Publications and events

Research and development

Call for checks on clinical trials
Amsterdam – The Netherlands-based Wemos Foundation has published a summary of reports about clinical trials from four African countries. The findings show that the trials were not always conducted according to ethical guidelines, putting the trial participants at risk of being harmed or having their rights violated. For example, some clinical trial participants were not well informed that they were signing up for a trial, and others agreed to participate because it was the only way for them to get treatment in their country. In case of physical harm, receiving financial compensation was shown to be extremely difficult. The report recommends that EMA should perform more checks on clinical trials conducted in low- and middle-income countries and should make its research reports and its good clinical practice (GCP) inspection reports public.

In April 2017 the European Parliament had reminded EMA of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting market authorization.

Clinical evidence: beyond RCTs
Randomized, controlled trials (RCTs) have long been presumed to be the ideal source of data on the effects of treatment. However, other methods of obtaining evidence for decisive action are receiving increased interest, prompting new approaches to leverage the strengths and overcome the limitations of different data sources. A new review article describes the use of RCTs and alternative data sources from the vantage point of public health, illustrates key limitations of RCTs, and suggests ways to improve the use of multiple data sources for health decision making.

Access to medicines

Access to cancer care
Amsterdam – The Access to Medicine Foundation has published an analysis of industry activities that aim to improve access to cancer care in low- and middle-income countries. This is the first landscape analysis of pharmaceutical companies’ actions to address cancer care in low- and middle-income countries. In its study, the Foundation describes and discusses 129 separate pricing and capacity building initiatives, matching them against companies’ oncology portfolios. The study also examines whether companies are linking their initiatives to products on the WHO's Essential Medicines List.

The cost of reaching the global health targets

An analysis published in *The Lancet Global Health* estimates the benefits and costs of reaching the 16 health targets of Sustainable Development Goal (SDG). The analysis includes 67 low- and middle-income countries that account for 75% of the world’s population. Achieving the SDG health targets could prevent 97 million premature deaths globally, and would require new annual investments increasing over time from US$ 134 billion currently to $371 billion by 2030. Approximately 25% of this cost is for medicines and other health products used to prevent or treat specific diseases, as well as training, outreach activities and campaigns. Modelling suggests that most of the costs can be met with domestic resources, although 32 countries will continue to need external assistance. High-income countries were not included in the analysis but other estimates show that all of them can afford to provide universal health coverage with essential health services to their citizens.

The analysis is intended as a tool to inform further research. It also highlights that achieving universal health coverage and the other health targets requires not only funding but political will and respect for human rights.


Framework for access to health products

Geneva – The WHO Essential Medicines and Health Products Programme has published a long-term framework for 2016–2030. The 2030 sustainable development agenda and the increasing globalization of health products development and supply have generated a need – and an opportunity – for WHO to adjust and strengthen its work in this area at the Organization’s headquarters, regional and country offices. The framework provides a broad vision and strategic direction to reinforce WHO’s ability to help Member States achieve universal access to safe and quality-assured health products and universal health coverage. WHO will pursue this aim by (i) supporting needs-based innovation and reinforcing health product selection, use, procurement and supply systems, and (ii) strengthening regulatory capacity and practices. To maximize results the focus will be on specific areas such as antimicrobial resistance, controlled substances, research and development preparedness for epidemics, and appropriate regulatory pathways for emerging health products.


Fair Pricing Forum Report

Geneva – WHO has published the report of the Fair Pricing Forum held on 11 May 2017 in Amsterdam. The multi-stakeholder discussion was seen as a first step towards identifying an actionable agenda towards fair pricing of medicines.

The report states that fair pricing does not necessarily mean low pricing, but rather a medicines price that allows for a reasonable return on investment in exchange
for an affordable product. Governments should be enabled to play a stronger role in negotiating prices and where appropriate, incentivizing research and development with priority given to products that respond to public health needs. The need for greater transparency on costs of development and production and pricing of medicines was recognized as a recurring theme.


**Draft pharmaceutical policy of India**

India – The Department of Pharmaceuticals of the Government of India has circulated its Draft Pharmaceutical Policy – 2017. The policy aims to make essential drugs widely accessible at affordable prices, provide a longer term stable policy environment for the pharmaceutical sector, make India self-reliant in end-to-end indigenous drug manufacturing, ensure that medicines for domestic consumption and exports are of world class quality, and create an environment for R&D to produce innovator drugs.


**WHO to develop an essential diagnostics list**

Geneva – At its 2017 meeting the Expert Committee on the Selection of Essential Medicines recommended that WHO should develop an Essential Diagnostics List (EDL). Like the established Essential Medicines List (EML), the EDL is intended to provide evidence-based guidance to countries to create their own national lists of essential diagnostic tests and tools. This is expected to facilitate access to priority diagnostic tests at affordable prices.

Diagnostic tests are essential to guide the appropriate use of medicines and to monitor their effectiveness and/or toxicity. With technological advances, medicines and diagnostics are increasingly interconnected. The Committee recommended that the EDL should initially focus on in vitro diagnostics and on priority areas such as tuberculosis, malaria, HIV and hepatitis B and C, and that it should be expanded as soon as possible to include tests that can guide the use of antimicrobials and medicines for non-communicable diseases. WHO has meanwhile begun to lay the groundwork for the preparation of the list.


**Preparedness**

**Pandemic emergency financing**

Sendai, Japan – The World Bank has launched a specialized type of bonds aimed at providing financial support to the Pandemic Emergency Financing Facility (PEF), a facility that will channel funding to developing countries facing the risk of a pandemic. This marks the first time that pandemic risk in low-income countries is being transferred to the financial markets.

The PEF will provide over US$ 500 million to cover developing countries against the risk of pandemic outbreaks over the next five years. The Facility has an “insurance” window and a “cash” window that will be available from 2018 for the containment of diseases that may not be eligible for funding under the insurance window.

The creation of the PEF in May 2016 was announced at the G7 Finance Ministers and Central Governors meeting in Japan. The Facility covers six viruses that are most likely to cause a pandemic, including
new orthomyxoviruses (new influenza pandemic virus A), *Coronaviridae* (SARS, MERS), *Filoviridae* (Ebola, Marburg), and other zoonotic diseases (Crimean Congo, Rift Valley, Lassa fever). Countries eligible for financing under the PEF’s insurance window are members of the International Development Association (IDA). PEF financing will be triggered when an outbreak reaches predetermined levels of mortality and spread. The determinations for the trigger are made based on publicly available data as reported by WHO.


### Drug resistance

**Gonorrhoea:**

**WHO calls for action**

Rio de Janeiro, Brazil – At the STI & HIV World Congress, held on 9–12 July 2017, WHO has called for international collaborative action to tackle antimicrobial resistance of *Neisseria gonorrhoeae*. WHO surveillance data show that this resistance is widespread and on the rise. The findings led to an update of WHO treatment recommendations in gonorrhoea in 2016. *N. gonorrhoeae* is listed among the WHO “High Priority” pathogens for development of new antibiotics, and is on similar priority lists in the U.S., UK and Canada. Only three new candidate medicines are at various stages of clinical development: solithromycin, zoliflodacin, and gepotidacin. Supporting the development of new antibiotic treatments for gonorrhoea is one of the key priorities of the Global Antibiotic Research and Development Partnership (GARDP), a not-for-profit organization launched in May 2016 by the Drugs for Neglected Diseases initiative (DNDi) and WHO.

In addition, non-drug measures are essential to control gonorrhoea, including information and education to promote safer sexual behaviour and encourage people to seek care, earlier diagnosis with point-of-care tests – ideally ones that can detect resistance – and effective tracking and reporting of new infections, antibiotic use, resistance and treatment failures.


### Antimicrobials:

**EU Action plan against resistance**

Brussels – The European Commission has adopted its new One Health Action Plan to tackle antimicrobial resistance (AMR) in both humans and animals. The first deliverable of the plan will be an EU guideline on the prudent use of antimicrobials in human health. In addition, the plan foresees more than 75 actions built on three main pillars: Making the EU a best-practice region; boosting research, development and innovation; and shaping the global agenda.

AMR is responsible for 25 000 deaths and a loss of €1.5 billion in the EU every year. The new action plan builds on the first EU AMR Action Plan which ran from 2011 to 2016. (1) Industry has expressed support for the EU leadership in the sustainable collaborative fight against antimicrobial resistance. (2)


### New data on antibiotics from Europe

A new report from the European Food Safety Authority (EFSA), EMA and the European Centre for Disease Prevention
and Control (ECDC) presents new data confirming the link between antibiotic consumption and antibiotic resistance in both humans and food-producing animals, and reflects improved surveillance across Europe. The findings confirm the conclusions of the first report, published in 2015, based on a more sophisticated analysis of new, better quality data.


Antiretrovirals: WHO drug resistance report

Geneva – WHO has released its HIV drug resistance report 2017, which was co-authored by the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the U.S. Centers for Disease Control and Prevention. The report reveals an increasing trend of HIV resistance to antiretrovirals.

In 6 of 11 countries surveyed in Africa, Asia and Latin America, over 10% of people starting antiretroviral therapy had a strain of HIV that was resistant to some of the most widely used medicines – a threshold that should trigger an urgent review of national treatment guidelines according to the report findings. Mathematical modelling shows that if no action is taken, an additional 135 000 deaths and 105 000 new infections could occur and HIV treatment costs could increase by US$ 650 million in the next five years.

Of 36.7 million people living with HIV worldwide, 19.5 million people were accessing ARV therapy in 2016. In most patients the treatment remains highly effective, but a growing number are experiencing the consequences of drug resistance. WHO is issuing new guidelines to help countries address HIV drug resistance.


Medicines use

Proton pump inhibitors: Study warns against overuse

A new study examines the association between the use of proton pump inhibitors (PPIs) and risk of all-cause mortality. The authors note that these products are widely prescribed, rarely deprescribed, and are available over the counter in several countries.

The risks of PPIs are well documented and include some serious adverse effects. The results of the study show an excess risk of death among PPI users, including those without gastrointestinal conditions, which increases with prolonged duration of use. The benefits of PPIs outweigh the risks if they are used for the approved indications. However, in the U.S. their use doubled between 1999 and 2012, and it has been estimated that 53-69% of PPI prescriptions are for inappropriate indications. The study concludes that may be warranted to limit PPI use and duration to instances where it is medically indicated.


Public health

Hepatitis: High mortality despite progress

Geneva – On World Hepatitis Day 2017 WHO has published new data from 28 high-burden countries, showing that national
efforts for effective prevention, diagnosis, treatment and care are gaining momentum. However, hepatitis C treatment remains expensive, and there is an urgent need to scale up access to hepatitis testing.

Viral hepatitis affected 325 million people and caused 1.34 million deaths worldwide in 2015, almost as many as tuberculosis and more than HIV. Most hepatitis deaths are due to hepatitis B and C.

Hepatitis C can be cured with direct-acting antivirals (DAAs). However, in 2015 only 7% of 71 million patients had access to DAAs despite dramatic price drops in some countries. The recent WHO-prequalification of a sofosbuvir active ingredient and a generic product will promote generic competition; other hepatitis C medicines are under assessment by WHO.

Hepatitis B affects 257 million people globally. Many countries have scaled up hepatitis B vaccination, and treatment with tenofovir (which in most cases needs to be taken for life), is generally affordable; however there is an urgent need to scale up diagnostic testing.


### Poliovirus

Geneva – At its fourteenth meeting held on 3 August 2017 by teleconference the Emergency Committee under the International Health Regulations (2005) (IHR) unanimously agreed that the risk of international spread of poliovirus remains a Public Health Emergency of International Concern (PHEIC) and has recommended to maintain the revised Temporary Recommendations for another 3 months.

The Committee was encouraged by the steady progress achieved in all three countries infected with wild poliovirus – Pakistan, Afghanistan, and Nigeria – and the fall in the number of cases globally, with no international spread detected in the last three months. However, risks remain as polioviruses are likely to be still circulating in areas with inaccessible populations, lack of services and/or security risks. The Committee was very concerned about new outbreaks of vaccine-derived poliovirus in the Democratic Republic of the Congo and in Syria, and by the delay in detecting these outbreaks, indicating serious persisting gaps in immunization and surveillance.

The Committee strongly urged global partners to support countries in implementing the Temporary Recommendations for immunization and cross-border control at this critical time and warned against complacency, which could easily lead to a resurgence of polio.

► WHO Statement, 3 August 2017.

### 2016 immunization coverage

Geneva – The latest joint WHO and UNICEF immunization estimates show that global immunization coverage has stalled at 86% since 2010, falling short of the target of 90%. Nearly 1 in 10 infants did not receive any vaccinations in 2016.

Worldwide, 10 million infants need to complete the full 3-dose immunization against diphtheria, tetanus and pertussis (DTP). Of these, 4 million live in just three countries – Afghanistan, Nigeria and Pakistan – where access to routine immunization services is also critical to achieving and sustaining polio eradication. 85% of children under one year globally have received a first dose of measles vaccine, 64% have received a second dose. Global coverage of rubella vaccines and the more recently recommended rotavirus and pneumonia vaccines is below 50%.
National coverage estimates often mask large inequities within countries. The report shows that there is generally less inequality now than 10 years ago, but that more efforts are needed to bring vaccines to households with low income and education levels.


**Maternal immunization safety monitoring**

Global efforts are underway to develop and implement new vaccines for use in pregnant women in low- and middle-income countries (LMICs), where there is the greatest burden of vaccine-preventable disease. As these efforts go forward, it is a critical time to formulate an organized and comprehensive approach to monitoring safety of maternal immunizations in LMICs. A new report by the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) looks at existing programmes, identifies gaps and outlines a roadmap for effective safety monitoring of maternal immunization.

The report was developed with support from the Bill & Melinda Gates Foundation and with input from a large multidisciplinary group of experts. Reference is made to relevant work done by other organizations, such as the 2017 CIOMS Guide to Active Vaccine Safety Surveillance.


**WHO medicines prequalification updates**

**Prequalified “Firsts”**

**Medicines:**

- First etravirine API, for manufacture of HIV medicines
- First kanamycin injection, for second-line treatment of tuberculosis
- First sofosbuvir API, for manufacture of hepatitis C medicines
- First generic oxytocin, to treat bleeding after childbirth
- First generic magnesium injection, for treatment of complications in pregnancy
- First prequalified pyrimethamine, for treatment of malaria
- First generic streptomycin, for treatment of tuberculosis
- First paediatric isoniazid/rifampicin 50/75 dispersible tablet

WHO-PQTm website. Prequalified lists:
- Active Pharmaceutical Ingredients
- Medicines/Finished Pharmaceutical Products

**Diagnostics:**

- First HIV self-test
  - WHO list of prequalified in vitro diagnostic products

**New proposed KPIs**

WHO-PQT has proposed new key performance indicators (KPIs) to measure programme responsiveness and prequalification timelines. The document proposes a harmonized approach to calculation of timelines (both WHO time and applicants’ “stop-clock” time) as well as targets for the proposed KPIs. Once the public comment phase is concluded, the KPIs will be implemented through a new IT system that is planned to go live in October 2018.