Publications and events

Access to treatment

2014 Access to Medicines Index launched
Haarlem – The 2014 Access to Medicine Index, launched on 17 November, presents an updated ranking of the top 20 pharmaceutical companies. Key findings suggest that companies do more to improve access although progress is uneven, and that pricing strategies are increasingly tailored. On the other hand, 18 of the 20 companies have been the subject of settlements or judgements regarding breaches in ethical marketing, bribery or corruption standards or competition laws in the last two years.

The Access to Medicines Foundation, based in the Netherlands, is an international not-for-profit organisation dedicated to addressing the challenges of access to medicine worldwide. The Index is published every two years and gives insights into what the pharmaceutical industry is doing to improve the situation. The Index is funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs and the UK Department for International Development.


New Lancet Commission on Essential Medicines Policies
The Lancet has commissioned a group of 19 independent experts in a variety of disciplines to generate a report which is planned to be published by the end of 2015, 30 years after the Nairobi Conference on the Rational Use of Drugs. The Commission will formulate recommendations for global essential medicine policies for the next two decades.

Global access to essential medicines is a highly charged political issue. Radical civil society action was required to force the pharmaceutical sector to provide life-saving ARVs to people living with HIV/AIDS. Today, the discussions need to include second-line and third-line antiretrovirals, as well as medicines for cancer, hepatitis C, and non-communicable diseases. The Commission's work will raise global awareness of the critical importance of essential medicines policies to achieve universal health coverage.


WHO invites hepatitis medicines for prequalification
Geneva – WHO has expanded its list of medicines invited for prequalification to include treatments for hepatitis B and C. The 12th Invitation for Expression of Interest (EOI) related to HIV and AIDS-related medicines includes sofosbuvir, simeprevir and ribavirin formulations. An additional dosage strength for flucytosine is also included.

► WHO Prequalification update, 19 September 2014.

The lists of medicines invited for prequalification (HIV/AIDS including hepatitis B and C, Malaria, Tuberculosis,
Reproductive Health, Influenza, Zinc, and Neglected Tropical Diseases) are available at http://apps.who.int/prequal - Information for applicants - Invitations for Expression of Interest (EOI).

**Antiviral Therapy special issue on access to HIV treatment**

London – A special issue of *Antiviral Therapy* on the subject of ARV access in resource-poor countries has been published in partnership with UNAIDS. It includes articles on all aspects of these life-saving medicines: discovery and development, production, market and pricing, procurement and supply, effective use in treatment regimens, and delivery to patients.

The special issue includes a review of the regulatory framework for access to safe, effective quality medicines. The article points to the disparities in regulatory capacity and describes how WHO-prequalification and related initiatives have increased access to good quality medicines worldwide and — perhaps more importantly — are now laying the groundwork for collaborative approaches aiming to ensure that pharmaceutical products meet the same, stringent quality standards in all parts of the world.

► *Antivir Ther.* 2014;19 Supplement 3.  
Full supplement freely available on the International Medical Press web site.  

**Intellectual property**

**Interagency symposium on access to medical technologies**

Geneva – The World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) have held their fourth trilateral symposium, titled “Innovation and access to medical technologies: challenges and opportunities for middle income countries”.

Middle-income countries today include many countries with a poor public health situation for large parts of their population. The symposium aimed to identify ways to strengthen the capacity of governments to develop and apply policies that ensure access to new products while fostering an environment conducive to innovation.

► *WTO News,* 5 November 2014.

**WHO report on patent status of hepatitis medicines**

Geneva – To help countries achieve equitable access to quality, effective, affordable and safe Hepatitis C treatments, WHO has published an analysis of the patent situation for seven new hepatitis treatments. The analysis, carried out by Thompson Reuters on behalf of WHO, provides crucial information about the patents themselves and the countries which they cover. This information is vital to inform government policies and actions when selecting and purchasing medicines for their populations.

► WHO publishes analysis of patent situation of new hepatitis treatments [web page].  
Published 4 November 2014.
NIH and FDA win top award for meningitis vaccine licensing deal
Washington – The National Institutes of Health (NIH) and the FDA have received the “2014 Deals of Distinction Award” for the year’s most outstanding intellectual property licensing deal for technology transfer of a new, low-cost serogroup A meningitis vaccine named MenAfriVac.

According to WHO, 80–85% of all meningitis infections in sub-Saharan Africa are from group A. The vaccine has a low production cost and does not require constant refrigeration. The technology was licensed from the NIH Office of Technology Transfer to PATH, a Seattle-based non-profit leader in global health innovation, and then sublicensed to the Serum Institute of India (SII) under the Meningitis Vaccine Project, a partnership of PATH and WHO.

The deal has enabled the manufacture of MenAfriVac at an affordable cost for 26 African countries where serogroup A meningitis is most common. To date, more than 150 million people in 12 African countries have been vaccinated, with no reported cases of serogroup A meningitis in vaccinated populations.

► Licensing Executives Society (USA and Canada) Inc. Press Release, 9 September 2014.

Medicines for children

Improving medicines for children in Canada
Ottawa – An expert panel report released by the Council of Canadian Academies addresses the importance of developing safe and effective medicines for children. The panel advises that studying medicines in children is always possible and is in their best interests. The report was requested by the Minister of Health, on behalf of Health Canada.

Children respond to medicines differently from adults, and many of the medicines that they take have not been proven safe and effective in children. The panel found that in the U.S. and the EU paediatric medicines research is encouraged, required, and monitored in ways that offer lessons for Canada, and that, while paediatric medicines research is a Canadian strength, it requires reinforcement and sustained capacity and infrastructure to realize its full potential. The report stresses the need for collaboration across sectors and countries, and for tailored solutions reflecting the unique Canadian context.

This comprehensive, evidence-based assessment of the state of research and regulations on children’s medicines will serve as an important resource for policy-makers, regulators, health care professionals and researchers in the years to come. It is available both in English and in French.


Medicines use

Study shows better drug and antibiotic use where there is policy implementation
A study of public sector medicines use and prescribing indicators indicates that between 2002 and 2008 implementation of rational medicines use policies in countries is associated with better medicines use in the public sector. For example, there was less antibiotic use for upper respiratory tract infection in those countries that reported implementation of policies than in those that did not.
Data came from surveys on medicine uses conducted in primary health care facilities by various researchers according to a methodology and indicators established by WHO in collaboration with INRUD, and from WHO databases for 2002–2008 on implementation of 36 policy variables.

Suboptimal medicine use is a global public health problem. The findings highlight the importance of WHO’s core normative functions, which have come under threat in recent years. The authors emphasize the importance of recognizing the critical role of the WHO and of ensuring that its core functions are sustained and enhanced.


WHO matters

Two WHO Expert Committee meetings held

Geneva – The World Health Organization (WHO) Expert Committees are the highest technical advisory bodies to the WHO Director-General and Member States. Two Expert Committee meetings on medicines were held concurrently in Geneva on 13–17 October 2014.

At its forty-ninth meeting, the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) adopted a number of specifications, general texts and International Chemical Reference Standards for The International Pharmacopoeia (see pages 431 ff. for an example of a global specification). The Committee further adopted 16 technical supplements and eight guidelines for manufacturers and regulators, including new guidance on good review practice prepared under the leadership of the Asian-Pacific Economic Cooperation’s Regulatory Harmonization Steering Committee.

At its sixty-fifth meeting the WHO Expert Committee on Biological Standardization (ECBS) discussed standards and guidance related to inactivated polio vaccine, changes in manufacturing, good manufacturing practices for biological products and regulatory risk assessment. It also reviewed studies to establish international standards, including the first WHO reference reagent for anti-malaria (Plasmodium falciparum) human serum to support the development of a malaria vaccine.

Cross-cutting topics addressed by both Committees included collaboration and capacity-building platforms, regulatory pathways for approval of needed products, and systems to prevent and manage medicines shortages.

The guidelines adopted by the Expert Committees are published as annexes to the WHO Technical Report Series. The texts adopted at this year’s meetings will be presented to the WHO Governing Bodies in 2015 for information and final comments, and will then constitute WHO technical guidance recommended for implementation by WHO Member States and other parties.

ECSPP: Guidelines are available at www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines

ECBS website: www.who.int/biologicals/expert_committee

WHO prequalification of medicines 2013 annual report

Geneva – The WHO Prequalification Team: medicines (PQTm) has published
its annual report for 2013. The year has seen a record number of products prequalified, including many ‘firsts’ of their kind. The prequalification teams for medicines, vaccines and diagnostics have been brought together within one WHO unit. A wide range of supporting activities, services and collaborative initiatives are ongoing to strengthen both prequalification and regulatory capacity in countries.

WHO currently has no regular budget to fund its prequalification activities. Financial support was received from UNITAID, which provided approximately 80% of the operational costs, from the Bill and Melinda Gates Foundation, and from the Global Fund, UNFPA and WHO’s Department of Neglected Tropical Diseases for procurement-related risk assessments by the Expert Review Panel (ERP). Although donor funding will continue, WHO is working towards a sustainable funding mechanism that will cover at least half of the operational costs for prequalification of medicines, diagnostics and vaccines.

In its 13 years of existence, PQTm has evolved into a global platform for regulators and manufacturers working together according to internationally recognized, harmonized quality standards. This enables them to cope with the challenges of today’s increasingly complex and globalized pharmaceutical markets.

More support from the global community is needed to achieve broader impact in this crucial task.


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