Access to essential, quality medicines and health technologies is a fundamental part of every person’s right to health
The current report summarizes the 2012 work of the Health Technologies and Pharmaceuticals (HTP) team, Division of Health Systems and Public Health (DSP), 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.

**Keywords**

Antibiotic Resistance  
Antimicrobial drug resistance  
Biomedical technology assessment  
Counterfeit Medicines  
Drug Resistance, Microbial  
Drugs  
Fake Drugs  
Health Technology  
Medicine  
Medicine, Evidence-Based  
Non-Prescription Drugs  
Technology health

---

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

Publications  
WHO Regional Office for Europe  
Scherfigsvej 8  
DK–2100 Copenhagen Ø, Denmark  

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

© World Health Organization 2012

All rights reserved. The Regional Office for Europe of the World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full.

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

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either express or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use. The views expressed by authors, editors, or expert groups do not necessarily represent the decisions or the stated policy of the World Health Organization.
**Content:**

**Introduction**  
Page 3

**Key activities and achievements of HTP team in 2012**  
Page 4

1. **Rational use of medicines**  
Page 4
   1.1 Use of antimicrobial medicines  
Page 4
   1.2 Antimicrobials consumption surveillance  
Page 4
   1.3 Rational use of medicines  
Page 5

2. **Regulatory support**  
Page 5
   2.1 “Substandard/spurious/falsely-labelled/falsified/counterfeit” (SSFFC) medicines  
Page 6
   2.2. Prequalification of medicines  
Page 6
   2.3. International Conference of Drug Regulatory Authorities  
Page 6
   2.4 Good Manufacturing Practice (GMP)  
Page 7

3. **Capacity building and evidence creation**  
Page 7
   3.1 Pharmaceutical country profiles  
Page 7
   3.2 Pharmaceutical expenditures  
Page 8
   3.3 Medicines consumption  
Page 8
   3.4 Pharmaceutical sector assessment  
Page 8
   3.5 Pricing and Reimbursement  
Page 8
Introduction

Access to essential, quality health technologies (HT) – medicines, medical devices and other essential health technologies – is a fundamental part of every person’s right to health. Country health systems must ensure access to quality HT and their rational and ethical use for individual and community wellbeing.

The organization and capacity of national health systems vary widely across the European Region. Challenges differ depending on these but lie in national policies, access, rational use, regulation and quality assurance. While access continues to be high in many European countries, the financial, economic and social crisis in Europe has, in the worst affected countries, highlighted and increased the gaps in access to health technologies. Those without health insurance coverage are vulnerable and are suffering the burden and consequences of the crisis. Growing inequality is fast becoming a pressing issue.

The current report summarizes the 2012 work of the Health Technologies and Pharmaceuticals (HTP) team, Division of Health Systems and Public Health (DSP), 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.

During 2012 our work in and with countries continued on the basis of best practices and networking with experts – taking into consideration both the potential of the eastern and the western parts of the region.

Much of our work is made possible through the very generous voluntary contribution of the Netherlands’ Ministry of Health, Welfare and Sport which forms the basis of a partnership programme between the Netherlands and WHO. In addition, HTP collaborates closely with some WHO Collaborating centres in the Region. Furthermore, HTP has, through country collaboration and networks, access to a very rich knowledge base with contribution from individuals and governments across the European Region. This cross European collaboration is instrumental in advancing national policies, access, rational use, regulation and quality assurance.

This report highlights the main collaboration and achievements in 2012.
Key activities and achievements of HTP team in 2012

1. Rational use of medicines

Appropriate use of quality health technologies can enhance the quality of care and improve the efficiency of the use of scarce health care resources. However, there are still major issues in Europe with rational prescribing and use.

1.1 Use of antimicrobial medicines

Antibiotics have been one of the greatest success stories in medicine. However, bacteria are rapidly evolving and adapting to find new ways to increase resistance to medicines. The inappropriate prescribing of antibiotics – and an over-reliance on these medicines – has led to an increase in resistant bacteria and there is now a fear that effective antibiotics might soon become obsolete. If we are to reverse this trend, action is required at all levels of the health care system. In relation to use of antimicrobial medicines we have over recent years focused our support on the creation of antimicrobials consumption surveillance systems in non-EU countries. We believe that having evidence, based on solid data, is one of the best foundations for raising concern and convincing stakeholders of the need for change. Hence HTP has focused assistance to countries in this area, to gather and analyse data on antimicrobial medicine consumption for national action.

Map.1 The status of surveillance of the antimicrobials consumption in the European Region of WHO for March 2013

1.2 Antimicrobials consumption surveillance

A surveillance network for European Union Members States is established and maintained by the European Centre for Disease Prevention and Control (ECDC). In order to develop a solid evidence base across Europe, non-EU countries with WHO/Europe and in collaboration with the Laboratory of Medical Microbiology (LMM) of the University of Antwerp are establishing a surveillance network on antimicrobial consumption in non-EU European countries. Training workshops on data collection and analysis of antimicrobial consumption were organized jointly by HTP and the LMM, UA in December 2011 (Antwerp, Belgium) and September 2012 (Utrecht, the Netherlands). During these workshops, participants from 13 Member States (Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Montenegro, Kosovo, Kyrgyzstan, Republic of Moldova, Serbia, Tajikistan, Turkey and Ukraine) became familiar with how to implement the WHO ATC/DDD methodology in order to collect antimicrobial consumption data.


1 ESAC-Net
1.3 Rational use of medicines

Irrational use of medicines is a major worldwide problem. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them appropriately².

As one of the key interventions to promote rational use of drugs, HTP together with Danish College of Pharmacy Practice, Copenhagen, Denmark, NIVEL (Netherlands institute for health services research) and IVM (Institute for Rational Use of Medicines), Utrecht, the Netherlands, organized a "Study tour on rational use of medicines" in November 2012 with participation of Denmark, Estonia, Lithuania, Latvia, the Netherlands and Turkey. More information on the study tour is available at:


The tour enabled participants in creating measures to improve systems and processes for rational use of medicines.

In the framework of the national programme to improve use of medicines, technical support was provided to the Czech Republic. This work includes containment of AMR in accordance with Antibiotics national Action plan and focuses on primary health care.

In 2012 in collaboration with IVM, the Netherlands, HTP started the development of the indicators for the rational use of medicines. More information is available at http://irum.im005.be/.

Health technologies assessments (HTA): In June 2012 in Riga, Latvia, the international forum, "Europe and the Russian Federation: vector development and harmonization" took place as result of collaboration between the World Health Organization and the Russian Academy of Medical Sciences. The forum was dedicated to harmonizing the approaches of the EU and the commonwealth of independent states (CIS) to the HTA, evaluation of innovative technologies in health care and the role of HTA in the development of health systems. The second session of the forum took place in Moscow in December 2012.

2. Regulatory support

In some European countries the lack of national regulatory capacity to ensure quality remains an issue, with the result that populations remain vulnerable and have distrust in their health systems.

² http://www.who.int/medicines/areas/rational_use/en/
2.1 “Substandard/spurious/falsely-labelled/falsified/counterfeit” (SSFFC) medicines

6 countries in WHO European Region were selected for a piloting of the global project on SSFFC medicines. Within the project framework, WHO conducted a workshop for the surveillance and monitoring of SSFFC medicines that took place in Manila, Philippines, 5 to 7 September 2012. More information available at:

http://www.who.int/medicines/services/counterfeit/en/

At the beginning of 2012, specialists from Belarus took part in the study tour in the pharmacy system and competences in Denmark and Europe organized by HTP on the basis of WHO Collaborating Center for Drug Policy and Pharmacy Practice, Danish College of Pharmacy Practice, Pharmakon.

2.2 Prequalification of Medicines (PQP):

In September 2012, the joint UNICEF Supply Division and WHO Prequalification of Medicines meeting with Manufacturers was held at UNICEF Supply Division premises in Copenhagen, Denmark. The meeting gathered more than 250 experts worldwide representing pharmaceutical manufacturers, donors and partner organizations and provided updates on WHO guidelines, and an overview of challenges in implementing stringent good manufacturing practice (GMP) and of deficiencies most commonly observed during WHO site inspections.

For more information see: http://www.unicef.org/supply/index_65333.html

With the technical support of HTP two national quality control labs (Russian Federation and Belarus) were prequalified. 8 products produced in the Region (manufacturers from Belgium, France, the Netherlands) were WHO prequalified and 2 manufacturers applied with 10 anti-TB products. More information on prequalification programme at: http://www.who.int/mediacentre/factsheets/fs278/en/

2.3 International Conference of Drug Regulatory Authorities

With the growing effect of globalization and increasingly limited resources, the collaboration of regulatory authorities is very important for public health. On 23-26 October 2012, WHO, the Council of Europe’s European Directorate for the Quality of Medicines and Health Care (EDQM), and the Estonian Medicines Agency organized the 15th International Conference of Drug Regulatory Authorities (ICDRA) in Tallinn, Estonia, with a pre-conference on 21-22 October 2012.

This year, around 300 experts from regulatory authorities, including more than 90 WHO Member States, were able to exchange their experiences in medicines quality, safety and regulation, discuss ways for increased collaboration and determine the priorities for action in national and international regulation of medicines, vaccines, medical devices and active pharmaceutical ingredients (APIs).
2.4 Good Manufacturing Practice (GMP)

On November 28-29, 2012 the Ukrainian State Training Center for Good Manufacturing/Distribution Practice of the State Administration of Ukraine on Medicinal Products (SAUMP) was audited by WHO Collaborating Center for Drug Policy and Pharmacy Practice, Danish College of Pharmacy Practice, Pharmakon in connection to the performance of GMP/GDP trainings. The overall conclusion of the auditors was quite positive. Results of the audit evidenced the high level of development of the Ukrainian GMP standards and trainings in particular.

3. Capacity building and evidence creation

There continues to be a wide variation in product prices in the Region, which may render some essential health technologies unaffordable for certain countries and populations. As innovation and utilization of new products is the main cause of the large increase in health expenditures over the last decade, the crisis has prompted policy-makers to scrutinize health technology expenditures. While medical innovation is desirable, not all countries use health technology assessment (HTA) to guide the process of introduction and use of new products to ensure optimal impact of funding available for health. Support to countries on HTA will remain a focus area in 2013.

3.1 Pharmaceutical country profiles

In 2012 a joint call for the 2011-2012 Global Fund/WHO Pharmaceutical country profiles project continued. In the WHO European Region the response rate so far is 27 Member States out of 53. Every four years, the World Health Organization carries out a global survey of the pharmaceutical sector of its 193 Member States. In each country, data is collected from different sources and consolidated in one single questionnaire (the Pharmaceutical Sector Country Profile). This data is used by countries as a baseline for planning and prioritizing work on medicines. More information about the project is available at WHO headquarters web site:

3.2 Pharmaceutical expenditures

In April 2012, an expert mission to Greece assessed the country pharmaceutical expenditures. As a result, a series of recommendations were provided in order to rationalize pharmaceutical expenditures and work to implement recommendations continues.

3.3 Medicines consumption

WHO/Europe supported the training of several experts from medicines agencies and health insurance companies in ATC/DDD methodology in Oslo, 7-8 June 2012. This training in WHO methodology on medicines classification and studying medicines consumption (ATC/DDD) takes place on a yearly basis in WHO collaborating centre for Drug Statistics Methodology. More information is available at:


3.4 Pharmaceutical sector assessment

A policy dialogue on medicines was organized in Chisinau, Moldova on 20–21 September 2012 with WHO support. The event was hosted by the Ministry of Health and brought together about 70 representatives of the Ministry, National Medicines Agency, National Health Insurance Company, Medical and Pharmaceutical University, professional associations, health care providers of different levels, international organizations, nongovernmental organizations and independent local and external experts. The purpose was to discuss the outcomes of the Moldovan pharmaceutical sector assessment performed by HTP in 2011-2012, focusing on availability and affordability of medicines, national procurement mechanisms, price regulation, prescription policies and rational use. For the report of the assessment, see above.

3.5 Pricing and Reimbursement

In July 2012 experts from the Republic of Moldova and Ukraine, with support from WHO/Europe, were trained in pricing policies, by the WHO Collaborating Centre of Pharmaceutical Pricing and Reimbursement Policies in Vienna, Austria.