



World Health
Organization



TOWARDS ACCESS 2030

WHO Medicines and Health Products Programme
Strategic Framework 2016 - 2030



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INTRODUCTION

The essential medicines and health products programme is a critical WHO area with a number of flagship and successful initiatives. Its core focus - **TO INCREASE ACCESS TO ESSENTIAL, HIGH-QUALITY, SAFE, EFFECTIVE AND AFFORDABLE MEDICAL PRODUCTS** - is highlighted in the Sustainable Development Goals and is represented agency-wide through programmes at regional and country levels.

The new 2030 development agenda and increasing globalization of health products development and supply have generated a need—and an opportunity—for WHO to adjust and strengthen its work in this area at all three levels of the Organization. WHO needs to ensure that headquarters, regional and country offices function more organically to deliver on development targets, and that health systems strengthening activities result in tangible progress for people everywhere. This new long-term framework for 2016–2030 aims to provide a broad vision and strategic direction to focus and reinforce WHO’s ability to help Member States achieve universal access to safe and quality-assured health products and universal health coverage.

EXECUTIVE SUMMARY

By 2030, the international community should have progressed to more sustainable policies and practices to safeguard the environment, end poverty and promote health throughout the life course. The new global agenda, articulated in the Sustainable Development Goals (SDGs), prioritizes equity and human rights-based approaches with an emphasis, in health, on universal coverage. This gives WHO, and the essential medicines and health products programme in particular, an opportunity to build on progress made so far and help to bring about access to quality essential medicines and health products for all.

The path to that goal is not without challenges. Rising prices of new pharmaceuticals, rapidly changing markets for health technologies, and lack of market incentives for older medicines are placing increasing pressure on health systems' capacity to provide full and affordable access to health care. In addition, the growing regulatory burden and lack of regulatory capacity in many Member States, and the rise in substandard and falsified products on all markets, are hampering efforts to ensure health products' quality, efficacy and safety. At the same time, innovation in medical research and development (R&D) has resulted in new products that, with increased access, can bring lasting improvements to public health. It is therefore all the more important now to strengthen health systems and capacities in under-resourced and fragile countries, and to find sustainable solutions through multi-sector partnerships.

WHO will pursue its vision and mission by focusing on two interlinked and mutually reinforcing strategic agendas to better support the development of health systems capable of expanding access to medicines

and health products: (i) supporting needs-based innovation and reinforcing health product selection, use, procurement and supply systems to increase access, and (ii) strengthening regulatory capacity and practices to ensure the quality, safety and efficacy of products and improve the efficiency of regulatory systems to secure health gains. To better mobilize resources and to maximize results, the WHO essential medicines and health products programme (referred to below as the Programme) will sharpen its focus on a number of thematic areas that reflect current global challenges to access. These include, among others, antimicrobial resistance, controlled substances, research and development preparedness for epidemics and best regulatory practices, including appropriate regulatory pathways for emerging health products.

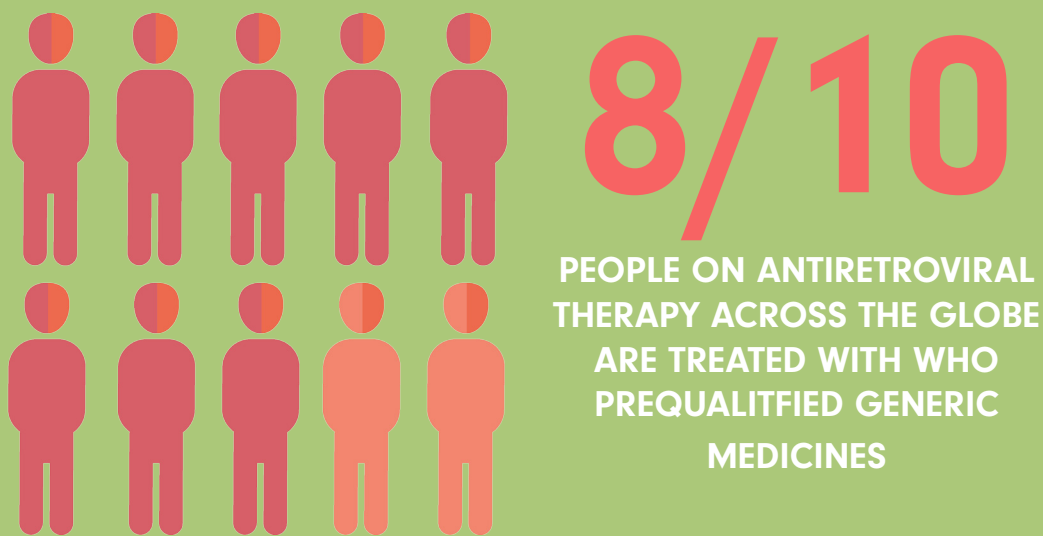
Under 'Towards Access 2030', the Programme will strengthen links with other health systems-related initiatives for synergy and policy coherence, leverage the experience and knowledge of WHO Regional and Country Offices to better align policies with implementation, and reinforce partnerships work to improve coordination for better outcomes. The Programme will report on its effectiveness using a results framework based on improved information systems and four broad measures: regional outcomes, by which regions' performance can be assessed through SDGs and other context-specific indicators; contribution to country outcomes; operational effectiveness, which applies indicators used by WHO; and organizational effectiveness, to track performance in key areas.

1

**CHANGING
LANDSCAPE:
FROM THE
MDGS TO
THE SDGS**

The work of WHO on essential medicines and health products has contributed steadily to international development targets for over 35 years and played a significant role in achieving the health related Millennium Development Goals (MDGs).

WHO played a pivotal role in expanding access to medicines and health products under the MDG agenda, including by working directly with countries to develop capacities and by providing a global platform to stimulate a public health driven R&D system. It contributed to the creation of global health financing and procurement programmes (The Global Fund to Fight AIDS, TB and Malaria, the GAVI Alliance, etc.) and facilitated the procurement of priority quality-assured, safe and effective health products.





Overall, WHO's work in the last 15 years has:

- ▶ Strengthened pharmaceutical systems in low- and middle-income Member States;
- ▶ Strengthened the capacities of national regulatory authorities to improve the quality of products;
- ▶ Helped to improve the quality of generic medicines production for major infectious diseases and reproductive health, expanding production capacity and spurring competition and reduced prices;
- ▶ Ensured availability of quality-assured vaccines and diagnostics;
- ▶ Created global platforms for a new health products research agenda that takes into account and addresses market failures;
- ▶ Continued to develop norms and standards for new medical products to promote quality, safety and efficacy;
- ▶ Convened and hosted an international mechanism to stop the circulation of substandard and falsified medical products.

MEDICINES, HEALTH PRODUCTS AND THE SDG AGENDA

The SDG agenda represents a shift of focus from specific diseases and population targets to a more comprehensive approach to health. SDG 3 emphasises the promotion of health throughout the life course and universal health coverage (UHC). And with the rise in epidemic prone pathogens, there is an increasing need for resilient health systems. This new agenda provides a clear case for WHO to scale up its work on strengthening pharmaceutical systems, taking into account the growing need for a wider range of health technologies, and also the opportunity to drive change through a more integrated structure and sharper focus on a number of emerging trends (see sections 3 and 4).

- ▶ The need to expand access to medicines and health products is highlighted in the SDGs specifically in two targets (3.8 and 3b, see Annex II) and more broadly in at least seven other targets under SDG 3. Access to health products will be a key indicator for countries' progress to UHC.
- ▶ Medicines and health products often make up the largest portion of countries' (and households') health spending – their impact on health financing places them in a central position in all discussions, strategies and plans for universal health coverage.
- ▶ Currently, the majority of people in low- and middle-income countries pay for medicines out-of-pocket, often leading to financial hardship. With the rise in non communicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden will become even greater, as will the need to accelerate progress towards effective and comprehensive UHC.
- ▶ Ensuring that quality essential medicines and health products are available in sufficient quantities and affordable to the population requires functioning regulatory and procurement systems, as well as legal provisions for UHC, governance and efficient management of resources. WHO is working with countries to promote and strengthen these functions.
- ▶ Finally, many public health needs in developing countries remain under-served by markets and R&D. It will be increasingly important to focus research efforts on diseases that affect developing countries disproportionately, ensuring that no one is left behind.

2

CHALLENGES, OPPORTUNITIES AND DOMINANT TRENDS

Within the context of health systems strengthening and universal health coverage, the Programme must focus on a number of emerging challenges and concerns that directly affect access to health technologies. In Towards Access 2030, we have identified the following areas relating to strengthening systems, specific products and specific diseases that need reinforced action and coordination in order to achieve impact.

STRENGTHENING SYSTEMS

QUALITY AND REGULATORY SYSTEMS

The regulation of health products is a critical component of every country's public health system and ensures that high-quality, safe and effective health products reach the people who need them most. Unfortunately, the capacity of many low- and middle-income countries to assess and approve health products remains limited, due to inadequate resources, overburdened staff, and incoherent policy frameworks. Additionally, regulatory legislation differs from country to country, resulting in delays for researchers and manufacturers who must navigate multiple regulatory systems to register the same health technology across countries.

To address these issues, WHO will intensify current efforts to support harmonisation initiatives in all countries, with particular focus on Africa, and to promote work sharing and convergence between regulatory authorities to ensure greater efficiencies and more rapid authorisation of life-saving health products.

WHO is already developing Good Regulatory Practices, Good Reliance Practices and quality management systems for regulatory agencies, in an effort to promote 'smart regulation', wise investment and the adoption of approaches that will best position regulators to effectively deal with current challenges. Partnerships and innovative approaches, such as the development of collaborative and reliance networks between regulatory authorities are some of WHO's current priorities coupled with plans to strengthen capacity for appropriate product oversight and local manufacturing to support access.

AFFORDABILITY

If new medicines and health products are to be used to optimal effect, they must be available at an affordable price. The price paid for new products as well as existing ones must be fair to all – affordable to countries working towards UHC, and sufficient to ensure a sustainable industry to produce them. Establishing this fair pricing model is urgent, as many newly available products, such as those for cancer or hepatitis C, are unaffordable even for high-income countries.

SUPPLY CHAIN CHALLENGES

There will be important changes in the global landscape with respect to procurement and the supply of products. Major global procurement agencies such as The Global Fund to Fight AIDS, TB and Malaria are 'graduating' countries away from reliance on donor funding. Supporting countries in transition to ensure access to medicines and health products through UHC will be a key task in the coming years. The development of appropriate governance mechanisms and legislation to ensure reliable systems for the procurement and supply of medicines and health products will also be a priority.

RESPONSIBLE USE OF MEDICINES AND HEALTH PRODUCTS

Work on responsible use will be reinforced to guarantee appropriate prescription and use of medicines and other technologies supplied through health facilities, improve the quality of care and reduce the risk of drug resistance. This will require training of health care workers, quality improvement processes, routine monitoring of medicines and technology use from data systems and effective pharmacovigilance.

MONITORING

A critical step in the development of health systems that promote access to medicines and health products is developing countries' capacities to measure and monitor quality, availability, price and use, as well as getting better information on how products are used so that we can adapt and improve. The emphasis should be on enabling systems to monitor all health products (not just medicines and vaccines) in a routine and consistent manner, including during emergencies. Without data systems, we cannot expect to measure access to health products and risks to health.

SPECIFIC PRODUCTS

NEEDS DRIVEN R&D

The implementation of the Global Strategy and Plan of action on Public Health, Innovation and Intellectual Property (GSPOA)¹, the follow-up work to the report of the Consultative Expert Working Group on Research and Development (CEWG)² and the report of the UN Secretary-General's High-level Panel on Access to Medicines³ have highlighted the need to change the way R&D is financed. However, and despite many efforts, there is still no global agreement on how to ensure new products are developed that meet priority health needs. Going forward, the need for new antibiotics to respond to the threat of AMR as well as new vaccines for emerging diseases will require the essential medicines and health products programme to intensify support of policy development to ensure that new products come through the pipeline to meet the needs of all countries.

NEW PRODUCTS

The emergence of biological products and cell and gene therapies will require new efforts in regulatory strengthening and harmonisation of standards. Biosimilars 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 and to support countries in establishing the necessary systems (regulatory frameworks, resources, capacity) to evaluate these products, monitor their use in their markets after approval, facilitate their uptake, and increase analogue competition and sustainable access to new medicines.

Medical devices are another example. They are increasing in number and complexity but many countries do not have a regulatory process for these products. WHO is already working on a regulatory framework for medical devices and will begin capacity building in this area.

¹ http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1

² The CEWG's mandate is "to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases."

³ <http://www.unsgaccessmeds.org/final-report/>

SPECIFIC DISEASES AND CONDITIONS

ANTIMICROBIAL RESISTANCE (AMR)

WHO is already strengthening its actions to contribute to addressing this priority global challenge via monitoring and surveillance of antibiotic use, capacity building for prescribers and dispensers, awareness-raising of consumers, and by advocating for expanded and better use of appropriate and quality-assured diagnostics. Going forward, the elements required for effective stewardship of antimicrobials at both national and global levels will be a key aspect of WHO's work.

NCDS AND AGEING

The 21st century is already seeing a global rise in ageing populations, non-communicable diseases and people with disabilities. To ensure both good health and wellbeing for these populations, there is a growing need for appropriate diagnosis and access to quality long-term treatment, as well as for products for assistive care. Assistive products will be some of the essential tools to rationalize health and welfare costs, enabling people in need to remain healthy, independent and productive. In parallel, innovative technologies and tools to prevent and combat dementia will require further advocacy and action at a global level.

HEALTH PRODUCTS FOR NEW AND RE-EMERGING THREATS

Infectious disease epidemics pose a clear and continuous risk to global health, security and economic prospects. Experience with past epidemics highlights the need, and the opportunity, to improve emergency preparedness, including importance of coordinated and proactive research as an integral element of the response to any epidemic. These efforts – in advance of and during epidemics – must overcome existing market failures in addressing neglected tropical diseases.

The Programme will continue to provide leadership in shaping this new model of R&D preparedness by outlining appropriate regulatory pathways, defining international reference preparations, strengthening regulatory capacity and efficiency, and promoting use of potential platforms to support development and production of health technologies for priority diseases with epidemic potential as well as their regulatory review. Monitoring and pharmacovigilance systems will also need to be in place to ensure the safety of experimental products during and after epidemics.



HARMONIZATION AND RELIANCE: THE KEY TO REGULATING HEALTH PRODUCTS IN A GLOBALIZED WORLD

Regulatory authorities in high-income countries have addressed resource challenges by establishing schemes that promote co-operation and work sharing between their regulators; for example, the Pharmaceutical Inspection Co-operation Scheme and the European Union drug regulatory network. Other regions, such as ASEAN and Latin America, have also established similar schemes.

WHO has for several years promoted the harmonization of regulatory standards for medical products at the global level. Several regulatory harmonization initiatives within African economic blocks are showing promise, for example, the East African Community (EAC).

The EAC medicines regulatory harmonization project serves as a model for the continent-wide African Medicines Regulatory Harmonization (AMRH) initiative spearheaded by the New Partnership for Africa's Development (NEPAD). This ambitious plan aims to expand access to medicines in African countries and hinges on strengthening NRAs on the continent.

WHO started collaboration with EAC in 2010 when it conducted a joint assessment exercise with EAC assessors for two AIDS medicines. One product became prequalified by WHO in August 2010 and was promptly registered in Uganda, Tanzania and Kenya. The other was prequalified in January 2011. A second joint assessment project involving all five EAC countries started in July 2013 with five products for reproductive health and to treat malaria. These products were registered in all five countries in 2014. And in 2015, EAC countries jointly assessed and registered the first biotherapeutics - bevacizumab and trastuzumab - two critical medicines for cancer.

It is anticipated that based on these and other experiences on the continent, African countries will establish the African Medicines Authority that will see increased efficiency and greater availability of essential medicines in the region.

COLLABORATIVE REGISTRATIONS SUPPORTED BY WHO

INNOVATION AND INFORMATION SYSTEMS FOR BETTER HEALTHCARE DELIVERY

22 African regulatory authorities across economic regions participate in the WHO collaborative registration process, which has made possible the granting of 152 national registrations of WHO prequalified medicines in median time of 78 days. Leading manufacturers of prequalified medicines now utilize the process as a standard way to make essential medicines available to patients faster. A Similar process is being piloted for medicines approved by Stringent Regulatory Authorities and accelerated registrations have already been granted in eight countries for antiretroviral medicines approved by the European Medicines Agency (EMA). Antiretrovirals, antimalarials, anti-TB and contraceptive medicines already approved by the EMA and the United Kingdom regulatory authority are now pending registration in 12 African countries.

While medical science has advanced considerably during the last half century, the ability of care givers in developing countries to access the information vital to the delivery of care remains limited. This is partly due to poor or no information systems. In the area of health products, information and vigilance systems are vital both for effective procurement and supply of the needed technologies and for patient safety through pharmacovigilance.

From a WHO perspective, information systems are also critical to build a sound evidence base that will allow better and more targeted actions to strengthen countries' health systems. For example, systems that can help to evaluate access to health products at all levels of the health system, vigilance systems for rapid, user-friendly reporting of unsafe products or unsafe use, or systems that measure consumption and use of antimicrobials, are all necessary tools that help WHO be more effective in its work.

3

VISION AND STRATEGIC AGENDA

VISION

A world where every child, man and woman has access to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life.

MISSION

The mission of WHO in this area is to support Member States to improve and sustain access to quality medicines and health products in order to achieve Access 2030 and universal health coverage. To that end, the Programme will provide leadership and technical expertise, define norms and standards, shape the research agenda according to public health needs, generate relevant evidence, articulate policy and monitor progress towards equitable access.

TWO STRATEGIC AGENDAS FOR STRONGER SYSTEMS

WHO is committed to universal access to quality, effective and safe medicines and health products and UHC. Towards Access 2030 will align the work of the various sections of the Programme to drive measurable improvements in countries' health and regulatory systems and address global challenges affecting the quality of and access to health products.

Future work will be structured according to two broad trajectories that are interlinked and mutually reinforcing in supporting health systems development, and take account of the life cycle of medicines and health products:

Fostering needs-based innovation and reinforcing health products selection, use and supply systems to increase access

Strengthening regulatory capacity and practices to ensure the quality, safety and efficacy of products and improve the efficiency of regulatory systems to secure health gains.



Facilitator role Strengthening the system to improve equitable access

- ▶ **Appropriate innovation** – foster public health driven R&D
- ▶ **Evidence-based selection** – promoting informed choices and improved resource allocation through use of Health Technology Assessment, the Essential Medicines List, priority lists of products/devices (including diagnostics) and technologies
- ▶ **Supply chain** – supporting proper governance and regulation of PSM systems, fostering efficient procurement, stock management and distribution systems, ensuring integrity of supply systems, strengthening the development of QA systems according to the MQAS , supporting the development of LMIS and a procurement system predicated on ensuring the purchase and supply of quality assured products
- ▶ **Strategic local/regional production** of quality essential medicines and health products according to countries'/region's capacities and needs
- ▶ **Pricing-financing-reimbursement** – promoting affordability and fair pricing, reducing out-of-pocket expenditure, supporting the use of TRIPS flexibilities for products still under patent, ensuring that equipment purchases are costed through their life-cycle
- ▶ **Quality use** – supporting countries in the responsible prescription and use of medicines and health products, in particular antibiotics, novel products and high risk medical equipment
- ▶ **Data systems for managing access to medicines, vaccines and other health products** – using routine data to support decision making of policy makers, system management and to improve accountability

Guardian role Improving regulatory pathways to access

- ▶ **Assuring quality products for public health challenges** – making Prequalification more relevant to post-2015 challenges
- ▶ **Building capacities and efficiencies to safeguard public health** – strengthening NRAs, harmonizing standards and promoting the convergence of practices, championing best regulatory practices, including reliance, and incorporating regulatory frameworks for new products
- ▶ **Responding to and minimizing health risks from medical products** – improving product safety and vigilance, expanding information systems
- ▶ **Accelerating R&D for emergencies** – establish regulatory pathways for the rapid assessment of clinical trials and innovative products
- ▶ **Establishing and maintaining international standards for better medicines and all health products** – promoting unified product standards, as well as a global nomenclature for medical devices

The Programme will enhance the following actions:

PROVIDING LEADERSHIP AND TECHNICAL EXPERTISE

Convening global, regional and national expertise, building consensus among Member States and advocating for public health oriented policies. The Programme provides leadership on all issues around medicines and health products across all disease areas, ageing and disabilities and will aim to be the centre of reference across WHO.

DEFINING NORMS AND STANDARDS

The Programme develops international norms and standards so that countries have a unified reference for medical and health products, which is particularly important in an increasingly globalised and interconnected world. These norms and standards are also critical tools for new R&D orientations in the context of products targeting neglected diseases, emerging pathogens and other innovative technologies. Another developing area is patient-tailored care, which may require different or additional standard setting approaches for individualised treatments.

SHAPING THE RESEARCH AGENDA

In the follow-up to recommendations of the CEWG, WHO has fostered the implementation of new concepts of R&D that address global health needs, including delinking the cost of R&D from price and volume to ensure affordability of any new products developed. WHO will also help to identify an operational research agenda and better define appropriate regulatory science and work in close collaboration with research institutions, academia and collaborating centres to move this agenda forward.

PROVIDING EVIDENCE TO SUPPORT POLICY DECISION-MAKING

Given the numerous expert committees it convenes and the vast pool of global expertise from which it can draw, the Programme is well placed to provide the most relevant and up-to-date evidence to support the development of national and international policies needed to increase access to medical and health products (including controlled substances) in a sustainable way.

CAPACITY DEVELOPMENT

The Programme provides technical support in different ways comprising: the setting of norms, standards and guidelines at a global level; the maintenance of a pool of experts and collaborating centres; individualised guidance to countries; regulators; procurement agencies and manufacturers (the latter to enhance good practices and quality; and training to improve access to health products. The essential medicines and health products Programme works with countries to facilitate implementation of the guidance and best standards set by the department. Technical advice and coordinating support are given to countries to empower them to harmonise systems, strengthen their infrastructure and mechanisms across the full spectrum of access to medicines and health products activities.

MONITORING ACCESS, QUALITY AND USE

The Programme has developed tools to help countries to monitor the availability and price of core medicines and other products in priority health areas. This area will increasingly become a priority and will require renewed efforts to respond to the SDG agenda, with the need to devise a clear way to monitor and evaluate progress towards access both in countries and globally, particularly to help identify areas of medicine shortages and to increase responsiveness to improve access to all health products. These efforts will be accompanied by focused work in pharmacovigilance, with a view to ensuring that expanded access truly helps achieve health gains through appropriate regulatory oversight and rapid reporting systems on adverse drug events.

SPOTLIGHTS

SAVING THE LIVES OF MOTHERS AND CHILDREN

Medical devices are indispensable tools for health care in prevention, diagnosis, treatment and rehabilitation. They range from basic equipment such as surgical gloves or scissors, to more sophisticated machinery like MRI scanners. Because they comprise such a vast variety of products, there are many millions of medical devices in circulation, some of which may be substandard in quality or difficult to use. For that reason, their selection, availability and appropriate use pose a significant challenge for weak or poor health systems.

One important area that WHO has targeted to improve the use of medical devices is reproductive, maternal, newborn and child health. Working with UNICEF and UNFPA, WHO has developed a comprehensive list of the medical devices required to set up a reproductive health service, improve access to these products in low- and middle-income countries, support quality of care, and strengthen health systems.

The Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health comprises approximately 500 devices and will be a key tool in providing a continuum of care to young women of child bearing age, pregnant women, their newborns and young children. The medical devices are classified according to the level of health-care delivery - health post, health centre and referral hospital. They were also chosen according to evidence of affordability, ease of use, durability, and other relevant factors to justify appropriateness for low-resource settings.

In African countries, where regulatory oversight is still weak, it will be important for regulatory authorities to apply the African Union Model Law on Medical Products Regulation in order to ensure that access to these key devices is also safe and of assured quality. The Model Law provides a guide for AU member states and regional economic communities in harmonizing regulatory systems and providing an enabling environment for the scale-up of health technologies.

A photograph of a man in a white uniform and red cap standing in a room filled with wheelchairs. The room appears to be a storage or distribution area for assistive devices. The image is overlaid with a semi-transparent orange filter. The text "LEAVING NO ONE BEHIND – THE ASSISTIVE PRODUCTS LIST" is centered over the image.

LEAVING NO ONE BEHIND – THE ASSISTIVE PRODUCTS LIST

WHO launched the world's first Priority Assistive Products List (APL) in May 2016 to increase access to technologies that can help older people and people with disabilities to lead a better and more productive life.

The List responds to a growing need for quality-assured, useful and affordable assistive products as life expectancy increases across many regions and to fulfill global commitments to people living with disabilities.

The 50 priority products included in the list are the result of a Global Survey and Delphi exercise. The Global Survey succeeded in capturing the views of people who need and use assistive products across the world. Respondents chose the 50 top priority assistive products from a list of 100. 44% of respondents were older people and/or people with disabilities from 161 countries.

Next steps for this effort include the development of minimum standards for the products in the APL and advocacy to ensure equitable access to quality assistive products in all health systems.

4

HOW WE WORK

Towards Access 2030 will be guided by a set of WHO corporate-wide principles (see Annex I) with the underlying core values of equity, fairness and transparency. The Programme will coordinate across the three organizational levels to promote and prioritize the following approaches: responsiveness to Member States' health needs; recognition of country ownership; adherence to the highest professional and ethical standards in technical work and stakeholder relations; outstanding leadership and service through information and knowledge sharing advocacy; commitment to partnerships; and accountability and focus on results by defining clear objectives, and organizing work and resources to achieve them.

REGIONS' AND COUNTRIES' KEY ROLE IN TOWARDS ACCESS 2030

While this strategic framework attempts to capture the broad strategic lines of current and future WHO health products work globally, it also aims to bring results and concrete improvements to people's lives. Regional and country offices' role is therefore critical both for informing Headquarters' normative and policy work, and for transforming strategic directions into impact by bringing context and on-the-ground experience into the equation.

Field offices, in particular regional ones, are connected to regional networks. Under Towards Access 2030 these will be leveraged to greater degree to facilitate both partnership building and identifying regional agendas WHO can support. Regional networks will also be key, along with input from countries, to advancing local production capacity building and could have a major impact on needs-based innovation for all regions.

To capitalize more fully on the wealth of knowledge and networks at the regional and country levels, we will strengthen the sharing of information and best practices between the three organizational levels, and establish platforms for policy discussions, data gathering and building an evidence base.

WORK ACROSS HQ ON THE HEALTH SYSTEM STRENGTHENING AGENDA

The Essential Medicines and Health Products Department (EMP) at headquarters works across all Geneva based departments involved in health system strengthening through its presence in the Health Systems and Innovation (HIS) cluster, and also through the UHC 2030 partnership. UHC 2030 provides a platform to: improve coordination of efforts for UHC at global level, strengthen multi-stakeholder policy dialogue and coordination of HSS efforts in countries, facilitate accountability for progress towards HSS and UHC, and build political momentum around a shared global vision of HSS for UHC.

These two platforms – HIS and UHC 2030 – provide EMP and regional and country programmes with the opportunity to position the access to health products agenda within WHO and more broadly. At the same time, UHC 2030 offers a forum for amplifying advocacy and fund raising efforts for UHC.

HOW WE WORK WITH PARTNERS AND STAKEHOLDERS

To pursue its vision and strategic agendas – and to make the greatest impact at country and regional levels – the Programme will strengthen its engagement with seven key stakeholder groups: (i) Member States, (ii) UN and other international partners, (iii) relevant WHO Departments (iv) research institutions and academia, (v) donors, (vi) civil society, and (vii) private sector. Each of these broad groups provides an opportunity for the Programme to act more as an agent of change by stimulating fruitful collaboration and synergizing action, and to be a more active and effective partner. The Programme will also pay special attention to improving coordination with partners at country level.

MEMBER STATES

Towards Access 2030 will help the Programme to give more targeted support to Member States to achieve global and national health objectives. This will include strengthened working relationships with Member States' regulatory authorities and pharmaceutical systems to support the two strategic agendas, as well as other key stakeholders.

UN AND INTERNATIONAL AGENCIES

WHO has a key role in providing technical expertise on regulation, access and innovation to development partners, particularly within the UN family, such as, for example, in the key health area of maternal and child commodities. International agencies involved in the purchase and supply of health products rely on WHO for a variety of core services, including quality assurance of health products as well as the use of standards and tools to improve convergence. A priority for WHO in the future will be to optimise information flows to these partners about the programme of work, including on issues such as assessment of product dossiers, information about risk management of products, and mechanisms to ensure continuous surveillance of products in the field.

Several partnerships have also been forged in the areas of intellectual property and local production, namely, with WTO, tWIPO, UNIDO and UNCTAD.

A promising new development involves the possible development of a global coalition of interested development agencies with a view to coordinating regulatory system strengthening efforts and achieving better outcomes.

WHO

Within WHO, the Programme is the centre of reference for all health product work and supports the activities of disease programmes on access to medicines and health products; it also provides extensive high-level technical and policy support to Member States and partners. Going forward, Headquarters will work with Regional Offices to enhance collaboration through mechanisms such as the Category 4 network as well as the sub-networks specific to medicines and health products. Through these and other, technical specialist networks, such as those on medicines pricing or regulatory convergence and harmonisation, Headquarters and Regional Offices will continue to support each other, and ensure that there are effective links between learning from country work, responding to requests for technical support and developing normative guidance and tools.

RESEARCH INSTITUTIONS AND ACADEMIA

WHO collaboration with these sectors has a long history. Some of these institutions have become WHO Collaborating Centres and work with us in a variety of ways – either through joint research work, often leading to new global standards, or by hosting WHO initiatives, such as the global pharmacovigilance database housed in the Uppsala Monitoring Centre. Towards

Access 2030 will focus priority areas of collaboration with these partners in the future, and leverage each entity's comparative advantages to achieve faster and better impact on access.

DONORS

Towards Access 2030 will require some fresh resources and new partnerships to deliver on the new areas of focus. We will target new and existing funding partners to establish or improve regular dialogue. Together, we will define areas of mutual interest for increased collaboration in the longer term, through a clear prioritization process that is based on best public health evidence. We will improve our results reporting to existing donors and information sharing with potential donors and their possible role as an access partner. EMP will step up its advocacy efforts for funding partners to contribute to the access agenda and engage convincingly and influentially in debates on global access.

CIVIL SOCIETY

Recognising this group's growing influence in global health, WHO will strengthen links with civil society to achieve results and policy impact. This will entail engaging civil society in policy and advocacy processes, strengthening partnerships with organizations and networks to channel their expertise and experience in countries, forging stronger partnerships with key global and regional civil society actors, think tanks and coalitions to amplify voice and advocacy, and foster participatory processes for equity, governance and the achievement of health related SDG targets.

PRIVATE SECTOR

The private sector plays a fundamental role in the health products area and regular dialogue with this group is necessary to move forward both the innovation/access and regulatory agendas. Guided by the FENSA agreement, WHO will seek to engage with the private sector to find solutions to health challenges, such as the need for public health driven R&D, pricing and affordability of health products, and leveraging innovative technologies and solutions for health. WHO has already started fruitful collaborations with this sector best exemplified by the development, with AVAREF's contribution, of at least one effective vaccine for Ebola, and through product development partnerships such as DNDi, FIND, MMV and CEPI.

HOW WE WORK AS A PROGRAMME

Our proposed strategic directions will be reflected in a WHO-wide programme that visibly and measurably supports countries to achieve their health goals, with improved effectiveness demonstrated in an organizational structure that is cross-cutting, sustainable within projected income, and provides incentives to increase both the quality and quantity of results delivery at global, regional and country levels. Innovation, replication opportunities and lessons learned will be explicitly considered in programme development and review. Increasingly, WHO will endeavour to respond to Member States' demand for relevant, tested, and cost-effective interventions, relying on regional and country office staff and expertise.

All technical programmes and activities will be designed through the lens of increased access to quality essential health products. They will adhere to WHO programme and project quality standards and processes, for which managers will be accountable, while greater investment in monitoring and evaluation will help identify improvements required to achieve sustainable results.

At Headquarters, EMP will consolidate the essential support functions that will help to reach our objectives. We will aim to publish and communicate our work not only through reports and electronic formats but through peer reviewed publications to promote the scientific and evidence base for access to medicines and health products. We will enhance our capacity for project management and ensure effective communication of results to donors and stakeholders.

5

**MEASURING
RESULTS**

The Programme will establish effective metrics that will demonstrate whether or not we have reached our objectives and take corrective measures when required. Those metrics will be based on established WHO Programme Budget indicators, in particular outcome 4.3, and focus on results and impact as opposed to simple activities or outputs. Frequency and timeliness of reporting will be determined based on their expected usefulness, relevance and speed of change. We will assess and report on progress in implementing Towards Access 2030 to funding partners and relevant stakeholders through annual and donor reports as well as through communication and outreach activities.

The ultimate goal of the Programme is to increase access to affordable, quality health products for as many people as possible. The achievement of that overarching goal presupposes progress and outcomes in a number of areas (see example table on the next page).

The Programme is currently reconciling all existing data collection systems and integrating them into a new framework to measure results. This framework will take into consideration:

- ▶ The broader SDG 3 target on access to medicines (provide access to affordable essential medicines to all) and the corresponding indicator that will be discussed and approved by UN Member States in March 2017 (proportion of health facilities that have a core set of essential medicines available and affordable on a sustainable basis);
- ▶ WHO's Programme Budget Outcome 4.3. (Improved access to, and rational use of, safe, efficacious and quality medicines and other health technologies), its indicator (Availability of tracer medicines in the public and private sectors) and corresponding output indicators:
 - Number of countries with national policies on medicines and other health technologies updated within past five years;
 - Number of countries that report data on product research and development investments for health;
 - Number of national regulatory authorities ensuring essential regulatory functions for vaccines.
- ▶ New trends that are acquiring more and more relevance in terms of needed attention and improved performance (AMR, medical countermeasures for emergencies, interdependency and interconnectivity of actions, etc.).

The following presents a few indicative examples of the components of the EMP results framework that is under development and that will become an integral part of this strategic framework.

OVERARCHING GOAL : ACCESS 2030

1 EFFECTIVE REGULATION

- ▶ Regulatory guidance adopted in countries, networks established and well-functioning, undertaking joint activities and promoting reliance.

2 QUALITY PRODUCTS

- ▶ PQ list recognized as a 'brand' and expanded to include products relevant to SDGs

3 NEEDS DRIVEN INNOVATION

- ▶ New products in the pipeline for neglected tropical diseases, epidemic prone pathogens and AMR

4 INTELLECTUAL PROPERTY

- ▶ Patent transparency for all patented essential medicines
- ▶ Strategic local/regional manufacture

5 EVIDENCE BASED SELECTION

- ▶ More countries effectively using EML, HTA and APL to select health products
- ▶ Essential Medical Devices and Diagnostics List and Priority Assistive Products List established and implemented.

6 PROCUREMENT AND SUPPLY

- ▶ Policy on governance mechanisms for procurement and support systems in place
- ▶ Monitoring of substandard and falsified products expanded
- ▶ Data on supply management available
- ▶ Improved planning to reduce stock-outs and over-stocks

7 FINANCING AND PRICING POLICIES

- ▶ Model legislation for reimbursement developed
- ▶ Greater global transparency in price setting

8 QUALITY AND APPROPRIATE USE

- ▶ Improved skills of prescribers and greater patient awareness of responsible use in the most vulnerable countries

9 DATA, MONITORING AND EVALUATION

- ▶ Data systems defined and established for measuring utilization of medicines and health products
- ▶ Indicators of improving access established for countries and measured

ENABLERS/INTERNAL RESULTS: consensus, collaboration, staff satisfaction

EMP will ensure that the process for the definition of the results framework harvests knowledge, expertise and good practices at regional and country levels, and will solicit broad participation and contribution from all relevant stakeholders.

ANNEXES

ANNEX I | WHO PRINCIPLES

WHO-WIDE PRINCIPLES ALIGNING HOW WE WORK

1 ACCOUNTABLE

- Acknowledge and take responsibility for meeting our objectives and commitments by setting and enforcing clear expectations at all levels
- Maintain high ethical and professional standards by asserting an evidence-based and independent perspective

2 COUNTRY-LED

- Follow governments' lead and help them take ownership of their decisions and plans
- Provide leadership in key public health debates
- Invite country participation in regional- and global-level dialogue
- Cultivate and reinforce country-level capacity to sustain achievements

3 INTERCONNECTED AND INTERDEPENDENT

- Seek and foster synergies across health areas that have the potential to optimize outcomes
- Strengthen internal and external collaborations that can speed or enhance outcomes

4 EFFICIENCY-DRIVEN

- Work efficiently, i.e., seek maximum results from limited resources
- Provide timely access to data and information so that all actors can react and work quickly
- Streamline processes that make it easier to collaborate with internal and external colleagues

5 IMPACT-ORIENTED

- Draw attention to new issues, encourage ongoing learning and innovation, and actively promote successful ideas and initiatives
- Set priorities and allocate resources in alignment with the delivery of results
- Improve programme performance, so that everyone who needs health products has reliable access
- Promote equity in access

ANNEX II | RELEVANT SDGs

RELEVANT SDG TARGETS FOR THE PROGRAMME

- Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all (3.8)
- 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, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, ... and, in particular, provide access to medicines for all (3.b)
- Reduce global maternal mortality (3.1)
- End preventable deaths of newborns and children under 5 years of age (3.2)
- End the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases (3.3)
- Reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being (3.4)
- Strengthen the prevention and treatment of substance abuse (3.5)
- By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes (3.7)
- Improve well-being of all populations including those with disabilities, NCDs and ageing (3)

3 GOOD HEALTH & WELL-BEING

Ensure healthy lives and promote well-being for all at all ages



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