EXECUTIVE BOARD
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5 December 2018

Medicines, vaccines and health products

Access to medicines and vaccines

Report by the Director-General

1. In May 2018, the Seventy-first World Health Assembly considered a report by the Director-General on addressing the global shortage of, and access to, medicines and vaccines.[1] The report focused on a list of priority options for actions to be considered by Member States and presented a comprehensive report by the Director-General on access to essential medicines and vaccines.

2. Having considered the report, the Health Assembly adopted decision WHA71(8), in which it decided to request the Director-General to elaborate a road map report, in consultation with Member States, outlining the programming of WHO's work on access to medicines and vaccines for the period 2019–2023, including activities, actions and deliverables. The Health Assembly also requested the Director-General to submit the road map report to the Seventy-second World Health Assembly, through the Executive Board at its 144th session.

3. In July 2018, the Secretariat initiated a process to consult Member States and an online consultation with Member States on the zero draft road map was conducted in the period July–September 2018, during which 62 countries provided feedback. In addition, a consultation with Member States on the zero draft was conducted on 10 and 11 September 2018 in Geneva, preceded by an informal discussion with representatives of the United Nations and other international organizations and non-State actors in official relations with WHO. The draft report was updated based on the feedback obtained by these consultation processes, including broadening of the scope to include medicines, vaccines and health products.

4. The revised draft road map for access to medicines, vaccines and other health products, 2019–2023, based on existing WHO mandates in key Health Assembly resolutions of the last 10 years related to access to safe, effective and quality medicines, vaccines and health products, and also reflecting the Thirteenth Global Programme of Work, 2019–2023, is contained in the Annex.[2]

ACTION BY THE EXECUTIVE BOARD

5. The Executive Board is invited to consider the draft road map for access to medicines, vaccines and other health products, 2019–2023, as contained in the Annex, and to provide further guidance as appropriate.

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[1] Document A71/12.

[2] In line with resolution WHA69.19 (2016) on the global strategy on human resources for health: workforce 2030, a health workforce impact assessment was carried out for the draft road map for access to medicines, vaccines and other health products, 2019–2023 (see https://www.who.int/hrh/documents/B144_HRH-links_160119-EMP.pdf, accessed 16 January 2019).

ANNEX

DRAFT ROAD MAP FOR ACCESS TO MEDICINES, VACCINES AND OTHER HEALTH PRODUCTS, 2019–2023

Comprehensive support for access to medicines, vaccines and other health products

Contents

I. Introduction and rationale

1. Equitable access to health products is a global priority, and the availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8.[1] Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation.

2. Access is a global concern, given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems' ability to provide full and affordable access to quality health care. The high percentage of health spending on medicines (20–60% as demonstrated in a series of studies in selected low- and middle-income countries) impedes progress for the many countries that have committed to the attainment of universal health coverage.[2] Furthermore, it is known that a large proportion of the population in low-income countries who spend for health do pay out-of-pocket for medicines. With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden on both governments and patients will become even greater.

3. Improving access to health products is a multidimensional challenge that requires comprehensive national policies and strategies. These should align public health needs with economic and social development objectives and promote collaboration with other sectors, partners and stakeholders; they also need to be aligned with legal and regulatory frameworks and cover the entire product life cycle, from research and development to quality assurance, supply chain management and use.

4. WHO's comprehensive health systems approach to increasing access to health products is guided by a series of Health Assembly and Regional Committee resolutions. These resolutions, nearly 100 in number (see Annex, Appendix 1) formed the basis for the previous report by the Director-General on this topic.[3] The present document responds to the Health Assembly's subsequent request for WHO to develop a road map describing its activities, actions and deliverables for improving access to medicines and vaccines, for the period 2019–2023.

II. General Programme of Work, 2019–2023

5. The Thirteenth General Programme of Work, 2019–2023[4] sets out three strategic priorities for ensuring healthy lives and well-being for all at all ages: achieving universal health coverage, addressing health emergencies and promoting healthier populations. These strategic priorities are supported by three strategic shifts: stepping up leadership; driving public health impact in every country; and focusing global public goods on impact (see Fig. 1).

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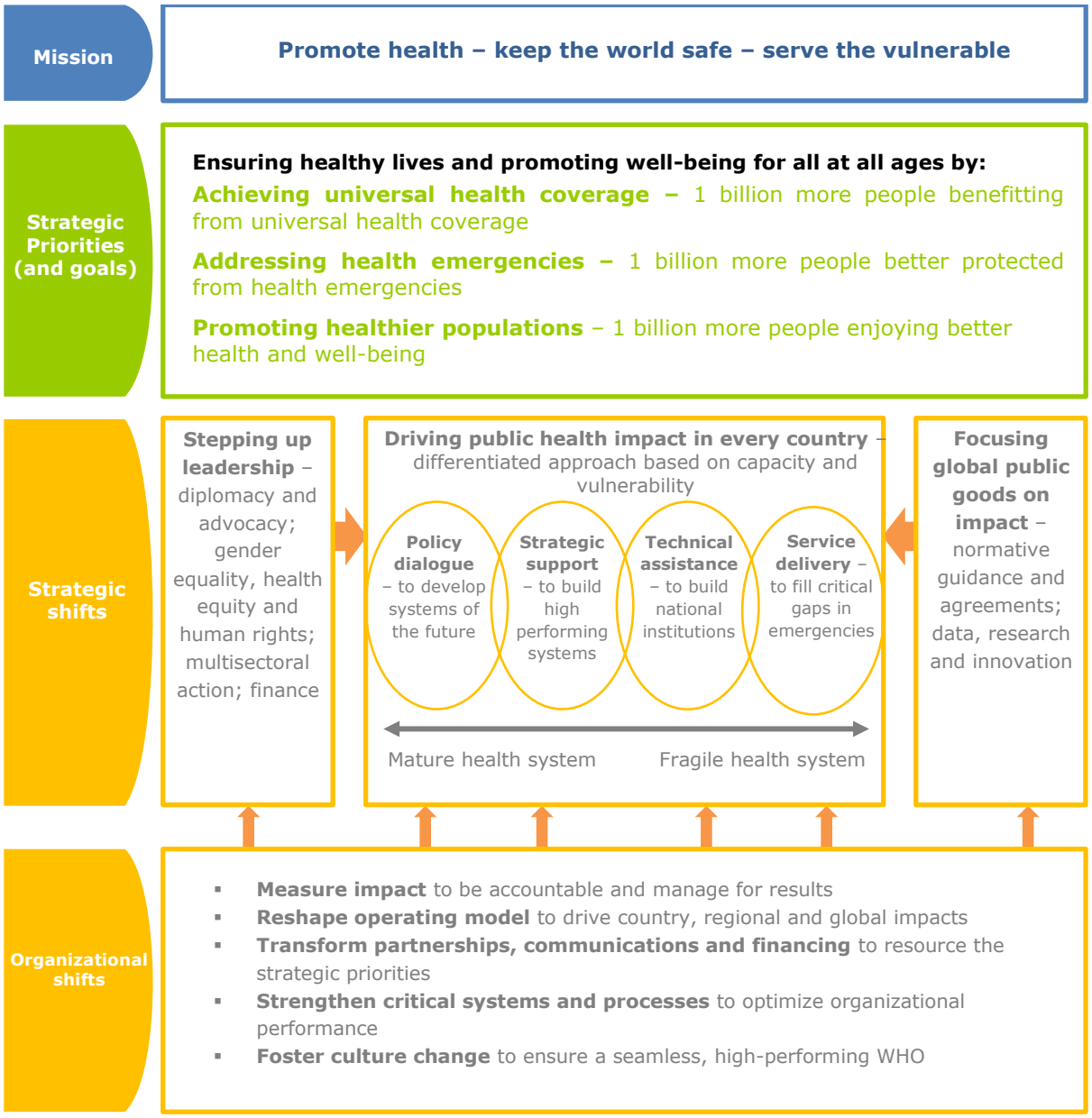
[1] Achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all.

[2] Reich MR, Harris J, Ikegami N, Maeda A, Cashin C, Araujo EC, et al. Moving towards universal health coverage: lessons from 11 country studies. The Lancet. 2016; 387:811-16 (https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60002-2.pdf).

[3] Document A71/12.

[4] Document A71/4.

Fig. 1. Overview of WHO's Thirteenth General Programme of Work, 2019–2023: strategic priorities and shifts[1]



6. The planning framework for the Thirteenth General Programme of Work provides a structure for identifying priorities at the country level and for the planning and budgeting of the work of WHO. It will ensure that the programme budget reflects the needs of the countries and that work at all three levels of the Organization is geared towards delivering country impact. This road map for access to medicines, vaccines and other health products, 2019–2023, aligns with the following outputs that have been identified within this framework:

[1] Previously issued in document A71/4.

- provision of authoritative guidance and standards on the quality, safety and efficacy of health products, including through prequalification services, essential medicines and diagnostics lists;

- improved and more equitable access to health products through global market-shaping and supporting countries to monitor and ensure efficient and transparent procurement and supply systems;

- country and regional regulatory capacity strengthened and supply of quality-assured and safe health products improved;

- research and development agenda defined and research coordinated in line with public health priorities;

- countries enabled to address antimicrobial resistance through strengthened surveillance systems, laboratory capacity, infection prevention and control, awareness-raising and evidence-based policies and practices.

III. How the road map was developed

7. The previous report (document A71/12) proposed priority actions based on the comparative advantage of WHO, whether the action provides value for money and if the actions lead to achievable and sustainable improvements. These prioritized actions form the basis for the activities, actions and deliverables outlined in the zero draft road map. It was developed based on input from all levels of the Organization, taking into consideration existing governing body documents, the programme budget 2018–2019 and relevant departmental and Regional Office strategies.

8. This revised road map takes into consideration the feedback received through the drafting and consultative processes described in paragraph 3 above of the report by the Director-General. All written contributions from the survey and other written submissions are available on http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/.

IV. Structure of the road map

9. The road map outlines the principles of WHO's work on access to health products, including essential health system components. It is structured around two interlinked strategic areas that are necessary to support access to health products:

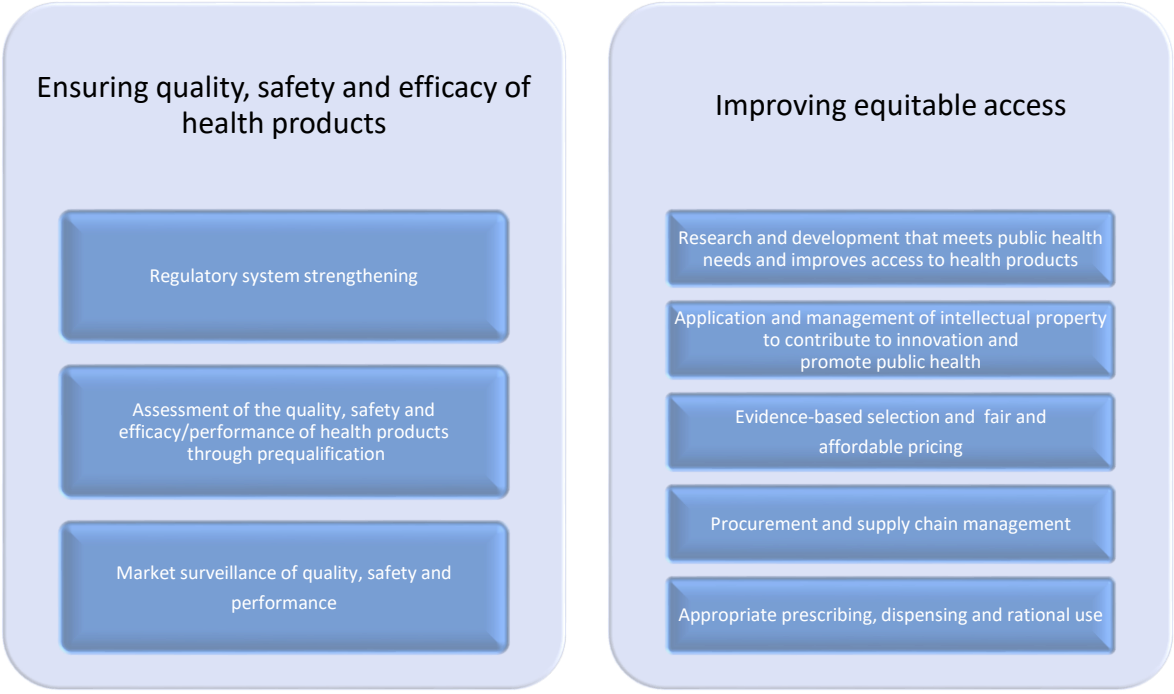
- ensuring the quality, safety and efficacy of health products;

- improving equitable access to health products.

Under each strategic area, the road map describes activities and puts forward the specific actions and deliverables for the period 2019–2023.

10. Fig. 2 shows the activities included under each strategic area; the activities are listed in sequential order of the product life cycle.

Fig. 2. Activities within the two strategic areas



V. A health systems approach to improving access to health products

11. The six components of a well-functioning health system outlined in the WHO document "Key components of a well-functioning health system"[1] include: Leadership and governance, health information systems, health financing, human resources, essential medical products and technologies, and service delivery. Ensuring access to health products depends on all of these, in particular governance, health information, financing and human resources. There is no one-size-fits-all approach to ensuring a functional health system and tailored strategies are required to adapt them to the local context.

12. Four key health system components of improving access to health products are detailed below; specific actions to address them are included in relevant activities under the two strategic areas of the road map provided in Sections VI and VII.

Financing of health products

13. Inadequate financing of health products, high prices of new health products and ineffective policy interventions and processes to manage expenditure, such as the ineffective use of generic policies, contribute to the challenges facing the health system in achieving universal health care. Evidence indicates that up to one fifth of health spending could be channelled towards better use by avoiding waste that occurs (a) when health products are priced higher than is necessary, (b) when less expensive but equally effective alternatives are not used and (c) when purchased products are not used at all.

[1] http://www.who.int/healthsystems/publications/hss_key/en/ (accessed 11 November 2018).

14. Activities in this road map support countries' ability to allocate resources more effectively through evidence-based decisions to ensure that cost-effective health products are included in a country's essential medicines list, essential diagnostics lists or reimbursement lists and through more efficient procurement and supply processes and rational use of medicines. Support for fair pricing[1] and policy implementation to reduce out-of-pocket expenditures will also be provided.

Governance of health products

15. The need for good governance is increasingly recognized as a major hurdle on the road to achieving universal health coverage. Weak governance complicates access to health products by fuelling inefficiencies, distorting competition and leaving the system vulnerable to undue influence, corruption, waste, fraud and abuse. Given the large role of health products in the provision of health care and the proportion of health spending they represent (as high as 60% for medicines in some countries),[2] improving governance will help prevent the waste of public resources needed to sustain health systems and provide quality and affordable care.

16. There is a pressing need to improve access to timely, robust and relevant information concerning health products. Unbiased information that is free of any conflict of interest is vital for the sound selection, incorporation, prescription and use of health products. Transparency of this information is central to accountability, strengthens confidence in public institutions and improves the efficiency of the system. Activities in the road map address the transparency of clinical trials enabling support for clinical trial registries and address price transparency through the Market Information for Access to Vaccines (MI4A platform),[3] for example.

17. The relationship between government and the private sector, such as pharmaceutical companies and medical device companies, requires particular attention. A question of growing importance is how to support governments to work effectively with the private sector and develop public policy while avoiding the risks of undue influence and maximizing benefits. WHO supports improving practices in both the public and private sectors to ensure that national policies reflect the central role of access to health products in achieving universal health coverage and in contributing to improved accountability.

A health workforce that ensures access to health products[4]

18. According to the High-Level Commission on Health Employment and Economic Growth, the global economy is projected to create about 40 million new health-sector jobs by 2030.[5] Most of these

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

[2] WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/handle/10665/153920/9789241549035_eng.pdf?sequence=1, accessed 11 November 2018).

[3] MI4A: Market Information for Access to Vaccines (http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/, accessed 11 November 2018).

[4] In line with resolution WHA69.19 (2016) on the global strategy on human resources for health: workforce 2030, a health workforce impact assessment was carried out for the draft road map for access to medicines, vaccines and other health products, 2019–2023 (see https://www.who.int/hrh/documents/B144_HRH-links_160119-EMP.pdf, accessed 16 January 2019).

[5] Working for health and growth: Investing in the health workforce. Report of the High-Level Commission on Health Employment and Economic Growth. Geneva: World Health Organization; 2016 (http://www.who.int/hrh/com-heeg/reports/en/, accessed 11 November 2018).

jobs, however, will be in middle- and high-income countries, leaving a projected shortage of 18 million health workers in low- and lower-middle-income countries. Part of the health workforce shortage concerns pharmacists, one of the specialized workforces required to ensure access to medicines and vaccines. There is also a shortage of biomedical engineers,[1] who play a crucial role in supporting the best and most appropriate use of medical technologies. Both pharmacists and biomedical engineers are essential to the development, production, procurement, distribution and appropriate use and maintenance of health products, as well as the supportive function of regulation.

19. The WHO Global Strategy on Human Resources for Health: Workforce 2030 addresses health workforce challenges. Many of the interventions needed to improve the workforce are cross-cutting, such as mainstreaming relevant competencies in the pre-service education curricula of health personnel, scaling up the training of pharmacists, pharmacy assistants and biomedical engineers, and ensuring dedicated training for personnel in administrative and management positions within the supply chain. Some of the actions needed to strengthen the health workforce responsible for health products may be similar to – or implemented as part of – broader health workforce policies, including improving public sector pay and incentives, establishing mechanisms for access to education and training in rural areas and reforming education strategies to reflect current and emerging health system needs.

20. Activities provided in the road map include support to ensure that the workforce is fit-for-purpose in key areas such as regulatory capacity, where specific competencies are required to ensure the quality, safety and efficacy of health products. Another key area is procurement and supply chain management, for which particular skills are required to forecast needs, procurement processes, warehousing and distribution, stock management and maintenance (of medical devices), for example.

Information on health products for decision-making

21. Information is essential for decision-making, monitoring policy implementation and establishing accountability. To make accurate and useful decisions, data and information are needed in such categories as national expenditures on health products; the procurement of health products, supply chain and distribution; pharmaco-vigilance and post-marketing surveillance; health insurance coverage; prescription prices of health products; and the availability of medicines, vaccines and other health products in health facilities.

22. Monitoring access to health products is a complex endeavour that requires gathering information from multiple sources and ensuring the interoperability of various data collection systems. Within the framework of the Health Data Collaborative, WHO is supporting countries to improve their capacity to collect, organize, analyse and use quality data for policy-making, to create standards of reference for data compatibility and to advance the harmonization of data collection tools.

23. WHO is working to develop an agreed list of indicators across all areas involved in improving access to quality health products. This list will contribute to the measurement of a Sustainable Development Goal indicator on access to medicines, also under development. Activities provided in the road map include support for platforms in collecting a wide variety of data such as the Global Observatory on Health Research and Development, the Global Surveillance and Monitoring System for substandard and falsified medical products, the shortages notification system and the global programme on surveillance of antimicrobial consumption.

[1] Specialists within the category of biomedical engineering include clinical engineers, biomedical engineering technicians, rehabilitation engineers, biomechanical engineers and bioinstrumentation engineers.

VI. Strategic area: Ensuring the quality, safety and efficacy of health products

24. National regulatory authorities in countries are responsible for the quality, safety and efficacy of health products. A weak regulatory system can have an impact on patient outcomes and has the potential to impair initiatives for improving access, for example by taking too long to approve products for use in a country. Unfortunately, the capacity of many low- and middle-income countries to assess and approve health products remains limited, with as few as 30% of national regulatory authorities globally having the capacity to perform all core regulatory functions for medicines.[1] This lack of regulatory capacity in many countries hampers efforts to ensure the quality, efficacy and safety of health products.

25. Key challenges include inadequate resources, overburdened staff and incoherent policy frameworks. Differences between regulatory systems cause delays for researchers and manufacturers, who must navigate multiple regulatory systems to register the same health product in different countries. The introduction of new therapeutic classes, such as biotherapeutics and similar biotherapeutic products, will require new capacities and updating of guidelines.

26. A specific challenge has been highlighted by the recent public health emergencies requiring an urgent need for health products and decision-making in a context that is different from "business as usual". Many countries do not have the regulatory pathways in place to enable rapid access to novel health products. Another specific challenge is related to the growing interest in local production of health products as a strategy to improve access, strengthen national health security and enhance industrial and economic development. In most cases, low- and middle-income countries seeking to embark on local production have limited regulatory capacity to ensure the quality of products manufactured.

27. The underreporting of adverse drug reactions and adverse events following immunization highlights the need for improved approaches to post-marketing surveillance. In addition, the rise in substandard and falsified products in all markets is hampering efforts to ensure the quality, safety and efficacy of health products. A review showed that the observed failure rate of tested samples of substandard and falsified medicines in low- and middle-income countries is approximately 1 out of 10. Substandard and falsified medical products endanger health, promote antimicrobial resistance, undermine confidence in health professionals and health systems, create distrust about the effectiveness of vaccines and medicines, waste the limited budgets of families and health systems and provide income to criminal networks.

28. The activities in this strategic area support countries to deliver regulation that protects the public while enabling timely access to, and innovation of, quality products. Activities focus on regulatory system strengthening, assessment of the quality, safety and efficacy of health products through prequalification, and market surveillance of quality, safety and efficacy.

29. **Regulatory system strengthening.** WHO develops international norms and standards so that countries worldwide can consistently regulate health products. It supports countries, including those with local manufacturing or those seeking to develop local manufacturing, to strengthen regulation and regulatory capacity. Its action supports expanding reliance on national regulatory authorities that meet international performance benchmarks (WHO listed authority) as assessed via the Global Benchmarking Tool for assessment of national regulatory systems. WHO facilitates work-sharing and convergence to ensure greater efficiencies and more rapid registration of health products. The further development of

[1] WHO Essential medicines and health products: Annual report 2017: Towards access 2030. Geneva: World Health Organization; 2018. Available at: http://apps.who.int/iris/handle/10665/272972.

reliance networks will contribute to increased efficiency. Specific actions proposed in this activity include support for preparing regulatory procedures for emergency and crisis situations.

30. **Assessment of the quality, safety and efficacy/performance of health products through prequalification.** Prequalification aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment, diagnostics and medical devices meet global standards of quality, safety and efficacy. Products that have been assessed and prequalified by WHO are eligible for international procurement and provide the extra assurance of quality, safety and efficacy. Drawing on the expertise of some of the best national regulatory authorities, prequalification provides a list of products that comply with unified international standards. In parallel, WHO supports countries in building national regulatory capacity through networking, training and information-sharing.

31. **Market surveillance of quality, safety and efficacy/performance.** This activity area supports countries to strengthen post-market surveillance and monitor substandard and falsified health products. It provides support for collecting safety data to detect, assess and prevent adverse drug effects. One strategic approach relies on the introduction of active surveillance of a limited number of priority health products (for example in HIV, tuberculosis and malaria treatment programmes or new vaccines). This leads to robust safety data for the specific products in the short-term and a sustainable pharmacovigilance infrastructure in the long-term. The WHO global surveillance and monitoring system for substandard and falsified medical products collects data in support of the prevention, detection and response to substandard and falsified health products.

Activity: Regulatory system strengthening

Action – Development and implementation of WHO technical guidelines, norms and standards for quality assurance and safety of health products

Deliverables
Guidelines, standards and biological reference materials to support decreased regulatory burden and support production and quality control of safe and effective health products.
Support for increased uptake and utilization of guidance and standards by Member States.

Action – Support improvement of regulatory systems, promoting reliance and collaboration

Deliverables
Smart regulation in an increasing number of countries by means of collaborative approaches to registration including reliance and regulatory networks.
Support for implementation of WHO quality standards[1] to decrease the regulatory burden.
Support for regulatory capacity strengthening towards WHO listed authority status, especially in countries manufacturing products for lower-middle-income countries or for local production to ensure quality of products.
Support for the use of the Global Benchmarking Tool for the formulation of country-specific institutional development plans and related provision of technical advice, training and measures.

[1] www.who.int/medicines/regulation/tsn/en/.

Action – Strengthen preparedness for entry of medicines, vaccines and other health products into countries experiencing a public health emergency or crisis

Deliverables
Support 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 public health emergencies and the strengthening of processes and services.
Support for the adaptation of regulatory requirements for public health emergencies and the use of networks for expedited evaluations during such emergencies.

Activity: Assessment of the quality, safety and efficacy/performance of health products through prequalification

Action – Maintain and expand the prequalification service

Deliverables
An efficient and effective prequalification programme maintained and optimized, in particular the prequalification of in vitro diagnostics and vector control products.
Scope of prequalification expanded to include potential conditions, such as noncommunicable diseases, based on an assessment of specific needs from the essential medicines list and the essential diagnostics list.
New routes to prequalification listing and new risk-based approaches.
Post-prequalification product quality assured.

Activity: Market surveillance of quality, safety and efficacy/performance

Action – Support strengthening national capacity to ensure the quality, safety and efficacy of health products

Deliverables
Support for development of national capacity to ensure quality of health products in the supply chain.
Support for development of national capacity for surveillance of safety of health products on national markets.
Improved prevention, detection and response to substandard and falsified health products.

VII. Strategic area: Improving equitable access to health products

32. Many people worldwide do not have adequate and regular access to health products. Many medical devices in resource-poor settings are broken, unused or unfit for purpose. Access depends on having appropriate products available at affordable prices. The introduction of new medicines and other health products and the rise of noncommunicable diseases are putting increasing pressure on health care systems around the world and on individuals who pay out-of-pocket in the case of lack of government financing. Lack of access can affect patient outcomes if patients go undiagnosed or untreated or receive suboptimal treatment and can contribute to the rise in antimicrobial resistance. Challenges for improving access occur throughout the system, ranging from inadequate investment in research and development, lack of effective policies, weak procurement and supply chain management, and inappropriate prescribing and irrational use of health products.

33. Research and development investments in neglected diseases have shown an annual decline of 2–3% from 2012 (US$ 3.3 billion).[1] Neglected diseases and other major global health problems cannot be addressed with the health products that are currently available in markets, including for emerging infectious disease pathogens, and new antibiotic therapies. Some of the key challenges facing R&D include setting priorities for research and development needs and incentivizing research and development for health products that have a potentially limited return on investment.

34. Poor selection of health products, inadequate financing and ineffective policy interventions and processes to manage expenditure, including out-of-pocket expenditure, contribute to a lack of access and unaffordable prices. There is an increasing need to ensure the sustainable availability of health products through careful management of affordable pricing for health systems and fair pricing for producers.

35. Inefficient procurement and supply chain management is another major challenge. The special skills required for the procurement of quality assured products are lacking in many countries. The supply chain requires a strong infrastructure and accurate data management systems. This can be particularly complex for vaccines and other temperature- or time-sensitive health products that require careful handling and efficient cold chain systems. Preventing, detecting and responding to shortages of health products is complex as well. In the case of infectious diseases, such shortages or stock-outs contribute to growing antimicrobial resistance and have an impact on health outcomes. Inefficient supply chain management can lead to high levels of wastage, with significant consequences in terms of access. Waste management is also an emerging public health problem, particularly for products such as antibiotics.

36. Local production of health products has been proposed as a strategy to improve access, strengthen national health security and enhance industrial and economic development. There are a number of barriers to developing local production, however, including policy incoherence, unreliable financing, lack of affordable, quality-assured materials and unavailable skilled workforce.

37. Particular challenges for medical devices include a lack of biomedical engineering capacity to advise on their suitability for use in resource-poor settings such as those with high temperature, fluctuating electricity or lack of clean water. Installation, maintenance services and user training are also often lacking, leading to unsafe handling practices with potentially harmful consequences, such as misdiagnosis due to improper use or calibration of equipment.

38. Estimates have shown that in low- and lower-middle income countries, less than 40% of primary-care patients in the public sector and less than 30% of primary-care patients in the private sector are treated in accordance with standard treatment guidelines.[2] 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. Policy approaches and interventions have been identified to improve the use of health products but have generally not been implemented over the past decade. Increasing burdens on health resources, the rise of antimicrobial resistance to dangerously high levels and the rise in noncommunicable diseases require a renewed focus on appropriate prescribing dispensing and use.

[1] Research and development funding flows for neglected diseases (G-FINDER), by disease, year and funding category. World Health Organization, Global Observatory on Health Research and Development, 2018 (http://www.who.int/research-observatory/monitoring/inputs/neglected_diseases/en/, accessed 11 November 2018).

[2] The World medicines situation 2011: Rational use of medicines. Geneva: World Health Organization; 2011.

39. Activities under this strategic area will support countries to achieve a continuous supply of quality, safe, effective and affordable health products through research and development that meets public health needs; the application and management of intellectual property standards; evidence-based selection and fair and affordable pricing; procurement and supply chain management; and appropriate prescribing, dispensing and rational use.

40. **Research and development that meets public health needs.** In line with the Global strategy and plan of action on public health, innovation and intellectual property, which recommends prioritizing needs for and promoting research and development, WHO is playing a role in facilitating research and development for neglected areas, where there is a compelling unmet public health need for new products, including by coordinating the efforts of different actors, setting research and development priorities, identifying associated gaps, defining desired product profiles and facilitating the development of affordable, suitable health products. The Global Observatory on Health Research and Development is central to setting priorities for product development and contributing to coordinated actions on health research and development. The R&D Blueprint supports the development of a global preparedness plan for addressing future epidemics. WHO, together with the Drugs for Neglected Diseases initiative, has set up the Global Antibiotic Research & Development Partnership to develop new treatments for bacterial infections.

41. **Application and management of intellectual property.** Since the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), many Health Assembly resolutions have requested WHO to address the impact of trade agreements and intellectual property protection on public health and access to health products. The Global strategy and plan of action on public health, innovation and intellectual property, along with other relevant resolutions, constitutes the basic mandate for WHO's work in this area. As requested by the plan of action, WHO has intensified its collaboration with other relevant international organizations, in particular through trilateral collaboration with WIPO and WTO, as well as with other organizations, including UNCTAD and UNDP. Trilateral cooperation with WIPO and WTO is fostering a better understanding of the linkage between public health and intellectual property policies and enhancing a mutually supportive implementation of those policies. This activity area supports countries by fostering innovation and access to health products through appropriate intellectual property rules and management and by providing technical support and capacity-building.

42. **Evidence-based selection and fair and affordable pricing.** Procurement and reimbursement of health products is guided by evidence-based selection (including health technology assessment). Adoption or expansion of national essential medicines or diagnostics lists requires the capacity and competency at the national level to translate findings from evidence to local contexts and to use findings for decision-making. This activity area contributes directly to improving the availability and affordability of health products. Actions will be carried out to support countries for appropriate selection of medicines, vaccines, diagnostics and other health products, transparent and fair pricing, and implementation of policies to reduce costs to both governments and individuals while ensuring quality, safety and efficacy 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 the advancement of strategic approaches to ensuring supply security and other pricing and purchasing policies.

43. **Procurement and supply chain management.** Good procurement practices play a key role in securing quality products at 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. WHO will continue to support collaborative efforts to optimize the procurement and supply chain for health products and to build competencies for the required skills, such as forecasting needs, procurement processes, warehousing and distribution, stock management and maintenance (of medical devices). WHO will contribute to the global understanding of supply and demand dynamics and to platforms for collaborative approaches to procurement and facilitating the development of supporting policies and guidelines for improved capacity. In addition, the activity will contribute to support supply management in emergencies and crisis situations which may create an urgent need for health products. Being prepared with the necessary products, plans and tools is essential for manufacturers, regulators, donor agencies, supply chain managers and health workers.

44. **Appropriate prescribing, dispensing and rational use of medicines.** This activity will contribute to ensuring health impacts and the effective use of resources. This will require training of health care workers, quality improvement processes and routine monitoring of the use of medicines. WHO will support countries by consolidating interventions 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 practices. Work on responsible use will be reinforced to guarantee the appropriate prescription and use of medicines and other health products. WHO will support countries in implementing stewardship programmes, with a focus on antimicrobials, and will support countries in developing policies and regulations to ensure access, appropriate prescribing, dispensing and use of controlled medicines while minimizing the risk of abuse. Capacity for monitoring will be provided especially for the use of antibiotics in health facilities and in the community.

Activity: Research and development for health products that meet public health needs

Action – Continue to set priorities for health research and development in areas of compelling health need

Deliverables
Information available through the Global Observatory on Health Research and Development: review of development pipelines; research and development road maps; target product profiles for missing health products to guide research and development priority-setting for unmet public health needs in areas of market failure.
Analysis of relevant information on the health research and development needs of low- and middle-income countries through the Global Observatory.
Continued development of the global development and stewardship framework to combat antimicrobial resistance, jointly with OIE and FAO and UNEP, including support for the development of the Global Antibiotic Resistance Partnership.

Action – Coordinated actions on health research and development

Deliverables
Facilitated discussion on the development of unifying principles for biomedical research and development.
A harmonized WHO methodology for Target Product Profiles.
Establishment of new research and development initiatives, where needed, and existing initiatives supported, including Global Antibiotic Research & Development Partnership, to develop missing health products in areas of market failure, including rare diseases and neglected tropical diseases, based on core principles of affordability, effectiveness, efficiency and equity.
Promotion of transparency in research and development costs; development of incentive mechanisms that separate/delink the cost of investment in research and development from the price and volume of sales; and establishment of additional incentives for research and development of new products where there are market failures. Support for implementation of schemes which partially or wholly delink product prices from research and development costs, including actions recommended by the Consultative Expert Working Group on Research and Development: Financing and Coordination (see document A71/13, para. 30).
Promotion of new and existing research and development initiatives that are complementary and well-coordinated.

Action – Support improved capacity for research and development and clinical trials in countries

Deliverables
Dissemination of and support for implementation of research and development models that promote innovation and access in line with principles of the Consultative Expert Working Group on Research and Development: Financing and Coordination.
Support for clinical trial registries and improving policy mechanisms for clinical trials, including capacity development.
Policies for prospective registration and public disclosure of the results of clinical trials and support for the monitoring of registration and results reporting.
Promotion of the transfer of technology and production of health products in low- and middle-income countries and support for improved collaboration and coordination of technology.
Support for effective and innovative global health research by strengthening the research capacity of disease-affected countries; promotion of the translation of evidence into interventions that reduce the burden of infectious diseases; and building resilience in the most vulnerable populations through the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases.

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

Action – Foster innovation and access to health products by appropriate intellectual property rules and management

Deliverables
Promotion of public health-oriented licensing agreements and transparency regarding the patent status of existing and new health technologies.
Information provided on country experiences promoting public health approaches in the implementation of health-related provisions of the TRIPS agreements, including relevant TRIPS flexibilities and intellectual property management.
A review of mechanisms and incentives for access to affordable health technologies enabled by publicly funded research and development.
Support for the expansion of the Medicines Patent Pool to patented essential medicines and patented medicines included in WHO treatment guidelines through identification of potential products for licensing.

Action – Provide technical support and capacity building

Deliverables
Technical support provided (as appropriate, upon request, in collaboration with other competent international organizations), including to policy processes and to countries that intend to make use of the provisions contained in TRIPS, such as the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to TRIPS, in order to promote access to pharmaceutical products.
Support for the consideration of public health implications when negotiating bilateral or multilateral trade agreements.
Facilitation of the assessment of the patent status of essential health products at national and regional levels, in collaboration with competent partners.
Continued strengthening of the trilateral collaboration between WHO, WIPO and WTO, including to implement this road map, as well as with other relevant international organizations such as UNCTAD and UNDP.

Activity: Evidence-based selection and fair and affordable pricing

Action – Support processes for evidence-based selection, including health technology assessment and their implementation

Deliverables
Normative guidance for the selection of essential health products and the use of these in the development of national selection processes, including model lists for essential medicines, diagnostics, medical devices and vaccines.
Capacity development for evidence-based selection and priority-setting using various tools, including health technology assessment in collaboration with relevant partners.
Information and knowledge exchange through global and regional platforms to support country decision-making processes on evidence-based selection and health technology assessment of essential health products.

Action – Encourage more transparent and better policies and actions to ensure fairer pricing and reduction of out-of-pocket payments

Deliverables
Policy guidance for more effective pricing policies to improve the affordability of essential health products to health systems and individuals.
Global and regional collaboration to increase price transparency, support decision-making on pricing and reimbursement, facilitate dialogue between public payers, government decision-makers and industry, and improve capacity for price negotiation.
Pricing and financing policies to reduce out-of-pocket payments, including the adoption of generics and biosimilars in the selection, procurement and use of medicines; reimbursement schemes, where appropriate, and control of mark-ups in the supply chain.
Support for national capacity for the regular monitoring and use of price and availability information for decision-making.

Activity: Procurement and supply chain management for quality-assured health products

Action – Support collaborative approaches to strategic procurement of health products

Deliverables
Compilation of best practices and normative guidance on innovative and collaborative approaches to strategic procurement.
Compilation of best practices and normative guidance on efficiencies for purchasing and quality assurance in procurement.
Support for development and strengthening of regional approaches, such as pooled procurement for purchasing, in collaboration with other partners and agencies.

Action – Support countries in efficient procurement and supply chain management of health products

Deliverables
Normative guidance for efficient procurement and supply chain management of health products (in collaboration with United Nations partners) for quality assurance, strategy development, planning, storage, distribution, waste management and performance assessment.
Knowledge-sharing and collaboration between countries, centres of excellence identified for training and technical support for quality assurance, forecasting of needs, procurement processes, warehousing and distribution, stock management and logistics management information systems, with an emphasis on leadership and systems management.
Collaborations with partners and United Nations agencies to improve coordination and facilitate more efficient procurement and supply chain management.
Tools and platforms for facilitating transparency regarding procurement of essential health products.
Policy guidance on strategic local production of health products.

Action – Improve capability and capacity for detecting, preventing and responding to shortages of medicines and vaccines

Deliverables
Global tools for early detection of shortages and rapid notification systems.
Framework of mitigation actions needed to prevent and respond to shortages.
Market analysis for key strategic products and dialogue with industry on establishing supply security, including investing in Market Information for Access to Vaccines (MI4A) through collection, analysis and sharing of global medicines and vaccines demand and supply information, identification of access risks (e.g. shortages) and corrective measures.

Action – Support for adequate supply management and appropriate use of health products in emergencies and crisis situations

Deliverables
Support for preparedness on supply chain needs and risk assessment.
Policies for donations of medicines, vaccines and other health products.
Support mechanisms (such as regional/ global virtual stockpiles and emergency health kits) for rapid mobilization and delivery of medicines, vaccines and health products in collaboration with partners.
Policies for safe disposal of health products in and after emergencies.

Activity: Appropriate prescribing, dispensing and rational use of medicines

Action – Interventions that improve use of health products

Deliverables
Support for strengthening national structures and capacity for the regular development and revision of national treatment guidelines that are aligned with both the national essential medicines list selection process and prescribing practices.
In collaboration with partners, support for regional/national capacity development of the pharmacy and allied workforce to strengthen the medication-use process, ranging from improving adherence to regulations and guidelines to ensuring patient safety.
Support for implementing stewardship programmes, with a focus on antimicrobials; guidance on alignment of standard treatment guidance, with resistance pattern and national action plans for antimicrobial resistance; and support for using the Access, Watch and Reserve (AWARE) and the AWARE Index for quality improvement and stewardship interventions.
Support for the development of national policies and regulations to ensure access, appropriate prescribing, dispensing and use of controlled medicines, including guidance on optimizing relevant legislation and support for strengthening the capacity of prescribers and dispensers to ensure access and quality of service and minimize the risk of diversion.

Action – Support capacity for monitoring

Deliverables
Support for improved prescribing and dispensing through better use of drug utilization data for evidenced-based decisions, analysis and policy action on health products.
Support to conduct surveys on the use of antibiotics in health facilities and the community, in order to inform and assess the impact of stewardship and interventions, as well as support to monitor and evaluate the consumption of medicines based on national imports and epidemiological trends.
Support for improved forecasting and quantification of controlled medicines to avoid over-stock and support for strengthened capacity of prescribers and dispensers to ensure the quality of service and minimize the risk of diversion.

VIII. How WHO will collaborate on access to health products

45. As described in the document *Towards access 2030*,[1] the key stakeholder groups with whom collaboration will be strengthened and sustained include United Nations and other international partners, research institutions and academia, donors, civil society and the private sector. Collaboration with each of these broad groups provides an opportunity for WHO to synergize action and to be a more active and effective partner. Collaboration with United Nations and other international agencies will focus on optimizing information flows, sharing information and implementing mechanisms to ensure coordination in the field. Collaboration with academia will continue to leverage each entity's comparative advantages so as to achieve faster and better impact on access, while collaboration with donors will focus on enhanced advocacy to enable funding partners to contribute to the agenda described in this road map. The growing importance of civil society's role in influencing health leads WHO to engage civil society in policy and advocacy processes and help channel their expertise and experience in countries. Lastly, WHO will seek to engage with the private sector to find solutions to health challenges, such as the need for public health-driven research and development, pricing and affordability of health products, and leveraging innovative technologies and solutions for health.

IX. How WHO will measure progress on access to health products

46. WHO's impact framework for the General Programme of Work and its targets and indicators are aligned with the Sustainable Development Goals and Health Assembly-approved resolutions and action plans. The present road map aligns with the Thirteenth General Programme of Work's outcome 1 (increase access to essential health services, including promotion, prevention, curative, rehabilitation and palliative care), with a focus on primary health care measured with a universal health coverage index; it also considers the other outcomes ensuring its indirect contribution to reaching them. The road map will be guided by the following related high-level targets/indicators of the Thirteenth General Programme of Work and those that may be developed to complement them.

[1] WHO Essential medicines and health products. Annual Report 2017. Towards Access 2030. Geneva: World Health Organization; 2018. Available at: http://apps.who.int/iris/handle/10665/272972 (accessed 11 November 2018).

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 second dose of MCV
Increase treatment coverage of rifampicin-resistant tuberculosis (RR-TB) to 80%	Coverage of multidrug-resistant (MDR)/RR-TB treatment as a percentage of estimated incidence

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[1]

Resolution[2] (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

[1] Previously issued in WHO document A71/12, Annex, Appendix 1.

[2] Unless otherwise indicated.

Resolution[1] (year)	**Title**
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
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

[1] Unless otherwise indicated.

Resolution[1] (year)	**Title**
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
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

[1] Unless otherwise indicated.

Resolution[1] (year)	**Title**
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
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

[1] Unless otherwise indicated.

Appendix 2

KEY MILESTONES

2019[1]

Strategic area: Ensuring the quality, safety and efficacy of health products

- Develop and implement plan for increased uptake and utilization of WHO guidance and standards.
- Publish performance data on all four collaborative procedures at least semi-annually (number of participant national regulatory authorities (NRAs), numbers of applications that went through the process, median NRA decision time and product classes involved in the process).
- Finalize good regulatory practices guidelines, principles and "how to" tools and guides on good reliance practices, and a guide for NRAs on value-added quality management.
- Finalize and implement process for defining, evaluating and designating WHO listed authorities.
- Finalize GBT indicators for levels 1, 2, 3 and 4 for those activities required for all regulatory functions (medicines and vaccines).
- Develop a model strategy and a prioritized plan of action for Member States/regions interested in quality local production, in collaboration with development partners.
- Provide training and capacity-building to strengthen local production of quality-assured products in at least two priority lower-middle-income countries (LMICs).
- Pilot the local production feasibility tool and risk assessment tool in at least two LMICs.
- Conduct landscape analysis of emergency regulatory procedures in LMICs.
- Develop criteria for prioritization for short-, medium- and long-term expansion of prequalification eligible health products.
- International Nonproprietary Names (INN).
- Develop and publish a post-prequalification risk-based product quality surveillance strategy for each product stream.
- GBT for devices finalized.
- Publish and maintain relevant databases on NRA status and WHO listed authorities that have reached maturity level 3 or 4.

Strategic area: Improving equitable access to health products

- Development of harmonized Target Product Profiles methodology.
- Development of Target Product Profiles in the area of antimicrobial resistance.

[1] Covered in programme budget 2018–2019.

- Update of WHO-WTO-WIPO Trilateral Study on Promoting Access to Medical Technologies and Innovation.
- Fair pricing forum.
- Model list of essential in vitro diagnostics established.
- Implementation of antibiotic categorization Access, Watch and Reserve (AWARE).
- WHO Model EMLs and EMLs for children.
- Technical Report of Expert Committee on Selection and Use of Essential Medicines.
- Market Information for Access to Vaccines (MI4A).

2020–2021

Strategic area: Ensuring the quality, safety and efficacy of health products

- Competencies framework and self-assessment tools available for use.
- Curriculum mapped and initial set of service providers identified for core elements.
- Workshops undertaken to promote the suite of regulatory guidelines.
- Expand development of a regulatory framework and harmonized guidelines through the African Medicines Regulatory Harmonization Initiative for all health products.
- Publish a curriculum for the regulatory oversight of local production of generic medicines and begin formal training of regulators in prioritized LMICs upon request.
- Training on use of health products in an emergency, including for use of products under Emergency Use Assessment and Listing (EU(A)L) procedures.
- Global regulatory networks established and maintained.
- Facilitated pathways for product registration.
- International listings serving interchangeability of generic medicines.
- International reference standards.
- Model regulatory framework for medical products developed.
- WHO certification and proficiency schemes.
- Pharmacovigilance training in active surveillance and detection of unknown risks.
- Develop tool kit for implementation of safety and vigilance activities.
- Develop global individual case safety reports database (Vigibase) that receives adverse drug events reports from Member States.
- Guidance for the implementation of the smart safety surveillance strategy, including risk-based prioritization of investments, work-sharing, joint activities and reliance.
- Additional countries supported to monitor, report and manage incidents of SF health products.
- Publish medical product alerts, e.g. (1) Drug Alerts (established under the Information Exchange System); (2) Rapid Alert System (to report SF medical products).

Strategic area: Improving equitable access to health products

- Further Target Product Profiles developed, including missing antibiotics and diagnostics for priority pathogens, missing diagnostics for sepsis, medical devices (including personal protective equipment).
- Pipeline road maps for research and development and for antifungals.
- Patent landscapes and updated patent status database for all patented drugs in the EML.
- Report on the cost of research and development for health products.
- Trilateral study: Promoting access to essential health products and innovation.
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Implementation plan.
- Antibiotic research and development and preclinical pipeline.
- Compendium of innovative health technologies for low resource settings.
- Global access to hepatitis C treatment report.
- WHO priority pathogens list: 2021 update.
- Guidelines for donations updated.
- Nomenclature, codification, classification and glossary of medical devices, including in vitro diagnostics and assistive devices and protective equipment.
- Establishment of tools and processes to guide countries in selection of vaccine products, inform research pipeline and support global demand forecasting.
- WHO Model Lists of Essential Medicines and Essential Medicines for Children.
- Model List of Essential Medicines lists and model list of essential in vitro diagnostics updated.
- Implementation guide for National Lists of Essential Medicines.
- List of priority medical devices for noncommunicable diseases, specifically cardiovascular, stroke, chronic obstructive pulmonary and diabetes, for primary care and emergencies.
- Pharmaceutical pricing policy guidelines.
- How to develop benefit package design.
- Guidance on promoting and monitoring transparency in medicines and health product prices.
- Interagency emergency health kit update.
- Shortages notification system.
- Guidelines on joint procurement of health product.
- Model quality assurance system for procurement updated.
- Guidance on sales, labelling and promotion of antimicrobial medicines.
- Guidance for implementation of antimicrobial stewardship programmes.
- Surveillance of antimicrobial consumption expanded.
- Measurement of antimicrobial use expanded.
- Tripartite surveillance on antimicrobial use/consumption expanded.

- Manuals on how to develop, implement and monitor national medicines and health products policy revised and developed.
- Expert Committee on Drug Dependence.
- Web-based information system on surveillance and health alert system for harmful psychoactive substances.
- Tools for monitoring the availability and predictors of access to medicines, vaccines and health support for products through country profiles, household surveys and health facility assessments.

2022–2023

Strategic area: Ensuring the quality, safety and efficacy of health products

- Publish the current list of all guidelines adopted each year, plus a table of all guidance undergoing development or revision.
- Publish the current status of all WHO physical standards/reference preparations: final (active), final (revoked), interim, under development (draft public), under development (no public draft available).
- Publish information on the establishment, discontinuation and replacement of the WHO biological reference materials as well as on the adoption of guidelines and recommendation.
- Publish performance data on all four collaborative procedures at least semi-annually.
- Update Emergency Use Assessment and Listing procedures as needed
- Maintain and update prequalification prioritization list.
- Publish lists of medicines and in vitro diagnostics allowed to be procured through the Expert Review Panel mechanism, products' prequalification or maturity level 4 (ML4) evaluation status; and 1 year due date for removal from the Expert Review Panel list.
- Publish key performance indicators for prequalification.

Strategic area: Improving equitable access to health products

- Budget of Global Antibiotic Research & Development Partnership increased to US$ 200 million and first product developed.
- Research and development road map for antifungals.
- Updated WHO guideline on country pharmaceutical pricing policies.
- Updated guideline on operational principles for procurement of medicines and vaccines.
- Updated good distribution practice.
- Updated patent status database for all Essential Medicines List medicines and new drugs in WHO Treatment Guidelines.
- Model Essential Medicines List updated.
- Updated guidelines for safe disposal and waste management, including for antimicrobials.

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