborating Centres in the region which contributed with their expertise. The report from this work will be published early in 2015 providing policy makers with an overview of policies which affect medicines throughout their lifecycle (from research and development to disinvestment), examining the current evidence base across Europe.

Support to countries in strengthening their systems for providing access to medicines is part of our engagement and assistance to countries in moving towards Universal Health Coverage (UHC). Transparency increases the understanding of the challenges health systems are facing in the medicines and health technology area. The aim of achieving value for money invites discussion and debate, and many European countries seek reform in their public pharmaceutical sector using transparency as the underlying principle in creating sustainable, healthy markets for medicines and other health technologies for the benefit of people and societies.

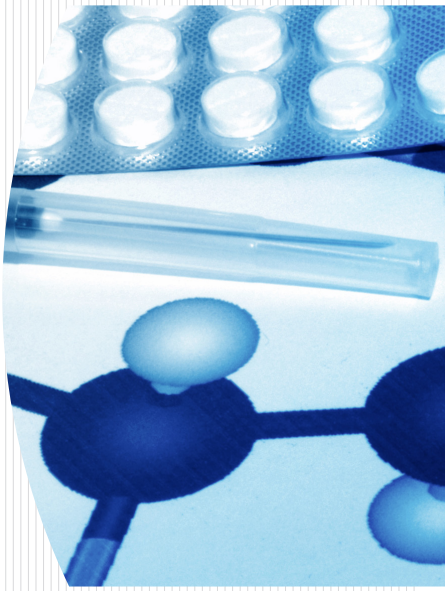
Appropriate use of medicines is another corner stone in HTP work and currently our focus is on two specific areas – medicines related to non-communicable diseases (NCD) and prudent use of antibiotics. Support is provided to countries on setting up medicines registers which allow monitoring the use of antimicrobial medicines. A number of antimicrobial medicines resistance (AMR) related activities have been carried out in 2014. 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 influencing the extent and appropriate 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 policies supported by reg-

ulations, evidence-based guidelines to promote optimal use of antimicrobials, and the engagement of civil society as well as health care professionals. Hence, AMR has called attention to the appropriate use of medicines, requiring urgent follow up and action in Member States. HTP spearheaded efforts in this work.

In terms of prevention and control of chronic NCDs, four specific health system assessment missions for better NCD outcomes were performed by WHO/Europe in 2014. Reports from these missions will be published in 2015 and feed into the NCD action plans being prepared by Member States. National and international funding for NCDs and management of medicines within health systems has been weak relative to the prevalent NCD burden and the cost of medicines in countries. Access to essential medicines and basic health technologies for NCDs is poor in many areas and WHO will assist Member States in their national efforts to tackle this problem. Ensuring the availability and accessibility to essential medicines for NCDs will strengthen health systems' ability to respond effectively to treatment and prevention of NCDs. The cost of inaction will be substantially more expensive than the current costs to implement a set of "best-buys" recommended by WHO to combat the four major NCDs (cardiovascular diseases, diabetes, chronic respiratory diseases and cancers). Strengthening primary health care by ensuring the availability of well-functioning public and private medicine supply chains can improve access to care and medicines to treat and prevent NCDs. The establishment of resilient health care systems to prevent and control chronic diseases requires mechanisms to ensure the access to affordable medicines and technologies for NCDs. This work continues and in 2014 several NIS countries started development of reimbursement lists to better cover relevant NCD related medicines.

Guidance in medical product regulation continues to be a crucial element of HTP's work. Convergence in regulation of medical products is desirable and HTP provides country specific support as well as support to the WHO Prequalification Programme where manufacturers from the European region can facilitate their regulatory affairs work through participation in the initiative. Several activities were carried out in 2014 to support regulatory work and facilitate regulatory networks.

Support to countries in strengthening their systems for providing access to medicines is part of our engagement and assistance to countries in moving towards Universal Health Coverage



Highlights of HTP Work with Countries

National Policies and Access to Medicines

Ensuring equitable access to and appropriate use of quality medicines and technology is a major challenge in the European region and an important concern for the people. Lack of pharmaceutical policies and inefficient use of medicines is one of the top sources of inefficiency in health systems. Pharmaceuticals are the main contributor to out-of-pocket health payments in the region, and consequently, to catastrophic and impoverishing medical expenditures in some settings. HTP worked both on bringing countries together to debate and discuss possible ways to progress as well as provided country specific support.

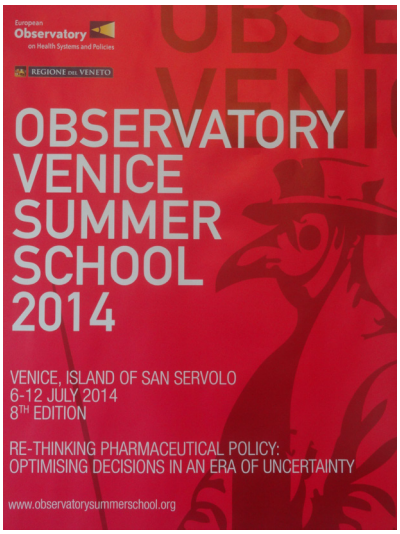
Observatory Venice Summer School: Re-thinking pharmaceutical policy: Optimizing decisions in an era of uncertainty, Venice, Italy July 2014

47 participants from across and beyond the European Region met for a week in Venice to become updated on developments in medicines policy and to rethink policy action at country level - as well as generate ideas for collaboration across countries on the future sustainability of pharmaceutical expenditure.

Organized by the European Observatory on Health Systems and Policies, the Veneto Region of Italy, the London School of Economics and Political Science (LSE) and WHO/Europe HTP, the 2014 Summer School mobilized a multidisciplinary team of experts with the insights of key international organizations including the European Commission and relevant professional and governmental organizations. The 6-day Observatory Venice Summer School 2014 entitled "Re-thinking pharmaceutical policy - Optimizing decisions in an era of uncertainty," combined formal teaching with a participative approach that included participant presentations, roundtables, panel discussions and group work. With increasing demand and several current highpriced medicines coming to the market, this was a very timely event giving participants tools and experience to facilitate appropriate use of medicines including balancing access and cost efficiency.

Pharmaceutical expenditure continues to be a key issue in most Member States of the Organisation for Economic Co-operation and Development (OECD) and emerging countries, presenting decision-makers with significant challenges about future sustainability.

The summer school provided a range of concrete options for policy related to the assessment of new healthcare technologies, the sharing of risks in novel therapies and the procurement of patent and off-patent drugs all of which can work together to optimize decisions on pharmaceutical policy.



Country specific support >

Linked to the signing of the Association Agreement with the EU and the recent as well as upcoming developments in Moldova's national intellectual property legislation, WHO/Europe, in collaboration with UNDP and the active support of WHO Headquarters, held a small scale national consultation on medicines policy and access to HIV treatments and other essential medicines in the context of current intellectual property protection. The national legislation on intellectual property facilitates the country's obligation to ensure access to affordable medicines for all, including people who live with HIV.

Observatory Venice Summer School

Appropriate 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 the patients' health, as well as to the health economy from suboptimal adherence to medicines. There is a clear relationship between medication adherence and improved outcomes. If adherence was improved, better results could be achieved along with savings made. Improving adherence is crucial for the future sustainability of the European health system. Pharmaceutical services can support patient adherence. Innovative interventions can support both clinicians and patients to get the best from medicines; 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, medication reviews, 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.

One of the multi-county activities include participation of HTP, WHO/Europe in the Piperska network of professionals sharing the common vision of enhancing the health of the public and the individual patient in a sustainable way through exchanging ideas and cooperation on the rational use of medicines and related therapies. In 2014 the Piperska network meeting took place in Vienna hosted by Hauptverband der Österreichischen Sozialversicherungstrage (HVSVT), Austria.

Participants discussed specific country experiences in introducing new high-cost medicines including, amongst others, for HCV, Type 2 diabetes and options for European cooperation in the rare diseases area along with possible initiatives to support appropriate use of medicines. The Piperska network generally meet once every year; the next meeting will take place in Brussels in March 2015.

Scientific meeting on drug utilization research, EuroDURG, August 2014

In August 2014, a scientific meeting on drug utilization research was organized by the European Drug Utilization Research Group (EuroDURG) in order to target research and policies on the adherence to medicines. Among topics discussed were drug utilization, research informing health policy, drug use and pharmacovigilance, cross-national and within population comparisons of drug utilization, validity of data sources and data linkage, and patient perspectives on rational drug use. HTP supported several countries in their analysis on antimicrobial medicines consumption as well as participation at this meeting during which countries presented their findings (see below). HTP also presented our cross country analysis and action taken at country level to address the antimicrobial medicines consumption findings. In collaboration with HTP and partners, Winnie de Bruijn, a Utrecht University pharmacy master student, presented a comparison of the utilization of boceprevir and telaprevir alongside the other treatments for HCV and health authority activities in Europe. This study provides a basic overview of consumption of HCV related medicines and will be useful when key stakeholders review utilisation of the next generation of Direct Acting Antivirals like sosfosbuvir.

Annual course in the Anatomic Therapeutic Classification (ATC)/Daily Defined Doses (DDD) methodology, Oslo, Norway, June 2014

The 2014 annual course in ATC/DDD Methodology was held at the WHO Collaborating Centre for Drug Statistics Methodology in Oslo. The course covered both the purpose and utiliza-

tion of the ATC/DDD Methodology and provided technical support to countries in building their medicines registries. This course provided a very useful basis for strengthening drug use monitoring and analysis and is key in refining country work in the area. Having reliable data and evidence on medicines use is instrumental for medicines policy action.

Satellite meeting on qualitative research linked to use of antibiotics: 5th Southeast European Conference on Chemotherapy and Infection, Bled, Slovenia, October 2014
The national drug regulatory agencies of Turkey, Montenegro, Kosovo, Serbia, Bosnia and Herzegovina; the Public Health Institute of the Former Yugoslav Republic of Macedonia, the Ministry of Health and the Medical University of Albania took part in a consultation on qualitative research on use of antibiotics. A research proposal including a semi-structured interview protocol was developed in collaboration with Copenhagen University (co-facilitator of the consultation). The study protocol will be used as a basis for investigation of knowledge, behaviors and attitudes of antibiotic use in Eastern Europe and Turkey. The meeting covered aspects related to the design, implementation and validation of qualitative studies, including ethical considerations, sampling, selection of participants, interview techniques, management of equipment and data, transcription, norms and validation tools. As an outcome of the workshop, the feasibility of qualitative research on antibiotics use in the participating countries was evaluated, resources required as well as project timeframe were identified and pilot countries selected. This research will be carried out in 2015 and will be an important element for countries in their development of policies and tools for prudent use of antibiotics. This work is part of the larger agenda linked to supporting countries with development of systems to facilitate appropriate 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 the patients' health

Antibiotic resistance affects the entire WHO European Region, driven by the overuse, underuse and misuse of antibiotics

Region-wide celebration of European Antibiotic Awareness Day, Stockholm, Sweden, 18 November 2014

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) on 18 November to raise awareness of this issue and emphasize every person's shared responsibility to help prevent it. For the past three years, WHO/Europe has joined in marking EAAD, with more countries taking part each year.

Experts from WHO/Europe and its partners answered questions on antibiotic resistance during a live Twitter chat on 18 November 2014. The chat was part of global activities also taking place across the WHO European Region, to emphasize the importance of the prudent use of antibiotics and to mark European Antibiotic Awareness Day (EAAD).

Pharmacists are among the best positioned to influence appropriate use of antibiotics, according to a 2014 survey in countries of the WHO European Region. As such, they have a crucial role in combating antimicrobial resistance, together with policy makers and practitioners. On this year's European Antibiotic Awareness Day, the World Health Organization advocated to improve prudent use of antibiotics through pharmaceutical services in Europe. Pharmacists are important allies to our fight against antibiotic resistance, as they often are the first point of contact for patients. They need to be enabled to deliver accurate information on proper antibiotic use. The report *Role of pharmacist in encouraging prudent use of antibiotic medicines and averting antimicrobial resistance*, developed by the HTP in collaboration with the Pharmaceutical Group of the European Union (PGEU), Europharm Forum, the WHO Collaborating Centre for Drug Development and Pharmacy Practice at Pharmakon was published and is available on the HTP web site in English and Russian. http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2014/the-role-of-pharmacist-in-encouraging-prudent-use-of-antibiotic-medicines-and-averting-antimicrobial-resistance-a-review-of-current-policies-and-experiences-in-europe

Country specific support >

Country conferences on the Access to Opioid Medication in Europe (ATOME) project in Vilnius, Lithuania; Bratislava, Slovakia and Warsaw, Poland, during 2014

WHO/Europe is involved in the ATOME project which aims to improve access to opioids across Europe. A consortium of academic institutions and public health organizations work together to help governments, particularly in Eastern Europe, identify and remove barriers that prevent people from accessing medicines that could improve end of life care, alleviate debilitating pain and treat heroin dependence. In this relation, three country conferences were carried out in 2014, for details see http://www.atome-project.eu/

Project to support costing of the positive list of medicines and promoting rational use of medicines, Chisinau, Moldova, July and November 2014

Non communicable diseases – chronic diseases (NCDs) are the main cause of morbidity and mortality in the Republic of Moldova and many other European Member States. Therefore access to NCD related medicines have high priority in both the Moldovan National Health Policy for 2007–2021 and the Health Care System Development Strategy for 2008–2017. The Ministry of Health, supported by HTP WHO/Europe, has launched a new project that builds on the evidence and experiences collected through previous studies and initiatives to improve access to medicines. This project looks specifically at the process, costing and steps followed in updating the positive list of medicines with a special focus on medicines that are used in NCD control. The rationale for collecting this information was to present recommendations for a possible action plan to the Ministry of Health of the Republic of Moldova to further improve availability and affordability of medicines for patients. The project would initially focus on the treatment of hypertension with the intent of later expanding to other NCD conditions. The ultimate objective of this activity is to improve morbidity and mortality rates of Moldovan citizens.

Furthermore, as part of the ongoing HTP WHO/Europe support to the Republic of Moldova on managing noncommunicable diseases, a training seminar on promoting appropriate use of medicines was held on 4–5 November 2014 in Chisinau. The lessons learnt will contribute to the development of guidelines for the selection of medicines on the reimbursement list for the Republic of Moldova.

The two-day seminar was attended by approximately 35 people representing the Ministry of Health, the National Health Insurance Company, the National Agency for Medicines and Medical Devices, the State Medical and Pharmaceutical University “Nicolae Testemitanu” and specialty commissions. The training focused on:

- the concept and basics of appropriate use of medicines
- tools for appropriate use of medicines
- pharmacovigilancephar

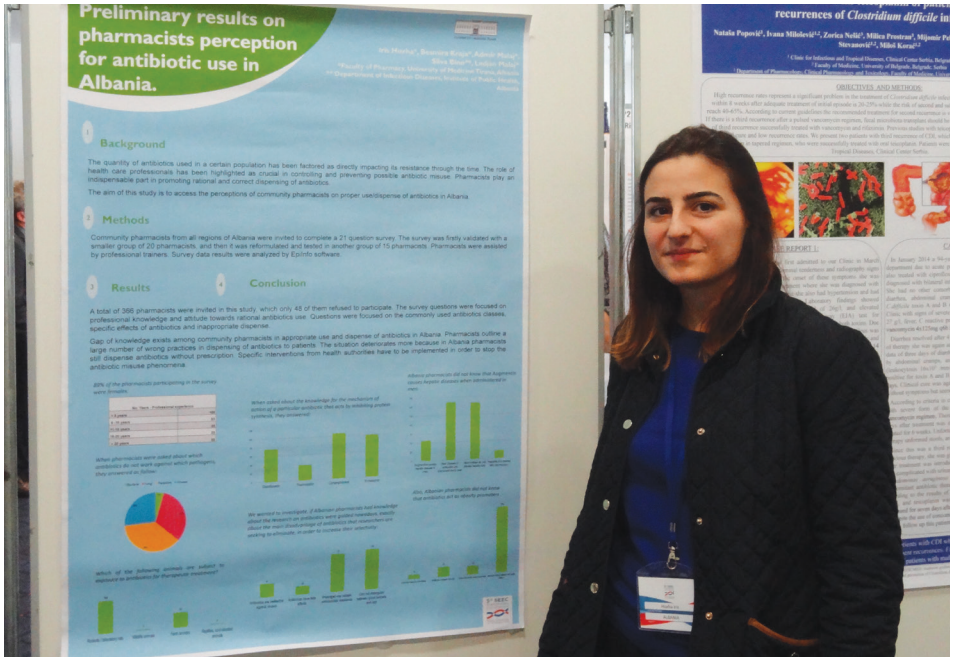
Country specific support >

- promotion of medicines
- role of pharmacoeconomics and cost-effectiveness
- incentives to promote appropriate use.

Appropriate use of medicines mission, Dushanbe, Tajikistan, September 2014
The purpose of this mission was to build on previous activities implemented by the Ministry of Health and Social Protection of Population of the Republic of Tajikistan with support of the WHO Country Office to strengthen the pharmaceutical sector in Tajikistan. It primarily involved generating evidence on prices, availability and affordability of medicines, a review of the procurement system of medicines and a study on appropriate use of medicines.

Workshop on Antibiotic Consumption and Antimicrobial Resistance (AMR), Tashkent, Uzbekistan, November 2014
In the framework of the Strategic Action Plan on Antibiotic Resistance 2011, the WHO Regional Office for Europe and partners conducted several workshops in Uzbekistan to increase the knowledge and capacity of different health care workers to address this public health threat. A workshop related to medicines covered antibiotics consumption monitoring as well as the WHO and Health Action International (HAI) perspective on medicines availability and affordability. The network of regional pharmacists, staff of the national regulatory authority, wholesalers and local manufactures participated in this workshop conducted by WHO/Europe in collaboration with Antwerp University and the Moldovan State Medical and Pharmaceutical University "NicolaeTestemitanu". During this activity the participants were trained in how to set up monitoring of antimicrobial consumption in their country and got an overview of other European countries in terms of antibiotic consumption and availability of essential medicines. With this training, Uzbekistan can join the HTP network of countries monitoring use of antimicrobial medicines.

AMR country assessment in the framework of Strategic Action Plan on Antibiotic Resistance, Tirana, Albania, November 2014
A joint mission to Albania composed of WHO, Rijksinstituut voor Volksgezondheid en Milieu, Netherlands (RIVM) and European Society of Clinical Microbiology and Infectious Diseases (ESCMID) experts took place to perform an assessment of the status of Albania regarding prevention and control of antibiotic resistance through surveillance, prudent use of antibiotics, and infection control. Special focus was on promoting national coordination and strengthening surveillance of antibiotic resistance/consumption as well as rational use of medicines. Recommendations were provided on how to set up surveillance of antimicrobial resistance and consumption of medicines in the country as well as improve rational use of medicines.



Pharmacists are among the best positioned to influence appropriate use of antibiotics

Both photos are from : Satellite meeting on qualitative research linked to use of antibiotics: 5th Southeast European Conference on Chemotherapy and Infection

Pricing and Reimbursement

Pharmaceutical Pricing and Reimbursement Information (PPRI) network meetings in Paris, France and The Hague, Netherlands, during 2014

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 27 EU Member States plus the following countries which participate in the WHO/ European Region: Albania, Croatia, Iceland, Israel, Kyrgyzstan, the Former Yugoslav Republic of Macedonia, Norway, Russia, Serbia, Switzerland, Turkey and Ukraine. Additionally, European and international institutions (European Medicines Agency, OECD, WHO, World Bank) have been involved in the PPRI project.

Two network meetings took place in 2014 to share experiences and major recent developments and changes in pharmaceutical pricing and reimbursement: 20 PPRI countries reported changes in their pharmaceutical policies (Switzerland, Denmark and the Netherlands reported that they had none). Most measures were reported by Greece and Portugal, followed by Ukraine and Iceland. The most frequently implemented measures were margin changes, price changes (including price cuts), changes in co-payments and changes in the reference price system.

During the Paris meeting an introduction into the French pharmaceutical system and pharmaceutical market was made and a similar introduction to the Dutch pharmaceutical system and pharmaceutical market was made during the meeting in The Hague. The PPRI network provides a very useful platform for pharmaceutical pricing and reimbursement policy discussion and the number of European Members have increased in 2014.

Pharmacoeconomics Course, Moscow, Russian Federation, December 2014

First Moscow Medical university of Sechenov with support from HTP WHO/Europe organized a workshop in Russian to provide countries with the updates on current requirements to pharmacoeconomics studies. The aim of the workshop is to increase participants' understanding in the basics of applied health economics and to facilitate the application of health economics into practice at national level. Participants included representatives from national drug regulatory agencies, ministries of health, health insurance funds and academia from Armenia, Azerbaijan, Belarus, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan.

The theoretical part of the workshop was supported by practical exercises where participants were able to implement pharmacoeconomic modeling as a tool for decision making and explore the basic principles of health technology assessment.

Country specific support >

Cyprus - WHO/Europe mission, Larnaca, Cyprus, April 2014
HTP WHO/Europe conducted a mission at the request of the Cyprus Ministry of Health in collaboration with the LSE/Health to study the current system of pharmaceutical pricing and coverage decisions. Overall, the objectives of this mission were to (a) determine whether prices for prescription pharmaceuticals in the public sector (tender system and negotiations) are optimal and in the public interest for the Cypriot government; (b) determine whether prices for prescription pharmaceuticals in the private sector (determined through external price referencing) are affordable for consumers/patients; (c) comment on how the public and private systems can be fused into one when health insurance will be implemented; and (d) provide a roadmap for health insurance implementation including an outline of the preparatory steps that need to be undertaken prior to full implementation of health insurance. A series of recommendations for follow up were presented to the Ministry of Health for their consideration.

Moldova – WHO/Europe mission, Chisinau, Republic of Moldova, June and November 2014
Support was provided in mapping the current situation of reimbursed drugs and the development of an action plan for the Ministry of Health of the Republic of Moldova.
See the section of Appropriate Use of Medicines

PPRI meeting, Paris

Health Technology Assessment (HTA)

HTA Capacity Building Workshop in Warsaw, Poland, September 2014

HTA is still in development and experiences across Europe vary substantially. HTA happens within the European Medicines Agency (EMA) recommended indication authorization and several countries are including HTA in their pricing and reimbursement decision making process. HTA is currently one of the elements that has most potential for influencing research and development in the future – and can be used strategically to reward innovation. HTP supported a capacity building workshop organized by ADVANCE-HTA - a research project funded by the European Commission's Research Framework Programme (FP7) with the aim to advance and strengthen the methodological tools and practices relating to the application and implementation of Health Technology Assessment (HTA) in Central European Countries. This workshop was hosted by the Polish HTA agency in Warsaw with the participation of Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Russia, Serbia, Slovakia, Turkey and Ukraine.

Country specific support >

HTA Forum, Moscow, Russian Federation, December 2014
Input was provided to the annual Health Technology Forum in Moscow, 2 December 2014 by sharing experiences on methodology as well as practical experiences and participation of experts from the Canadian Centre of Applied Research in Cancer Control (ARCC).

Medicines Regulation

WHO Surveillance and Rapid Alert System for Substandard/Spurious/ Falsely labeled/Falsified/Counterfeit (SSFFC) Medical Products

The manufacturing, distribution and sale of SSFFC Medical Products have been widely and consistently recognized as an unacceptable risk to public health by the WHO, international forums and countries. To fight against this, WHO has initiated a project specifically focused on building global capacity for a more systematic approach to the surveillance, monitoring and alerting of SSFFC medical products. The long term objective of this project is to significantly improve the quantity, quality and analysis of data on the incidence of SSFFC Medical products through the creation of a global surveillance and monitoring database of reliable, validated and accurate data. The success in combating SSFFC medical products depends on the effective collaboration of WHO Member States and national medicines regulatory authorities (NMRAs).

Multi-country SSFFC Workshop (medical products Global Surveillance and Alert System training), Istanbul, Turkey, May 2014

A workshop, hosted by the Ministry of Health of Turkey and the Medicines and Medical Device Agency, was held on the implementation of a surveillance and rapid alert system for SSFFC medical products by WHO in May 2014 in Istanbul. Experts representing 19 countries of the WHO European Region were trained to report incidents involving SSFFC to the new system through the use of a WHO Rapid Alert Form.

The objectives of the workshop were:

- to understand the importance and benefit of reporting incidents involving SSFFC;
- to train the pilot countries in the submission of reports of SSFFC using the new rapid alert system;
- to practice the completion and submission of reports based upon real incidents that have occurred previously;
- to recognize the benefits in working closely with pharmacovigilance and laboratory experts;
- to understand WHO country and regional office responsibilities with respect to SSFFC;
- to encourage pilot countries to establish networks within their respective countries with relevant stakeholders in order to capture reports of SSFFC.

After the workshop nearly all of the countries trained began their reporting to the global Surveillance and Monitoring System.

Pharmacovigilance Workshop, Copenhagen, Denmark, March 2014

Pharmacovigilance (PV), - defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem"- , is a core component of the pharmaceutical management system and represents an arm of patient-oriented care. It aims to ensure the best use of medicines for the prevention and treatment of diseases.

Mindful of the complexity of treatment for multidrug- and extensively drug-resistant tuberculosis (M/XDR-TB), and the additional challenges which programmes will face with the arrival of the new anti-TB drugs entering the market ahead of the completion of Phase 3 trials, the first workshop on pharmacovigilance was organized to focus on the specifics of TB and M/XDR-TB care. It successfully brought together drug regulatory and TB control experts from eight countries in eastern Europe (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Republic of Moldova, Russian Federation, Ukraine) and Vietnam, as well as experts

from WHO/Europe and WHO headquarters (Global TB Programme, Safety and Vigilance Programme), the Global Drug Facility, the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden, and the Green Light Committee (GLC/Europe). The event was supported by USAID in the framework of the WHO-USAID regional platform project for TB control in WHO European Region and was held 3-7 March 2014, in Copenhagen, Denmark.

The meeting was organized in the framework of the "Consolidated Action Plan to Prevent and Combat M/XDR-TB in the WHO European Region, 2011–2015", which aims to contain the spread of drug-resistant tuberculosis by achieving universal access to prevention, diagnosis and treatment of M/XDR-TB in all Member States of the European Region by 2015.

Countries identified the major gaps and challenges for the implementation of PV for anti-TB drugs and developed action plans to address them, in order to strengthen national surveillance networks and improve data recording and reporting. It was concluded that effective pharmacovigilance at national level will require close collaboration between the government structures concerned and other stakeholders for technical assistance and funding.

As an outcome, in the weeks following the workshop, the participants will finalize their plans, identify how to incorporate them into existing strategic documents (e.g. national strategic plans, concept notes for Global Fund support), organize national training within the country, and start to advocate for resources and actions to better protect patient safety.

Countries identified the major gaps and challenges for the implementation of PV for anti-TB drugs and developed action plans to address them

Multi-country SSFFC workshop, Istanbul

It is important from now on to advocate for PV in TB care at the country level such as the Ministry of Health and Global Fund, through GLC/Europe and other technical and funding partners.

Third WHO Interregional Training Workshop on Registration and Qualified Practice of Traditional Medicine / Complementary Medicines (TM/CAM) Macao SAR, China, June 2014

More than 30 participants from 18 countries and special administrative regional governments across six WHO regions, as well as two temporary advisors from Australia and India attended the workshop. A presentation on the ethical framework and good governance principles to be considered in providing and regulating TM/CAM were done. The European region was represented by Turkish Ministry of Health.

The participants were familiarized with the key points of WHO Traditional Medicine Strategy 2014-2023, the global situation in the area of national policies and regulations on TM/CAM practices, and the ethical framework and good governance principles to be considered in providing and regulating TM/CAM. The information, experiences and lessons related to TM/CAM education, registration and practice in the countries the participants represented were also shared through group discussions and plenary sessions. The priorities for action and recommendations were agreed by the participants before closing the workshop.

WHO/Europe contributed in the capacity building of inspectors and distributors. During the local training workshop on the introduction of the WHO Good Distribution Practices, experiences were shared in mainland China in developing and implementing the national good supply practice (GSP).

Global Vaccine Safety Initiative (GVSI) meeting, Tianjin, China, October 2014

HTP EURO participated in the GVSI meeting which gathered participants from over 40 countries including regulators, pharmacovigilance specialists, multilaterals agencies, donors and industry. The meeting was the opportunity to display progress made in decentralizing vaccine pharmacovigilance capacity-building with presentations from countries demonstrating the increase of AEFI (adverse events following immunization) monitoring, improved collaboration between immunization programmes and regulatory authorities, and examples of enhanced pharmacovigilance activities.

WHO/Europe contributed in the capacity building of inspectors and distributors

37th Annual Meeting of the WHO Programme for International Drug Monitoring, Tianjin, China, October 2014

The 37th Annual Meeting of the WHO Programme for International Drug Monitoring gathered representatives from national pharmacovigilance centres and WHO collaborating centres in pharmacovigilance. Presentations from the four WHO collaborative

centres highlighted what they can offer to countries in support of pharmacovigilance. Series of working groups took place resulting in recommendations to countries, collaborating centres and WHO to take medicines pharmacovigilance forward. Eight working groups were organized to discuss current activities and to plan future interventions in pharmacovigilance:

1. WG1 Challenges and opportunities in facilitating collaboration between Public Health Programmes and National Centres
2. WG2 Global information exchange during crisis
3. WG3 Evaluating benefit/risk assessment in drug regulatory decisions
4. WG4 Systematic data collection of drug exposure during pregnancy
5. WG5 Target safety communication to consumers
6. WG6 Signal Detection in Low and Middle Income Country (LMIC) Settings
7. WG7 Patient reporting and involvement of civil society
8. WG8 Signal detection in vaccines

HTP will be involved in follow up action including the importance of collaboration between programmes such as TB, Malaria, Immunizations, etc. and pharmacovigilance centres.

Recommendations were developed for national centres:
- Strengthen PV function in the countries using current expert and training recourses and existing guidelines
- Starting negotiations with health programmes on collaboration, information exchange, and development of PV activity plan for the health programme
- Joint mobilization of funds to adequately cover all activities
- Implementation, monitoring and evaluation of the PV function within the health programmes

WHO will continue work on facilitation of PV implementation into the health programme at regional level and country level.

WHO/Europe Support to the WHO Prequalification of Medicines Programme

WHO pre-qualification of medicines is a service provided by WHO to assess the quality, safety and efficacy of medicinal products.

In 2014 Regional Office support to the WHO medicines prequalification programme focused on further advocacy of local manufacturers and quality control laboratories to participate in the programme. In addition, our work focused on facilitation of the national registration of the WHO prequalified medicines. This was done using the collaborative procedure established by the WHO Prequalification of Medical Products Programme

WHO will continue work on facilitation of PV implementation into the health programme at regional level and country level

The International Conference of Drug Regulatory Authorities is strategic opportunity for drug regulatory authorities to become closer

(WHO/PQP). This year's activities resulted in the prequalification of seven medicinal products manufactured by five companies in European region. Technical advice was provided to additional two manufacturers preparing their applications to the programme.

Four quality control laboratories were prequalified during the 2014 and others are in the assessment of the laboratory information files.

Four countries in the region participated in the collaborative registration. Within this procedure five WHO prequalified antiretroviral and anti-tuberculosis medicines received fast track national registration in Ukraine and Kyrgyzstan. Many applications are in the assessment and validation process. The main challenge in this process is application for the national registration which depends fully on manufacturers. Currently the WHO/PQP is analyzing this process to develop recommendations providing technical support to the national regulatory authorities and advocating manufacturers to apply.

WHO pre-qualification programme: annual consultation of UNFPA/UNICEF/ WHO with medical product manufacturers focusing on prequalification, UN City, Copenhagen, Denmark, September 2014

Hosted jointly by WHO/Europe, UNICEF and UNFPA, an annual event takes place at UN City Copenhagen and provides a forum at which medicines and diagnostics manufacturers from around the world, quality, safety and efficacy experts, procurement agencies, and international donors working in public health, come together to focus on production and supply of quality essential medicines, priority diagnostics and vaccines.

The pre-qualification meeting this year saw an overwhelming participation of more than 400 manufacturers around the globe. For the first time this meeting also covered vaccines. It was a particularly important meeting for the WHO Prequalification Team since it enabled reaching out to a significant number of manufacturers: both those already working with us and those who are considering doing so. For UNICEF and UNFPA the meeting was an opportunity to inform manufacturers about their procurement needs and requirements. The opportunity offered manufacturers one-on-one meetings with WHO, UNFPA, UNICEF and GDF teams, and was particularly appreciated. It was a shared platform for the three organizations to work towards the common goal.

Presentations from the annual consultation of UNFPA/UNICEF/WHO medical product manufacturer focusing on prequalification, Copenhagen, Denmark, 22 – 25 September 2014, can be found here: http://www.euro.who.int/en/health-topics/Health-systems/medicines/multimedia/presentations-who-prequalification-programme-annual-consultation-of-unfpaunicefwho-medical-product-manufacturer-focusing-on-prequalification2

International Conference of Drug Regulatory Authorities (ICDRA)

The International Conference of Drug Regulatory Authorities (ICDRA) is strategic opportunity for drug regulatory authorities to become closer, discuss trends and challenges, but also share solutions found at different parts of the globe. ICDRA provides a forum to determine priorities for action in national, regional and international regulation of medicinal products. The 2014 meeting was hosted by ANVISA, the Brazilian Drug Regulatory Authority and provided an overview of the progress of medical product regulation, convergence and current challenges. Special focus was given to biologicals and cell therapy, pharmacovigilance, SSFFC and medical devices. Recommendations from the meeting can be found here: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/

ICDRA meeting in Brazil

Publications

Report on "The role of pharmacist in encouraging prudent use of antibiotics and averting antimicrobial resistance: A review of policy and experience in Europe"

Based on the results of a literature review of the Good Pharmacy Practice (GPP) guidelines by FIP and WHO, a survey was conducted in the WHO European Member States, outlining the roles of pharmacists. Pharmacists are often the first point of contact for patients, their potential as important allies in the fight against antimicrobial resistance (AMR) has been outlined in the report. According to the survey, pharmacists are among the best positioned to influence the appropriate use of antibiotics and, therefore, have a crucial role to play in combating AMR alongside policy-makers and general practitioners: every player is key. The report illustrates that pharmacists already have experience in treating patients with antibiotics, both responsibly and within an appropriate legal framework. It also indicates, however, that in many countries the general public can still buy antibiotics over the counter without a diagnosis or prescription and use them at will. The report is available in English and Russian and can be found here:
http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2014/the-role-of-pharmacist-in-encouraging-prudent-use-of-antibiotic-medicines-and-averting-antimicrobial-resistance-a-review-of-current-policies-and-experiences-in-europe

AMR consumption data - New data on antibiotic use in European Region

HTP WHO/Europe and the University of Antwerp, Belgium in collaboration with the WHO Collaborating Centre for Drug Statistics Methodology and European Centre for Disease Prevention and Control (ECDC) have made the first collection and analysis of data on antibiotic use in 13 countries and areas in Eastern Europe and Central Asia. This research is vital to address the challenge of antibiotic resistance and results were published in the Lancet Infectious Diseases in March 2014. A four-fold difference in antibiotic consumption across the European Region was found after collection and analysis of wholesale data from six south-eastern European and seven central Asian areas and countries. This complements the work that was carried out in 29 countries (the 28 EU Member States plus Norway) participating in the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) of the European Centre for Disease Prevention and Control. This research is vital to address the challenge of antibiotic resistance.
http://www.euro.who.int/en/health-topics/Health-systems/medicines/news/news/2014/03/new-data-on-antibiotic-use-in-european-region

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 Pharmaceuticals (HTP) Programme
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