PROMOTING ACCESS, QUALITY AND INNOVATION
TO SAVE AND IMPROVE LIVES

Essential Medicines and Health Products
Since the turn of the century greater importance has been placed on access to medical products, resulting in many more people tested and treated for priority diseases – i.e. HIV/AIDS, tuberculosis and malaria – and maternal and child conditions. But much remains to be done to ensure all health systems can deliver on the full range of essential medical products needed by communities, and to address the growing burden of non-communicable diseases.

The new 2030 agenda, summarised in the Sustainable Development Goals (SDGs), sets a clear path for future action by placing equity and universal health coverage on centre stage. The health goal, SDG 3 - ‘Ensure healthy lives and promote wellbeing for all at all ages’ – underscores the importance of access to medical products by aspiring to:

• End the epidemics of AIDS, tuberculosis, malaria and other communicable diseases by 2030
• Achieve universal health coverage, and provide access to safe and effective vaccines and medicines for all
• Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines.

The moment is favourable for a sustained global effort to expand access to medical products and save and improve lives.

The vision of the WHO Essential Medicines and Health Products Department (EMP) is closely aligned with SDG 3 by striving for a world where every child, man and woman can afford and has access to the quality medicines and health products they need to lead a healthy and productive life.
Built on three main pillars – access, innovation and regulation – EMP offers guidance, technical assistance and capacity building to promote access to quality treatment at affordable costs, while also incentivizing innovation and the development of vaccines, medicines and diagnostics based on public health needs. In addition, the department develops international standards for the manufacturing and regulation of medical products and contributes to the harmonisation of these to ensure their quality and facilitate their availability on globalised markets. EMP further aids the global health community by providing a range of services to international agencies involved in the purchase and supply of health products and to manufacturers. Those services include:

• Assessment of diagnostics, medicines and vaccines purchased by the Global Fund to Fight AIDS, TB and Malaria, Gavi, the Vaccine Alliance, UNICEF and UNFPA, thereby ensuring that donor investments are well spent
• Advising on selection and use of essential medicines and medical devices for better and more cost-effective public health outcomes.

THREE PILLARS TO PROVIDE COMPREHENSIVE ASSISTANCE TO COUNTRIES

“As we transition to the Sustainable Development Goals, EMP will become an even more critical actor in promoting affordable access to essential quality health products, strengthening health systems and achieving universal health coverage.”

Marie-Paule Kieny, Assistant-Director General, Health Systems and Innovation, WHO
EMP GOALS

Assist countries to build their capacity, know-how, policies and information to increase access to quality essential medicines and other health products.

Promote fair and affordable prices and improve mechanisms for financing and for coverage of essential medicines and health products in social protection schemes.

Improve quality and safety of products, through the establishment and implementation of global standards, strengthening regulatory systems, and reducing substandard and falsified medicines.

Improve selection, prescribing, dispensing and use of medical products to ameliorate health outcomes.

Support the implementation of policies, transparency and good governance in the medical products sectors.

Spur greater R&D and innovation of medicines and other health products to address diseases in developing countries and respond to public health needs globally.
“Ensuring equitable access to quality medical products in globalised markets are challenges too great for any government to address alone. National authorities increasingly call for collaboration, harmonisation of standards and a common point of reference. That is what EMP is providing.”

Gugu N. Mahlangu, Director-General, Medicines Control Authority of Zimbabwe
TWELVE KEY AREAS WHERE WHO/EMP IS MAKING A DIFFERENCE

1. **PRIORITISING MEDICINES FOR HEALTH SYSTEMS:**
Since 1977 WHO has published a biennial model Essential Medicines List to assist countries select medicines for their health systems on the basis of public health needs, efficacy and cost-effectiveness. The last list, published in May 2015, included new treatments for hepatitis C and several cancers. Since 2007, WHO also publishes a list of essential medicines for children, and has spearheaded efforts to improve and increase the availability of paediatric medicines.

2. **IMPROVING QUALITY TO INCREASE ACCESS:**
EMP provides a vital service to countries, global health initiatives and UN agencies by assessing the quality, safety and efficacy of medicines, vaccines and in vitro diagnostics that are procured with donor funding. Today, most of the internationally procured vaccines and medicines for priority diseases are prequalified by WHO. Many of these are inexpensive generics, which have promoted greater access for more patients.

3. **STRENGTHENING HEALTH SYSTEM CAPACITY FOR MEDICINES ACCESS:**
Partnering with the EU and the African Caribbean and Pacific Group of States (ACP), WHO is supporting 15 African countries to improve their pharmaceutical systems, including the selection of essential medicines for the healthcare system, upgrading their supply and distribution channels and promoting responsible prescription and use of medicines, thereby improving patient treatment.

4. **ADDRESSING PATENT BARRIERS TO ACCESS:**
WHO has established a fruitful collaboration with WIPO and WTO to support their members build intellectual property systems that support innovation and access to medical products. EMP provides training and technical support to countries in these areas, including on increasing transparency on the patent situation of patented essential medicines by publishing patent landscapes, i.e. for the new hepatitis C treatments.
“Money alone is not enough, particularly when it is directed at buying specific health commodities. 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, Ministry of Health Kenya
FAST-TRACKING REGULATORY PROCEDURES:

By providing a common work platform and training, WHO is assisting several countries in Africa to carry out joint reviews and assessments of medical products to accelerate the availability of medicines to patients. One such example, the Zazibona initiative, is allowing Zambia, Zimbabwe, Botswana and Namibia to share data and practices in assessing priority products, thereby saving resources and time to register medicines.

STRENGTHENING NATIONAL REGULATORY SYSTEMS:

EMP has developed a five step capacity building programme to strengthen regulatory bodies through technical advice, training and seminars. So far, 127 national regulatory authorities have built their capacities thanks to EMP. In addition, EMP supports regional and sub-regional regulatory harmonization initiatives, centres of excellence and training networks.

INCREASING TRANSPARENCY AND ACCOUNTABILITY ON MEDICINES’ AVAILABILITY AND PRICES:

45 countries are working to improve governance in their pharmaceutical sectors with support from the United Kingdom and Germany. As a result, Ghana has abolished a value added tax on selected medicines; Jordan has adjusted its price setting mechanism and lowered the price of numerous medicines; and Peru has empowered consumers by providing an online data base of comparative prices enabling them to make informed choices when purchasing medicines.

GIVING NAMES TO DRUGS:

Since 1953 WHO has been in charge of assigning International non-proprietary names (INNs) to medicines. INNs, often referred to as generic names, ensure that there is only one recognisable name for each active ingredient used in medicines globally, so that the scientific community, manufacturers, governments, procurement agencies and consumers have one common language when they talk about medicines. As of end 2015, WHO has named close to 10 000 active pharmaceutical substances.
PROTECTING PATIENTS’ SAFETY:
In an increasingly globalised world, medical products constantly move across borders and information sharing across countries has become vitally important to protect patients’ safety. In partnership with the Uppsala Monitoring Centre in Sweden, WHO runs an international monitoring programme and a database of adverse reaction reports, used to monitor and promote the safety of medicines and vaccines. In parallel, WHO collects complaints on in vitro diagnostics and assists countries to improve vigilance. In addition, EMP partners with Member States in the fight against substandard, spurious, falsely labelled, falsified and counterfeit medical products through a dedicated monitoring and alert system.

HARMONISING QUALITY SPECIFICATIONS FOR MEDICINES AND VACCINES:
EMP is in charge of developing and updating global technical specifications for the quality, safety and efficacy of medicines and vaccines, and also the WHO International Pharmacopoeia, a global reference tool containing quality specifications and analytical methodologies. WHO therefore provides a common point of reference to promote harmonized standards of quality. EMP also coordinates the preparation and supply of international chemical reference standards and international biological reference standards.

ACCELERATED R&D IN EMERGENCIES:
During the West Africa Ebola epidemic, EMP, in collaboration with other sections of WHO, played a crucial role in accelerating vaccine clinical trials by establishing multi-country review committees to carry out ethical and regulatory reviews simultaneously. In addition, EMP has introduced an emergency procedure under its Prequalification Programme for rapid assessment and availability of diagnostics, medicines and vaccines for deployment during epidemics.

TRANSFERRING TECHNOLOGY FOR PRIORITY HEALTH PRODUCTS:
EMP has strengthened the capacity of 13 manufacturers in developing countries to produce more than 300 million annual doses of pandemic influenza vaccine. Production output is expected to increase to 600 million doses by 2016. EMP also transferred technology for the production of rabies monoclonal antibodies to three manufacturers in developing countries and created a hub for the development of biosimilars of these products to promote their manufacture for a fraction of the current sale price.
Adapting to emerging challenges

WHO is constantly adapting its activities to address emerging challenges, including:

- the price of new health technologies,
- accelerated research and development (R&D) and regulatory pathways for epidemic-prone diseases, such as Ebola
- regulation of medical devices
- regulation of biotherapeutic products
- antimicrobial resistance, and
- the impact of globalised markets on the quality of health technologies and their availability in health systems.
WHO is currently engaged in a number of high-profile global issues with the aim of bringing about positive change in the next five years.

AFFORDABLE MEDICINES

EMP will launch a global dialogue with key stakeholders to devise ways in which high-priced medicines can become more affordable to health systems while also incentivising industry to carry out public health driven research.

PROMOTING NEEDS-BASED R&D

WHO has led the global dialogue on sustainable sources of financing for R&D for priority health technologies for developing countries in light of market failures. Important results to date are the creation of a Global Observatory for Health R&D, an R&D Fund for developing country diseases, and the current development of an R&D blueprint for epidemic prone pathogens such as Ebola and MERS.

POLIO END GAME STRATEGY

EMP is contributing to the WHO Polio Endgame Strategic Plan 2013-2018 by assuring the quality of vaccines and facilitating access in developing countries.

INFORMED DECISION-MAKING WHEN SELECTING HEALTH TECHNOLOGIES

Working with a range of stakeholders, EMP is promoting a better understanding of the health technology assessment tool (HTA) to support low and middle-income countries make cost-effective selections for their health systems.

ACCESS TO QUALITY ASSURED VACCINES

EMP is contributing to the Global Vaccine Action Plan (GVAP 2011-2020) by strengthening the national regulatory systems overseeing the production and distribution of vaccines.

REGULATING BIOLOGICALS

Biotherapeutic products have proven effective in treating many life-threatening and chronic diseases. But access to such products has so far been relatively limited because of their low availability and high prices. As more countries start to produce biotherapeutics and patents expire, a new era of “similar” products is emerging. EMP is stepping up its work on biotherapeutic products, particularly through the provision of norms and standards to address these demands.
EMP is contributing to WHO’s global strategy to address AMR by providing guidance to Member States on the responsible prescription and use of antibiotics. In addition, the department is exploring ways to incentivise R&D for new antibiotics.

Many countries do not have an effective regulatory system in place for medical devices. WHO is working towards the establishment of a model to assist Member States establish or further develop a framework for monitoring the quality, safety and performance of medical devices on their markets.

Pain management and end-of-life medical options are more in demand as people live longer and cancer incidence rises. EMP provides a global policy platform within the UN system to ensure that strict regulation of controlled substances does not hamper access for patients, assists countries to access medication for pain and palliative care, and trains health professionals in prescribing and dispensing these medicines.

A high priority for low- and middle-income countries where cancers, like most non-communicable diseases (NCDs), are on the rise and expected to increase by about 70% over the next two decades. EMP is developing a model list of cancer medical devices to aid countries select essential devices cost-effectively.

It is estimated that more than a billion people today need assistive health technologies, such as wheelchairs, prostheses, mobility, hearing, low-vision, cognitive and communication aids. Only 5-15% of them are currently accessing these technologies. EMP is developing a list of priority assistive products to increase their affordability and quality, thereby promoting access.

A challenge in most societies, substandard, spurious, falsely labelled, falsified and counterfeit medical products require strong regulatory oversight and effective surveillance mechanisms. To date, EMP has already trained 95 Member States and 18 of the largest International procurers to detect and respond to substandard and falsified products, and plans to extend workshops in Latin America and South East Asia in the next two years.
THE DEPARTMENT

The current EMP department was born in 1981 as the Action Programme on Essential Drugs and concentrated on access to medicines. The department today counts 160 staff and covers all health technologies grouped into three functional areas (access, innovation and regulation) and three product streams – diagnostics and medical devices, medicines and vaccines. Staff expertise covers all key areas in the health technologies field – from policy to research and development and technology transfer, manufacturing and regulation to access, selection and use. As well as working with Member States, EMP provides technical support to other WHO departments and to UN and procurement agencies, particularly those involved in the purchase of health products for developing countries. The Global Fund to Fight AIDS, TB and Malaria, Gavi, UNICEF, UNFPA and UNITAID all rely on EMP’s prequalification to select health products for procurement.

FINANCING

Total planned budget for the 2016-2017 biennium: US$ 171 million, covering headquarters and regional offices

Contributors

Government and intergovernmental organizations:

Australia, Brazil, Canada, People’s Republic of China, the European Commission (Directorate-General for Development and Cooperation; and the Directorate-General for Research and Innovation), France, Germany, India, Japan, the Netherlands, Republic of Korea, Switzerland, the United Kingdom and the United States of America.

Foundations and non-governmental organizations


International agencies and global health initiatives

The UN Commission on Life-Saving Commodities, the Global Fund to Fight Aids, Tuberculosis and Malaria, the Gavi, the Global Alliance for TB Drug Development, UNCTAD, UNFPA, UNICEF, UNITAID, World Intellectual Property Organization, World Trade Organization and the World Bank.

http://www.who.int/medicines/en/
“Our charge is to take care of the health of the population of Vietnam, 92 million people, and our work every year is supported not just by the government but also the World Health Organization. We are very proud of what we have achieved but there are still a lot of challenges that need to be met.”

Luong Ngoc Khue, MD, PhD, Director of Vietnam’s Medical Service Administration