Publications and events

Global health

WHO publishes 2015 World Health Statistics

Geneva – WHO has published its 2015 World Health Statistics, assessing progress made in Member States towards health-related goals.

2015 is the final year for the United Nations’ Millennium Development Goals (MDGs), which were set by governments in the year 2000. By the end of this year, if current trends continue, the world will have met global targets for turning around the epidemics of HIV, malaria and tuberculosis, and will have made substantial progress in reducing maternal and child deaths. However wide gaps persist between and within countries.

With regard to essential medicines the report shows that access is still limited, especially where drugs are not available in the public sector and where prices have increased as a result of increases in countries’ wealth. [According to World Bank data, 73% of the world’s poor today live in middle-income countries – Ed.]

Countries will decide on new global goals for 2030 at the UN General Assembly in September. Additional emerging challenges to tackle in the post-2015 agenda include the growing impact of noncommunicable diseases and the changing social and environmental determinants that affect health.


Sixty-eighth World Health Assembly closes

Geneva – The Sixty-Eighth World Health Assembly, held on 18–26 May 2015 in Geneva, adopted a number of landmark resolutions and decisions, including an historic resolution on air pollution, the first global plan of action on antimicrobial resistance, a new global malaria strategy and decisions on the International Health Regulations.

In decisions stemming from the 2014 Ebola outbreak, the Assembly gave the go-ahead for structural reforms intended to enable WHO to respond effectively to future emergencies. A US$ 100-million contingency fund will be set up for in-field operations. Delegates appreciated Organization’s key coordination role in supporting development of Ebola vaccines, diagnostics and medicines (see also pages 161–162). They further requested WHO to continue helping countries to strengthen national health systems.

In other decisions related to medical products the Assembly agreed to improve access to sustainable supplies of affordable vaccines, to prepare the phased withdrawal of oral polio vaccines, to strengthen emergency and essential surgical care including access to safe anaesthetics such as ketamine (see also page 160), and to postpone the review of the Member State mechanism to combat substandard, spurious, falsely labelled, falsified and counterfeit medical products until 2017.

► WHO Media centre. Sixty-eighth World Health Assembly [web page].
WHO updates essential medicines lists

Geneva – WHO has published the 2015 editions of its *Model List of Essential Medicines* and its *Model List of Essential Medicines in Children*. Among the medicines that have been added are five new direct-acting oral antivirals to treat hepatitis C, 16 anti-cancer medicines and five anti-tuberculosis medicines, four of which – including bedaquiline and delamanide – target multi-drug resistant tuberculosis.

The essential medicines lists are updated every two years by a WHO Expert Committee, based on evaluations of the efficacy, safety and cost-effectiveness of the proposed medicines. As governments and institutions around the world are increasingly using the WHO list to guide the development of their own essential medicines lists, the changes could have enormous public health impact globally. This year, the Committee underscored the urgent need to take action to promote equitable access to several new highly effective medicines, some of which are currently too costly even for high-income countries.

► WHO News release, 8 May 2015.

Access to new medicines in Europe

Copenhagen – The WHO Regional Office for Europe has released a report on access to new medicines in Europe. The study features findings from 27 countries and explores different approaches that health authorities in European countries are using to deal with high spending on new medicines.

As the number of new medicines introduced in Europe rises, governments need novel policy approaches to evaluate the cost-effectiveness of new drugs and make informed public health choices. The report outlines possible policy directions and choices that may help governments to reduce high prices when introducing new drugs. The findings suggest that cooperation and transparency are the best tools to ensure equitable pricing and access.

► WHO Regional Office for Europe. Press release, 26 March 2015.


Ketamine not to be placed under international control

Vienna – During its 58th Session held on 9–17 March 2015 in Vienna, the United Nations Commission on Narcotic Drugs (CND) deferred action on the scheduling of ketamine as an internationally controlled substance.

Ketamine is a widely used anaesthetic included in the WHO essential medicines list. The Government of China postponed its proposal to include ketamine in a Schedule under the 1971 Convention on Psychotropic Substances and suggested that more information should be gathered. WHO and a number of governments welcomed China’s decision, seeing that international controls would limit access to a needed medicine especially in the developing world, and that countries can impose national controls to minimize abuse and trafficking.

► Live reporting from the 58th Session of the Commission on Narcotic Drugs and its Special Segment on the 2016 UNGASS, 13 March 2015.
**Medicines quality**

**Falsified antimalarials less common than previously thought**

Two studies of antimalarial drug quality conducted in Cambodia and Tanzania found no evidence of falsified medicines in either country. Previous reports had suggested that up to one third of antimalarials could be falsified. However, substandard drugs were found in 31% of samples in Cambodia and in 12% of samples in Tanzania. The results highlight the need to strengthen regulatory systems, enabling them to carry out effective routine surveillance.

In Tanzania, one fourth of 1 737 samples analyzed were WHO-prequalified, and these were less likely to be of poor quality than those not prequalified. These are the first published results from the ACT Consortium’s drug quality programme, which analyzed over 10 000 samples from malaria-endemic countries over five years. The studies were funded by the Bill & Melinda Gates Foundation; the Cambodia study also received support from the UK Department for International Development. Results from Nigeria, Equatorial Guinea, Ghana and Rwanda will be published in the next few months.

► [London School of Hygiene and Tropical Medicine, News, 20 April 2015](#).

**Ebola**

**Focus on vaccination and malaria in Ebola-affected countries**

Geneva – WHO has called for intensification of routine immunization services in all areas of Ebola-affected countries, and for mass measles vaccination campaigns in areas that are free of Ebola transmission. The Ebola outbreak, which has infected some 24 000 people and killed around 10 000 of them, has also reduced vaccination coverage in Guinea, Liberia and Sierra Leone as health facilities and staff have focused on halting the outbreak.

The malaria burden has also increased as patients have been unable or afraid to seek treatment during the Ebola outbreak. To reduce the number of febrile people with malaria presenting at Ebola evaluation facilities, WHO recommended mass drug administration of anti-malarial medicines to all eligible people in areas heavily affected by Ebola. An estimated 3 million people have been reached in Sierra Leone and Liberia from October 2014 to January 2015 through door-to-door distribution.

The focus on vaccinations and malaria is part of WHO’s efforts to support countries in early recovery on their way to rebuilding their health systems.

► [WHO News, 20 March 2015](#).

**First Ebola vaccine efficacy trial launched in Guinea**

Conakry – The Guinean Government with the World Health Organization (WHO) has initiated the first efficacy trial of an Ebola vaccine. Ring vaccination tests of VSV-EBOV, a lead Ebola vaccine developed by the Public Health Agency of Canada, are to be conducted in one of the areas in Guinea where most Ebola cases occurred. The concept of the trial is based on vaccinating the “rings” – the group of contacts of a newly diagnosed Ebola “index case” – either immediately after confirmed diagnosis of the index case, or three weeks later. This strategy allows all known contacts to be vaccinated within a short period of time and constitutes an alternative to the use of a placebo.
The Guinea Ebola vaccine trial is a coordinated effort among numerous international partners. A total of around 10,000 people in 190 rings are planned to be vaccinated. Results could be available as early as July 2015.

**WHO proposes emergency use assessment procedures**

**Geneva** – WHO has proposed a set of Emergency Use Assessment and Listing (EUAL) procedures for in vitro diagnostic products, medicines and vaccines intended to address a public health emergency caused by a disease. It applies when the community may be willing to tolerate less certainty about the safety and efficacy of a product (or its safety and performance in the case of a diagnostic), given the high morbidity and/or mortality of the disease and the shortfall of options to diagnose, prevent and/or treat it.

An EUAL is granted on a defined minimum level of information, making a product available for a time-limited period in an emergency while further data are being gathered and evaluated. It is important to note that the procedures are not the same as WHO prequalification and should not be thought of as such.

**WHO lists Ebola diagnostic tests for emergency use in West Africa**

**Geneva** – WHO has listed four diagnostic tests as being eligible for UN procurement in Ebola affected countries, after successful assessment through the EUAL procedure. As the Ebola outbreak is winding down, sensitive, effective diagnostic tests are important to identify any remaining infections and keep them from spreading.

The EUAL evaluation for diagnostics comprises three key components: (1) a review of technical documentation relating to safety and performance; (2) a review of documentation about the manufacture of the product and the manufacturer’s quality management system (QMS); and (3) an independent laboratory evaluation coordinated by WHO to determine the product’s performance and operational characteristics.

**Hepatitis**

**WHO publishes first hepatitis B treatment guidelines**

**Geneva** – WHO has issued its first-ever guidance for the treatment of chronic hepatitis B. This disease has a huge health impact as it can lead to cirrhosis and liver cancer, and the medicines that can prevent the development of these conditions are currently out of reach for many patients.

The WHO guidelines for the prevention, care and treatment of persons living with chronic hepatitis B infection cover the full spectrum of care, with a focus on settings with limited resources, and taking into account special populations such as people co-infected with HIV, children and adolescents, and pregnant women.

Key recommendations include the use of simple tests to assess the stage of liver disease, prioritizing treatment for those with cirrhosis, the use of tenofovir or entecavir to treat chronic hepatitis B, and
regular monitoring to assess treatment outcomes and detect liver cancer at an early stage. To prevent new hepatitis B infections, WHO recommends to vaccinate all children with a first dose given at birth. WHO’s recently launched policy on injection safety, calling for the worldwide use of “smart” syringes to prevent the re-use of syringes or needles, will also help prevent new hepatitis B infections. In 2014 WHO published its first guidelines on treating hepatitis C. ► WHO News release, 12 March 2015.

Patent landscapes of hepatitis C medicines
Geneva –WHO has analyzed the patent situation for new hepatitis treatments to provide clarity on whether or not the medicines are patent-protected in individual countries. Updated information has been published for sofosbuvir in about 20 countries, as well as on ledipasvir and daclatasvir, the latter with a complete data set for the primary patent.

Hepatitis C Virus infection is a chronic disease that often leads to severe liver disease and kills between 350 000 and 500 000 people annually. The World Health Assembly, in its Resolution WHA67.6, requests WHO to assist Member States in ensuring equitable access to quality, effective, affordable and safe hepatitis treatments. ► WHO Essential medicines and health products. News, 24 March 2015.

Hepatitis C diagnostics needed
An article in The Lancet Global Health emphasizes the importance and economic impact of reliable diagnostics in the fight against hepatitis C. This disease is severely underdiagnosed, especially in limited-resource settings. The authors advocate for a concerted effort to develop and fund appropriate diagnostic tests, which will maximize the effect of treatment programmes and thereby reduce the overall cost to health systems. ► Denkinger CM, Kessel M. Diagnostics for hepatitis C: an urgent need for action. The Lancet Global Health 2015;3(4), e195, April 2015. DOI: http://dx.doi.org/10.1016/S2214-109X(15)70092-6.

Note: Hepatitis C diagnostics are among the priority products assessed by the WHO prequalification team in view of procurement by international organizations. At the end of 2014 four products were under full assessment, seven were under abbreviated assessment in recognition of stringent regulatory approval, and for 17 products completion of dossiers was ongoing. For more information on WHO prequalification of in vitro diagnostics see WHO Drug Information 28(3);2014: 312-316, and the article starting on page 133 of this issue.

Dementia

Advancing research and care
Geneva –At the First Ministerial Conference on Global Action Against Dementia, hosted by WHO on 16–17 March 2015, the Government of the United Kingdom announced that over US$ 100 million will be invested in a pioneering new global Dementia Discovery Fund. Major pharmaceutical companies have committed in principle to investing in promising research efforts for dementia that could bring about a breakthrough in treatment.

An estimated 47 million people are living with dementia worldwide. This number is expected to triple by 2050, with enormous personal, social and economic consequences that could affect low- and middle-income
countries disproportionately. The conference participants – which included representatives of 80 WHO Member States, 80 philanthropic foundations, 45 on-governmental organization and four United Nations agencies – adopted a call for action on dementia at the global level. (1)

London – On the first day of the WHO conference the MHRA published the conclusions of a workshop held with representatives of ten regulatory authorities in November 2014. The participants identified six areas to work towards addressing the scientific gaps in the understanding of dementia, enabling regulators to contribute to strategies to bring innovative therapies to the market. (2)

► (1) WHO News release, 17 March 2015.
(2) MHRA News, 16 March 2015.

WHO matters

**WHO prequalification programme proposes new financing model**

Geneva – The WHO prequalification programme for in-vitro diagnostics, medical devices, medicines and vaccines has called for comments on its new financing model for its services and support to normative and regulatory functions, which are increasingly considered to be a global public health good.

In the last two decades, prequalification has helped to greatly increase access to affordable, quality-assured medical technologies in low- and middle-income countries. Its standards and processes are now being leveraged in collaborative procedures and regional regulatory networks, enabling regulators to speed up product assessments in countries, organize joint reviews and develop and introduce standard regulatory dossier formats.

While no major changes will be made to the fees currently charged for initial assessment and major variations, an annual financial contribution from manufacturers is proposed to be introduced. The model aims to generate at least 50% of the funds required to operate the prequalification programme, which is currently funded entirely by international donors through short-term grants.

The new model was designed following discussions with representatives of prequalification stakeholders and a review of a range of alternative options. WHO then sought additional input — via questionnaire — in order to assess whether any of the parameters of the model required adjustment. The input received is now under review.

► WHO Essential medicines and health products. Call for public comments on the new financing model for WHO Prequalification and supporting regulatory functions [webpage].

**WHO officials meet with CFDA Vice Minister**

On March 27, 2015, the Vice Minister of the China Food and Drug Administration (CFDA), met with a WHO delegation to exchange opinions on various medicines-related topics including drug prequalification, general assessment of drug regulatory systems, the reform of drug evaluation and approval systems, and poliomyelitis vaccines. The main directors of CFDA’s Department of Drug and Cosmetics Supervision and relevant directors of Department of International Cooperation attended the meeting.

► CFDA Press release, 31 March 2015.
Upcoming events

3rd International PPRI Conference on medicines pricing and reimbursement

The 3rd Pharmaceutical Pricing and Reimbursement Information (PPRI) conference will be held on **12-13 October 2015** in Vienna, Austria. Registration will close on 30 September.

The event will be organized by the WHO Collaborating Centre on Pharmaceutical Pricing and Reimbursement Policies. Titled “Challenges Beyond the Financial Crisis” it will take a critical look at recent developments, policy reforms and initiatives taken to maintain access to medicines in a context of financial crisis.


2015 WHO-UNICEF-UNFPA meeting with manufacturers

The 2015 joint WHO-UNICEF-UNFPA meeting with pharmaceutical and diagnostics manufacturers and suppliers will be held in Copenhagen during the week of **23-27 November**.

More information will be published on the three organizations’ websites closer to the event.