

# Health Technologies and Pharmaceuticals (HTP) programme Annual Report

# 2013

Division of Health Systems and Public Health (DSP)

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### Keywords

Regulation; Antibiotic resistance; Antimicrobial drug resistance; biomedical technology assessment; Counterfeit medicines, Microbial; drugs; medicines; Fake Drugs; Health Technology; Medicines, Evidence-based; Non-prescription Drugs; Technology Health

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# National policies

Health 2020 is the World Health Organization's (WHO) new European regional health policy framework. It aims to support action across government and society to "significantly improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred health systems that are universal, equitable, sustainable and of high quality". The policy framework is evidence based and peer-reviewed. It makes the case for investment in health and creating societies where health is valued. It details the ways that good health benefits all in society. Good health is vital for economic and social development and supports economic recovery. It gives policy-makers a vision, a strategic path, a set of priorities and a range of suggestions about what works to improve health, address health inequalities, and ensure the health of future generations. It identifies strategies for action that are adaptable to the many contextual realities of the European Region. It is in this context that the Health Technologies and Pharmaceutical Programme (HTP), Division of Health Systems and Public Health (DSP), at the WHO Regional Office for Europe (WHO Europe) is working with countries to support relevant reform processes in the areas of medicines and medical device policy and strategy.

A national policy for medical products is a crucial component of a national health strategy. A national medicines/medical product policy is a visionary document setting the stage for the future development of the sector. It deals with the development, provision and use of medicines and medical products within a health care system. One of WHO's goals is to support countries in developing medical product policies as well as promoting and monitoring access to essential medical products.

In 2013 several countries received assistance in the area of medicines policies from WHO Europe through the HTP programme.





## Estonia

In September, the first stakeholder consultation on an Estonian draft medicines policy took place. The consultation was prepared and chaired by the Ministry of Social Affairs and included participants from the industry, wholesale and retail associations, the physicians' association, the National Regulatory Agency, the Ministry of Finance, the National Health Insurance Fund, the Competition Board, the London School of Economics and Political Science (LSE, a WHO Collaborating Centre in Health Systems and Pharmaceutical Policies), the WHO Country Office in Estonia, and the HTP programme. The consultation was held to establish a dialogue and outline next steps in updating the Estonian medicines policy.

## Kyrgyzstan

In February 2013, in collaboration with the HTP programme, the Ministry of Health in Kyrgyzstan had a series of discussions on new medicines policy development as part of the Medicines Transparency Alliance (MeTA) project.<sup>1</sup> It was agreed that this work on the development of the country's national drug policy would focus on the following key challenges:

- Strategic Management and leadership
- Affordability of medicines (including prices, pricing, procurement and financing mechanisms)
- Rational use of medicines
- Quality of medicines

## Central European countries

Spending on medicinal products is a large share of the health budgets in many European countries – in OECD countries they account for 18% of health spending and in low- and middle- income countries it ranges from 20 to 60% of health spending.<sup>2</sup> In light of the economic recession, some governments have been reducing pharmaceutical budgets and, using an array of policy instruments to cut costs, including pricing and reimbursement mechanisms. In this context, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovenia and Slovakia met for policy dialogue in May 2013 on the specific challenges of pharmaceutical expenditure in central Europe. The effects and effectiveness of various policies, tools and options within pharmaceutical pricing and reimbursement were reviewed and discussed. The event targeted senior policy-makers and was hosted by the Slovakian Ministry of Health and jointly organized by the HTP programme and the European Observatory on Health Systems and Policies.

Experts shared their experience and assessed the current situation in their respective countries, identifying the key challenges they are facing. The open discussions, exchange of experience and information contributed to exploring policy options for maintaining access to essential medicines and how to improve access to new medicines.



1 MeTA (Medicines Transparency Alliance) initiative aims to improve access to quality-assured essential medicines in low-income countries through a multi-stakeholder collaboration involving representatives of the public sector, the private sector and civil society. More details at <http://www.who.int/medicines/areas/coordination/meta/en/>  
2 WHO Guideline on Country Pharmaceutical Pricing Policies, <http://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf>

# Regulation

Medical product regulation is an important area where WHO works globally to develop recognized and other medical product norms, standards and guidelines for medicine quality, safety and efficacy. Via the HTP programme, the WHO Regional Office for Europe provides guidance, technical assistance and training, and supports countries in building effective medicine regulation systems that promote and protect public health. The regulation of medical products varies across European countries and quality remains an important issue. Regulatory convergence is desirable and the HTP programme will continue to support countries in moving ahead in this area.



**In the framework of improving medical product regulation as part of health systems strengthening, the HTP programme provides assistance to Member States in building national medicines regulatory capacity. Activities undertaken in 2013 include:**

- Based on the results of an in-depth regulatory assessment in the Republic of Moldova, a road map to improve the regulatory system was developed and discussed through several stakeholder round tables. This work has directly supported the Republic of Moldova in the pharmaceutical sector reform process.
- Kyrgyzstan, Georgia and Ukraine applied to participate in the collaborative procedure between the World Health Organization Prequalification of Medicines Programme<sup>3</sup> and national medicines regulatory authorities to assess and accelerate the national registration of WHO prequalified pharmaceutical products. This will result in the quicker national marketing authorization of WHO prequalified products in the countries. In addition, Ukraine has amended existing regulation and exempt fees for the fast track registration of these medicines.
- Overall there has been good progress on WHO Prequalification of medicines from European manufacturers – 18 products, manufactured by 6 companies in the European Region, were prequalified by the WHO PQ programme in 2013. One of them is the anti-tuberculosis product *Cycloserine* produced in the Russian Federation. The benefits to Russian pharmaceutical manufacturers in participating in the WHO PQ programme were presented and discussed in the framework of the XV annual conference “State Regulations in the Area of Drugs and Medical Devices Circulation “, October, Moscow, the Russian Federation.
- A joint WHO-UNICEF-UNFPA meeting with pharmaceutical and diagnostics manufacturers and suppliers was hosted jointly by WHO, UNICEF and UNFPA at the UN-City in Copenhagen, Denmark. It provided a forum where manufacturers; quality, safety and efficacy experts; procurement agencies; and international donors working in public health could discuss production, procurement and supply related issues around quality essential medicines and priority diagnostics. It is an annual meeting that facilitates collaboration between industry and UN organizations. It also facilitates collaboration with other partners to increase access to essential, quality medicines and medical devices.
- A pilot project on pharmacovigilance for antiretroviral medicines “Improving patient safety, patient care and treatment outcomes for people living with HIV/AIDS treatment” has been launched in Ukraine and Belarus leading to in the national pharmacovigilance conference held in October, Kiev, Ukraine.
- The 2nd global meeting within the project on Substandard/Spurious/ Falsely-Labelled Falsified/Counterfeit Medical Products (SSFFC) took place in November, Geneva, Switzerland to evaluate the results of a pilot project in Ukraine, Georgia, Kyrgyzstan, Belarus, Russian Federation and Croatia.
- To support Ukraine’s ratification of the Medicrime Convention convention, the HTP programme took part in the Medicrime conference in June, Kiev, Ukraine.
- An assessment of the medicines regulatory situation was undertaken by the HTP programme in October, Tbilisi, Georgia and recommendations on regulatory system improvement were provided.

3 The Prequalification (PQ) Programme, set up in 2001, is a service provided by the World Health Organization (WHO) to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. More details at <http://www.who.int/topics/prequalification/en/>

# Rational use of medicines

Antibiotic resistance affects the entire WHO European Region, driven by the overuse, underuse and misuse of antibiotics, as well as by overprescription. Although some efforts have been made to combat indiscriminate use, many countries have no national regulation or enforcement on antibiotic usage; healthy animals are given antibiotics to promote growth or prevent disease; commercial companies actively promote antibiotics and in several countries antibiotics are available over the counter (OTC).

For the practical implementation of the European Strategic Action Plan on Antibiotic Resistance, the WHO Regional Office for Europe focuses mainly on non-EU Member States, although guidance and support is offered to all Member States of the Region. Methods used by the HTP programme are similar to those of partner organizations such as the European Centre for Disease Prevention and Control (ECDC) which allows for cross Europe comparisons of data. Efforts in countries are centred on coordination between sectors of government, academia and industry, human and animal health, etc. Through the HTP programme, WHO supports countries in the development of their national action plans, setup or strengthen

surveillance on antibiotic consumption and resistance through a number of activities, including country missions, workshops, capacity building, facilitating twinning between national reference laboratories and tailored consultancy.

The WHO Regional Office for Europe works actively on promoting rational use of antibiotics through providing direct support to countries to establish evidence on antimicrobial medicines consumption, policy options to address findings, training and helping countries building capacity among health professionals and relevant stakeholders to improve prescribing and use.







In 2013 the following activities took place:

## Pilot project on monitoring consumption of antibiotic use

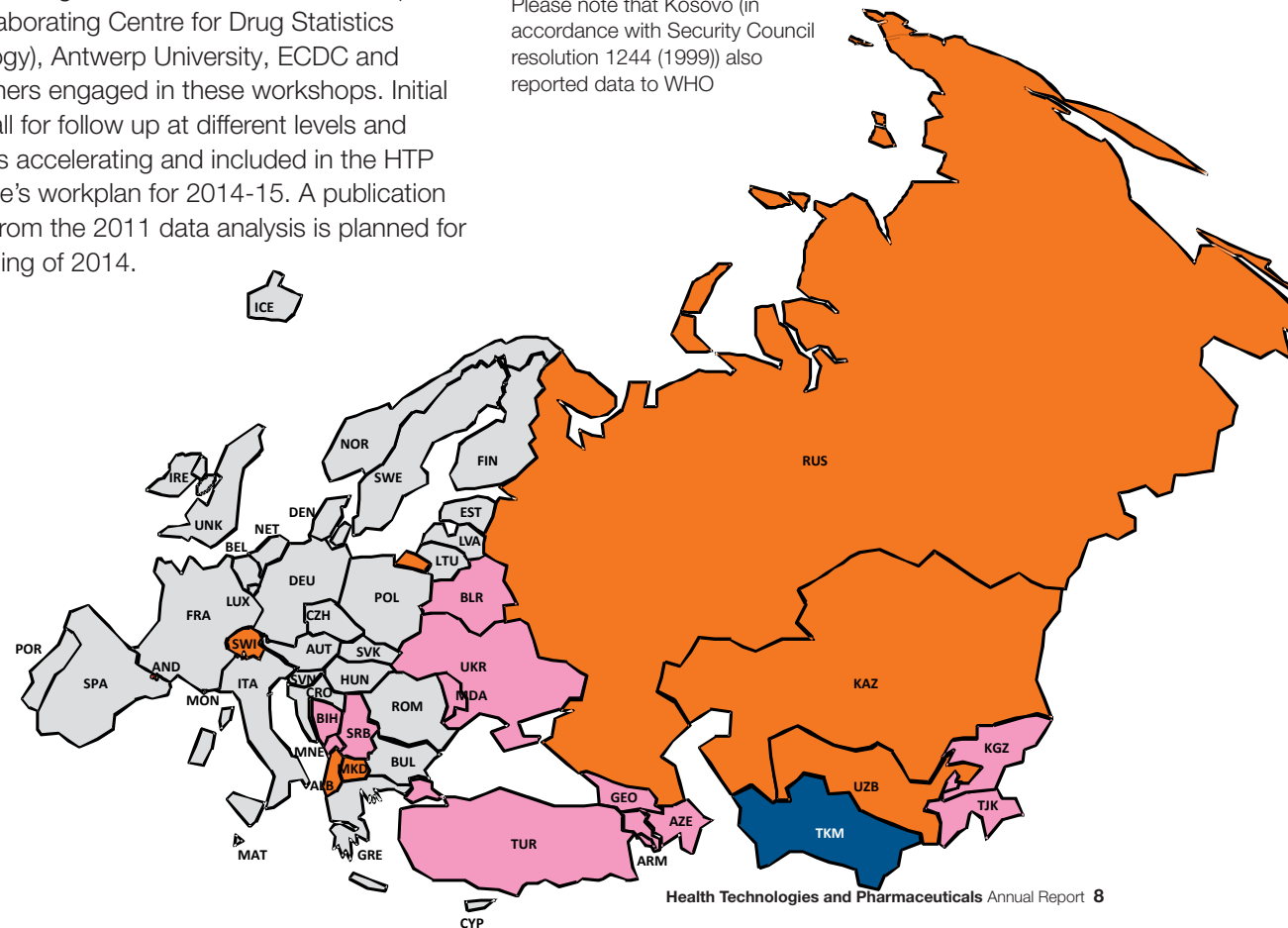
Monitoring of antimicrobials consumption data is an important component of antimicrobial resistance (AMR) surveillance, and is a crucial element for prevention of the further development of antimicrobial resistance in the populations. Until now, there has been very limited data on consumption of antimicrobials publicly available in non-EU countries.

To address this gap the HTP programme and relevant Member States have been working closely with Antwerp University, Belgium, who played a leading role in setting up the European Surveillance of Antimicrobials Consumption (ESAC). The aim of the collaboration is to develop estimates of antimicrobials consumption in non-EU countries of the WHO European Region for further establishment of surveillance systems, support of national stewardship models (including AMR strategies and national medicines policies) and feeding the policy development as well as implementation of control and adherence measures both into health and economic sectors. Within the framework of this collaboration the 3rd and the 4th workshop on antimicrobial use in non-EU countries took place in 2013.

During these workshops the focal points from 19 non-EU countries, who have been collecting and analysing national data on antimicrobial consumption in the community and in the hospital sector, presented the preliminary results and received the consultation on data analysis from the Norwegian Institute of Public Health (a WHO Collaborating Centre for Drug Statistics Methodology), Antwerp University, ECDC and other partners engaged in these workshops. Initial findings call for follow up at different levels and this work is accelerating and included in the HTP programme's workplan for 2014-15. A publication of results from the 2011 data analysis is planned for the beginning of 2014.

-  Countries which report to ECDC
-  Countries which reported 2011 data to WHO
-  Countries to join ESAC
-  Countries in the process of collecting data

Please note that Kosovo (in accordance with Security Council resolution 1244 (1999)) also reported data to WHO





## Rational Use of Medicines



In 2013 the HTP programme continued its participation in the Piperska Group for rational prescribing.<sup>4</sup> The 6th annual Piperska meeting was held in May 2013 and, hosted by the Institut Català de la Salut in Barcelona. A wide range of topics was covered, from interface management to biosimilars. The Group discussed the issue relevant to many countries on how financing for new premium-priced medicines can be sustained and a number of examples and options were shared. A number of the group members have published their findings and more information can be found here <http://www.piperska.org/resources/publications>.

In May 2013 the HTP programme organized a study tour in Utrecht, Netherlands, on the rational use of medicines for representatives from Azerbaijan, Bulgaria, the Republic of Moldova, Romania, Serbia and Montenegro. The tour was for officials from the ministries of health, insurance funds, and medicines agencies, working on the different aspects of rational medicines use. It was hosted by the Nederlands Instituut voor Gezondheidszorg (Netherlands Institute for Health Services Research, NIVEL) and the Instituut voor Verantwoord Medicijngebruik (Netherlands Institute of Rational Pharmacology, IVM).

The focus of the study tour was on the selection of medicines for reimbursement, given the context of the ongoing financial crisis, where cost-containment is one of the crucial aspects of rational medicines use. Participants met with different level stakeholders involved in rational use of medicines in Holland, and were able to discuss their national perspectives and capacities. In addition, possible options to target the challenges from different angles were discussed.

Participants' feedback was positive and it is hoped to continue this interaction study tour based on the requests and needs of the Member States.

## European antibiotic awareness day (EAAD)

In 2013 through the HTP programme, WHO Europe continued joint organization of European Antibiotic Awareness Day with the ECDC. The EAAD is held on the 18th of November to raise awareness about the threat to public health of antibiotic resistance and to promote prudent antibiotic use.

Besides support to national campaigns, to mark European Antibiotic Awareness Day WHO Europe and its partners held a live Twitter chat on antibiotic resistance. Experts from the Regional Office, the ECDC and the European Commission replied to the questions from a large number of public participants.



<sup>4</sup> This is a network of health care professionals who share the common vision of enhancing the health of the public and the individual patient in a sustainable way through exchanging ideas and co-operation around the rational use of pharmacological and related therapies.

# Access to medicines

## a) Pricing & Reimbursement

Inadequate access to essential medical products poses a serious threat to the well-being of a large part of the population in the European Region. Via the HTP programme, ensuring that patients have access to essential and affordable medicines is one of WHO Europe's core objectives. The following activities were undertaken in 2013:

## *Access to medicines for noncommunicable diseases*

The HTP team took part in 4 country assessments in Hungary, Kyrgyzstan, the Republic of Moldova and Tajikistan on access to medicines for treatment of noncommunicable diseases (NCDs). These were undertaken within the framework of complex WHO NCD assessments with a focus on health system barriers over the period May – July 2013.

It was discovered that in Kyrgyzstan and Tajikistan, medication for simple hypertension and diabetes type 2 is not affordable for the majority of the population. At the same time, there is an overuse of medications which do not present the first line of treatment (e.g. beta-blockers). Access to statins for risk groups is almost non-existent and cancer treatment for patients in Tajikistan accounts for up to 500 days of minimal wages for a

course of treatment (according to WHO/HAI (Health Action International) methodology<sup>5</sup> any treatment, which costs more than one day of minimal wage per month is regarded as non-affordable).

In all countries, therefore, the development of consistent mechanisms of medicines selection for inclusion in standard treatment guidelines, procurement and reimbursement lists should be a first priority. At the same time the implementation of updated treatment guidelines into the prescribing practice and education as well as development and effective use of information systems for monitoring of use of medicines should be ensured. Regulation of pricing systems must be in place, complementary to the creation of right demand for needed medicines.

5 More information at [http://www.who.int/medicines/areas/access/Medicine\\_Prices\\_and\\_Availability/en/](http://www.who.int/medicines/areas/access/Medicine_Prices_and_Availability/en/)





## *Pharmaceutical Pricing and Reimbursement policies Information (PPRI)*

As in previous years, in 2013 the HTP programme was an active member of the PPRI network attending meetings in March, London, United Kingdom and in November, Budapest, Hungary. PPRI, is a networking and information-sharing initiative on burning pharmaceutical policy issues from a public health perspective. The PPRI network consists of more than 60 members, mainly competent authorities and third party payers from a total of 38 countries. The network includes representatives from all 27 European Union Member States plus Albania, Canada, Croatia, Iceland, the former Yugoslav Republic of Macedonia, Norway, Republic of Serbia, Switzerland, South Africa, South Korea and Turkey. Additionally, European and international institutions (European Commission DG Trade, European Medicines Agency, OECD, WHO, World Bank) are or have been involved in the PPRI project. The project is coordinated by Gesundheit Österreich (the Austrian Health Institute) which is the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

## *Exchange of experiences and best practices*

Based on the request from Azerbaijan Ministry of Health, the HTP programme organized a study tour on pricing and reimbursement in Austria and Denmark for 3 experts involved in the development of medicines pricing system in Azerbaijan. The study tour was supported by Pharmakon in Denmark and the Austrian Health Institute, WHO Collaborating Centres for Drug Policy and Pharmacy Practice Development and for Pharmaceutical Pricing and Reimbursement Policies respectively.

The purpose of their visit was to learn about health care systems in general and pharmaceutical pricing in particular.

During the visit, the experts had the opportunity to meet with representatives from the Danish Health and Medicines Authority, the Austrian Federal Ministry of Health, the Austrian Association of the Social Insurance Institutions and the Austrian Chamber of Pharmacists to learn how prices are set in Austria, Denmark and other European countries. Particular areas of focus were on the role of discounts, mark-ups, taxes and reimbursement.



## Access to medical innovation

In November in Brussels, the HTP programme contributed into the European Public Health Association (EUPHA) roundtable on access to medical innovation in times of austerity: a right for all or a privilege for the wealthy?

Research investments and innovation in Europe – what is the current focus and what are the gaps – were discussed, together with issues around access to medicines in Europe; this included recent trends generally speaking and for new, high priced medicines specifically.

More focus is required on market entry prices, to ensure that new therapies are affordable and can be used as alternatives to present treatment when relevant. There are also suggestions around possible delisting of products - if insufficient evidence of cost-benefit ratios do not materialise in the first years of use. There was a lively discussion and many suggestions offered, including possible future steps to be debated such as challenging the current pricing structures for new medicines, a critical evaluation of the role and value of new cancer medicines pre-launch including reconsideration of health outcomes to make sure these are clinically meaningful and possibly de-linking research and development (R&D) from production of medicines.

### b) Procurement and Supply Management (PSM)

Efficient procurement and supply management activities are fundamental to country health systems performance. In order to ensure effective and quality-assured health products, the HTP programme actively supported countries to develop policies and principles on procurement and supply management. In addition, continues to support country capacity development. In 2013 particular focus was on support to PSM of TB medicines.

On 17 – 21 June 2013, in collaboration with the Ministry of Health of the Republic of Belarus and WHO Country Office, the HTP programme organized a 5 day workshop focusing on forecasting and quantification of anti-tuberculosis medicines as well as monitoring and evaluation as an essential part of health system operations for 17 national experts in Belarus.

The workshop took place at the educational and conference centre IBB “Johannes Rau” in Minsk and was based on the outcomes of the WHO assessments conducted in 2009 -2011.

Several systematic issues affecting the health system’s performance were identified and emphasis was given to quality management, forecasting and quantification, procurement planning, monitoring and evaluation and standard operational procedures.

During the workshop, a group of WHO experts used a practical approach where participants not only received theoretical information but also hands-on tools to use in their daily work. These practical tools facilitate forecasting and quantification calculations, and assist in a development of a procurement plan with indicators. To encourage a practical outcome, 3 draft work plans were created. These plans are based on the theoretical input and discussions, as well as the practical input from the participants.

The draft plans are focused on 3 subjects:

- forecast and quantification
- procurement
- monitoring and evaluation.

The draft plans were written together with the stakeholders, reflecting their real work conditions and relations. This resulted in very interesting interactions and clearly showed that this workshop is able to fill the gaps to support existing health system functions that are already in place.

# Product value assessment including **Health Technology Assessment**

Modern medical technology today represents an essential tool in providing high quality clinical care, but also a critical decision-making challenge.

Support by the HTP programme to Health Technology Assessment (HTA) activities in eastern Europe started in 2011 and is ongoing.

The HTP programme continued support to HTA capacity development through several country and subregional events including the 3rd Russian HTA Forum, which took place in September in the Russian Federation.

In addition a workshop was held in Slovakia to support the development of a national, well functioning system of HTA in line with the EU Directive on Cross Border Provision of Health Care Services.



The HTP programme participated in the 8th International Symposium on Evidence-Based Health Care organized by the Central and Eastern European Society of Technology Assessment in Health Care "CEESTAHC" in Warsaw. During this event emerging Good Practices in HTA were shared and discussed.

During 2012-13 the HTP programme was engaged in a large scale to the project in Bulgaria for purchasing high cost equipment of the latest technology to support the Bulgarian Ministry of Health in needs assessment and strategic planning to achieve the best possible and long lasting results. Through this work positive results were achieved including substantial savings.

HTA is a way to strengthen evidence based selection and rational use of health technologies and increase efficiency when introducing and using these in health care.<sup>6</sup>



6 More information at <http://www.advance-hta.eu/>

# Medical Devices – Health Technologies (HT)

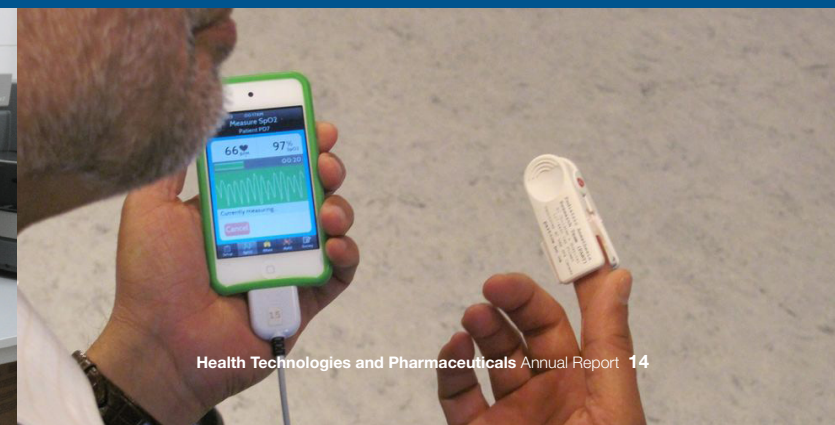
Medical devices and health technologies is an area of rapidly growing importance on global, regional and national levels. Access to and rational use of quality health technologies and medical devices requires close collaboration between many different stakeholders, including governments, health care providers, manufacturers, patient associations and regulatory agencies.

In 2013, the HTP programme worked with WHO headquarters on a global overview on medical devices and facilitated the 2nd round of the global baseline country survey on health technologies in the European Region.

In February the team from WHO Regional Office for Europe participated in Meeting on HT innovation at UNICEF-Copenhagen to co-create new medical devices for the diagnosis of pneumonia in children. This work is taken forward by the Interagency Pneumonia Innovations Team. The approach is to build a strong community of support for the UNICEF, WHO and Bill and Melinda Gates Foundation (BMGF) agenda in the area of pneumonia diagnostics and treatment innovation for children.

Together with participants from Bosnia and Herzegovina, Israel, Kyrgyzstan, the Republic of Moldova, Montenegro, the Russian Federation, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine and Uzbekistan the HTP programme took part in 2nd Global Forum on Medical Devices in Switzerland in November 2013.

The Second Global Forum on Medical Devices provided the global public health community with opportunities for information exchange and collaboration to increase access to high-quality, safe, and appropriate priority medical devices. It was concluded that the situation around regulation for medical devices needs to be addressed by countries as well as through regional forums. WHO continues its work to support acceleration of development of technical specifications and listing of essential medical devices. Further, with the help of the HTP programme, countries need to establish and improve systems for regulation of medical devices. There will be more focus on health technology management both in country initiatives, sharing strategies and results across countries and regions to identify best practices. For patient safety it is important that all medical devices are controlled, whether manufactured in the country or imported. In this area, therefore, the HTP programme will continue to provide workshops for key stakeholders working in organizations or institutions in developing countries, helping as well in sharing both success and failures in the medical devices area. Important is also to sustain innovation in low income countries and to improve knowledge of health care workers for an appropriate selection and use of medical devices based on evidence.



# WHO Regional office for Europe **List of Member States and Acronyms**

Acronym	Description
ALB	ALBANIA
AND	ANDORRA
ARM	ARMENIA
AUT	AUSTRIA
AZE	AZERBAIJAN
BLR	BELARUS
BEL	BELGIUM
BIH	BOSNIA AND HERZEGOVINA
BUL	BULGARIA
CRO	CROATIA
CYP	CYPRUS
CZH	CZECH REPUBLIC
DEN	DENMARK
EST	ESTONIA
FIN	FINLAND
FRA	FRANCE
GEO	GEORGIA
DEU	GERMANY
GRE	GREECE

Acronym	Description
HUN	HUNGARY
ICE	ICELAND
IRE	IRELAND
ISR	ISRAEL
ITA	ITALY
KAZ	KAZAKHSTAN
KGZ	KYRGYZSTAN
LVA	LATVIA
LTU	LITHUANIA
LUX	LUXEMBOURG
MAT	MALTA
MON	MONACO
MNE	MONTENEGRO
NET	NETHERLANDS
NOR	NORWAY
POL	POLAND
POR	PORTUGAL
MDA	REPUBLIC OF MOLDOVA
ROM	ROMANIA

Acronym	Description
RUS	RUSSIAN FEDERATION
SMR	SAN MARINO
SRB	SERBIA
SVK	SLOVAKIA
SVN	SLOVENIA
SPA	SPAIN
SWE	SWEDEN
SWI	SWITZERLAND
TJK	TAJIKISTAN
MKD	THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA
TUR	TURKEY
TKM	TURKMENISTAN
UKR	UKRAINE
UNK	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
UZB	UZBEKISTAN



# 2013 activities, Health technologies and Pharmaceuticals (HTP)

## JANUARY

Meeting with Executive Board of the Europharm Forum, WHO, Denmark  
Consultation on health technology innovation, UNICEF, Denmark

## FEBRUARY

Joint monitoring mission, TB, The Republic of Moldova  
Annual workplan consultation with WHO CC Pharmakon, Denmark  
Country visit: Kyrgyzstan, for follow up on MeTA project and discussions with MoH on medicines policy development  
3rd workshop, antimicrobial medicines use in non-EU countries, Belgium

## MARCH

PQ consultation with Greek medicines manufacturers, Denmark  
Participant, in the Technical Advisory Group consultation on EAAD, ECDC, Sweden  
Observer, International Medical Devices Regulators Forum, France  
PPRI network meeting, United -2Kingdom  
Joint GDF and GLC mission, TB, Kyrgyzstan

## APRIL

PSM trainings with focus on TB, Ukraine  
Observer, WHO Expert Committee meeting on Essential Medicine, Switzerland  
AZE study tour on pricing and reimbursement, Denmark and Austria  
NCD joint mission, Tajikistan

## MAY

Participant, ECDC ESAC-Net meeting, Sweden  
Participant, Piperska group meeting, Spain  
NCD joint mission, Republic of Moldova  
NCD joint mission, Kyrgyzstan  
Rational use of medicines study tour for specific countries, Netherlands  
Policy dialogue, pricing and reimbursement, Slovakia

## JUNE

Participant, Medicrime Conference, Ukraine  
Training workshop on monitoring and evaluation, forecasting and quantification of anti-TB medicines, Belarus  
NCD joint mission, Hungary  
Country visit related to pharmaceutical sector reform, Tajikistan  
Participant, ECDC hosted meeting TATFAR US/EU Working Group on standards for measuring antimicrobial use in hospitals, Sweden

## JULY

Participant, in the Technical Advisory Group consultation on EAAD, ECDC, Sweden

## AUGUST

Participant, Global Chief Pharmacist meeting, Ireland  
Participant, FIP Conference, Ireland

## SEPTEMBER

Participant, 5th International Conference Pharmaceutical Life Cycle, the Netherlands  
Joint UN meeting with medical product manufacturers, UN City, Denmark

Participant, WHO country and Regional Advisers meeting on medicines, medical devices and vaccines, Switzerland  
Participant, 3rd HTA Forum, Russian Federation  
Policy dialogue, Estonia  
Participant, 36th Annual Meeting of Representatives of National Centres participating in the WHO Programme for International Drug Monitoring, Italy

## OCTOBER

Regulatory assessment mission, Georgia  
Participant, 8th Symposium on Evidence-based Health care, CEESTAHC, Poland  
Participant, Health systems for health and wealth in the context of Health 2020: follow-up meeting on the 2008 Tallinn Charter, Estonia  
Participant, national pharmacovigilance conference, Ukraine  
Country visit, NRA participation in the collaborative procedure with the WHO PQ of medicines Programme, Ukraine  
Workplan consultation with WHO CC GOEG, Austria  
Participant, EURIPID and PPRI meeting, Hungary  
Participant, XV annual conference on drugs and medical devices, Russian Federation

## NOVEMBER

Country visit: Kyrgyzstan, to work with National TB and HIV/AIDS programme on the gaps in access to the priority essential medicines, as well as to work with NRA on participation in the WHO collaborative procedure with the PQP.  
4th workshop on antibiotic medicines use in non-EU countries, Netherlands  
Participant, EMA consultation on AMR, United Kingdom  
EAAD, ECDC WHO Twitter chat on AMR  
Participant, 2nd Global Medical Device Forum, Switzerland  
Participant, 2nd global meeting of the Member State Mechanism meeting on SSFFC, Switzerland  
Country visit: Uzbekistan, to plan national AMR action

## DECEMBER

Participant, 1st Conference on TB Pharmaceutical Management for priority countries of WHO European Region, Turkey  
Participant, 1st seminar on managed introduction of new technologies and medicines and prioritization in the health care system - a European perspective, Norway



## Publications

1. Bolokhovets G., Polishchuk O. et al. "Quality control versus quality assurance as a part of medicines regulation in 10 non-EU countries" accepted as an abstract and presented at the 5th Pharmaceutical Life Cycle International Conference, September 2013, the Netherlands
2. Muller T., Bolokhovets G. et al. WHO Regional Office for Europe Regional Pharmaceutical Situation Report see <http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2013/whoeurope-regional-pharmaceutical-situation-report>



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