2017 saw a smooth transition to the newly named Access to Medicines, Vaccines and Pharmaceuticals (MVP) cluster...
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Change has been a recurring theme in the work of the Essential Medicines and Health Products (EMP) department within the World Health Organization (WHO), and 2017 was no exception. Member States are increasingly requesting our support to improve their health systems and strengthen their ability to ensure equitable access to safe and effective, quality-assured medicines and health products. At the same time, the global market for pharmaceuticals and medical products continues to evolve rapidly. More than ever, there is a need for strong regulatory systems, quality manufacturing, efficient supply chains, effective post-market surveillance and greater affordability of health products.

In 2017, EMP continued to work at country level, as well as regionally and globally, to support all of this and more, with norm setting and regulatory strengthening, and national level technical assistance and training. EMP has also widened its network of strategic partnerships and has been able to utilize its unique position at country level to convene diverse stakeholders to come together and work towards a common aim.

Within WHO, 2017 was also a year of significant change, with the handover of leadership from Dr Margaret Chan to Dr Tedros Adhanom Ghebreyesus as the new Director-General.

Dr Tedros brought with him a new approach to the programme of work for 2019 to 2023. With its strong emphasis on country impact, WHO’s new programme of work fully ensures that EMP’s strategic vision of empowering Member States will reach strong results for people and communities.

Under the new programme of work, EMP’s position within the Organization has also changed: having been a part of the Health Systems and Innovation Cluster, EMP became its own cluster in October 2017. Building on the work of the department under the previous administration, 2017 saw a smooth transition to the newly named Access to Medicines, Vaccines and Pharmaceuticals (MVP) cluster, reflecting a much-welcomed increased emphasis within WHO on ensuring access to safe and affordable medicines and health products, especially in low- and middle-income countries.

Going forward, MVP’s work will continue to be guided by Towards Access 2030: WHO Essential Medicines and Health Products Programme Strategic Framework 2016-2030. This framework informed the work of our entire team in 2017 and will continue to do so, as we support Member States to meet the 2030 health-related Sustainable Development Goal targets, and succeed in providing every child, man and woman with access to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life.

Dr Suzanne Hill
Director
Essential Medicines and Health Products

Mariângela Simão
Assistant Director-General
Access to Medicines, Vaccines and Pharmaceuticals
2017 AT A GLANCE

30 new products added to the latest Essential Medicines List, including
2 oral cancer medicines

& the first combination therapy to treat all six types of HEPATITIS C

12 families of ANTIBIOTIC-RESISTANT BACTERIA posing the greatest threat to human health identified with a view to guiding the discovery of new treatments

1st-time prequalification of a generic HEPATITIS TREATMENT, increasing the number of quality-assured medicines for this deadly disease

€56.5 million in pledges in 2017 to develop new ANTIBIOTIC TREATMENTS through the Global Antibiotic Research and Development Partnership

Child-friendly medicines for HIV, TB & MALARIA more available in 15 AFRICAN COUNTRIES, thanks to a partnership between the European Commission, the African, Caribbean & Pacific island countries & WHO
The latest edition of the Essential Medicines List classifies ANTIBIOTICS into 3 categories - ACCESS, WATCH & RESERVE - with recommendations on when each category should be used.

The guidance will help countries improve antibiotic treatment and minimize the risk of resistance.

**17** VECTOR CONTROL PRODUCTS FOR MALARIA PRE-QUALIFIED, paving way for increased control of malaria and other major vector-borne diseases

**1ST PILOT PROJECT** to prequalify 2 BIOLOGICAL CANCER TREATMENTS

**1ST FAIR PRICING FORUM** held to develop strategies for more AFFORDABLE MEDICINES

**LANDMARK REPORTS** showed the wide reach of substandard and falsified medical products in low- and middle-income countries, calling on governments to join WHO in the urgent fight to prevent, detect and respond to this global health risk

72 MEDICINES, 10 VACCINES, 9 DIAGNOSTICS

prequalified to prevent, test and treat priority diseases

**2** ORAL CANCER MEDICINES are the first combination therapy to treat all six types of HEPATITIS C.
KEY ACHIEVEMENTS
WHO’s objective is for every country to have a competent national regulatory authority (NRA) with oversight of quality-assured medical products, and since 1997 WHO has played a critical role in supporting 130 countries strengthen their regulatory systems. However, much remains to be done, with only 30% of national NRAs deemed to have strong enough oversight. With an increasingly global manufacturing supply chain, it is critical that countries work together, relying on each other’s strengths, and as far as possible sharing the same standards and data. WHO empowers countries to strengthen their own regulatory systems, rely on work done by other regulators and at the same time work together in regional networks.

GUIDELINES FOR COOPERATION

One of MVP’s key roles is the development of regulatory guidelines for countries. In 2017 two key pieces of guidance were added, covering desk assessment of compliance with good manufacturing, laboratory and clinical practices for medical products, and outlining collaborative procedures to assess and accelerate national registration of pharmaceutical products and vaccines. These two guidelines are part of a package of guidance that promotes convergence of regulations, and reliance between regulatory authorities. This enables them to optimise their scarce resources and get quality medicines and health products into the supply chain faster.

WHO also works with countries to support implementation of guidelines, such as through an implementation workshop for WHO Guidelines on evaluation of similar biotherapeutic products (SBPs) for regulators from 10 Russian speaking countries, held in 2017.


3 Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine

4 http://www.who.int/biologicals/publications/trs/areas/biological_therapeutics/TRS_977_Annex_2.pdf

WHO has played a critical role in supporting 130 countries strengthen their regulatory systems.
The positive outcome of the WHO assessment will go a long way in re-affirming India’s role in global health, including the strength of its pharmaceutical sector and vaccine regulatory capacity.

Dr Henk Bekedam
WHO Representative to India.

VACCINE MANUFACTURING REGULATION IN INDIA

Ensuring that NRAs can meet WHO standards is another key area of work, and in 2017, a team of international experts convened by WHO worked together to assess India’s NRA to see if it meets WHO standards for vaccine regulation. The conclusion was that it is well equipped to produce and monitor safe, effective and quality vaccines. This will facilitate WHO prequalification of Indian manufacturers, which will allow them to supply vaccines through the international procurement system, a major breakthrough for vaccine supplies to low- and middle-income countries. To support India in sustaining its regulatory capacity, the WHO team supported the development of a detailed and updated plan covering the activities to further strengthen regulatory capacity in the coming years.
WHO’s objective is for every country to have a **competent national regulatory authority** to ensure the **quality, safety and efficacy** of **medical products**.

**MEDICINES NOMENCLATURE**

Since it was set up in 1953, WHO’s International Nonproprietary Name (INN) programme has provided a common name for each medicine, but studies have found that pharmacy students in general do not learn about INN, nor do they understand the value of the stem word used to give medicines a globally recognized nomenclature. In 2017 WHO launched the School of INN, to educate pharmacy students on how to design and construct an INN, and to provide information to healthcare professionals on the importance for patient safety of having one reference generic name for all medicines, regardless of their brand.  

**BIOOTHERAPEUTIC TREATMENTS**

After consultation with stakeholders and world experts in May 2017, WHO made a number of decisions on biotherapeutic treatments. One such decision is that the emergence of biological products and cell and gene therapies will require new efforts in regulatory strengthening and harmonization of standards. Biosimilars—biopharmaceutical products designed to have similar active properties to previously licensed products—represent effective treatment options at more affordable prices, but the uptake of these products has been slow. It is important for WHO to educate health professionals and patients on biosimilars.

WHO is also working hard to support countries in establishing the regulatory frameworks, resources, and capacity to evaluate these products, facilitate their uptake, conduct post-marketing monitoring, and increase analogue competition and sustainable access to new medicines.

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5. [https://www.youtube.com/watch?v=efjbk5o_xBk&feature=youtu.be](https://www.youtube.com/watch?v=efjbk5o_xBk&feature=youtu.be)
Through its prequalification process, WHO rigorously assesses products and inspects manufacturing sites, supports countries wishing to improve their manufacturing capacity, and works with national regulators to register products quickly. WHO prequalification is not an end in itself. Rather, it is a vital step to ensure that international procurers to low-income countries are providing access to quality-assured, safe and effective medicines, vaccines, in vitro diagnostics and vector control products.
MALARIA CONTROL

In 2017, a slew of malaria control products became prequalified in record time, starting with prequalification of an indoor residual spray, which represented a milestone in terms of procurement and access. The product, which is not hazardous to spray operators or residents of treated homes, is effective for up to eight months in preventing mosquitoes from breeding in walls, eaves and other indoor surfaces. By December 2017, 17 vector control products had been prequalified, helping to increase the range of tools available to prevent transmission of malaria, as well as other vector-borne diseases such as dengue fever, Chikungunya, Zika virus disease and Chagas disease. Prequalifying a range of vector control products is key because rotation of different modes of action reduces the risk of resistance.

COLLABORATIVE REGISTRATION PROCEDURE

In November 2017 Ghana hosted a meeting to facilitate national authorization of prequalified oral cholera vaccine. This was the first time the Collaborative Registration Procedure (CRP) had been used for a vaccine product: a new type of cholera vaccine that is easier to deliver in challenging field conditions and is much less costly than previous alternatives. Cholera vaccination is an important part of a comprehensive prevention package, but the disease is often dealt with in the context of disasters. The CRP facilitated accelerated registration in a number of countries, including in the Caribbean region, and was particularly important given the recent cholera outbreak in Haiti.

This vaccine is prequalified by WHO and meets its high standards for quality, safety and efficacy. The CRP relied on assessment information confidentially shared by WHO, and verified documentation provided by the manufacturer to ensure it was the same product. This case demonstrates the way the CRP is facilitating access to high quality and life-saving medicines in the region. In the context of limited human resources and financing, the CRP is serving as a mechanism for reliance on trusted authorities for their reviews of products regarding safety, quality, and efficacy. It is providing a regulatory channel for manufacturers to expeditiously send these high-quality products to countries where they are needed.

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AT-HOME HIV TESTING

In resource-constrained settings, a lack of health facilities and poor laboratory infrastructure can make getting tests—such as those for HIV—to those who need them particularly challenging. In 2017, WHO prequalified an at-home HIV test, which can overcome this hurdle and other barriers to HIV testing related to privacy and safety concerns. WHO guidelines recommend HIV self-testing as a complementary approach to reach those who remain undiagnosed due to fear of stigma and discrimination. The test uses oral fluid as a specimen and provides results in as little as 20 minutes.

With more countries than ever signed up to offer HIV self-testing, the prequalification opens the door to greater access to the test itself via international financing and procurement agencies, which have already pledged support for procurement and deployment of the tests. These pledges include a specific agreement on affordable pricing for 50 lower-middle income countries in Africa and Asia between the test manufacturer and the Bill and Melinda Gates Foundation, a key funder of WHO prequalification.

SNAKE ANTIVENOM

In 2017, WHO continued to develop the regulatory response and action to address the unmet need for snake antivenom products. Snake bites cause an estimated 81,000 to 138,000 deaths worldwide resulting from 1.8 million to 2.7 million cases of snakebite envenoming.6 Immunotherapy with animal-derived antivenom preparations has been the primary treatment for snakebite envenoming for over 120 years. When antivenoms are manufactured in compliance with current good manufacturing practices, and subjected to rigorous preclinical and clinical evaluation before registration, they are very effective products, especially if administered soon after a snakebite at an adequate dose. However, many countries experience poor availability of quality-assured products due to lax control and regulation and a lack of incentives for manufacturers to produce them.

EMP, together with WHO’s Department of Control of Neglected Tropical Diseases, has updated the 2nd edition of the Guidelines for the Production, Control and Regulation of Snake Antivenom Immunoglobulins and further developed its support to Member States with a technical assessment process for antivenom products brought to market, in order to be able to provide evidence-based recommendations. This process has focused first on Sub-Saharan Africa, with five assessments initiated in 2017. Overall, WHO is providing technical support to manufacturers to improve and expand production of good quality antivenoms, strengthening regulatory control and surveillance and establishing a prequalification pathway for the products.

1.8 to 2.7 million
cases of snakebite envenoming

In 2017, WHO prequalified an at-home HIV test. Results in **20min**
ENSURING MEDICINES ARE AFFORDABLE

Affordable pricing for medicines has long been a controversial topic: with pharmaceutical manufacturers citing incentives to innovate as the reason behind high prices, whilst low- and middle-income countries decry being priced out of the market for life-saving medicines. Today, even wealthy countries struggle with expensive medicines as new and high-priced products are coming to market. At the same time, some of the oldest and cheapest medicines are disappearing from the market.

FAIR PRICING FORUM

In 2017 WHO and the Government of The Netherlands organised the first ever Fair Pricing Forum on medicines. The event brought together more than 230 participants from WHO Member States, the pharmaceutical industry, insurers, and non-governmental organizations to have meaningful and in-depth dialogue about how fair pricing could meet the needs of both suppliers and buyers of medicines.

WHO reiterated that fair pricing does not mean low pricing. Rather, it is sustainable pricing that does not bankrupt payers but also rewards research and innovation. The forum created space for discussion of difficult topics, including the current value-based pricing system, the need for better transparency on prices, and de-linking the cost of research and development from medicines pricing. The forum was the start of an ongoing dialogue between stakeholders on these important issues.

HEPATITIS C AND CANCER TREATMENT PREQUALIFICATION

One key mechanism for low- and middle-income countries to access affordable quality-assured medicines is through the WHO prequalification system (see p. 8). In 2017 there were two important firsts for WHO: the prequalification of two generic medicines for hepatitis C and an active ingredient, and the announcement of a pilot prequalification for biosimilar treatments for cancer. Prequalification of sofosbuvir brings

The first WHO prequalified generic of this [hepatitis C] product will give large procurers and countries the assurance of quality for an affordable product.

Dr Suzanne Hill
Director Essential Medicines and Health Products.

1ST FAIR PRICING FORUM
held to develop strategies for more AFFORDABLE MEDICINES
hope to the estimated 80-110 million people suffering from chronic hepatitis C, for whom this ground-breaking treatment has so far been unaffordable. Sofosbuvir is a highly effective direct acting antiviral with a 95% cure rate and a significantly shorter treatment period than earlier hepatitis C medicines. Generic competition for sofosbuvir has already reduced the price of treatment and contributed to patient access.

Similarly, planned prequalification of biosimilar versions of two cancer treatments on WHO’s Essential Medicines List should bring previously unaffordable treatments to a wider group of patients. Under the pilot project, manufacturers will be invited to submit biosimilar versions of biotherapeutic medicines rituximab (used to treated non-Hodgkin’s lymphoma and chronic lymphocytic leukaemia) and trastuzumab (used to treat breast cancer). If successful, the pilot project will bring affordable alternatives to cutting-edge cancer treatments within reach of low- and middle-income countries.
WHO decided that giving biologics a generic name, or ‘bio-qualifier’, would hamper parallel efforts to promote biosimilar medicines as more affordable options in low- and middle-income countries, as it would differentiate between the originator and the copy. That distinction could support an already widespread misperception that the similar is of lesser quality than the originator. That misperception is another reason why educating medical professionals will be an important step WHO aims to take in the future.

**PARTNERSHIP FOR MEDICINES IN AFRICA**

Increasing access to affordable medicines not only requires action on pricing but also on investment in universal health coverage (UHC) and health systems strengthening. The EC/ACP/WHO Renewed Partnership, a five-year project to increase access to medicines in 15 countries concluded in 2017, having made progress in increased availability of child-friendly medicines notably for HIV, TB and malaria; streamlined registration processes for some medicines, and progress towards UHC.

However, the conclusion of the project (a partnership between the European Commission, African, Caribbean and Pacific Island countries and WHO) left much work to do. This was especially so in three key areas:

1. investment of time and resources by African governments to strengthen the medicines supply chain to rural areas;
2. reaching UHC, whereby citizens are protected from catastrophic health spending;
3. keeping substandard and falsified medicines off the market.

Money alone is not enough. We need technical assistance on policies and best practices and enhanced capabilities to improve the system. That is where WHO is playing a critical role.

Pauline Duya
pharmacist
Ministry of Health, Kenya

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7 Burundi, Cameroon, Congo, Democratic Republic of the Congo, Ethiopia, Ghana, Guinea, Kenya, Mali, Mozambique, Senegal, Tanzania, Togo, Zambia, Zimbabwe
Increasing **access** to affordable medicines not only requires action on pricing but also on investment in universal health coverage.

Child-friendly medicines for **HIV, TB & MALARIA** more available in **15 AFRICAN COUNTRIES**, thanks to a partnership between the European Commission, the African, Caribbean & Pacific island countries & WHO.
WHO’S ESSENTIAL LISTS FOCUSING SUPPLY AND INCREASING ACCESS

Since WHO launched the Essential Medicines List (EML) in 1977, many countries have adopted the concept of essential medicines and have developed lists of their own, using it as a guide. The EML is updated and revised every two years by the WHO Expert Committee on the Selection and Use of Essential Medicines.

2017 ESSENTIAL MEDICINES LIST UPDATE

In 2017 the committee carried out an extensive revision of the EML. The update saw new additions to treat HIV, hepatitis C, tuberculosis and leukaemia, as well as advice on the rational use of antibiotics (see p. 22).\(^8\) The new list adds 30 medicines for adults, several of which are also indicated for children, and specifies new uses for nine products already listed, bringing the total to 433 drugs deemed essential for addressing the most important public health needs.

The updated EML includes two oral cancer treatments (dasatinib and nilotinib) for the treatment of chronic myeloid leukaemia that has become resistant to standard treatment. Also on the list is a new pill for hepatitis C that combines sofosbuvir and velpatasvir as the first combination therapy to treat all six types of hepatitis C. For HIV treatment, a new drug, dolutegravir, has been added, as well as updated recommendations for pre-exposure prophylaxis (PrEP) with tenofovir alone, or in combination with emtricitabine or lamivudine.

new products added to the latest Essential Medicines List, including

2 oral cancer medicines

&

the first combination therapy to treat all six types of HEPATITIS C

ESSENTIAL DIAGNOSTICS LIST

One of the recommendations of the 2017 Expert Committee on the Selection of Essential Medicines was that WHO develop an Essential Diagnostics List (EDL).9 This list will become an important contribution to UHC by providing evidence-based guidance to countries to create their own national lists of essential diagnostic tests and tools. A national list helps prioritize what diagnostic tools—used to diagnose disease and also to monitor medication effectiveness or toxicity—should be made available and affordable to best address a country’s disease burden.

The Committee recommended that the EDL list initially focus on in vitro diagnostics for priority areas such as, hepatitis B and C, HIV, malaria and TB, but that it should be expanded as soon as possible to other important conditions, including non-communicable diseases. Work began in 2017 to lay the groundwork for the list, with the creation of the Strategic Advisory Group of Experts on In Vitro Diagnostics, which will advise WHO on global policies and the development of the EDL.10

Making sure all people can access the medicines they need, when and where they need them, is vital to countries’ progress towards universal health coverage.

Dr Mariângela Simão
WHO Assistant Director-General for Access to Medicines, Vaccines and Pharmaceuticals

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PHARMACOVIGILANCE

Pharmacovigilance—the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem—has historically been the domain of developed countries. Until recently new products were licensed in countries where surveillance systems are robust years before they reached developing-country markets. However, the new health product pipeline now includes products such as malaria vaccines and new tuberculosis treatments, which will launch either exclusively in low- and middle-income countries, or simultaneously in low-, middle-income and high-income countries.

Moreover, in the face of developing public health emergencies such as the 2014-2016 Ebola epidemic, when the approval process for new products is typically accelerated, there may be limited safety data and it is pharmacovigilance that can help identify potential safety signals that may not have been found before. In 2017 WHO partnered with the Bill & Melinda Gates Foundation to expand its work in tackling this challenge in developing countries. The partnership will strengthen, expand and streamline pharmacovigilance systems in low- and middle-income countries, focusing initially on the safety of three priority medicines and vaccines that will be introduced in the next few years.

SUBSTANDARD AND FALSIFIED PRODUCTS

WHO launched two key reports on substandard and falsified medicines in 2017. WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products outlines the three main causes of such products entering the supply chain: constrained access to safe, affordable, quality medical products; lack of good governance; and weak technical capacity and tools at country level. Prevention, detection and response are the three keys to

Prevention, detection and response are the three keys to tackling substandard and falsified medicines

Governments, product developers, and the global health community must work together to prioritize and invest in pharmacovigilance.

Trevor Mundel
President of Global Health, Bill and Melinda Gates Foundation

one in 10 medical products in low- and middle-income countries may be substandard or falsified

tackling the problem. The report, based on data gathered over a four-year period since the WHO’s Global Surveillance and Monitoring System was set up, shows that one in 10 medical products in low- and middle-income countries may be substandard or falsified, with antibiotics and malaria medicines at the top of the list. The report also presents case studies to illustrate the forces that drive the trade in these dangerous products and actions needed to address it.

A companion report, A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products, reviews the current literature, and also presents two impact models, one for childhood pneumonia, and one for malaria. It concludes that greater investment in post-market surveillance, and on strengthening national regulatory capacity, are key to addressing the problem.

STAYING AHEAD OF ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) threatens to compromise access to quality medical treatment: without effective antibiotics, treatment of bacterial diseases, as well as major surgery and cancer chemotherapy are all in jeopardy. In 2017 EMP continued its work in monitoring antibiotic consumption and use, developing guidance on how to best use the antibiotics that are still effective, and advocating for development of new antibiotics.

PRIORITY PATHOGENS

A key achievement in 2017 was the publication of WHO’s first ever priority pathogens report, detailing the 12 families of bacteria that pose the greatest threat to human health. The priority pathogens list is divided into critical, high and medium priority categories. The critical category includes multidrug resistant TB, and other bacteria that pose a particular threat in hospitals and nursing homes and among patients treated with medical devices such as ventilators and catheters. The intention is to incentivize governments to support investments in both basic science and advanced research and development by the public and private sectors to strive for new antibiotic discovery, and to target those efforts where they are most needed. High-priority pathogens include those responsible for gonorrhoea and food poisoning caused by salmonella.

We need effective antibiotics for our health systems. We have to take joint action today for a healthier tomorrow.”

Mr Hermann Gröhe
former Federal Minister of Health, Germany

ANTIBIOTIC PIPELINE

There is a serious lack of antibiotics under development, according to a report published by EMP in 2017. Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline, including Mycobacterium tuberculosis shows that most of the drugs currently in the clinical pipeline are modifications of existing classes of antibiotics and are only short-term solutions. The report makes a clear case for new drug development.

families of ANTIBIOTIC-RESISTANT BACTERIA posing the greatest threat to human health identified with a view to guiding the discovery of new treatments
RATIONAL USE

In the meantime, it is crucial to make the best use of existing antibiotics to ensure that resistance is minimized through rational and judicious use. WHO’s 2017 major update of its EML reflects the latest knowledge on AMR, reviewing and categorizing antibiotics in a way that encourages optimal use.

WHO experts have grouped antibiotics into three categories – ACCESS, WATCH and RESERVE – with recommendations on when each category should be used. Antibiotics in the ACCESS group should be available at all times as treatments for a wide range of common infections, the WATCH group includes antibiotics that are recommended as first- or second-choice treatments for a small number of infections, whilst the RESERVE group includes antibiotics that should be considered last-resort options, and used only in the most severe circumstances when all other alternatives have failed. Together, these three categories are known as the AWaRe classification.

MORE FUNDING

Adequate funding is also crucial to combat antibiotic resistance, and 2017 saw a €56.5 million boost in pledges to develop new antibiotic treatments through the Global Antibiotic Research and Development Partnership.¹⁵ The Partnership was established in May 2016 by WHO and the Drugs for Neglected Diseases Initiative, and the new funding will support its four programme areas: sexually transmitted infections, neonatal sepsis, paediatric antibiotics, and revival of abandoned antibiotic development projects that may help identify new drug opportunities.

AWaRe will help countries to ensure access to optimal antibiotic treatment while containing use of the more vital treatments in order to minimize resistance.

Dr Abdul Ghafur
infectious disease expert and coordinator of the Chennai Declaration

¹⁵ https://www.gardp.org/about/
It is crucial to make the **best use of existing antibiotics** to ensure that resistance is minimized through rational and judicious use.
REGULATORS NEED TO GEAR UP FOR EMERGENCIES

In many low- and middle-income countries, NRAs struggle to keep pace with the day-to-day business of registering new products and monitoring those already on the market. Limited capacity and lack of resources make it even harder for them to be prepared to deal with serious epidemics and public health emergencies. When a public health emergency occurs in a poorly regulated environment, it leaves the population vulnerable to fake products and dubious remedies. Products of uncertain quality and safety are often marketed and sold via the Internet or other uncontrolled supply channels in such situations. At the same time, candidate products developed during an emergency may be cutting edge and are a challenge for even the best-resourced NRAs to evaluate, let alone those in resource-constrained settings.

Such issues became apparent during the 2014-2016 Ebola crisis in West Africa. A lack of capacity and experience of communicating with stakeholders, particularly the media and general public, led to a clinical trial for an Ebola vaccine candidate being halted in one country because of adverse publicity directed against the NRA for authorizing the trial to take place. One solution is for country and regional NRAs to strengthen regulatory collaboration, as well as building their own capacity.

CAPACITY BUILDING

In May 2017, WHO held an informal consultation on options to improve regulatory preparedness and on how WHO can support the process. The meeting revealed that stakeholders who are developing products do not always engage regulators early and often enough, or have a good enough understanding of regulatory details and nuances. This is important to keep programmes on track along a successful developmental pathway during a public health emergency.

The meeting also showed that regulators can be powerful advocates at a national level for the benefits of international collaboration in the contentious areas of data and sample sharing. The consultation concluded with a number of recommendations for WHO to move this agenda forward, including providing guidance to develop procedures and pathways for unlicensed medical products during a public health emergency, and the early introduction of communication plans. Emergency Use Assessment and Listing procedures, developed as a response to lack of regulation for potential diagnostics, treatments and vaccines for Ebola, are also useful to help NRAs test and regulate candidate products in an emergency situation, and should be promoted and adapted.16

One of the follow-up outcomes of the consultation was the organisation of a simulation exercise to test the African Vaccine Regulatory Forum (AVAREF) Guideline for Joint and Assisted Reviews of Clinical Trial Applications in emergency situations, held in Accra, Ghana on 26 November 2017. The exercise brought together regulators and ethicists from low- and middle-income countries on regulatory preparedness for future public health emergencies. A hypothetical scenario involving Middle East respiratory syndrome-coronavirus infection was developed as a case study for the exercise. The objective was to stimulate discussion on how regulatory networks and the AVAREF joint review guideline could be used to greatest advantage to support the expedited development and use of candidate vaccines and in vitro diagnostics.

The exercise was organized by WHO and the African Union’s New Partnership for Africa’s Development with the support of the Coalition for Epidemic Preparedness Innovations and involvement of other partners, including the European and Developing Countries Clinical Trials Partnership, the Bill and Melinda Gates Foundation, the US
Candidate products developed during an emergency may be cutting edge and are a challenge for even the best-resourced NRAs to evaluate.
Cholera is a disease of inequity that affects the poorest and most vulnerable. It is unacceptable that nearly two decades into the 21st century, cholera continues to destroy livelihoods and cripple economies. We must act together. And we must act now.

Dr Tedros Adhanom Gebreyesus
Director-General, WHO
CARFENTANIL

Against the backdrop of fentanyl overdose deaths reaching records levels in several countries, including the US and Canada, WHO’s Expert Committee on Drug Dependence (ECDD) met in November 2017. It recommended the most stringent level of international control for the synthetic opioid carfentanil, an analogue of fentanyl. The drug has been included into Schedules I and IV of the 1961 UN Single Convention on Narcotic Drugs. Schedule I substances are subject to strict drug control measures, whilst additional control under Schedule IV imposes the strongest possible regulations on substances by prohibiting production and supply of substances except under licence for specific purposes, such as medical treatment and research.

In the case of carfentanil, a veterinary product used to restrain and capture large animals, there is no indication for human use.

Carfentanil is so toxic that a dose equivalent to a few grains of salt can produce lethal effects. As such, it has potential for use as a chemical weapon. The ECDD also recommended five other fentanyl analogues (acryloylfentanyl, fluoroisobutyrfentanyl, furanyl fentanyl, ocfentanil, and tetrahydrofuranyl fentanyl) be controlled by Schedule I of the 1961 UN Single Convention on Narcotic Drugs. The decision was part of a wider ECDD review of New Psychoactive Substances, synthetic drugs developed to produce effects on the central nervous system similar to those of other psychoactive substances, such as opioids, cannabis or amphetamines.

Carfentanil is so toxic that a dose equivalent to a few grains of salt can produce lethal effects.
CANNABIDIOL

Cannabidiol, a compound of the cannabis plant was also reviewed at this meeting. With growing interest in the use of cannabis for medical indications including for palliative care, more scientific evidence on its therapeutic use and side effects has been gathered, and the committee reviewed this evidence relating to cannabidiol. Recent animal and human studies have shown that it could be used to treat epileptic seizures, and the current evidence also shows that it is unlikely to be abused or create dependence seen with other cannabinoids, such as Tetra Hydro Cannabinol, or THC. As such, there is no reason for it to be scheduled. The ECDD will revisit the topic in June 2018, after a comprehensive review of cannabis and cannabis related substances.

Growing interest in the use of cannabis for medical indications including for palliative care
AN ACCESS ROADMAP

Member States agreed at WHO’s Executive Board meeting in January 2018 that it should provide an ‘access roadmap’. This would outline WHO’s programme of work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023. The roadmap, which aims to enhance WHO impact in countries, will be submitted to the Seventy-second World Health Assembly in 2019 for its consideration and endorsement.

WHO’S PROGRAMME OF WORK ON ACCESS TO MEDICINES AND VACCINES

<table>
<thead>
<tr>
<th>Year</th>
<th>Activities</th>
<th>2023</th>
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<tbody>
<tr>
<td>2019</td>
<td>Aim: enhance WHO impact in countries</td>
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PREQUALIFICATION

2018 will see the beginning of work to expand, streamline and accelerate the prequalification programme. The aim is for the programme to address a larger number of diseases, including non-communicable diseases such as cancer and diabetes, and to find ways to make health products available to countries faster.

IMPROVING ACCESS TO ASSISTIVE TECHNOLOGY

As people age, including those with disabilities, their function declines in multiple areas and their need for assistive products increases accordingly. WHO estimates that over 1 billion people need one or more assistive products, the majority of them older adults and people with disabilities. Today, only an estimated 10% of those in need have access to assistive products. To improve access to high quality, affordable assistive products in all countries, WHO introduced the first Priority Assistive Products List in 2016. The list was the initial stage of a broad agenda that will be implemented over 2018, including shaping markets for these products in order to achieve more competitive prices; policy development to support countries in streamlining the provision of assistive products; and ensuring that assistive technology is covered in UHC schemes.

OPTIMIZING ANTIBIOTIC USE TO MINIMIZE RESISTANCE

The AWaRe grouping of antibiotics is intended to assist countries in their efforts to combat antimicrobial resistance, in particular resistance to antibiotics. Adapted to national contexts, AWaRe can transform into a useful operational tool for medical prescribers and optimize antibiotic treatment as well as reduce resistance. In late 2018 WHO will launch the AWaRe campaign to encourage governments to adopt the AWaRe categorisation by adjusting their national essential medicines lists. If achieved, this could represent a tangible progressive step for countries, and could go a long way towards meeting the WHO priority of reducing antimicrobial resistance globally.

NEW PLAN TO SUPPORT REGULATORY AUTHORITIES

The Regulation of Medicines and other Health Technologies 2019-2023 Strategic Plan will support NRAs deliver regulation that not only protects the public, but also enables innovation in product development and timely access to quality products. At country level the plan prioritizes improving regulatory systems, promoting reliance and collaboration and improving NRA’s preparedness for a public health emergency. The plan commits WHO to maintenance and expansion of the prequalification service, and to more effective coordination across all levels of the organization, as well as with external partners.

ONLY 10% OF THOSE IN NEED HAVE ACCESS TO ASSISTIVE PRODUCTS
DONORS & FUNDING

FINANCIAL OVERVIEW

(Does not include the planned budget of WHO Country and Regional Offices).

2016-17 IMPLEMENTATION:

$98 874 561

16% CORE FUNDS

84% SPECIFIED FUNDING
DONORS AND PARTNERS

• EMP continued to enjoy close and expanding working relations with government donors including Brazil, France, Germany, Japan, Republic of Korea, the Netherlands, Sweden, Switzerland, the United Kingdom (Department for International Development and the Fleming Fund) and the United States of America (United States Agency for International Development, US Department of Health and Human Services and the US Food and Drug Administration).

• In 2017 EMP established new partnerships with the governments of Austria, Canada and Norway; the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Foundation for Innovative New Diagnostics and Médecins Sans Frontières.

• The European Commission Directorate-General for Development and Cooperation continues to provide invaluable support to WHO’s work to improve pharmaceutical policies and systems in sub-Saharan Africa; antimicrobial resistance and health solutions to tackle neglected tropical diseases.

• The Bill and Melinda Gates Foundation together with Gavi, the Vaccine Alliance, the Global Fund, the United Nations International Children’s Fund, Unitaid, and World Bank continued to provide critical support the WHO Prequalification Programme and expanding support to strengthen regional and national regulatory systems.

• MVP/EMP continues to draw on the technical expertise of its worldwide network of collaborating centres and nongovernmental organizations in official relations with WHO.

• The People’s Republic of China, France, Japan, Republic of Korea, the Netherlands and Norway provided technical expertise and country experience through the secondment of national professional staff.
FULL LIST OF CONTRIBUTORS

GOVERNMENT AND INTERGOVERNMENTAL ORGANIZATIONS
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FOUNDATIONS AND NON-GOVERNMENTAL ORGANIZATIONS
Bill and Melinda Gates Foundation, the Fleming Fund, International Federation of Medical and Biological Engineering, Foundation for Innovative New Diagnostics and Médecins Sans Frontières.

INTERNATIONAL AGENCIES
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OTHER FUNDS
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