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Roadmap for access 2019-2023

Comprehensive support for access to medicines and vaccines

Zero draft

The zero draft Roadmap for access 2019-2023 has been developed for the purposes of consulting with Member States on its development.

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Introduction and rationale

The overall mission of WHO identified in the Global Programme of Work (GPW) 2019-2023 is three-fold: (i) promote health, (ii) keep the world safe and (iii) serve the vulnerable. Specifically, these goals are the "triple billion" to be achieved by 2023: 1 billion more people enjoying better health and well-being, 1 billion more people protected from health emergencies, and 1 billion more people benefitting from universal health coverage.

Achieving universal health coverage (UHC) requires a consistent emphasis on building strong and resilient health systems. Some of the greatest challenges to achieving UHC stem from persistent barriers to accessing health services and to accessing affordable and quality-assured health products. Equitable access to health products is a global priority. Every disease strategy includes access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation. The availability, accessibility, acceptability, and affordability of medicines and vaccines of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8[1].

Over the past decade a large number of new medicines and health products have been developed and commercialized, presenting new opportunities and challenges for health systems. General infrastructure improvements and societal development have, along with health systems strengthening and access to medical products, resulted in better health outcomes in many countries. There has been progress in prevention and treatment of some diseases contributing to quality of life improvements and in certain settings, an increase in life expectancy.

Access to medicines and vaccines is a multidimensional problem. It therefore requires comprehensive national policies and strategies, together with legal and regulatory frameworks that meet health system needs and cover the entire product lifecycle—from R&D to quality assurance, regulatory approvals and market authorization, supply chain management, and prescribing, dispensing and use. These policies and strategies should balance public health needs with economic and social development objectives, and promote collaboration with other sectors, partners and stakeholders.

WHO takes a comprehensive health systems approach to increasing access to health products. Activities are guided by a series of World Health Assembly and Regional Committee resolutions spanning the decade from 2007 to 2017 and earlier. These resolutions, numbering almost 100 (Annex 1) were used to develop the report on 'Addressing the global shortage of, and access to, medicines and vaccines' presented to the 71st World Health Assembly in May 2018.[2] As a result, WHO was requested to develop a roadmap to outline the programming of WHO's work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019-2023.

[1] UHC for all by 2030

[2] A71/12

Roadmap 2019-2023

How the roadmap was developed

The report on 'Addressing the global shortage of, and access to, medicines and vaccines' presented to the 71st World Health Assembly in May 2018 proposed actions for prioritization according to: WHO's comparative advantage, providing value for money, and leading to achievable and sustainable improvements. These prioritised actions form the basis for the activities, actions and deliverables outlined in this report.

The actions for prioritization as described in the WHA report have been consolidated into 10 action areas as shown in Figure 2.

Figure 2: Figure 2: Activity areas to be addressed during 2019-2023

This zero draft roadmap was developed by WHO based on input from all levels of the organization. It takes into consideration existing documents, including governing body documents, the programme budget 2018-2019, and relevant departmental and Regional strategies. Consultation with Member States is now required to finalize the document.

This draft describes each activity area, how it contributes to increasing access, and its alignment with various global and Organizational strategic documents. It also puts forward the specific actions and key deliverables for each activity over the period 2019-2023.

Activity areas

1 Research and development for medicines and vaccines that meet public health needs

Health research and development (R&D) that is guided by public health needs is required for improving access to medicines and vaccines. This is especially important for neglected diseases as well as emerging infectious disease pathogens, and new antibiotic therapies and other medical products that promise limited return on investment. The current market model also fails to deliver products for certain priority target groups such as children and pregnant women. In line with the Global strategy and plan of action on public, health, innovation and intellectual property (GSPA), which recommends prioritizing needs for, and promoting research and development, WHO is playing a catalytic role in the R&D for these neglected areas where there is a compelling unmet public health need for new products. The role for WHO includes coordinating the efforts of different actors by setting R&D priorities, identifying R&D gaps, defining desired product profiles, and in facilitating the development of affordable, suitable new treatments, diagnostics and devices. This work is needs-driven and evidence-based and guided by the principles of affordability, effectiveness, efficiency, and equity in line with the CEWG report. .

This activity area contributes to product development processes, more coordinated action on health R&D and improved capacity for carrying out R&D and conducting clinical trials in countries. Specific action on R&D preparedness for emergencies are described in Activity 7.

The Global Observatory on health research and development, recently established by WHO, is central to setting priorities for product development and to contributing to coordinated actions on health R&D. It has been tasked to coordinate the development of new medical products to take the place of those that become ineffective, and through the R&D Blueprint to develop a global preparedness plan for addressing future epidemics.

Specific actions

- Continue to set priorities for health research and development in areas of compelling health need
- Contribute to coordinated actions on health research and development
- Support improved capacity for R&D and clinical trials in countries

Research and development for medicines and vaccines that meet public health needs

Deliverables

Continue to set priorities for health research and development in areas of compelling health need	**When**
1. Analyse and publish antibiotic preclinical and clinical pipeline and a list of prioritized research and development needs for communicable diseases, non-communicable diseases, immunization, reproductive, maternal, child and adolescent health and ageing, and antibiotic-resistant bacteria and in-vitro diagnostics	Ongoing
2. Finalize the global development and stewardship framework to combat AMR jointly with OIE and FAO	Mid-term

Ensure coordinated actions on health research and development	**When**
1. Facilitate discussion on unifying principles for biomedical research and development	Long-term
2. Develop a harmonized WHO methodology for Target Product Profiles	Short-term
3. Set up new R&D initiatives and support existing ones, including GARDP that follow the needs-driven and evidence-based and guided by the core principles of affordability, effectiveness, efficiency, and equity and the principle of delinkage.	Ongoing

Improve capacity for R&D in countries	**When**
1. Disseminate and support implementation of policy options for designing R&D models that promote innovation and access in line with the CEWG principles	Mid-term
2. Develop sustainable financing mechanisms models for R&D where the market does not attract sufficient investments	Long-term
3. Support clinical trial registries and improving policy mechanisms for clinical trials, including capacity development	ongoing

2 Fair pricing and financing policies

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available in health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at prices that are sustainable and affordable. The concept is applicable to other health products as well, as access depends on appropriate selection, affordable prices and sustainable financing.

Many people worldwide do not have adequate and regular access to even a limited basket of basic, low-cost essential medicines: for example, the largest majority of poor and unvaccinated children now live in middle-income countries. The high burden of out-of-packet payments for medicines and health products frequently increase inequities in many countries, leading to catastrophic payments and impoverishment of individuals and families. Poor selection of medicines and health products, inadequate domestic or government financing and ineffective policy interventions and processes to manage expenditure and out of pocket expenditure (for medicines and some vaccines) contributes to a lack of access to medicines and health products and unaffordable prices. One of the major challenges is to provide and sustain access to health products and to understand the impacts of the introduction of new technologies, and to strike a balance between the health gains and costs, and ensuring the sustainability of health systems. This requires appropriate financing policies that underpin sustainable access. There is an increasing need to ensure sustainable market availability of health products through a careful management of affordable pricing to the health systems and fair pricing[3] to the producers.

This activity area contributes directly to improving the availability and affordability of essential medicines and vaccines, and health products. Actions will be carried out to support countries for appropriate selection of medicines, vaccines, diagnostics and other health technologies, their transparent and fair pricing and the implementation of policies to reduce costs to both governments and individuals while ensuring quality, safety and efficacy (Activity 6) and sustainable supply . Additional work on support for evaluating the benefit of future technologies as they are developing will be carried out in addition to strategic approaches to ensuring supply security (Activity area 4) and other pricing and purchasing policies.

[3] A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines.

Fair pricing and financing policies

Specific actions

Deliverables

Support processes for selection and health technology assessment and their implementation in countries	**When**
1. Develop and revise normative guidance for the selection of essential health products and use of these in development of national selection processes including model lists for essential medicines, diagnostics, medical devices and vaccines.	ongoing
2. Provide guidance and support capacity development for evidence-based selection and priority setting using various tools including health technology assessment	ongoing
3. Promote collaboration, information and knowledge exchange to support country decision making process on coverage of essential health products. Established global and regional platforms for health technology assessment (for information exchange, knowledge and evidence- dissemination and capacity building)	ongoing

Encourage more transparent and better policies and actions to ensure fairer pricing	**When**
1. Develop and revise of policy guidance for more effective pricing policies to improve affordability of essential health products to health systems and individuals.	ongoing
2. Support implementation of policy guidance for more effective pricing policies to improve affordability of essential health products to health systems and individuals.	ongoing
3. Promote global and regional collaboration to increase price transparency and support decision making on pricing and reimbursement and facilitate dialogue between public payers, government decision makers and industry.	ongoing

Support for financing policies and the reduction of out of pocket payments	**When**
1. Support for implementation of financing policies and policies to reduce out of pocket payments including the adoption of generics and biosimilars in selection, procurement and use of medicines; reimbursement schemes where appropriate and development of national health financing strategies respecting equity and solidarity principles.	ongoing
2. Create and support regional networks of policy-makers responsible for financing/pricing and reimbursement policies used to achieve UHC	ongoing

3 Application and management of intellectual property to contribute to innovation and promote public health

The impact of intellectual property protection on innovation and access to health products, in particular, the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) and regional and bilateral free trade agreements, has been one of the most debated topics in recent years. Since the entry into force of the TRIPS Agreement, many resolutions of the World Health Assemblies have requested WHO to address the impact of trade agreements and intellectual property protection on public health and access to medicines. In 2006, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) submitted its report containing 60 recommendations aimed at fostering innovation and improving access to medicines. Based on these recommendations an Intergovernmental Working Group negotiated the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, that now along with other relevant resolutions constitutes the basic mandate for WHO's work in this area. WHO will take into account other relevant publications and resources, including the UN High Level Panel Report on Access to Medicines.

As requested by the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHO has intensified its collaboration with other relevant international organizations, including UNCTAD, WIPO and WTO. The Trilateral Cooperation with WIPO and WTO is fostering a better understanding of the linkage between public health and intellectual property policies and to enhance a mutually supportive implementation of those policies.

The objective of the work of this activity area is to promote medical research and development, innovation and increased access to medicines, vaccines, diagnostics and related health technologies to improve the health and wellbeing of all, according to the Sustainable Development Goal 3. This action supports Member States to design trade and intellectual property policies with public health objectives by incentivizing needs driven innovation and access to affordable health products. This includes the appropriate use of public health related safeguards included in trade agreements and a public health oriented management of intellectual property.

Specific actions

- Foster innovation and access to health products by appropriate IP rules and management
- Provide technical support and capacity building
- Research the relationship of access to health products, innovation and IP

Application and management of intellectual property to contribute to innovation and promote public health

Deliverables

Foster innovation and access	**When**
1. Develop best practices for licensing for publicly funded R&D results, including IP, regulatory and patent information for existing and new health products	ongoing
2. Provide information on best practices in the implementation of health related provisions of the TRIPS agreements, including relevant TRIPS flexibilities and IP management	ongoing
3. Investigate access barriers and solutions for existing and new health technologies	Mid-term

Provide technical support and capacity building	**When**
1. Provide as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products	ongoing
2. Support countries to take into account public health implications when negotiating bilateral or multilateral trade agreements	Mid-term
3. Facilitate the assessment of the patent status of essential medical products at national and regional level in collaboration with competent partners	ongoing

Research the relationship of access to health products, innovation and IP	**When**
1. Strengthen collaboration between WHO, WIPO, WTO, and with other international organizations such as UNCTAD and UNDP	ongoing
2. Support the work and expansion of the Medicines Patent Pool to essential medicines under patent	Mid-term

4 Procurement and supply chain management

The continuous supply of quality, safe, effective and affordable medicines and vaccines is one of the building blocks of every well-functioning health system. Good procurement practices play a key role in securing affordable prices and ensuring adequate and timely supply, while good supply chain management ensures that quality products are available at all levels of the health system. Over the last two decades, significant achievements have been made improving access to products for a number of vertical public health programmes (such as those for TB, HIV/AIDS and Malaria), however new challenges are arising with the transition of countries from donor support for these products.

The supply chain is often weakened by poor infrastructure and by lack of accurate data management systems. This can be particularly complex for vaccines and other temperature time sensitive health products that require careful handling and efficient cold chain systems. The complex, widespread and increasing challenges related to shortages of health products affect access to medicines and vaccines in countries at every level of development. In the case of infectious diseases, the implications of these shortages go beyond affecting just the individual to impact on public health. Inefficient distribution and use can lead to high level of wastage with related consequences in terms of availability, affordability and access. Waste management is an emerging public health problem particularly for products such as antibiotics and hormones.

This activity area addresses the need for improved capacity for procurement and supply chain management and for better data and market analysis to inform policy decisions. WHO will continue to support collaborative efforts to optimize the procurement and supply chain for medicines and vaccines and will contribute to the global understanding of supply and demand dynamics of medicines and vaccines, and will contribute to platforms for collaborative approaches for procurement, facilitating development of supporting policies and guidelines for improved capacity.

Specific actions

- Support collaborative approaches for strategic procurement
- Support countries for efficient procurement and supply chain management
- Improve capacity for detecting, preventing and responding to medicines and vaccines shortages

Improve procurement and supply chain management

Deliverables

Support collaborative approaches for strategic procurement	**When**
1. Collect and share best practice on collaborative approaches for strategic procurement and develop normative guidance as needed	ongoing
2. Explore policy options to achieve economies of scale for purchasing and quality assurance	Mid-term
3. Support development and strengthening of regional approaches such as pooled procurement for medicines/ vaccines purchasing, in collaboration with other partners and agencies.	ongoing

Support countries for efficient procurement and supply chain management in countries	**When**
1. Revision and development of normative guidance for efficient procurement and supply chain management (In collaboration with UN partners) including operational principles for procurement of medicines and vaccines and guidelines for safe disposal and waste management including for antimicrobials.	Mid-term
2. In collaboration with UN partners provide technical support and capacity building for efficient procurement and supply chain management and assessment, for quality assurance in procurement, strategy development, planning, storage, distribution and waste management	ongoing
3. Promote knowledge sharing and collaboration between countries and identify centres of excellence to provide training and technical support to countries to implement Good Procurement Practices and	Mid-term
4. Establish and maintain collaborations with partners and UN agencies to improve coordination and more efficient procurement and supply chain management	ongoing

Improve capacity for detecting, preventing and responding to medicines and vaccines shortages	**When**
1. Develop tools for early detection and rapid notification systems for medicines and vaccines shortages	ongoing
2. Develop framework of mitigation actions needed to prevent and respond to shortages	Mid-term
3. Undertake market analysis for key strategic products and engage in dialogues with industry on establishing supply security, including investing in Market Information for Access (MI4A) by collecting, analysing and sharing global medicines and vaccines demand and supply information, identifying access risks (e.g. shortages) and corrective measures.	Mid-term

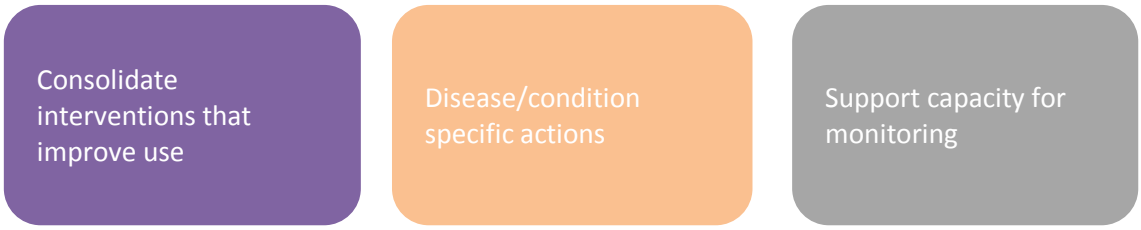
5 Appropriate prescribing, dispensing and use of medicines

An estimated half of all medicines in the world are inappropriately prescribed, dispensed or sold. This is compounded by the fact that a similar proportion of people use their medicines incorrectly. Factors that contribute to inappropriate prescribing, dispensing and use include an inadequately trained workforce, incorrect diagnoses, the prohibitive costs or simple unavailability of medicines, and activities related to product marketing and promotion.

Appropriate prescribing, dispensing and use is essential for ensuring health impact and effective use of resources. Policy approaches and interventions have been identified to improve use of health products but have generally not implemented over the past decade. Increasing burdens on health resources, the rise of antimicrobial resistance and the need to improve access to palliative care provides a new focus on the need to improve prescribing dispensing and use of medicines. Antimicrobial resistance is rising to dangerously high levels in all parts of the world, and is accelerated by the misuse and overuse of antibiotics. Underuse of controlled substances is prevalent, with only about 10% of those who need treatment actually receiving it. The rise in non-communicable diseases and the additional burden it places on health systems require a renewed focus on appropriate prescribing dispensing and use.

WHO will support countries by consolidating interventions that improve use and ensuring that guidance is in line with country needs. Support will be provided to ensure that prescribers have the capacity to implement clinical guidelines and other proven strategies and that policy guidance is aligned from selection of medicines to prescribing. WHO will provide additional support on disease or condition specific areas of public health concern. The role of monitoring (Activity area 9) of health products is elaborated in Activity 9 but is also address here as it is deemed critical to the understanding and improvement of the appropriate use.

Specific actions



Appropriate prescribing, dispensing and use of medicines

Deliverables

Consolidate interventions that improve use	**When**
1. Ensure that WHO normative guidance is in line with country needs	Mid-term
2. Provide support for strengthening national structures and capacity for regular development and revision of national treatment guidelines aligned with both the national EML selection process and prescribing.	ongoing
3. In collaboration with partners, support regional/ national capacity development of pharmacy and allied workforce to strengthen the medication-use process from improving adherence to ensuring patient safety	Mid-term

Disease/condition specific actions	**When**
1. Support countries in implementing stewardship programmes with a focus on antimicrobials, provide guidance on alignment of standard treatment guidance in line with resistance pattern and national AMR action plans and support Member States in using AWaRe and the AWaRe Index to support quality improvement and stewardship interventions.	ongoing
2. Support countries to develop policies and regulations to ensure access, appropriate prescribing, dispensing and use of controlled medicines including the development of guidance on optimising the relevant legislation and support to strengthen capacity of prescribers and dispensers in useful approaches to ensure the quality of service and to minimize the risk of diversion	ongoing

Support capacity for monitoring	**When**
1. Support countries to improve prescribing and dispensing through improving data collection via drug utilization, analysis and policy action on medicines and health technologies.	Lon-term
2. Support countries to conduct surveys on use of antibiotics in health facilities and community in order to inform and assess the impact of stewardship and interventions and support countries to monitor and evaluate consumption of medicines based on national imports and epidemiologic trends.	ongoing
3. Support to improve forecasting and quantification of controlled medicines to avoid over-stock, as well as strengthen capacity of prescribers and dispensers in useful approaches to ensure the quality of service and to minimize the risk of diversion	ongoing

6 Regulatory systems to ensure quality , safety and efficacy of medicines and vaccines

National Medicine Regulatory Authority is responsible for the safety, quality and efficacy of medical products. An effective regulatory authority gives people confidence that the products they need and use are safe and effective. A weak regulatory system has the potential to undermine access initiatives, for example by taking too long to approve products for use in a country. In the case of vaccines, for instance, increasing vaccine hesitancy can be corrected through strong pharmacovigilance systems that detect Adverse Events Following Immunization (AEFI), manage cases and report AEFI to national structures that have expertise assess the information and ensure effective communication for the community that maintains community confidence in vaccination programmes.

This activity area supports countries to deliver regulation that protects the public yet enables timely access to, and innovation for, quality products. The action directly contributes to safe, effective and quality medicines and vaccines and is aligned with the Programme budget 2018-2019 output 4.3.3. The activity area focuses on the development and implementation of technical guidelines, norms and standards for the quality assurance and safety of medicines and vaccines; support to procurement agencies for ensuring quality through the prequalification programme; and strengthening national capacity. Regulatory preparedness for public health emergencies is described in Activity area 7.

Specific actions

- Support improvement of regulatory systems, promoting reliance and collaboration
- Maintain and expand the prequalification service
- Support strengthening national capacity for ensuring quality, safety and efficacy of health products

Regulatory systems to ensure quality, safety and efficacy of medicines and vaccines

Deliverables

Support improvement of regulatory systems, promoting reliance and collaboration	**When**
1. Implementation of smart regulation in an increasing number of countries through reliance and NRA networks	ongoing
2. Support for implementation of WHO quality standards to decrease the regulatory burden	ongoing
3. Support regulatory capacity strengthening towards WHO Listed Authority status especially in countries manufacturing products for LMICs of for local supply to ensure quality of products	ongoing

Maintain and expand the prequalification service	**When**
1. Maintain an efficient and effective prequalification including, strengthening the PQ of in vitro diagnostics (PQDx) and continuing to evolve the processes and procedures for PQ of vector control products, and developing new, or updating existing, norms and standards, across all product streams.	ongoing
2. Develop new routes to prequalification listing and new risk-based approaches to support time-limited procurement and expand the types of products eligible for pre-qualification.	ongoing

Support strengthening national capacity for ensuring quality, safety and efficacy of health products	**When**
1. Support development of enhanced national capacity to ensure quality of health products in the supply chain	Ongoing
2. Support developed of national capacity to monitor and manage safety of health products on national markets	Mid-term
3. Improved prevention, detection and response to Substandard and Falsified (SF) health products	Ongoing

7 Preparedness for emergencies

A public health emergency – responding for example to an emerging infectious disease or a shortage of critical essential medicines or tests – requires decision-making in a context that is different to "business as usual". Being prepared with the necessary plans and tools, and being rehearsed, is just as essential for regulators as for other actors in an emergency situation. WHO has considerable experience in helping regulators improve and test their preparedness so that they are sufficiently robust and responsive in a public health emergency. However too many countries that have not yet experienced a public health emergency remain inadequately prepared.

A public health emergency may create an urgent need for vaccinations, treatments and emergency response sites. Emergency plans should provide for the stockpiling of essential pharmaceuticals and medical supplies, and should consider the logistics of distributing essential supplies to areas of greatest need following an emergency event.

This Activity area focuses on regulatory preparedness and support for supply management and appropriate use of health products in emergencies. Preparedness for R&D is addressed primarily through the R&D Blueprint, the global strategy and preparedness plan for rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis. With WHO as convener, the broad global coalition of experts who have contributed to the Blueprint come from several medical, scientific and regulatory backgrounds. WHO Member States welcomed the development of the Blueprint at the World Health Assembly in May 2016.

Specific actions

- Support regulatory preparedness for a public health emergency
- Support for adequate supply management and appropriate use of health products in emergencies

Preparedness for emergencies

Deliverables

Improve regulatory preparedness for a public health emergency	**When**
1. Support regulators for strengthening regulatory procedures for risk-based evaluations during public health emergencies through the revision of regulatory procedures and standards for risk-based evaluations during PHEs and the strengthening of processes and services.	ongoing
2. Support the adaption of regulatory requirements for PHEs and the use of networks for expedited evaluations during PHEs	ongoing

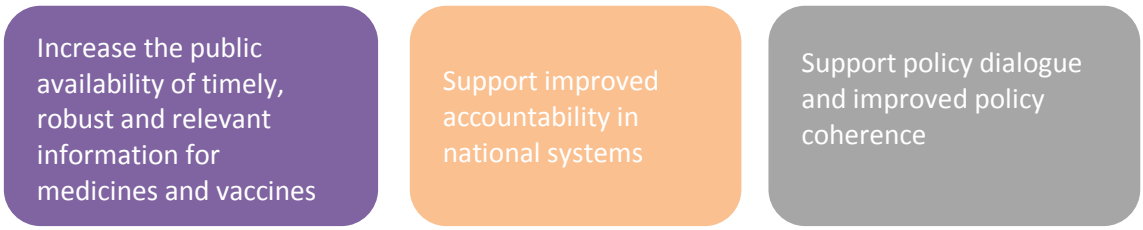
Ensure adequate supply and appropriate use of essential medicines and vaccines	**When**
1. Support development of regional and national standards on the role of the pharmaceutical workforce in manmade and natural disasters and pandemics	ongoing
2. Facilitate interregional mechanisms (regional/ global virtual stockpiles) for rapid mobilisation and delivery of products needed in in manmade and natural disasters and pandemics	ongoing

Weak governance is increasingly recognized as a major challenge for the achievement of universal health coverage. Weak governance leaves the pharmaceutical system vulnerable to ineffective management, undue influence, corruption, waste, fraud and abuse. Corruption is estimated to lead to losses of up to 6% of the annual global health expenditure, or US$ 300 billion. Such waste of public resources reduces a government's capacity to provide good quality medicines and vaccines. Lack of transparency contributes to poor accountability and weakens trust in public institutions. A question of growing importance is how to manage interactions between governments and the private sector to avoid risks of undue influence.

There is an urgent need to improve transparency and access to timely, comprehensive information with regards to medicines and vaccines. Moreover, supply chain transparency and good procurement practices contribute to the efficiency of the system. Unbiased information free of conflicts of interest is necessary for the sound selection, incorporation, prescription, and use of health products. Given the large role that medicines play in healthcare budgets and the provision of healthcare, improving transparency and accountability will help countries prevent the waste of resources necessary to sustain health systems, provide quality and affordable care, and attain universal health coverage. This activity area will support countries to strengthen the public availability of timely, robust and relevant information, and improve accountability.

WHO will support better practices both from government and private sector to develop and implement national policies that reflect the need to improve access to medicines and vaccines as essential to achieving universal health coverage. Improved accountability is essential to track progress made on essential medicines policies to support UHC and achievement of SDGs. Policy dialogue is essential for good governance and WHO will support the involvement of relevant stakeholders in discussions on development and monitoring of policy for medicines and vaccines access.

Specific actions



Good governance

Deliverables

Increase the public availability of timely, robust and relevant pharmaceutical and health product information	**When**
1. Support the development and implementation of policies for prospective registration and public disclosure of the results of clinical trials and support the monitoring of registration and the development of systems to monitor results reporting on an ongoing basis.	ongoing
2. Develop and maintain tools and platforms for facilitating transparency and accountability regarding access to essential health products	Mid-term
3. Develop self-evaluation tools to assess transparency and accountability and for relevant national institutions on, efficacy, safety, quality as well as availability and prices of health products	Mid-term

Support improved accountability in national systems	**When**
1. Develop, revise and support implementation of policy guidance for improved accountability with regards to medicines and vaccines such as ethical marketing, management of conflict of interest and codes of conduct.	ongoing

Support policy dialogue and improve policy coherence	**When**
1. Support the involvement of relevant stakeholders in discussions on development and monitoring of policy for medicines and vaccines access	Mid-term
2. Support policy coherence to ensure that health remains at the centre of decisions regarding medicines and vaccines, purchasing, supply, distribution, prescribing and use.	Mid-term

9 Collection and use of key data on medicines and vaccines

Monitoring access to medicines and vaccines is a complex endeavour that requires availability of information from multiple sources. Information regarding research pipelines, national health expenditures for health products, procurement of medical products, supply chain and distribution, pharmacovigilance and post-marketing surveillance, health insurance coverage and prescription data, price of health products, health facility data on availability of medicines, vaccines and other health products is just a short list of what is needed for decision making processes to address and improve availability and affordability of health products. A core challenge is the interoperability among data collection systems.

Within the framework of the Health Data Collaborative (HDC), WHO has been supporting countries to improve their capacity to collect, organize, analyse and use quality data for policy making and to create the standard of reference for data compatibility. Several WHO initiatives have brought attention to the need to work on agreed indicators that can inform the work to improve access to health products, among many the Global Vaccine Action Plan (GVAP), the Global action plan on antimicrobial resistance (GAP-AR), the Global strategy and plan of action on public health, innovation and intellectual property (GSPOA).

WHO is working on developing a set of agreed indicators that can be used for monitoring performance of all the areas involved in ensuring access to quality health products. The first step is the development of a global accountability mechanism for monitoring access to essential medicines that can ensure high level political support, the prioritization of technological advances in data collection and the usability of the systems for decision making. This mechanism builds on national capacity strengthening for the implementation, maintenance and improvement of the systems over time, leveraging existing technical support programmes and ensuring the development of strong and transparent data collection and information management systems. Furthermore, WHO is working on the SDG indicator on access to medicines that represents a global monitoring tool and draws attention to this critical component of the universal health coverage efforts.

The activity area will directly contribute to inform policy decision making in countries, better monitoring of policy decisions, better ability to detect, prevent and respond to substandard and falsified medicines and to understand consumption and use patterns of medicines for monitoring appropriate use. Each strategic activity of this roadmap, with its specific actions and deliverables, will require a monitoring system to ensure results are achieved and corrective actions are set up in a timely manner if needed.

Specific actions

- Development, harmonization and improvement of WHO data collection systems for routine monitoring
- Improve global and regional monitoring of access to medicines and vaccines
- Strengthen national capacity to collect, analyse and use data for policy decision making

Deliverables

Development, harmonization and improvement of data collection systems for routine monitoring	**When**
1. Harmonize, mainstream and improve surveys on the pharmaceutical sector and access and availability of health products, ensuring coordination with other existing mechanisms (i.e. SF mechanism, pricing, SARA, GBT, etc)	ongoing
2. Integrate existing data collection tools and ensure synergies among various technical and disease-specific programmes	Mid-term
3. Develop new or adapt tools to cover all areas relevant to access to medicines (procurement, insurance schemes, health accounts, etc)	Long-term

Improve global and regional monitoring of access to health products	**When**
1. Develop the SDG indicator on access to medicines and ensure regular reporting	Mid-term
2. Identify of a set of indicators to create a dashboard for global monitoring for health products in consultation with all relevant stakeholders and set up missing data collection systems to ensure regular reporting	Long-term

Strengthen national capacity to collect, analyse and use data for policy decision making	**When**
1. Strengthen national systems to improve monitoring for selected disease areas and for the use, misuse and availability of controlled medicines, and ensure integration of national data collection tools for disease-specific programmes into global databases on availability, affordability and use of health products.	Mid-term
2. Coordinate the work of the Health data collaborative in its efforts to build national capacity, improve interoperability and quality of data for pharmaceutical products	ongoing
3. Within the global action plan for antimicrobial resistance, provide support to Member States for the collection and analysis of data on consumption and use to inform antimicrobial resistance strategies, for better planning for procurement and supply and to inform policy on access and rational use and support monitoring of WATCH and RESERVE antibiotics to identify areas of under or over use.	ongoing
4. Leverage the work of technical programmes and relevant stakeholders to build and strengthen capacities in national authorities like Health Insurance Funds and NRAs for setting up and management of processes for data gathering, validation and analysis	Long-term

10 Health workforce capacity for access to medicines and vaccines

The development, production, procurement, distribution and appropriate use of health products, as well as the supportive functions of regulation, all require a competent, health workforce[4]. Low- and lower-middle-income countries continue to have a low density of pharmacists compared to high and upper-middle-income countries. Challenges include inadequate numbers of pharmacists and pharmacy support workforce cadres, issues of maldistribution, uneven implementation of education, staff management and retention strategies. Multi-pronged strategies are required to improve forecasting, planning, education, deployment, retention and performance management of human resources for health. Developing and scaling up a more systematic approach to improving the skills of the pharmaceutical workforce and for monitoring its size, composition, skill sets, training needs and performance will contribute to ensuring the quality and availability of medicines and vaccines.

This activity area is in line with WHO's Global Strategy on Human Resources for Health: Workforce 2030. This action is cross-cutting across all areas of the roadmap. The International Pharmaceutical Federation's Pharmaceutical Workforce Development Goals,2 developed in alignment with WHO's Global Strategy, provide detailed guidance specific to the pharmaceutical workforce, including on addressing the workforce supply, retention, working conditions and remuneration, education and training capacity, and comprehensive data and evidence to inform workforce planning.

Some of the required actions to strengthen the health supply chain workforce may be similar to - or be implemented as part of - broader health workforce policies. This includes improving public sector pay and incentives; establishing rural pipelines to education and training to facilitate education and deployment in under-served areas; reforming education strategies to adapt content and modalities of training to current and emerging health system needs; and exploring the potential of greater delegation of tasks to cadres with shorter training. Other interventions may need to be more specific to the supply chain workforce, such as mainstreaming relevant competencies in the pre-service education curricula of health personnel; scaling up training of pharmacists and pharmacy assistants; and professionalizing the personnel in administrative and management positions within the health supply system through more dedicated training. Key skills are particularly required in forecasting of needs, procurement, quality assurance, warehousing and distribution, stock management, with an overarching need for leadership and systems management.

Specific actions

Improve capacity of the workforce for access

Monitoring and evaluation of pharmaceutical workforce development policies

[4] Cometto et al. Journal of Pharmaceutical Policy and Practice 2014, 7(Suppl 1):I1 http://www.joppp.org/content/7/S1/I1

Health workforce capacity for access to medicines and vaccines

Deliverables

Improve capacity of the workforce for access	**When**
1. Support mainstreaming of relevant competencies in the pre-service education curricula of health personnel;	ongoing
2. Support scaling up training of pharmacists and pharmacy assistants; and professionalizing the personnel in administrative and management positions within the health supply system through more dedicated training.	Long-term
3. Support capacity for forecasting of needs, procurement, quality assurance, warehousing and distribution, stock management, with an overarching need for leadership and systems management.	Mid-term

Monitoring and evaluation of pharmaceutical workforce development policies	**When**
1. Support the inclusion of key indicators on pharmaceutical workforce data and health workforce planning activities (skill mixes, advanced and specialist practice, capacity) in national HR policies and plans	Mid-term
2. Support the collection of comprehensive data on supply chain personnel (and especially on the administrators, logistics managers, warehouse and transport personnel, clerks and other support cadres) means that critical capacity gaps go unnoticed, and often neglected in national health and human resources policies and strategies.	Long-term

How WHO will work

The activities of WHO are underpinned by the impact and accountability framework Global Programme of Work (GPW)[5] and by the WHO Programme Budget,[6] and are tightly linked to the SDGs. The GPW presents four strategic shifts that will drive public health work in countries, along a continuum of health system maturity (Figure 3). In more mature health systems, the Organization will concentrate on supporting policy dialogue to guide their evolution; while in fragile situations more attention will be paid to ensuring service delivery and filling critical gaps.

Figure 3: Continuum of support to be provided by WHO under the four modalities.

Careful coordination is required across the three levels of the Organization to ensure that work responds to the needs of Member States. Connections to Regional networks will be leveraged to facilitate common agendas and stronger partnerships. Greater attention will be paid to sharing information and data, and to establishing platforms for better policy discussions.

Principles and implementation enablers

- ✓ Universal health coverage is at the centre of the Organization's priorities.
- ✓ WHO will continue on its concurrent tracks of carrying out normative work and supporting countries to implement the resulting norms and guidelines.
- ✓ Given its comparative advantage as a government partner and its strengths in convening stakeholders, WHO will emphasize garnering and sustaining political will and collaboration. Political will is particularly crucial to the development and implementation of policies that concern regulation, pricing and domestic investment.
- ✓ Activities will ensure an end-to-end flow of actions that address health systems issues.
- ✓ Activities aim towards the outcomes and targets in the 13th GPW, the Programme Budget 2018-2019, and the SDGs, in particular target 3.8.

[5] http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/

[6] http://apps.who.int/iris/bitstream/handle/10665/272406/WHO-PRP-17.1-eng.pdf?sequence=1&isAllowed=y

Collaboration

The pharmaceutical system includes myriad stakeholders including pharmacists, health care workers, patient groups and consumers, wholesalers, academic institutions, donors, policy-makers, regulatory authorities, United Nations organizations, nongovernmental organizations and the private sector. The challenge at the global, regional and country levels is to coordinate and harness the contributions of the many different entities to improve access to safe, effective and quality medicines and vaccines. WHO will continue using its convening power to support increased interorganizational, regional and country collaboration in order to network, share best practices and improve information sharing.

How WHO will measure progress

The WHO General Programme of Work Impact Framework and its 42 targets and indicators are aligned with the Sustainable Development Goals and World Health Assembly approved resolutions and action plans. The Access Roadmap aligns with GPW Outcome 1: *Strengthened health systems in support of universal health coverage without financial hardship, including equity of access based on gender, age, income, and disability;* and considers the other outcomes ensuring its indirect contribution to reaching them. The roadmap will be complemented by an overall results framework, guided by the following related high-level GPW targets/indicators and those that may be developed to complement them:

WHO IMPACT AND OUTCOME FRAMEWORK (2019-2023)	
Target	**Indicator**
Increase availability of essential medicines for primary health care, including the ones free of charge to 80%	1. Availability of essential medicines for primary health care, including the ones free of charge
	2. Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
Increase the availability of oral morphine in facilities caring for patients in need of this treatment for palliative care at all levels from 25% to 50%	Availability of oral morphine in facilities at all levels
Increase service coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for severe mental health disorders to 50%	1. Proportion of persons with severe mental disorder who are using services (%)
	2. Coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for substance use disorders
Increase coverage of 2nd dose of measles containing vaccine (MCV) to 90%	Coverage of 2nd dose of measles containing vaccine (MCV)
Increase treatment coverage of RR-TB to 80%	Coverage of MDR/RR-TB treatment as a percent of estimated incidence

Annex 1: Appendix 1 to A71/12

A71/12

APPENDIX 1

KEY RESOLUTIONS OF THE HEALTH ASSEMBLY AND REGIONAL COMMITTEES, AND REGIONAL COMMITTEE DOCUMENTS FROM THE PAST 10 YEARS RELEVANT TO ACCESS TO SAFE, EFFECTIVE AND QUALITY MEDICINES, VACCINES AND HEALTH PRODUCTS

Resolution[1] (year)	**Title**
Health Assembly	
WHA70.7 (2017)	Improving the prevention, diagnosis and clinical management of sepsis
WHA70.12 (2017)	Cancer prevention and control in the context of an integrated approach
WHA70.14 (2017)	Strengthening immunization to achieve the goals of the global vaccine action plan
WHA70.16 (2017)	Global vector control response: an integrated approach for the control of vector-borne diseases
WHA69.1 (2016)	Strengthening essential public health functions in support of the achievement of universal health coverage
WHA69.11 (2016)	Health in the 2030 Agenda for Sustainable Development
WHA69.20 (2016)	Promoting innovation and access to quality, safe, efficacious and affordable medicines for children
WHA69.21 (2016)	Addressing the burden of mycetoma
WHA69.23 (2016)	Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
WHA69.25 (2016)	Addressing the global shortage of medicines and vaccines, and the safety and accessibility of children's medication
WHA68.2 (2015)	Global technical strategy and targets for malaria 2016–2030
WHA68.6 (2015)	Global vaccine action plan
WHA68.7 (2015)	Global action plan on antimicrobial resistance
WHA68.15 (2015)	Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage
WHA68.18 (2015)	Global strategy and plan of action on public health, innovation and intellectual property
WHA68.20 (2015)	Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications
WHA67.1 (2014)	Global strategy and targets for tuberculosis prevention, care and control after 2015
WHA67.6 (2014)	Viral hepatitis
WHA67.14 (2014)	Health in the post-2015 development agenda
WHA67.19 (2014)	Strengthening of palliative care as a component of comprehensive care throughout the life course
WHA67.20 (2014)	Regulatory system strengthening for medical products
WHA67.21 (2014)	Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy
WHA67.22 (2014)	Access to essential medicines
WHA67.23 (2014)	Health intervention and technology assessment in support of universal health coverage
WHA67.25 (2014)	Antimicrobial resistance

[1] Unless otherwise indicated.

[2] Unless otherwise indicated.

Resolution[1] (year)	Title
WHA66.7 (2013)	Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children
WHA66.12 (2013)	Neglected tropical diseases
WHA66.22 (2013)	Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
WHA65.3 (2012)	Strengthening noncommunicable disease policies to promote active ageing
WHA65.4 (2012)	The global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level
WHA65.5 (2012)	Poliomyelitis: Intensification of the global eradication initiative
WHA65.17 (2012)	Global vaccine action plan
WHA65.19 (2012)	Substandard/spurious/falsely-labelled/falsified/counterfeit medical products
WHA65.21 (2012)	Elimination of schistosomiasis
WHA65.22 (2012)	Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
WHA64.5 (2011)	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
WHA63.1 (2010)	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
WHA63.12 (2010)	Availability, safety and quality of blood products
WHA62.10 (2009)	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
WHA62.16 (2009)	Global strategy and plan of action on public health, innovation and intellectual property
WHA61.1 (2008)	Poliomyelitis: mechanism for management of potential risks to eradication
WHA61.15 (2008)	Global immunization strategy
WHA61.21 (2008)	Global strategy and plan of action on public health, innovation and intellectual property
WHA60.1 (2007)	Smallpox eradication: destruction of variola virus stocks
WHA60.13 (2007)	Control of leishmaniasis
WHA60.16 (2007)	Progress in the rational use of medicines
WHA60.20 (2007)	Better medicines for children
WHA60.28 (2007)	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
WHA60.29 (2007)	Health technologies
WHA60.30 (2007)	Public health, innovation and intellectual property
Regional Committee for South-East Asia	
Document SEA/RC70/7	Hepatitis
Document SEA/RC70/8	Tuberculosis: 'Bending the curve'
Document SEA/RC70/9	Access to medicines
Document SEA/RC69/9	Antimicrobial resistance
SEA/RC68/R3 (2015)	Antimicrobial resistance
SEA/RC68/R5 (2015)	Cancer prevention and control – The way forward
SEA/RC66/R7 (2013)	Effective management of medicines
SEA/RC65/R3 (2012)	Consultative Expert Working Group on Research and Development: Financing and Coordination
SEA/RC65/R6 (2012)	Regional strategy for universal health coverage

[1] Unless otherwise indicated.

Resolution[1] (year)	Title
SEA/RC64/R3 (2011)	2012: Year of Intensification of Routine Immunization in the South-East Asia Region: Framework for increasing and sustaining coverage
SEA/RC64/R5 (2011)	National essential drug policy including the rational use of medicines
SEA/RC63/R4 (2010)	Prevention and containment of antimicrobial resistance
SEA/RC62/R6 (2009)	Measures to ensure access to safe, efficacious, quality and affordable medical products
SEA/RC61/R5 (2008)	Dengue prevention and control
SEA/RC60/R5 (2007)	The new Stop TB Strategy and its implementation
SEA/RC60/R8 (2007)	Challenges in polio eradication
Regional Committee for Africa	
AFR/RC66/R2 (2016)	Regional strategy on regulation of medical products in the African Region, 2016–2025
AFR/RC64/R4 (2014)	Regional Strategic Plan for Immunization 2014–2020
AFR/RC63/R4 (2013)	Addressing the challenge of women's health in Africa: Report of the Commission on Women's Health in the African Region
AFR/RC63/R6 (2013)	Regional strategy on neglected tropical diseases in the WHO African Region
AFR/RC63/R7 (2013)	The WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection; recommendations for a public health approach – implications for the African Region
AFR/RC62/R2 (2012)	HIV/AIDS: Strategy for the African Region
AFR/RC62/R7 (2012)	Consideration and endorsement of the Brazzaville Declaration on noncommunicable diseases
Regional Committee for the Eastern Mediterranean Region	
EM/RC63/R.3 (2016)	Improving access to assistive technology
EM/RC63/R.5 (2016)	Strategic framework for blood safety and availability 2016–2025
EM/RC59/R.3 (2012)	Health systems strengthening in countries of the Eastern Mediterranean Region: challenges, priorities and options for future action
Regional Committee for the Western Pacific	
WPR/RC66.R1 (2015)	Viral hepatitis
WPR/RC65.R5 (2014)	Expanded programme on immunization
WPR/RC64.R5 (2013)	Hepatitis B control through vaccination: setting the target
WPR/RC63.R4 (2012)	Regional action plan for neglected tropical diseases in the Western Pacific (2012–2016)
Regional Committee for Europe	
EUR/RC66/R5 (2016)	Strengthening people-centred health systems in the WHO European Region: framework for action on integrated health services delivery
EUR/RC66/R9 (2016)	Action plan for the health sector response to HIV in the WHO European Region
EUR/RC66/R10 (2016)	Action plan for the health sector response to viral hepatitis in the WHO European Region
EUR/RC65/R5 (2015)	Priorities for health systems strengthening in the WHO European Region 2015–2020: walking the talk on people centredness
EUR/RC65/R6 (2015)	Tuberculosis action plan for the WHO European Region 2016–2020
EUR/RC64/R5 (2014)	European Vaccine Action Plan 2015–2020
Directing Council of the Pan American Health Organization	
CD55.R5 (2016)	Plan of action for the prevention and control of HIV and sexually transmitted infections 2016–2021

[1] Unless otherwise indicated.

Resolution[1] (year)	**Title**
CD55.R7 (2016)	Plan of action for malaria elimination 2016–2020
CD55.R8 (2016)	Resilient health systems
CD55.R9 (2016)	Plan of action for the elimination of neglected infectious diseases and post-elimination actions 2016–2022
CD55.R12 (2016)	Access and rational use of strategic and high-cost medicines and other health technologies
CD54.R7 (2015)	Plan of action for the prevention and control of viral hepatitis
CD54.R9 (2015)	Strategy on health-related law
CD54.R15 (2015)	Plan of action on antimicrobial resistance
CD52.R10 (2013)	Chronic kidney disease in agricultural communities in Central America