Publications and events

Access to medicines

UNHRC resolution on access to medicines
Geneva – The UN Human Rights Council (UNHRC) has adopted by consensus a resolution on access to medicines that reaffirms the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The resolution urges all States, the WHO and relevant organizations to promote innovative research and development to address health needs in developing countries, including access to quality, safe, efficacious and affordable medicines, taking into account the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. It further calls on member states to make full use of the flexibilities provided by the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to continue collaborating, “as appropriate, on models and approaches that support the delinkage of the cost of new research and development from the prices of medicines, vaccines and diagnostics for diseases that predominantly affect developing countries”. A panel discussion will be held in March 2017 on best practices and challenges in access to medicines.

► Intellectual Property Watch news. 1 July 2016.

WHO to convene stakeholders on fair medicines pricing
Geneva – In an online commentary the WHO Assistant Director-General for Health Systems and Innovation, Dr Marie-Paule Kieny, has announced that WHO is planning to convene governments, patient groups and industry stakeholders to develop a fair pricing model that can affordably deliver the medicines needed by patients.

As some new medicines are unaffordable even for wealthy countries, and some older medicines are in great shortage, new approaches are needed to reach universal health coverage, which is at the centre of global health efforts under the Sustainable Development Goals. Dr Kieny proposed that, for this objective to be reached by 2030, the public and private spheres should enter into a social contract, enabling innovation and generic production to respond effectively to global public health needs by providing, quality, safe, effective treatments which are both available and affordable.

► WHO Media Centre. Commentary by Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation. 5 July 2016.

New book on intellectual property rules and access to medicines
Amsterdam – A book and web site launched by Health Action International (HAI) describe the impact of the patent system on access to medicines and encourage governments to use available legal flexibilities to safeguard access to
needed treatment. The web site provides information about the relationship between intellectual property and access to medicines as well as more in-depth analyses into key issues, along with resources and infographics.

► HAI Press release, 13 July 2016.

**Medicines Patent Pool signs new licences**

Geneva – The Medicines Patent Pool (MPP) has announced new generic manufacturing licences for four antiretrovirals – lopinavir/ritonavir, atazanavir and raltegravir – as well as the direct-acting antiviral daclatasvir to treat hepatitis C. The MPP has signed licences with Aurobindo, Desano, Emcure, Hetero Labs, Laurus Labs, Lupin and new partner Zydus Cadila for a total of nine new agreements to produce generic versions of key WHO-priority treatments for HIV and hepatitis C.


**Hepatitis C patent landscape**

Geneva – WHO has published updated patent information for seven new hepatitis C medicines which are included in the WHO List of Essential Medicines: sofosbuvir, ledipasvir, daclatasvir, simeprevir, paritaprevir, ombitasvir and dasabuvir. The reports cover more than 40 countries, territories and regions and provide clarity on whether or not the medicines are patent-protected in individual countries. This knowledge is important for governments in making treatment available to their populations.

► WHO Public health, innovation, intellectual property and trade. WHO updates patent information on treatments for Hepatitis C [web page].

**Insulin patent landscape**

A new publication in the *Journal of Pharmaceutical Policy and Practice* provides an overview of the patent landscape for insulin. The authors conclude that the global market dominance of expensive analog over human insulins, offered by a few manufacturers, will likely continue even though many patents for insulin analogs will expire soon. A way forward would be to find generic manufacturers that will offer acceptable off-patent human insulin products for export. (1)

The paper is one in a series produced under the ACCISS Project, a multi-year effort to understand what is causing the barriers to insulin access and to address the inequities in the global market. (2)


(2) Health Action International. ACCISS study [web site]. http://haiweb.org/what-we-do/acciss/

**Pharmacovigilance**

**Two new CIOMS publications**

Geneva – The Council for International Organizations of Medical Sciences (CIOMS) has released two new publications for health professionals involved in safety surveillance of medicines.

The publication *Evidence Synthesis and Meta-Analysis for Drug Safety, Report of CIOMS Working Group X* is for readers who are interested in analysis of drug safety data or meta-analysis more generally. It provides the rationale for
why and when a meta-analysis should be considered in the context of regulatory decision-making, and describes the tasks, data collection, and analyses that need to be carried out to inform those decisions. While most guidance and reviews in this area give more attention to assessment of pre-defined benefits, this report focuses on combining evidence on harms that emerge in the post-market setting.

The book titled *Development and Rational Use of Standardised MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA – Second Edition* is useful for those wishing to search databases on Individual Case Safety Reports (ICSRs) coded according to the MedDRA® system. It provides examples of standardized queries that are relevant in different contexts such as systematic analyses, interventional clinical trials, signal detection or safety signal assessment.

CIOMS is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. Its publications are available directly from CIOMS (www.cioms.ch) or from the WHO bookshop (http://apps.who.int/bookorders/).

| CIOMS News, 30 August 2016 |

**Disease updates**

**Polio virus: public health emergency of international concern**

Geneva – At the advice of the Emergency Committee under the International Health Regulations (2005) (IHR), the WHO Director-General has declared the continuation of the public health emergency of international concern with regard to the spread of both wild poliovirus and circulating vaccine-derived poliovirus.

Temporary recommendations will remain in place for countries that are infected by, vulnerable to, and/or exporting the two types of virus.

The Committee was gravely concerned about information indicating that wild poliovirus had been circulating undetected in Nigeria for several years and would likely spread to Cameroon, Chad and Niger, as well as the deteriorating security in parts of Afghanistan which may delay efforts for polio eradication.

| WHO Statement, 22 August 2016 |

**Zika: public health emergency continues**

Geneva – Based on the advice provided by the Emergency Committee under the International Health Regulations (2005) at its third and fourth meetings (1, 2), the WHO Director-General has declared the continuation of the Public Health Emergency of International Concern posed by Zika virus infection and has reaffirmed the existing recommendations for public health measures. At the time of the fourth Committee meeting, there were no reports of confirmed cases of Zika virus among people who attended the Games. The Committee reaffirmed its previous advice that there should be no general restrictions on travel and trade with areas with Zika virus transmission, including the cities in Brazil that will be hosting the Paralympic Games. Acknowledging that the impact of Zika virus is a long term concern, the Committee recommended focus on several new research issues. It further recommended that the Director-General should consider developing an appropriate infrastructure and response plan within WHO.

WHO, the Pan American Health Organization (PAHO) and partners have
set out their strategic response to Zika. A greater focus will be placed on preventing and managing medical complications, information and counselling services, and integrated vector control measures. Implementation of the strategic response plan from July 2016 to December 2017 will cost US$ 122 million. (3)

► (1) WHO Statement, 14 June 2016.
(2) WHO Statement, 3 September 2016.
(3) WHO Note for the media, 17 June 2016.

Sexually transmitted infections: new WHO treatment guidelines

Some antibiotics are failing in the treatment of these STIs as a result of misuse and overuse. Without effective treatment, complications can result that can cause serious illness and sometimes death. The new recommendations are based on the latest available evidence. For gonorrhoea, the new WHO guidelines recommend against the use of quinolones due to widespread high levels of resistance. For syphilis, the new WHO guideline strongly recommends a single dose of benzathine penicillin given by injection, instead of oral antibiotics. WHO is working with partners to help address prevailing shortages of benzathine penicillin.

WHO is calling on countries to update their national treatment guidelines and to start using the updated recommendations immediately.


Non-communicable diseases: uneven progress
Geneva – A new WHO report highlights the need to intensify national action to meet the global targets to protect people from heart disease, cancers, diabetes, and lung diseases. Globally, these four noncommunicable diseases (NCDs) remain the leading causes of mortality. The sustainable development goals include a goal to reduce, by one third, the premature mortality from NCDs in people aged under 70 years.

The findings of a global 2015 survey show that a number of countries have adopted measures to prevent tobacco use, harmful use of alcohol, unhealthy diet, and physical inactivity. However, progress is insufficient and uneven.

► WHO Note for the media, 18 July 2016.

Hepatitis B and C: need for more access to testing and treatment
Geneva – WHO has urged countries to increase access to hepatitis testing and treatment and to step up preventive strategies. This follows the adoption, at the 2016 World Health Assembly, of the first ever Global Health Sector Strategy and global targets to fight viral hepatitis. The Second World Hepatitis Summit will take place in Brazil in March 2017.

Globally, 400 million people are infected with hepatitis B and C, more than 10 times the number of people living with HIV. Only one in 20 people with viral hepatitis is diagnosed with the disease, and only one in 100 is being treated.

Direct-acting antivirals can cure more than 90% of patients within 2-3 months. While their high costs continue to put
treatment out of most people’s reach, prices are declining especially in countries that have access to generics. For example, in Egypt the cost of a hepatitis C treatment course dropped from US$ 900 in 2014 to less than US$ 200 in 2016.


HIV

Key challenges
Durban – At the International AIDS Conference in Durban, South Africa, WHO has flagged four key challenges to the global HIV response. Firstly, the number of new infections has remained high, and renewed attention must be paid to prevention, for example by exploiting new interventions such as pre-exposure prophylaxis (PrEP). Secondly, while WHO has recommended that all people diagnosed with HIV start antiretroviral therapy (ART) as soon as possible, there is a need for more ready access to simple and affordable testing services and for tailored treatment programmes to reach all those in need. Thirdly, vigilance and quick action are required to minimize the emergence of drug resistance, and lastly, there is a need for sustainable financing of the global response. (1)

HIV and injectable contraceptives
Geneva – WHO will convene an expert review group later in 2016 to examine the links between the use of various hormonal contraceptive methods and women’s risk of HIV acquisition. The expert review group will assess whether current WHO guidance needs to change in light of the findings of a WHO-commissioned systematic review, published in AIDS on 9 August 2016 (2).

While the data continue to indicate no association with risk of HIV acquisition for oral contraceptive pills, injectable norethisterone enanethate and levonorgestrel implants, they strengthen existing concerns about a possible increase in risk of HIV acquisition in women using injectable depot medroxyprogesterone acetate. (3)

► (1) WHO Note for the media, 15 July 2016.

Vaccines

Yellow fever emergency vaccination campaigns
Geneva – The Emergency Committee under the International Health Regulations (2005) determined that the current status of the yellow fever outbreaks in Angola and the Democratic Republic of the Congo (DRC) does not constitute a Public Health Emergency of International Concern (PHEIC) at this time, but requires sustained scaled up response activities and close monitoring. (1)

In the last two weeks of August 2016, more than 7.7 million people in Kinshasa and a further 1.5 million people in DRC’s border regions with Angola were vaccinated in an emergency campaign accomplished through an extraordinary network of partnerships and collaborations. The campaign built on previous emergency campaigns led by national governments, which had reached more than 13 million people in Angola.
and more than 3 million in DRC since the beginning of the outbreak in December 2015 (2).

To achieve maximum population coverage the recent campaign used the ‘fractional dosing’ approach recommended by the WHO Strategic Advisory Group of Experts (SAGE) on Immunization, whereby one fifth of the regular dose of yellow fever vaccine can confer immunity for at least 12 months (3). Full doses were given to pregnant women and infants, who may have a weaker immune response. A USAID-funded study will evaluate the immune response achieved during the campaign.

The International Health Regulations still require a full dose for travellers. A 2014 amendment entered into force in July 2016 under which all countries recognize that a single full dose confers life-long immunity.

WHO has prequalified yellow fever vaccines from four different vaccine manufacturers which together produce an annual volume of around 80-90 million doses. A global stockpile of 6 million doses is funded by Gavi, the Vaccine Alliance. The stockpile was depleted twice between February and June 2016 due to the need to control outbreaks. (3)

► (1) WHO Statement, 31 August 2016.
(2) WHO News release, 2 September 2016.
(3) WHO Statement, 17 June 2016.

Global vaccine quality control laboratories networking meeting
Lage Vuursche, Netherlands – At a meeting hosted jointly by WHO and the Dutch National Institute for Public Health and the Environment (RIVM) from 30 August to 2 September 2016, participants from 22 countries agreed to establish a global network of control laboratories performing lot release of WHO-prequalified vaccines.

Lot release by regulatory authorities is an important element in the regulation of vaccines. It serves to confirm that each batch of a vaccine meets the specifications of the product as laid down in the approved marketing authorization. WHO-prequalified vaccines are used to immunize 65% of infants worldwide. The proposed network – the first at the global level – is intended as a platform for participating laboratories to share information in order to strengthen mechanisms for reliance and work-sharing and promote harmonization of testing. This is expected to result in more effective and streamlined processes both for regulators and for manufacturers, thus increasing global access to WHO-prequalified vaccines at affordable costs.

► WHO Immunization standards. WHO-RIVM Global Vaccine Quality Control Laboratories Networking Meeting [web page].

WHO matters

New WHO guideline welcomed
The Hague, Netherlands – New guidelines have been released jointly by WHO and the International Pharmaceutical Federation (FIP) on providing medicines for children when no authorized product exists.

Health professionals all over the world have long struggled with the lack of authorized and commercially available child-specific medicines. They are often forced to use adult medicines when treating children for example by crushing tablets, or to make products from scratch. These approaches pose a certain risk of inaccurate dosing and can impact on the quality, safety and efficacy of the
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medicine. The new guidance provides advice based on available evidence, best practices and sound scientific and therapeutic principles, and provides practical examples.

FIP-WHO technical guidelines: Points to consider in the provision by health care professionals of children-specific preparations that are not available as authorized products.

WHO Prequalification Team offers GMP pre-inspections
Geneva – To assist manufacturers in resource-limited countries who are keen to attain product prequalification, the WHO Prequalification Team (PQT) is initiating a pilot collaboration enabling manufacturers to request verification of their compliance with the principles of good manufacturing practice (GMP) even before they have submitted an application for WHO prequalification.

The concept of this approach has been tested successfully in cooperation with the Nigeria’s National Agency for Food and Drug Administration (NAFDAC) and the Pharmaceutical Manufacturers Association of Nigeria (PMG-MAN).

► PQ Update, 17 June 2016.

MQAS Finished pharmaceutical product questionnaire posted
Geneva – WHO has posted a Word version of the Interagency Finished Product Questionnaire (1) on its website, for ease of use by manufacturers and other parties.

The Interagency FPP questionnaire is an appendix to the WHO Model Quality Assurance System (MQAS) for procurement agencies (2). It is the common format to be used by manufacturers to submit product data to international organizations. Such data are reviewed for those needed medicines of which no WHO-prequalified or stringently authorized products are available.

The WHO MQAS was updated in 2014 in collaboration with the Interagency pharmaceutical working group, which brings together the major organizations involved in international procurement of medicines.

► (1) WHO MQAS Appendix 6 - Interagency finished pharmaceutical product questionnaire based on the model quality assurance system for procurement agencies. Available at: WHO. Essential medicines and health products. Guidelines. – Distribution
