Publications and events

Access to medicines

Hepatitis C medicines landscape
Geneva – Unitaid has published a landscape analysis of the current state of technologies for the treatment of hepatitis C virus (HCV) and of the market dynamics that affect access to HCV medicines.

The report finds that DAAs are now becoming more widely available and affordable, but intellectual property barriers have created a dual market with prices remaining high in some countries. However, even where generics are available at affordable prices financing is lacking, and there is too little screening and demand for HCV testing. The market for generics has developed fast but remains fragile because of the uncertain demand and uptake.(1)

In October 2017 the international humanitarian organization Médecins Sans Frontières (MSF) announced that it has secured deals for the two key DAAs sofosbuvir and daclatasvir at US$120 per 12-week treatment course. MSF’s work on HCV is partially supported by UNITAID.(2)

In December 2017, the MPP announced that it will include information on anti-cancer products in its patent and licensing database, MedsPaL, as a first step in upgrading the database to include all patented treatments on WHO essential medicines list.(1)

► (1) MPP Press release, 4 October 2017.
(2) MPP Highlight, 12 December 2017.

MPP licence for bictegravir
Geneva – The Medicines Patent Pool (MPP) and Gilead Sciences have signed a licence for bictegravir, an integrase inhibitor which is under review in the U.S. and the EU as part of a once-daily, single-tablet HIV regimen. The licence allows manufacturers to develop and sell generic medicines containing bictegravir, if approved in the U.S., in 116 low- and middle-income countries where more than 30 million people live with HIV.

The MPP and Gilead are also expanding the geographical scope of licences on other HIV products, enabling generic medicines to be supplied to additional countries.(1)

In December 2017, the MPP announced that it will include information on anti-cancer products in its patent and licensing database, MedsPaL, as a first step in upgrading the database to include all patented treatments on WHO essential medicines list.(1)

(2) MSF Press release, 31 October 2017.

New methodologies for Access to Medicine Index
Amsterdam – The Access to Medicine Foundation has published the updated methodology for its 2018 Access to Medicine Index. This latest methodology focuses on areas where the 20 major pharmaceutical companies assessed in the Index have the greatest potential to make a difference. New indicators have been developed in response to changing global health priorities, including one that captures how companies are responding to R&D priorities set by WHO and others, and new metrics that will evaluate the quality of access initiatives and how impact is being assessed. The 2018 Index will also assess companies’ actions in relation to cancer for the first time, along with their actions on 76 other high-burden diseases, conditions and pathogens.(1)
In August 2017 the Foundation had published the methodology for its 2018 Antimicrobial Resistance Benchmark, the first independent framework for assessing action by pharmaceutical companies to combat antimicrobial resistance. (2) The first antimicrobial benchmark report is expected to be published in early 2018.


### Safety and efficacy of medicines

#### Expedited approval and label changes

A study of 382 FDA-approved medicines found that products approved through expedited pathways had more safety-related label changes after approval, particularly for the types of changes representing the highest risk warnings. The authors recommend that the reasons for this finding should be explored to inform appropriate policy interventions.

Of 382 new pharmaceutical products included in the study, 135 (35%) were associated with an expedited development or review pathway. Products approved through an expedited pathway had a 48% higher rate of changes to boxed warnings and contraindications than those approved through other pathways, and of 67 changes to boxed warning sections reviewed in the study only 3 served to describe reduced risks for patients.

► Mostaghim S, Gagne JJ, Kesselheim AS. Safety related label changes for new drugs after approval in the US through expedited regulatory pathways: retrospective cohort study. BMJ 2017;358:j3837. doi: https://doi.org/10.1136/bmj.j3837

#### Real-world data may support new indications

A newly published study used insurance claims data from a nationwide health care database to compare outcomes of patients newly prescribed telmisartan or ramipril. The study replicated the inclusion and exclusion criteria of a randomized clinical trial (the ONTARGET trial) that established a supplemental indication for telmisartan, and used propensity score matching to balance 74 patient characteristics. Similar to the randomized clinical trial, the study based on real-world data revealed a decreased risk of angioedema with telmisartan compared with ramipril. The authors conclude that in certain situations database studies may support the demonstration of effectiveness of approved medications in applications for additional indications.


#### Medicines quality

### One in ten medical product in developing countries is substandard or falsified

Geneva – Two new WHO reports suggest that an estimated one in ten medical products in developing countries is substandard and falsified, meaning that hundreds of thousands of people die or suffer grave health consequences from such products every year. The first report is based on data collected by the Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in-vitro diagnostic tests during its first four years of operation. (1) The second is a study on the
Quality of cardiac drugs in Africa

A sample testing study of seven routinely used cardiovascular medications (anticoagulants, antihypertensives and statins) in ten Sub-Saharan African countries found a significant proportion of poor quality products at licensed pharmacies and unlicensed street-markets. Of 1530 samples tested, 16.3% had a content of active ingredient below 85% or above 105% of that declared on the packaging. The proportion of substandard products was particularly high for amlodipine (29%), captopril (26%), generic products (23%), and for medicines produced in Asia (35%). 50% of drugs produced in Asia and sold in street-markets were found to be substandard. The authors conclude that continued monitoring strategies are required to fight poor quality medicines.


Survey of antimalarials in Myanmar

A survey of 153 artemisinin-containing antimalarial samples purchased in private drug stores in different regions of Myanmar found that more than 35% of the collected drugs were oral artesunate and artemether monotherapies, which are not recommended for the treatment of malaria. The survey also provided the first description of falsified parenteral artesunate circulating on the market. The authors call for more oversight of medicines quality by regulatory authorities.


Public health updates

Antibiotic resistance

The pipeline is running dry

Geneva – A new WHO analysis confirms that the world is running out of new antibiotics to combat the growing threat of antimicrobial resistance. A review of new antibiotics and biologicals in clinical development shows that very few of them will add value to the current treatment arsenal for the 13 WHO-identified priority pathogens, and that there are very few oral antibiotics in the pipeline although these are essential for treating infections outside hospitals or in resource-limited settings.

To counter this threat, WHO and the Drugs for Neglected Diseases Initiative (DNDi) have set up the Global Antibiotic Research and Development Partnership (GARDP). Germany, Luxembourg, the Netherlands, South Africa, Switzerland, the United Kingdom and the
Wellcome Trust have pledged more than €56 million for the development of new treatments.


WHO. Prioritization of pathogens to guide discovery, research and development of new antibiotics for drug resistant bacterial infections, including tuberculosis. September 2017.

New WHO guidelines on antibiotic use in animals

Geneva – New WHO guidelines (1) recommend that farmers and the food industry should stop the routine use of antibiotics in healthy animals, except if a disease has been diagnosed in other animals in the same population. Where possible, sick animals should be tested to determine the most effective and prudent antibiotic to use, avoiding antibiotics classified as “highest priority critically important” for human health.

The new guidelines were informed by recent research that found that interventions restricting antibiotic use in food-producing animals reduced antibiotic-resistant bacteria in these animals by up to 39%.(2)

► WHO News release, 7 November 2016.

(1) WHO guidelines on use of medically important antimicrobials in food-producing animals. 2017.


Website on antimicrobial susceptibility

United States of America – To enable health professionals to manage the use of antimicrobials better, the FDA has launched a website that provides updated information about when bacterial or fungal infections are likely to respond to a specific medicine.

► FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria [web page].

Antibiotic resistance in Australia

A recent report has revealed that antibiotic resistance in Australia is increasing and requires major efforts to control the spread of resistant strains. Despite some recent gains in efforts to encourage more careful use of antibiotics, as much as 56% of samples of enterococci can be resistant to vancomycin according to the report – a level higher than in any European country. Antibiotic use has been falling in Australian hospitals, but concerning levels of inappropriate prescribing remain both in hospitals and in the community. Methicillin-resistant *Staphylococcus aureus* (MRSA) has become the most common type of MRSA infection in the community and is now a more common cause of bloodstream infections than hospital-associated strains of MRSA. This is concerning, as no country has yet found effective interventions to control the spread of community-associated MRSA.


Antibiotic consumption

The seventh report of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) shows that overall the sales of antibiotics for animal use decreased by 13% in Europe between 2011 and 2015, but that there are substantial differences between countries. A drop in sales of at least 5% was observed in 15 of the 25 countries that provided data for the full period. However, antibiotic sales increased by more than 5% in eight countries. Given
the substantial decline in the sales of antimicrobials for food-producing species in some countries, there is hope that decreases can also be achieved in others.\textsuperscript{(1)} A new set of indicators will be used in the EU to assess Member States’ progress in reducing antimicrobial resistance and antimicrobial consumption in both the human and animal sectors. The indicators are based on data gathered through existing EU monitoring networks and are presented in the form of a scientific opinion.\textsuperscript{(2)}

In the United Kingdom, sales of antibiotics for use in animals fell to their lowest level since 1993. Sales of antibiotics that are critically important for humans accounted for less than 1% of all antibiotics sold for use in animals in 2016.\textsuperscript{(3)}

In the U.S, antimicrobial sales for use in food-producing animals decreased for the first time in fifteen years. From 2015 to 2016 domestic sales and distribution of antimicrobials fell by 10% overall, and by 14% for medically important antimicrobials. These figures do not yet reflect changes in Guidance for Industry, which resulted in a voluntary transition of medically important antimicrobials used in the feed or water of food-producing animals from over-the-counter to either prescription or Veterinary Feed Directive marketing status, and withdrawal of all approved production indications (growth promotion and feed efficiency) for the affected products on 1 January 2017.\textsuperscript{(4)}

\textbf{Non-communicable diseases}

\textbf{Slow and uneven progress}

\textit{Geneva} – WHO has published its report on progress made by Member States to fight non-communicable disease (NCD). Heart and lung diseases, stroke, cancer and diabetes cause millions of untimely deaths before age 70 each year, of which 80% occur in low- and middle-income countries. The \textit{WHO NCD Progress Monitor 2017} provides data on 19 indicators showing how countries build capacities to reduce and treat NCDs and how they address the four main risk factors: tobacco, unhealthy diet, physical inactivity and harmful use of alcohol.

The ten best-performing countries were Costa Rica and Iran (15 of 19 indicators achieved); Brazil, Bulgaria, Turkey and the United Kingdom (13 indicators achieved); and Finland, Norway, Saudi Arabia and Thailand (12 indicators achieved). But progress around the world has been uneven and insufficient to meet the Sustainable Development Goals target to reduce premature NCD deaths by one third by 2030. No country from the WHO Africa region achieved more than 8 of the 19 indicators; six achieved none of them.

The findings will underpin a WHO report that will be submitted to the United Nations Secretary General ahead of the third UN High-level Meeting on NCDs in 2018.

\textsuperscript{(1)} EMA Press release 16 Oct 2017.
\textsuperscript{(2)} EMA News, 26 October 2017.
\textsuperscript{(3)} MHRA Press release, 27 October 2017.
\textsuperscript{(4)} FDA Releases Annual Summary Report on Antimicrobials Sold or Distributed in 2016 for Use in Food-Producing Animals. 7 December 2017.
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disease, cancers, diabetes and respiratory disease and reduce suffering from mental health issues and the impact of violence and injuries. The announcement came ahead of the WHO Global Conference on Noncommunicable Diseases, co-hosted by WHO and the President of Uruguay.
► WHO Statement, 10 October 2017.

The Montevideo Roadmap
Montevideo – At the opening of the three-day Global Conference on Noncommunicable Diseases in Montevideo, hosted by WHO and the Presidency of Uruguay, governments endorsed the Montevideo Roadmap 2018–2030 on non-communicable diseases. The roadmap highlights the need for coordinated action from all sectors and the civil society to promote health and prevent and control NCDs. It also points out that most of the untimely deaths caused by NCDs - primarily heart and lung diseases, cancers and diabetes – could have been prevented by action against tobacco, air pollution, unhealthy diets, physical inactivity, and harmful use of alcohol, as well as by improved disease detection and treatment.

Tuberculosis

WHO Global Tuberculosis Report 2017
Geneva – WHO has released its Global Tuberculosis Report 2017. The findings show that progress is not on track to reach global targets. Tuberculosis remained the top infectious killer in 2016. It also caused the most deaths related to antimicrobial resistance and the most deaths among people with HIV.

In 2016, there were an estimated 10.4 million new tuberculosis cases worldwide, 10% of which were among people living with HIV. Seven countries (India, Indonesia, China, Philippines, Pakistan, Nigeria and South Africa) accounted for 64% of the total burden. An estimated 1.7 million people died from tuberculosis. There were an estimated 490 000 new cases of multi-drug resistant tuberculosis, almost half of them in India, China and the Russian Federation.

Gaps in care and financing persist. Of the 10.4 million new cases, only 6.3 million were detected and officially notified in 2016. Only one in five patients with multi-drug resistant infections started treatment, and most people eligible for preventive tuberculosis treatment are not accessing it. Investments for tuberculosis care and prevention in low- and middle-income countries fall almost US$ 2.3 billion short of the US$ 9.2 billion needed in 2017. In addition, at least an extra US$ 1.2 billion per year is required to accelerate the development of new vaccines, diagnostics, and medicines.

Ministerial Conference on Ending TB
Moscow/Geneva – At the WHO Global Ministerial Conference on Ending TB in the Sustainable Development Era, held in Moscow on 16–17 November 2017, 75 ministers agreed to take urgent action to end tuberculosis (TB) by 2030. The Moscow Declaration to End TB is a promise to increase multisectoral action, track progress and build accountability. More than 1000 participants took part in the two-day conference. Further commitments from heads of state will be sought at the first UN General Assembly High-Level Meeting on TB in 2018.
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### Hepatitis

São Paulo, Brazil – Over 900 delegates from 110 countries met at the World Hepatitis Summit 2017, held on 1–3 November 2017 in Brazil to discuss a common goal: the elimination of viral hepatitis. This biennial event is a joint initiative between the World Health Organization (WHO) and the World Hepatitis Alliance (WHA). The Summit closed with the launch of the São Paulo Declaration for a broad and coordinated approach to support implementation of WHO's Global Hepatitis Strategy.\(^{(1)}\)

Hepatitis causes more than 1.3 million deaths every year, and an estimated 328 million people are living with hepatitis, of which an estimated 71 million people have chronic hepatitis C infection. Despite some dramatic price reduction for new hepatitis C medicines, funding for key hepatitis services remains a major constraint in most countries. On the eve of the Summit WHO reported that close to 3 million people have accessed curative treatment for hepatitis C, and 2.8 million more embarked on lifelong treatment for hepatitis B in 2016. Hepatitis B infection rates in children under five have fallen due to better vaccine coverage. However the delivery of other prevention services remains low, leading to continuing rates of new infections including 1.75 million new hepatitis C cases every year. A functional cure for hepatitis B infection and more effective point-of-care diagnostics for hepatitis B and C need to be developed.\(^{(2)}\)


### Polio

Geneva – The WHO Emergency Committee under the International Health Regulations (2005) (IHR) regarding the international spread of poliovirus has unanimously agreed that the risk of international spread of poliovirus remains a Public Health Emergency of International Concern (PHEIC) and recommended the extension of revised Temporary Recommendations for a further three months.

In reaching this conclusion the Committee considered the potential risk of further spread of poliovirus through population movement particularly between Afghanistan and Pakistan, Nigeria and its Lake Chad neighbours, and countries bordering the Syrian Arab Republic, where a large outbreak is ongoing. The continued circulation of poliovirus in these countries demonstrates significant gaps in population immunity at a critical time in the polio endgame, when the world is closer to polio eradication than ever before in history. Following the global withdrawal of the type-2 component of oral poliovirus vaccine in April 2016, population immunity to type-2 polioviruses is rapidly waning. The global shortage of inactivated polio vaccine poses an additional risk. The Committee also noted with concern the recent detection of a single, highly diverged vaccine-derived type-2 poliovirus in sewage in Mogadishu, Somalia, with genetic evidence of more than three years of replication without detection.

\[^{(1)}\] WHO Statement, 14 November 2017.

### Cholera

Geneva – A new strategy to fight cholera has been launched by the Global Task Force on Cholera Control (GTFCC), a diverse network of more than 50 UN and international agencies, academic institutions and NGOs. The strategy aims to reduce cholera deaths by 90% by the year 2030 through early detection and response to outbreaks. By implementing the Roadmap,
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up to 20 countries could eliminate cholera by 2030.

Advances in water sanitation and hygiene have made Europe and North America cholera-free for several decades, and the introduction of oral cholera vaccine has bridged the gap between emergency response and longer-term control. However, cholera continues to kill an estimated 95 000 people annually and affects another 2.9 million, mostly in communities burdened by conflict, lack of infrastructure, poor health systems, and malnutrition. Protecting these communities before cholera strikes is more cost-effective than responding to outbreaks. Two WHO-prequalified oral cholera vaccines are now available and individuals can be fully vaccinated for just US$6 per person, protecting them from the disease for up to three years.

Plague

Geneva – An unusually large outbreak of plague has been reported from Madagascar. In response WHO delivered nearly 1.2 million doses of antibiotics to health facilities and mobile clinics across the country. The Organization also released US$1.5 million from its emergency funds to allow for immediate support until more substantial funds are received. WHO called for US$5.5 million to respond to the outbreak.(1)

In October, ten suspected cases reported from Seychelles tested negative for plague.(2)

Between 1 August and 22 November 2017 the Ministry of Public Health of Madagascar reported a total 2 348 cases of plague, including 202 deaths. By the end of November the outbreak had slowed down, with a steady decline of new cases seen over several weeks. However, more infections of both bubonic and pneumonic plague are expected until the end of the plague season in April 2018.(3)

Plague is curable if treated early. It is endemic to Madagascar, where around 400 cases are reported annually. But this outbreak affected large urban areas, and more reported cases than usual were associated with pneumonic plague, which is more readily transmitted between patients than bubonic plague.

► (1) WHO News release, 6 October 2017.
(2) WHO News release, 18 October 2017.

Marburg virus

Uganda – An outbreak of Marburg virus disease has occurred in eastern Uganda on the border with Kenya. The first confirmed case was detected by the Ministry of Health on 17 October 2017. An emergency response was initiated with support from WHO, the U.S. Centers for Disease Control and Prevention (CDC) and the African Field Epidemiology Network (AFNET). WHO deployed a rapid response team to the remote mountainous area and released US$623 000 from its Contingency Fund for Emergencies. Health workers followed up with 316 close contacts of the patients in Uganda and Kenya. The outbreak, which claimed three lives, was successfully controlled only weeks after it was first detected.

Marburg virus disease is a rare and often fatal disease for which there is no specific treatment. It is caused by a virus from the same family as the Ebola virus. Transmission is by direct contact with the blood, body
fluids and tissues of infected persons or wild animals, for example monkeys and fruit bats.

WHO News release, 8 December 2017.

Yellow fever

Geneva – The International Coordinating Group (ICG) on vaccine provision for yellow fever has released 1.4 million vaccine doses to help control an outbreak in Nigeria. The first case was confirmed in August 2017; by 21 November 2017 a total 276 suspected cases had been reported in fourteen states of Nigeria.

The International Coordinating Group (ICG) coordinates the timely and equitable provision of vaccines during outbreaks. Its members include the International Federation of Red Cross and Red Crescent Societies (IFRC), Médecins sans Frontières (MSF), the United Nations Children's Fund (UNICEF), and WHO. The ICG maintains an emergency stockpile of 6 million doses of yellow fever vaccine, funded by Gavi, the Vaccine Alliance. In 2017, nearly 6 million doses from the stockpile were deployed for emergency vaccination campaigns.

WHO News release, 1 December 2017.

Diphtheria

Yemen – Diphtheria has made a comeback in war-torn Yemen, with 189 clinically diagnosed cases and 20 deaths – mostly children and young adults – in three months. WHO delivered 1000 vials of life-saving anti-toxins and 17 tonnes of medical supplies. Antibiotics and vaccines are also critical to treating and preventing the highly infectious respiratory disease; however both are in short supply in Yemen. WHO, UNICEF, and partners have worked with available supplies, vaccinating 8 500 children under five years in two districts of the worst-affected governorate during November. A vaccination campaign targeting 300 000 children younger than 12 months began on 25 November. Further vaccination rounds for more than 3 million children and young adults in priority districts are due in December. (1)

Diphtheria is also rapidly spreading among Rohingya refugees in Cox’s Bazar, Bangladesh. More than 110 suspected cases, including 6 deaths, have been clinically diagnosed. This could be just the tip of the iceberg in this extremely vulnerable population. WHO and partners have vaccinated more than 700 000 people against cholera and more than 350 000 children against measles and rubella. WHO has procured 1000 vials of anti-toxins to treat people that are already infected. A campaign targeting all children up to 6 years with pentavalent (DPT-HepB-Hib) and pneumococcal vaccines is in preparation. (2)

WHO News release, 6 December 2017.
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Prequalification

**Stability data requirements**
The WHO Prequalification Team-Medicines (PQT-m) has published updated information on minimum stability data required at the time of filing a generic product application.(1) Previously three months’ stability data at the time of submission had been accepted for reproductive health and second-line anti-tuberculosis products as an interim exception to encourage the submission of poorly-represented products on the list of WHO-prequalified products. This exception has been re-evaluated, and it has been concluded that it is no longer needed.

The minimum stability requirements for all products at the time of submission to PQT-m are six months’ accelerated and six months’ long-term stability data. This is in line with the requirements of most major regulators.(2)

► (1) WHO Prequalification News, 26 September 2017.

**Presubmission meetings**
The WHO Prequalification Team – medicines (PQT-m) has published detailed information about pre-submission meetings. These meetings provide an opportunity for advice and guidance prior to submission of a medicines dossier. They are compulsory for new applicants, and are useful for all applicants to address issues specific to their intended dossier.


Prequalified “Firsts”
- First praziquantel active pharmaceutical ingredient (API)
- First generic dolutegravir tablets, for treatment of HIV
- First linezolid API, for use in medicines to treat drug-resistant tuberculosis
- First terizidone finished product, to treat drug-resistant tuberculosis
- First entecavir finished product, to treat hepatitis C

► WHO prequalification website: https://extranet.who.int/prequal/

- First prequalified vector control product: SumiShield 50WG for use as an indoor residual spray. The product comes as a water-dispersible granule containing the active ingredient clothianidin.

► WHO. Prequalification Vector Control. Prequalified Lists [webpage].

**Target product profile for rapid cholera tests**
In order to treat cholera and quickly stem a potential outbreak, it is important to have a rapid and accurate diagnosis. Rapid diagnostic tests for cholera exist, but recent published evaluations show their accuracy is not optimal.

WHO has developed a target product profile describing the type of assays together with desired and acceptable key attributes. The target product profile provides a clear and tangible vision and focus for product development. Applications for prequalification assessment will be accepted as of 1 January 2018.

► WHO Essential medicines and health products. WHO outlines requirements for rapid cholera tests to prevent major outbreaks. 9 November 2017.
New essential medicines lists online
The updated WHO Model List of Essential Medicines for adults (EML) and WHO Model List of Essential Medicines for Children (EMLc) have been published in the WHO Technical Report Series, in replacement of the unedited version published in June 2017.

The 2017 report uses a new format that sets the stage for future developments. Available treatments – for example antibiotic and diabetes medicines – are presented for diseases or syndromes rather than individual medicines, facilitating broader comparisons and more selective listing.

The report has a new, user-friendly structure and layout. Concise, uniform summaries of the public health relevance, evidence of benefits and harms and the Committee’s considerations and decisions are found in the body of the report. The table of content has clickable hyperlinks to each chapter and section. The EML, EMLc, the Anatomical Therapeutic Chemical (ATC) Classification System and an alphabetical list of essential medicines with ATC numbers are found in the annexes.


Outcomes of programme review
Resolution WHA68.18 requested WHO to commission a review of its global strategy and plan of action on public health, innovation and intellectual property. The independent review panel has now published its findings. The panel concluded that the eight elements of the strategy remain broadly valid, but that the actions for its implementation should be more focused.

Among the priority actions to improve access to health products the panel recommended that WHO should continue to support Member States in strengthening regulatory capacity, regional harmonization and other collaborative initiatives, and that Member States and funders should support the WHO Prequalification of Medicines Programme to include newer essential health products. To promote more sustainable financing Member States should, among other things, encourage the implementation of schemes that partially or wholly delink product prices from research and development costs.


Framework for action against antimicrobial resistance
Over 100 country representatives and experts from the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE) and WHO met in Geneva, Switzerland on 9–10 November 2017 to discuss a future global framework for actions to achieve objectives 4 and 5 of the Global action plan on antimicrobial resistance. (1) The future global framework for development and stewardship to combat AMR aims to support research and development of new, affordable medicines, testing tools and vaccines, and to promote affordable access to new and existing antimicrobials along with stewardship policies for their appropriate use.


WHO guidance on medicines quality

The Expert Committee for Specifications on Pharmaceutical Preparations oversees the maintenance of *The International Pharmacopoeia* (Ph. Int.) and provides guidance for use by relevant WHO units and regulatory authorities in WHO Member States. At its Fifty-Second Meeting, held in Geneva, Switzerland, on 16–20 October 2017, the Committee adopted the international guidance and good practices texts listed below, subject to their finalization as agreed at the meeting. The consultation versions of the texts are available at www.who.int/entity/medicines/areas/quality_safety/quality_assurance/projects.

For publication as annexes to the WHO Technical Report Series (2018):

- Considerations for requesting analysis of medicines samples (revision)
- WHO model certificate of analysis (revision)
- WHO guidance on testing of “suspect” falsified medicines
- WHO guidelines on good herbal processing practices (GHPP) for herbal medicines
- WHO good manufacturing practices for herbal medicines (maintenance)
- Good Pharmacopoeial Practices: Chapter on compounding
- Good Pharmacopoeial Practices: Chapter on monographs on herbal medicines
- Guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems (revision)
- Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions
- Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (revision)
- Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

The Committee furthermore endorsed the proposed approach to conducting solubility studies for the purpose of revising the WHO biowaiver list.

For inclusion in *The International Pharmacopoeia*:

- General chapter on capillary electrophoresis
- Monographs on antimalarials:
  - Pyrimethamine (revision)
  - Pyrimethamine tablets
- Monographs on antiviral medicines, including antiretrovirals:
  - Atazanavir sulfate (revision)
  - Atazanavir capsules (revision)
  - Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets (revision)
  - Ganciclovir
  - Ganciclovir for injection
- Monographs on antituberculosis medicines:
  - Capreomycin sulfate (revision)
  - Capreomycin powder for injection (revision)
  - Moxifloxacin hydrochloride
  - Moxifloxacin tablets
  - Protonamide (revision)
  - Protonamide tablets
- Monographs on anti-infectives:
  - Amoxicillin trihydrate (revision)
  - Clavulanate potassium
  - Amoxicillin and clavulanic acid
  - Clindamycin palmitate hydrochloride

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1 Subject to approval by the world pharmacopoeias in their final round of review
• Clindamycin palmitate powder for oral solution

Texts adopted for inclusion in *The International Pharmacopoeia (continued)*

Monographs on medicines for chronic diseases and for mental health:
• Atenolol (revision)
• Dacarbazine (revision)

Monographs on other medicines:
• Ciclosporin (revision)

In addition the Committee adopted alternative methods for the revision of the following 32 monographs that currently prescribe titrations using mercuric acetate: Amiloride HCl,2 Amitriptyline HCl, Biperiden HCl, Chlorhexidine dihydrochloride, Chlorpromazine HCl, Dopamine HCl, Edrophonium chloride, Ephedrine HCl, Ethambutol HCl, Fluphenazine HCl, Homatropine hydrobromide, Homatropine methylbromide, Ketamine HCl, Lidocaine HCl, Loperamide HCl, Metoclopramide HCl, Morphine HCl, Naloxone HCl, Neostigmine bromide, Pilocarpine HCl, Procarbazine HCl, Procuguanil HCl, Propranolol HCl, Pyridostigmine bromide, Pyridoxine HCl, Quinine dihydrochloride, Quinine HCl, Suxamethonium chloride, Tetracycline HCl, Thiamine hydrobromide, Thiamine HCl and Verapamil HCl.

The Committee adopted the following texts on radiopharmaceuticals, developed by the International Atomic Energy Agency (IAEA) in accordance with the agreed procedure:
• General monograph on radiopharmaceuticals (revision)
• Fludeoxyglucose (18F) injection (revision)
• Sodium pertechnetate (99mTc) injection (fission) (revision)
• Sodium pertechnetate (99mTc) injection (non-fission) (revision)
• Technetium (99mTc) bicsate complex injection (revision)
• Technetium (99mTc) colloidal sulfur injection (revision)
• Technetium (99mTc) colloidal tin injection (revision)
• Technetium (99mTc) mebrofenin complex injection (revision)
• Technetium (99mTc) medronate complex injection (revision)
• Technetium (99mTc) mertiatide complex injection (revision)
• Technetium (99mTc) pentetate complex injection (revision)
• Technetium (99mTc) sestamibi complex injection (revision)
• Technetium (99mTc) succimer complex injection (revision)
• Technetium (99mTc) tetrofosmin complex injection (revision)
• Technetium (99mTc) tin pyrophosphate complex injection (revision)
• Gallium (67Ga) citrate injection (revision)
• Iobenguane (123I) injection (revision)
• Iobenguane (131I) injection (revision)
• Sodium (125I) iothalamate injection (revision)
• Sodium iodide (131I) capsules (revision)
• Sodium phosphate (32P) injection (revision)
• Samarium (153Sm) lexidronam complex injection (revision)
• Strontium (89Sr) chloride injection (revision)
• Yttrium (90Y) silicate injection (revision)

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2 HCl = hydrochloride