2016 saw the beginning of change for Essential Medicines and Health Products (EMP), heralded by new leadership in the department and a new global agenda. While building on the progress made in previous years, we steered our course to adapt to new challenges, such as the rising cost of innovative health products, an ageing population with a greater prevalence of non-communicable diseases (NCDs), the worrying rise of antimicrobial resistance, and our heightened vulnerability to epidemics.

These are the areas in need of progress to align with the Sustainable Development Goals (SDGs), especially in terms of achieving universal health coverage (UHC), which is contingent upon access to safe, effective, quality and affordable essential medicines and health products for all.

The opportunity to support Member States and other international agencies improve access to essential medicines and health products continues to grow. This is welcome but it also presents a challenge. Requests for EMP support sometimes exceed our capacity. We need to work smarter if we want to sustain the gains we have secured. This means a more strategic deployment of our resources and working in stronger partnership with other WHO teams and key stakeholders to reduce duplication and optimize output.

For that reason, we began a consultative process in June 2016 to articulate a vision and strategic framework for the department, one that will equip us to be even more relevant in the SDG era and one that we believe will be more fit-for-purpose for our Member States. The resulting document, Towards Access 2030, was finalised by December and is now fully published.

That vision and framework begins to be visible through some of our achievements in 2016, as I hope will emerge from the highlights in this report. It is an approach to our work that will evolve over time and is based on better data and a critical focus on tangible results for patients, communities, countries.

I would like to extend my thanks to the EMP department, and all WHO staff with whom we work closely around the world, and a warm welcome to Emer Cooke, our new Head of Regulation of Medicines and other Health Technologies, and Deudedit Mubangizi, who became Coordinator, Prequalification in 2016. In particular, I am grateful to my predecessor, Kees De Joncheere, and to Lembit Rago, both of whom oversaw much of the work that has led to the achievements we see today.

Suzanne Hill
2016 BY NUMBERS

17 countries trained to conduct antimicrobial consumption surveys using new WHO methodology

50 technologies listed in new Assistive Products List to help older people and those living with disabilities achieve a better quality of life

113 new health products prequalified marking an increase of 14% from 2015

2 Zika tests accepted into the Emergency Use, Assessment and Listing procedure

190 facilities in 19 countries monitored for insulin availability through new smartphone app

8 snakebite treatments in the pipeline for quality assurance

392 sub-standard and falsified medical (SF) products reported to WHO global monitoring system and 4 global alerts issued on risk products

2 innovative technologies prequalified to test infants for HIV

3,600 health workers trained across Africa 2012-2016 to strengthen pharmaceutical systems and improve access to quality medicines in partnership with the African, Caribbean and Pacific Island countries and the European Union

10 new psychoactive substances recommended for international scheduling as dangerous to public health

20 tertiary care hospitals in India joined WHO’s Global Vaccine Safety Multi Country Collaboration pilot to collect and assess adverse events from vaccines

5 national drug regulatory authorities assessed with WHO benchmarking tool

2 new partnerships launched – GARDp, to address antimicrobial resistance, and Smart Safety Surveillance to improve pharmacovigilance

4 new publications providing countries with guidance on medical devices

224 INNs assigned to medicines
R&D and Innovation

Promoting new R&D for antibiotics

WHO and the Drugs for Neglected Diseases initiative (DNDi) launched GARDp (Global Antibiotic Research and Development Partnership), a not-for-profit partnership to promote R&D for new antibiotics where old ones no longer work against resistant bugs. GARDp has received seed funding and pledges exceeding €5 million (for 2016-2018) from the governments of Germany, the Netherlands, South Africa, Switzerland and the United Kingdom of Great Britain and Northern Ireland.

HIGHLIGHTS

Just four days after Zika was declared a public health emergency, EMP opened the Emergency Use, Assessment and Listing procedure (EUAL) for Zika in vitro diagnostics. The EUAL procedure is run by EMP’s Prequalification Programme and aims to fast-track quality assessments of experimental products during public health emergencies. The listing of products by WHO gives procurement agencies a guarantee of acceptable quality and performance standards. To date, the EUAL has received 17 Zika diagnostic tests for assessment and has listed two of these for procurement;

- EMP developed a candidate reference preparation for Zika to guide manufacturers in developing diagnostic tests in a record three months;
- EMP validated and made available the first WHO reference preparation to provide independent checks on Zika in vitro diagnostics;
- A WHO International Standard for Zika nucleic acid test was established by EMP’s Expert Committee for Biological Substances.

Medical products for epidemics: The R&D Blueprint

The WHO R&D Blueprint is a WHO-wide initiative that aims to prevent epidemics by expediting the development and availability of new vaccines, drugs and tests via an agreed R&D strategy and framework. It includes an initial list of 10 priority disease families that demand R&D attention now because of the risk they pose in the future. EMP made significant contributions to the Blueprint, mostly during the Zika public health emergency.
Addressing market failures: The snake-bite challenge

Around five million people are bitten by snakes every year, causing around 125,000 deaths and 400,000 people to be permanently disabled or disfigured; most affected are children, women and agricultural workers from rural and poor environments. The lack of availability of quality antivenoms is a prime example of the market not responding to a public health need due to insufficient market incentives.

Over the course of 2016, WHO took action to bolster the manufacture of antivenoms, including through a decision to assess antivenoms for sub-Saharan Africa through the Expert Review Panel (ERP). The Expert Review Panel (ERP) expedites the availability of health products for time-limited use in special circumstances of public health need by assessing the quality risks of products that do not meet all stringent quality requirements. Eight dossiers were submitted for evaluation in 2016, with first approvals expected in the first half of 2017.

In addition, to strengthen procurement and the quality of production, in 2016 WHO updated the 2008 Antivenom Guidelines. This involved a comprehensive review of the guidance for the production, control and regulation of snake antivenom immunoglobulins. Major updates included a list of medically important snakes to reflect new species discoveries and recent name changes. The updated guidelines were officially endorsed in October 2016 by the Expert Committee on Biological Standardization (ECBS).

Understanding patents: Breaking down barriers to improved access

WHO supports Member States understand their rights to access essential medicines at affordable prices under the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). In 2016, EMP offered technical advice to Columbia, Ethiopia and South Africa, on the use of TRIPs flexibilities to improve access to affordable medicines.

One of the best examples of increasing the supply of life-saving medicines is the multi-agency work done to improve access to a potential cure for hepatitis C for millions of people. An understanding of intellectual property rights was central to this achievement. WHO assessed and published the patent situation of the new and effective directly acting antivirals (DAAs) to treat hepatitis C, allowing countries to review their options for local production and procurement, and provided technical assistance to countries on how to introduce the new treatments at affordable prices.
Selection, pricing and supply

The Assistive Products List
A fundamental SDG principle is to ‘leave no one behind’. As people live longer, their health needs also broaden. The rise in non-communicable diseases (NCDs), partly due to longer life spans, has made it imperative that innovation and R&D respond to the challenge by providing new products to help older populations and people with disabilities lead quality lives.

In May 2016, WHO launched the Priority Assistive Products List. The list aims to increase access to quality assured technologies that can help older people and those living with disabilities to lead a better and more productive life. It includes 50 priority products that were identified following a global survey in which 161 countries took part.

Ten countries have already used the list to improve or develop a national list, enhancing access for millions more in need. Beyond 2016, WHO will step up its advocacy work and deliver minimum quality standards to further equitable access for all to first-rate assistive products.

A partnership to expand access to medicines in Africa
With the aim of improving access to quality medicines, the European Union in partnership with the African, Caribbean and Pacific Group of States and WHO worked with the governments of 15 African countries* over four years to strengthen their pharmaceutical systems.

All project participants and partners met in Addis Ababa in June 2016 to assess results to date and discuss future actions to ensure continual progress towards access to quality medicines and universal health coverage.

* Burundi, Cameroon, Congo, Democratic Republic of Congo, Ethiopia, Ghana, Guinea, Kenya, Mali, Mozambique, Senegal, Tanzania, Togo, Zambia, and Zimbabwe
Medicines are the foundation of a health system. Without them, patients will not seek medical attention and health facilities lose credibility.”

Donatien Bigirimana
Medicines Adviser, WHO Burundi

Over four years, the partnership obtained impressive results. Some examples include:

- In Ethiopia, the Government has defined the list of priority medicines to be covered by the national insurance scheme, marking a first step towards universal health coverage;
- Pricing surveys conducted in Burundi and Mali have led to new legislation fixing prices in the private sector to limit expenditure for patients;
- Regulators from most of the 15 countries participated in training workshops to acquire additional skills to assess and register medicines more efficiently, so that quality treatments may be made available to patients;
- Improved detection techniques have led to the increased capacity of Ethiopia and Mozambique to screen for substandard and counterfeit products at ports of entry;
- National essential medicines lists were updated according to the most recent evidence to include more medicines for non-communicable diseases and treatments for children.

Donatien Bigirimana, who works as Medicines Adviser in the WHO Burundi office and contributed to the project, says that the first thing patients ask when they front up to a health facility is: Do you have medicines? “Medicines are the foundation of a health system,” he explains. “Without them, patients will not seek medical attention and health facilities lose credibility.”

NCD medicines availability survey
Non-communicable diseases (NCDs) kill 40 million people each year, equivalent to 70% of all deaths globally. Each year, 15 million people die from a NCD between the ages of 30 and 69 years; over 80% of these premature deaths occur in low- and middle-income countries (LMICs).

In 2016, WHO offices in 19 LMICs in the African, Americas and European regions piloted a smart-phone/tablet-based app to survey the price and availability of medicines for cardiovascular diseases and diabetes. In total, 190 facilities were surveyed, including tertiary hospitals, primary health clinics and private pharmacies. The app allowed data collectors to travel to facilities and enter data using their devices. The information was then transferred directly to a global database. The tool is designed to avoid duplication of efforts and potential manual entry errors which happen when data are collected on paper and then transferred to an electronic format.

Early analysis of the results suggests that while access to anti-infectives is generally adequate, availability of essential medicines to treat NCDs is low in all countries surveyed. See below:
It is important that countries regularly survey and collect data in order to monitor and evaluate the effectiveness of policies on medicines. This is an area of work that EMP is intensifying to better support Member States address access gaps.

Analyzing the impact of medicines prices on health systems

Recent innovative treatments for certain conditions are extending life with fewer side effects than older treatments and giving hope to many patients. But these medicines are not affordable to most of the people who need them. New treatments for hepatitis C and cancer - both widespread conditions globally – can cost from $50,000 annually to well over $150,000.

A study by EMP staff published in PLOS Medicine in May 2016, shows that the prices of sofosbuvir and ledipasvir/sofosbuvir, two important new medicines for treating hepatitis C, vary greatly between countries worldwide, raising serious concerns about the viability of reducing the global hepatitis C burden. After adjusting for average 2015 exchange rates and purchasing power, the study reveals that the cost of treating the entire hepatitis C infected population in each of the 30 countries examined would range from 10.5% of total pharmaceutical expenditure in the Netherlands to 190.5% in Poland.

The study gave EMP some evidence on which to build future work to develop a ‘fair pricing model’ - one that can affordably deliver the medicines needed by patients while keeping companies interested in developing new and better treatments.

Regulation

Harmonizing standards and promoting quality for patients

At the core of WHO’s Constitution is a requirement “to develop, establish and promote international standards with respect to biological and pharmaceutical products”.

The standards are used in the development, production, procurement and use of essential health products, ensuring that they meet acceptable standards of quality, safety and efficacy all over the world. In short, they save lives. Having a unified reference for health products is particularly important for new R&D orientations in the context of products targeting neglected diseases, emerging pathogens and other innovative technologies. Highlights from 2016 include:

- 224 international non-proprietary names assigned to chemical and biological substances, marking an increase of 67% since only five years ago and demonstrates the value of this service provided by WHO;
- WHO established five written regulatory standards for pharmaceuticals, including for hepatitis C, and the first regulatory standard for medical devices. In addition, eight written standards for biologicals were established, including for new vaccines and blood products;
- 11 measurement standards were established - six for in vitro diagnostics, including for Zika, Ebola, dengue, hepatitis and five for blood products. These standards are used as tools for the development of products, their licensing and lot release;
- WHO updated the International Pharmacopeia - a global reference tool containing quality specifications for medicines and analytical methodologies – with a special focus on medicines for maternal, child and adolescent health. The specifications are used alongside other guidance to assess medicines and active pharmaceutical ingredients for prequalification.
Regulating new products: medical devices and biotherapeutics

Devices to improve healthcare require robust regulatory support to ensure the products are safe and quality-assured. However, many countries do not have such processes in place. This affects especially developing countries, where regulatory systems are often weaker and exposure to substandard and falsified products is greater.

Over the course of 2016 WHO worked with Member States and other partners to improve the situation and will publish a pioneering guide, the ‘Global Model Regulatory Framework for Medical Devices’, in 2017.

Basic elements for medical devices legislation

- Premarket, placing on the market and postmarket.

- Have all three types of elements
- Have premarket and placing on the market elements
- Have premarket and postmarket elements
- Have placing on the market and postmarket elements
- Have only premarket elements
- Have only placing on the market elements
- Do not have any type of element
- Data not available
- Not applicable

*Status as of July 2016
As with devices, the emergence of biological products and cell and gene therapies requires new regulatory skills and knowledge to ensure therapeutic value and protect patients. The demand for such products has grown in line with the number of people living longer with NCDs. Biosimilars offer effective treatment options at more affordable prices than their originals, but uptake has been slow.

WHO took some significant steps in 2016 to address this through:

- Extensive preparation work to update the guidelines used to evaluate biosimilars (generic versions of biotherapeutics), due to be published in 2017, and developments to improve awareness of the benefits of biosimilars amongst healthcare professionals and patients.

- Transferral of technology for the production of rabies monoclonal antibodies to three manufacturers in developing countries and creation of a hub for the development of biosimilars to promote their production at a fraction of the current sale price.

**New guidance to strengthen regulation**

To support regulators bring new products to market, WHO provides a range of materials, including two new guides that were developed over 2016. “Good Regulatory Practices” is a world first compendium of international standards, smart legislation and the best guidelines to establish effective regulatory systems. It will be published in 2017. WHO also published “Good data and record management practices”, which helps regulators identify insufficient or false data about health products and indicates areas of improvement for manufacturers, thereby promoting better health products and patient safety. As a testament to rising demand for such advice, the website received over 3,500 sustained unique visits from the time it was launched in October 2016, to the end of the year.
Vaccine safety
In 2016, WHO’s work on vaccine safety progressed across the board, including by:

• Piloting a global network of hospital-based sentinel sites for vaccine safety signal verification – the Global Vaccine Safety Multi Country Collaboration, which enhances the capacity for vaccine safety assessment in LMICs. The pilot was delivered in India, which set up a national multi-centre network of 20 tertiary care hospitals across the country to collect systematic data on known adverse events and assess potential signals.

• Expanding Vaccine Safety Net, a digital platform that accredits websites providing the highest standards of information on vaccine safety. There are now 47 sites in 11 different languages.

• Supporting the development of new recommendations on ‘Active Vaccine Safety Surveillance’, published by The Council for International Organizations of Medical Sciences (CIOMS). These recommendations help decision-makers generate and understand reliable data about specific safety concerns.

A new fee structure for WHO Prequalification
WHO introduced a new financing arrangement in 2016 to ensure the financial sustainability and quality of its Prequalification Programme in the coming years. The arrangement is based on an improved fee structure that aims to make the programme better equipped to address current global quality challenges in the medical products area, to lay the ground for strengthening and expanding services provided, and to improve financial predictability and transparency.

The new arrangement involves a scale of fees differentiated by type of product, its public health relevance and the current market. Manufacturers wishing to have their products prequalified by WHO in order to sell them through the United Nations and international supply systems will pay fees as they would for any other regulatory authorization. The fees will cover manufacturing site inspections, product assessments, training and any mentoring needed by companies to bring their products up to standard. The arrangement is projected to generate $20 million annually in cost recovery.

Other PQ developments
• The Model Dossier. Launched in September 2016, the Model Dossier aims to reduce the number of deficiencies in pharmaceutical product submissions by illustrating the best way for applicants to submit data for prequalification. It also serves as a training tool for regulators and facilitates the harmonization of regulatory requirements;

• Foundation of a global network of national control laboratories (NCLs) in 22 countries to expedite the vaccine prequalification process. NCLs check that biological products are assessed for quality and consistency of production;

• In 2016, Prequalification trained regulators from 30 Member States in the application of best practice guidelines in product assessment at a national level;

• WHO also strengthened the network of laboratories that check the quality of medicines by increasing the number of prequalified quality control labs (QCLs). Over 2016, five more QCLs were approved, taking the total to 41 and significantly strengthening quality assurance capability in LMICs.
Launch of new pharmacovigilance project
Pharmacovigilance is becoming increasingly important as more medicines are developed for LMICs, where pharmacovigilance systems are often under-resourced or non-existent. In light of this, 2016 heralded a new partnership between WHO and the Bill and Melinda Gates Foundation – the Triple S Project, standing for Smart Safety Surveillance. The initiative aims to strengthen, expand and streamline pharmacovigilance systems in Africa, Asia and Latin America. Focusing initially on the safety of new priority medicines for TB and malaria and possibly vaccines, the project could expand to scale up the strategies that work well to additional countries and products.

Mitigating the risk of substandard and falsified (SF) medical products
In 2013, WHO launched the Global Surveillance and Monitoring System for SF medical products to improve global capacity to detect, prevent and respond to those products, in order to protect public health. In 2016:

- 392 SF medical products were reported through the GSMS from 49 Member States, reflecting a continued increasing trend from previous years;
- WHO provided technical assistance to develop SF monitoring to 30 Member States;
- Almost 30 countries were trained on prevention and detection of SF products and appropriate response;
- Four global medical product alerts were issued for falsified medicines and vaccines circulating in South East Asia and West and Central Africa. When alerts are disseminated, WHO relies on partners, such as National Medicines Regulatory Authorities or non-governmental organizations, to increase vigilance of supply chains;
- WHO launched a new portal for the WHO SF database, including a library of pictures, for appointed national regulatory authority personnel. The tool allows checking and collating information on SFs, especially for Member States with restricted access to resources and laboratories;
- In Tanzania, WHO piloted a smartphone application for healthcare professionals to report suspicious SF medical products to the National Medicines Regulatory Authority in under 90 seconds.

These efforts will be accompanied by advocacy to governments, product developers and the global health community to work together to prioritize and invest in pharmacovigilance.
In 2016, 392 SF medical products were reported from 49 Member States, reflecting a continued increasing trend from previous years. Since 2013, WHO has held 17 workshops training over 400 regulatory personnel and establishing focal points in 126 Member States and 18 of the largest international procurement agencies. In 2016 alone, almost 30 countries were trained on prevention and detection of SF products and appropriate response.

In Tanzania, WHO piloted a smartphone application for healthcare professionals to report suspicious SF medical products to the National Medicines Regulatory Authority in under 90 seconds.

Countries shaded in green are those in which GSMS training has taken place.

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Since its inception almost 1400 substandard and falsified products from all therapeutic categories have been reported to the system and WHO has provided technical assistance in hundreds of urgent cases and issued 17 global medical product alerts, with numerous local and regional warnings.
Alignment for accelerated access

A harmonized approach to meeting the challenges of today is essential to the functioning of NRAs, which need to operate increasingly across borders as medical product manufacturing becomes more globalized, and optimize output with limited resources. This was the main theme of ICDRA 2016 (International Conference of Drug Regulatory Authorities).

In 2016, WHO built on the progress of previous years by providing technical advice and training to help accelerate harmonization, including progress in Africa, a new regional network in Asia and - under the auspices of the Pan American Health Organization - the Caribbean. For example:

- The African Vaccine Regulatory Forum (AVAREF) (founded by WHO in 2006 as a platform for strengthening regulatory capacity for clinical trials) extended its remit to include medicines and diagnostics. The ground-breaking decision to share intelligence, resources and capacity for ethical and regulatory evaluations across all health products ultimately serves to improve access to essential health products for some of the world’s most vulnerable populations;

- Progress was also made towards a pan-African regulatory authority (AMA) as AVAREF extended its membership over 2016 to the Economic Community of West African States, SADC and The Intergovernmental Authority on Development.

- The WHO South-East Asia Region Members launched the South-East Asia Regulatory Network (SEARN). The network connects every one of the region’s national 11 regulatory authorities for the first time, covering Bangladesh, Bhutan, Democratic People’s Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste. SEARN will help to harmonize existing regulations and streamline work-sharing arrangements in order to strengthen the work of individual NRAs through collective efforts;
WHO’s Collaborative Registration Procedure (CRP) accelerates the registration of prequalified medicines by a group of NRAs through sharing the product information collected during the prequalification submission stage. Over 2016, 40 different essential medicines were made available in a median of 74 days, when it usually takes three times as long. By the end of 2016, 30 Member States were participating in the procedure.

“SEARN will strengthen health systems across South-East Asia and help fulfill each person’s right to the highest attainable standard of health.” Dr G N Singh, the Drugs Controller General of India, Central Drugs Standard Control Organization

Cross-cutting work

Measuring antimicrobial Resistance (AMR)

AMR is driven by numerous complex factors, but over-use, misuse and irresponsible use are the leading causes. One of the solutions, therefore, is to promote more responsible use of antimicrobials among populations. In order to do that, we need to know about current practices in countries and what and how much are they consuming. In short, we need to measure and analyze use.

To that end, in consultation with key national and regional partners, EMP has developed a methodology for monitoring antimicrobial consumption and is piloting surveys in 17* countries in Africa, Asia and the Pacific. The methodology enables countries to retrieve valuable information on the overall level of use of antimicrobials (including antibiotics, TB, malaria and HIV medicines) and to monitor which classes of antimicrobials are used.

The survey will fill critical knowledge gaps on national and global consumption trends and will allow the identification of overuse of antimicrobial medicines, but also, and just as importantly, limited access and under-use of these medicines. This valuable information will support policymakers in taking future decisions and actions to improve access and use of antimicrobials. The methodology is based on annual surveys, so it can help to monitor changes and potential improvements from year to year and allow for any policy adjustment that may be needed.

WHO is supporting the implementation of this methodology at country level by providing training to local authorities, particularly in low- and middle-income countries (LMICs), where information on antimicrobial use is desperately lacking. Over 2016, around 65 people in 17 countries were trained on how best to use the survey.

dependence producing properties, potential harm to health and potential medical benefits of psychoactive substances. It does this through the Expert Committee on Drug Dependence (ECDD), which meets annually to review psychoactive substances and provide recommendations for scheduling (or de-scheduling). WHO then communicates the ECDD’s recommendations to the Commission on Narcotic Drugs (CND), the governing body of the UNODC.

In 2016 the ECDD discussed the potential role of cannabis for medical use on the basis of two studies it had commissioned to review available evidence. The medical use of cannabis is an important agenda item for a number of Member States, some of which have endorsed the use of the substance; it is also the object of strong advocacy from a number of civil society groups, whose main demand is that cannabis be removed from the list of CND substances harmful to human health.

The ECDD concluded that the available evidence on cannabis and its clinical uses remains insufficient to take any decision on either the substance’s removal from CND lists or to endorse its medical use. At the same time, given the fact that it is used medically in some countries, the Committee called for a special session to be held specifically on cannabis by 2018, where new studies WHO has commissioned will be reviewed.

Improving health outcomes for women over the reproductive cycle

The reproductive cycle is a model of healthcare that focuses on the main points of interface with health services in a young woman’s life: reproduction, maternal, newborn and child health. In 2016, for the first time, WHO published a list of medical devices to cover the pathway: the Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health.

The guide, developed in partnership with the United Nations Children Fund (UNICEF) and the United Nations Population Fund (UNFPA) presents 100 clinical interventions for the life course and the 500 medical devices necessary to deliver them safely and effectively. This is critical given the volume of devices in circulation, some of which may be substandard in quality or difficult to use. Now, healthcare professionals across a range of settings have ready access to evidence-based information on the best and most cost-effective interventions.

Reviewing cannabis from a medical perspective

Under the international drug conventions (the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances – UN Organization for Drug Control, UNODC), WHO’s role is to evaluate the
**SPOTLIGHT**

First WHO prequalified hepatitis C rapid test opens the door to expanded treatment

In December 2016 WHO prequalified its first hepatitis C virus (HCV) rapid diagnostic test, a tool that will aid diagnosis of HCV in low- and middle-income countries and improve access to treatment.

The newly prequalified test, manufactured in South Korea, is a point-of-care diagnostic, which makes it particularly appropriate for low-resourced countries, where testing laboratories and trained personnel may be scarce. Resembling a pharmacy pregnancy test, it does not require hospital facilities or electricity and can be performed by health workers with limited training. The test gives a result within 20 minutes.

WHO acceptance of the test came at a time when direct acting antivirals (DAAs), new and highly effective medicines for HCV, are becoming increasingly affordable and available in low- and middle-income countries.

“The majority of people with chronic hepatitis C don’t know they have the infection and miss the opportunity to be cured,” said Dr Gottfried Hirnschall, WHO Director for the Department of HIV and Global Hepatitis Programme. “Making the first WHO prequalified test available in countries can greatly contribute to achieving the goal of eliminating hepatitis.”

There are only very few HCV rapid tests on the market, and they are either not quality-assured or too expensive for countries with limited resources. This means that patients may potentially be misdiagnosed – either as false positives or false negatives. The newly prequalified test is expected to be more affordable, as well as guaranteeing quality, safety and performance. Agencies that procure or purchase health products for low-resource countries, such as Médecins Sans Frontières and UNITAID, have been waiting for such a test in order to scale up diagnosis and treatment.

Making vaccines go the extra mile: new norms for different temperatures

In October 2016, new guidelines were published on the stability of vaccines when removed from the cold temperature at which they are licensed for storage. The guidelines, “Extended Controlled Temperature Conditions”, give assurance of vaccine stability at a higher temperature for a short period of time, reducing dependency on refrigeration or wet ice vaccine distribution. This guidance has the potential to increase access to safe vaccines to millions more people living in tropical climates or remote areas, where there is often little equipment to control temperatures.

Subject to authorization by the manufacturer, it hails a revolution in the availability of access to the vaccines included in the guidance for meningitis A, cholera, human papillomavirus, hepatitis B and diphtheria.

A new model for regulatory system strengthening

In 2016 WHO along with a range of partners (MSH, USP, Koica-MFDS, USAID and the World Bank) met with the Directorate General for Drug Administration (DGDA) of Bangladesh to discuss how best to support the DGDA in strengthening the regulatory system as a coalition of develop-
Looking forward: Towards Access 2030 and other developments

Anticipated benefits from a coalition-based approach to regulatory system strengthening includes a more efficient use of overall resources, greater consistency in standards and approach, improved outcomes and impact, and less burdensome interventions for regulatory authorities. The goal is to use the pilot to inform and formalize the operation of a coalition based approach that could be used in other countries.

Institutional development plan for Bangladesh NRA

Bangladesh road map (2016-2020)

5 years Institutional Development Plan

- Roadmap
- Self-assessment
- Interim Assessment
- Formal Assessment
- Mid year review
- Annual review

- 2016
- 2017
- 2018
- 2019
- 2020

EMP elaborated its vision and strategic framework – Towards Access 2030, which will inform the future work of the department to help countries meet SDG 3 and reach UHC. Implementation of the framework will build on work started in 2016 to increase quantitative and qualitative data informing our policies and work, and a renewed focus on impact in countries.

EMP began an extensive audit of antibiotic medicines for adult and paediatric use for its Essential Medicines List. The result, due for publication in 2017, will guide prescription and use with a view to preserving antibiotics and reducing the risk of resistance.

A November meeting of an informal advisory group on medicines pricing resulted in an extensive report calling for WHO to carry out data collection and analyses to better advise Member States on viable strategies to address the spiralling cost of medicines and achieve a ‘fair pricing’ system.

A small group of EMP technical staff participated in an exercise to identify priority bacteria to guide R&D into new antibiotics.

Work began in 2016 to devise and improve access indicators for medicines and health products. The indicators should be ready by 2018.
FUNDING, DONORS & PARTNERS

Financial overview

Planned Programme Budget for biennium 2016-2017: US$ 105.7 million

Does not include the planned budget of WHO Country and Regional Offices. Funded with 17% of core funds and 83% of voluntary contributions.

Funded with:

- **Foundations and Institutions**: 37%
- **Pooled funds**: 7%
- **Government and Intergovernmental organizations**: 15%
- **International agencies**: 41%

Donors

Extending thanks to existing donors and partners

- EMP continues to depend heavily on voluntary contributions from government donors including France, Germany, Japan, the Netherlands, the United Kingdom, Sweden and the United States.
- 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.
- The Bill and Melinda Gates Foundation and international agencies – namely, Gavi, the Vaccine Alliance, UNFPA, UNICEF, UNITAID and the World Bank – continue to provide critical support the WHO Prequalification Programme and a broadening set of activities key to regulatory systems strengthening and to ensuring medical product quality.
- Contribution from the OPEC Fund for International Development has enabled the development and publication of a very first WHO list of priority medical devices for cancer management.
- EMP continues to draw on the technical expertise of its worldwide network of Collaborating Centers and non-governmental organizations in official relations with WHO.
- The Republic of China, France, Japan, the Netherlands, Republic of Korea and Thailand provide technical expertise and country experiences through the secondment of national professional staff.
Expanding the donor base and extending thanks to new donors and partners

- New contributions from the European Commission enable WHO to develop and roll-out health solutions to tackle neglected tropical diseases in endemic areas, and to map the global threat of antimicrobial resistance.

- Switzerland provides support to regulatory systems strengthening in Sub-Saharan African regional economic communities.

- The International Vaccine Initiative has provided support to the Developing Country Vaccine Regulators’ Network.

- Germany and the United Kingdom (Fleming Fund) provide support to optimize the use of antimicrobial medicines as a component of the Global Action Plan on Antimicrobial Resistance.

- Médecins Sans Frontières has contributed to the testing of antivenom products as part of a new WHO initiative to reduce and control the global health burden caused by snakebites.

- Through collaborative efforts, the United States Food and Drug Administration supports regulatory systems strengthening to improve access to safe and effective biological products.

Full list of contributors

**Government and intergovernmental organizations**
Brazil, People’s Republic of China, the European Commission (Directorate General for Development and Cooperation), France, Germany, Japan, Republic of Korea, the Netherlands, Sweden, Switzerland, Thailand, the United Kingdom and the United States of America.

**Foundations and non-governmental organizations**

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