World Health Organization

SEVENTY-FIRST WORLD HEALTH ASSEMBLY **A71/12**
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Addressing the global shortage of, and access to, medicines and vaccines

Report by the Director-General

1. In January 2018, the Executive Board, at its 142nd session, noted an earlier version of this report[1] and adopted decision EB142(3) in which it recommended to the Seventy-first World Health Assembly the adoption of a draft decision 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, including activities, actions and deliverables for the period 2019−2023; and to submit that road map report to the Seventy-second World Health Assembly for its consideration in 2019, through the Executive Board at its 144th session.

BACKGROUND

2. In May 2017, the Seventieth World Health Assembly noted the report on addressing the global shortage of, and access to, medicines and vaccines and agreed to include the subject on the agenda of the Board at its 142nd session.[2] The current report is based on a review of: progress reports on related resolutions from across the Organization; reports considered by Health Assemblies and sessions of the regional committees; work on access to medicines and vaccines by other United Nations bodies, including the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines;[3] and work carried out by partners and non-State actors in official relations with WHO. Attention is drawn to the Director-General's report on the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.[4]

3. This report contains three sections: (i) an executive summary (paragraphs 4–11) of the report on access to medicines and vaccines, focusing on a list of priority options for actions to be considered by Member States; (ii) an update on the progress made in implementing those elements of resolution WHA69.25 (2016) pertaining to the global shortage of medicines and vaccines (paragraphs 12–15); and (iii) a comprehensive report by the Director-General on access to essential medicines and vaccines (Annex), which includes the following appendices: a list of key resolutions of the Health Assembly and regional committees, and regional committee documents from the past 10 years related to access to safe, effective and quality medicines, vaccines and health products

[1] See document EB142/13 and the summary records of the Executive Board at its 142nd session, sixth meeting.

[2] See document A70/20 and the summary records of the Seventieth World Health Assembly, ninth meeting, section 2.

[3] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: promoting innovation and access to health technologies. Geneva: United Nations High-Level Panel on Access to Medicines; 2016 (http://www.unsgaccessmeds.org/final-report, accessed 19 February 2018).

[4] See document A71/13.

(Appendix 1); a list of documents reviewed for the purposes of preparing this report (Appendix 2); a review of the recommendations of the report of the High-Level Panel on Access to Medicines and WHO's activities in the area of access to medicines (Appendix 3); and a non-exhaustive list of bodies in the United Nations system and related organizations, WHO collaborating centres, partners and non-State actors in official relations with WHO that carry out work on access to medicines (Appendix 4).

EXECUTIVE SUMMARY

4. Access[1] to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals.[2] Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines. Access is a global concern in view of the: rising prices of new medicines that place increasing pressure on the ability of all health systems to provide full and affordable access to health care; persisting problems of shortages and stock outs of essential medicines, especially for noncommunicable diseases, and vaccines; and increasing numbers of substandard and falsified medical products that pose an unacceptable risk to public health. In addition, problems such as antimicrobial resistance and opioid misuse highlight the need to improve appropriate use of medicines.

5. WHO plays a fundamental role in ensuring access to safe, effective and quality medicines and vaccines around the world through its strategic and normative work and technical support at the global, regional and national levels. The Organization takes a comprehensive health-systems approach that addresses all stages of the pharmaceutical value chain, including: needs-based research, development and innovation; public health-oriented intellectual property and trade policies; manufacturing processes and systems; pricing policies; integrity and efficiency in procurement and supply chain management; and appropriate selection, prescribing and use. WHO supports good governance and strengthening of regulatory capacity, monitoring systems and workforce capacity, and collaborates with a multitude of stakeholders.

6. Increasing access to medicines and vaccines is a complex issue. Although many activities contribute to improving access to medicines and vaccines, there is a need to prioritize and invest in those where WHO has an advantage compared with other organizations and that provide value for money, are fit for purpose, and lead to achievable and sustainable improvements. The Secretariat has undertaken a comprehensive review of the major challenges to ensuring access to safe, effective and quality medicines and vaccines and analysed progress made to date. On the basis of this review and in accordance with WHO's draft thirteenth general programme of work 2019–2023, the Secretariat has identified the actions listed below that could be prioritized for implementation. All these actions fall under WHO's existing mandate (see Appendix 1 to the Annex) and are all, to a greater or lesser extent, currently being undertaken by the Secretariat. Confirmation of this approach would enable the Secretariat to focus its activities on those actions with the greatest potential impact.

7. The extension and broadening in scope of the following actions is considered by the Secretariat as having the greatest potential impact on access to safe, effective and quality medicines, with the least complexity and requiring the fewest resources to implement.

[1] http://www.who.int/medicines/areas/policy/en/ (accessed 22 February 2018).

[2] Target 3.8 of the Sustainable Development Goals: 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.

- Engender and facilitate the development of political will at the national and regional levels to ensure the affordability and availability of safe, effective and quality medical products through effective regulation and policy implementation, particularly the implementation of pricing and financing policies that encourage fair pricing and domestic investment in universal coverage schemes that reduce out-of-pocket payments.

- Support increased interorganizational, regional and country collaboration, networking and training on specific topics such as: governance; regulation; quality and safety; intellectual property and trade policies, including action through WHO's trilateral collaboration with WIPO and WTO; pricing; procurement; reimbursement; and appropriate use.

- Consolidate and enhance the Secretariat's contribution to product development across different diseases, including effective prioritization of research and development needs through the Global Observatory on Health Research and Development and building on the success of existing research and development models such as the Global Antibiotic Research and Development Partnership.[1]

- Support expansion of the Medicines Patent Pool to include all antimicrobial medicines and patented medicines from the WHO Model List of Essential Medicines.

- Build capacity, in collaboration with other partners, for the implementation of intellectual property laws that are in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and that make adequate use of its flexibilities.[1]

8. In addition, the continuation of WHO's normative work to specify standards and guidance for the development, regulation, production, selection, pricing, procurement, distribution, prescription and use of medicines and vaccines is likewise considered as having a high impact on access to safe, effective and quality medicines, with low complexity and requiring resources for implementation that are mostly available.

9. The extension and broadening in scope of the following actions is considered as having a potentially high impact on access to safe, effective and quality medicines, but involves greater complexity and requires additional resources.

- Support the development and implementation of systems at national levels for collecting and monitoring key data on medicines and vaccines, such as availability, price, expenditure, usage, quality and safety, and ensuring use of these data for better evidence-based policy-making.

- Develop policies that promote transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups.[2]

- Provide support to Member States to develop collaborative approaches for strategic procurement based on existing models.

[1] See also document A71/13.

[2] See recommendation 4.3.4. and 4.3.5 in Appendix 3 to the Annex.

- Develop a more systematic approach to providing technical support for improving the skills of the pharmaceutical workforce and monitoring its size, composition, skill sets, training needs and performance.

10. The continuation of WHO's support to ensure that regulatory systems have the capacity to provide access to safe, effective and quality medicines and vaccines in addition to support for the development of international regulatory convergence and harmonization initiatives are considered as having a potentially high impact on access to safe, effective and quality medicines and vaccines, but involve greater complexity and require additional resources. WHO will continue to support the availability of good-quality generic products for procurement by global agencies and countries through its Prequalification of Medicines programme, which will evolve to meet the changing health needs of countries.

11. Lastly, there are numerous actions that have a potentially high impact, but are also highly complex and require significant additional resources. Examples of such actions are shown below.

- Support the development, implementation and monitoring of national medicines policies to reinforce strategies for the appropriate use of medicines.

- Tackling undue influence and corruption in the pharmaceutical system, particularly in procurement and supply chain management.

- Facilitate discussion on unifying principles for biomedical research and development.[1]

PROGRESS IN IMPLEMENTING THOSE ELEMENTS OF RESOLUTION WHA69.25 PERTAINING TO THE GLOBAL SHORTAGE OF MEDICINES AND VACCINES

12. In May 2016, the Sixty-ninth World Health Assembly adopted resolution WHA69.25 addressing, inter alia, the global shortage of medicines and vaccines. In the resolution, the Director-General was requested "to develop an assessment of the magnitude and nature of the problem of shortages of medicines and vaccines", to develop "a global medicine shortage notification system that would include information to better detect and understand the causes of medicines shortages" and "to report on progress on, and outcomes of, the implementation of this resolution to the Seventy-first World Health Assembly".

13. In July 2017, the Secretariat hosted a technical consultation to review existing systems for reporting medicines shortages, including databases of regulatory authorities, as well as those for substandard and falsified medical products and adverse events. This information will be used in the design of a global reporting system for shortages and stock outs. Given that countries will rely on different sources of information to contribute to a global reporting system, regulatory agencies, national procurement authorities, manufacturers and those programmes that procure and deliver medical products were identified among the entities that could contribute. Inclusion criteria, security and interoperability with other reporting systems were also discussed. The global reporting system will be limited to medicines included on the WHO Model List of Essential Medicines.

[1] See also document A71/13.

14. In advance of a global reporting system, the Secretariat has been assessing the magnitude and nature of the problem of shortages of medicines and vaccines through literature reviews, analysis of existing national notification databases, and interviews with stakeholders. In consultation with partners, the Secretariat is conducting various surveys to gather additional information, especially from countries without a publicly available national reporting mechanism.

15. Regional work on causes of, and solutions to address, shortages has included discussions and a survey conducted in the Eastern Mediterranean Region in 2016, a survey conducted in the Western Pacific Region in 2017 and a vaccines survey conducted in the European Region in 2016.

ACTION BY THE HEALTH ASSEMBLY

16. The Health Assembly is invited to adopt the decision recommended by the Executive Board in decision EB142(3).

ANNEX

ACCESS TO ESSENTIAL MEDICINES AND VACCINES

Report by the Director-General

Overarching issues and context

1. Access to safe, effective, quality and affordable medicines and vaccines for all is a specific component of target 3.8 of the Sustainable Development Goals.[1] Access to safe, effective and quality medicines has been recognized as a crucial element for solving numerous important public health problems and features in many Health Assembly resolutions covering work across the Organization (see Appendix 1). Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines.

2. Access to medicines and vaccines is of global concern. There is increasing pressure on health systems to provide affordable access to health care, particularly with the introduction of new high-priced medicines and health products. Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food.[2] With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden for patients and governments will become even greater. Some countries are reporting difficulties in obtaining both traditional and new vaccines in the quantities needed, as well as in accessing sufficient financial resources to meet the increasing costs of paying for vaccines and their delivery.

3. The availability of medicines and vaccines is still poor in some countries, particularly for noncommunicable diseases. Data collected by the Secretariat over the past two years show that less than 10% of facilities in some countries have a complete "basket" of essential medicines for treating noncommunicable diseases.[3] The supply chain system in many countries continues to underperform, leading to stock outs and the inability to deliver quality services. In addition, increasing numbers of substandard and falsified medical products pose an unacceptable risk to public health.

4. The rise of antimicrobial resistance and opioid misuse has highlighted the need for appropriate prescribing and dispensing to ensure appropriate use. The serious lack of new antibiotics under development to combat the growing threat of antimicrobial resistance calls for greater investment in the research and development of innovative medicines.

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[1] Target 3.8 of the Sustainable Development Goals: 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] WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1, accessed 19 February 2018).

[3] Improving access to medicines in the South-East Asia Region: progress, challenges, priorities. New Delhi: World Health Organization Regional Office for South-East Asia; 2017 (http://apps.who.int/iris/bitstream/10665/258750/1/9789290225904-en.pdf, accessed 19 February 2018).

5. Access to safe, effective and quality medicines and vaccines requires above all sufficient political will at the national level. It also requires a comprehensive health-systems approach that addresses all stages of the pharmaceutical value chain, including: needs-based research, development and innovation; public health-oriented intellectual property and trade policies; manufacturing processes and systems, including strategic and sustainable local production that ensures quality products; pricing policies and coverage schemes that contribute to the attainment of universal health coverage; integrity and efficiency in procurement and supply chain management; and appropriate selection, prescribing and use. Strong regulatory systems to oversee the quality, safety and efficacy of medicines and vaccines are also required, as well as effective monitoring systems to inform policy. Strong governance is needed to ensure accountability and tackle vulnerabilities to corruption. In addition, a well-trained workforce is needed throughout the system, as well as collaboration with all stakeholders involved.

6. Access to other health technologies,[1] including medical devices and assistive technologies, is also essential for a well-functioning health system and for achieving the health-related Sustainable Development Goals. Health technologies are essential for screening, diagnosis, treatment, rehabilitation and even palliative care, and are often required for appropriate medicine delivery. Many of the barriers to improving access to medicines are similar to those for medical devices. However, the selection process, training for proper use, maintenance (where appropriate) and infrastructure support, and ensuring sustainable access to medical devices are even more complex. Nevertheless, proposals for the way forward for improving access to medicines and vaccines may be relevant and research and support for improving access to other health technologies has to be further developed.

Progress in improving access

7. WHO plays a fundamental role in ensuring access to safe, effective and quality medicines and vaccines around the world through its strategic and normative work and technical support at the global, regional and national levels. The following is a summary of the main challenges related to access and the activities carried out by WHO to address them, based on a review of progress reports and other documents (Appendix 2).

(a) Political will and governance

8. Political will is essential for securing the resources required for sustainable access to safe, effective and quality medicines and vaccines and is reflected in the development and implementation of national medicines and immunization policies. The high percentage of health spending on medicines (20–60% in low- and middle-income countries) impedes progress for the many countries that have made a commitment to universal health coverage.[2,3] Strong policies must reflect both an increasing need for financial coverage for health services and the need to ensure equitable access to quality care. Robust processes, including transparency and civil society participation, are needed to decide which services to provide, which patients receive health services, how to reduce out-of-pocket

[1] The term "health technologies" refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. See resolution WHA60.29 (2007) on health technologies.

[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. Lancet. 2016;387:811-16. doi: 10.1016/S0140-6736(15)60002-2.

[3] WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1, accessed 19 February 2018).

payments and how to fund health care. Strong governance not only ensures efficient use of funds, but also improves trust in the health care system and contributes to the proper use of quality medicines and vaccines.

9. 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.[1] In addition, weak governance in the pharmaceutical system continues to be an issue for countries due to a lack of transparency and accountability, unclear roles and responsibilities, and a lack of oversight. Experience in some countries with decentralized health systems showed five or more years of prolonged confusion over roles and responsibilities within their immunization programmes, with inadequate accountability mechanisms and oversight to control how resources were spent and prioritized, making it impossible to achieve improvements in immunization coverage.[2] A question of growing importance is how to manage interactions between governments and the private sector to avoid risks of undue influence. In recent years, there has been an increase in the number and scope of access initiatives being carried out by pharmaceutical companies and there is a need to ensure that public health interests remain at the centre of such initiatives.

10. The Secretariat has supported the development of strong policies, as outlined in the following sections of this report. More work is required to update policy guidance and support countries to develop and implement national policies that reflect the need to improve access to medicines and vaccines as essential to achieving universal health coverage.

11. In October 2017, WHO published a policy brief on responding to industry initiatives to increase access to medicines and other health technologies in order to support Member States in this respect.[3] The Secretariat has field-tested a revised version of the pharmaceutical system transparency and accountability assessment tool.[4]

12. WHO plays a leadership role in the improvement of transparency with regard to immunization and vaccine safety through the establishment of National Immunization Technical Advisory Groups,[5] which provide independent, evidence-informed advice to health authorities on policy issues related to immunization and vaccines. Regional and country collaboration platforms have been established in all WHO regions to share experiences, document evidence and develop a policy dialogue on how countries can use national medicines policies to improve access to essential medicines.

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[1] The world health report 2010: Health systems financing – the path to universal coverage. Geneva: World Health Organization; 2010 (http://apps.who.int/medicinedocs/documents/s20169en/s20169en.pdf, accessed 19 February 2018).

[2] Strategic Advisory Group of Experts on immunization. 2016 Midterm review of the global vaccine action plan. Geneva: World Health Organization; 2016 (http://www.who.int/immunization/sage/meetings/2016/october/1_Draft_GVAP_Assessment_report_2016_for_Yellow_Book_28_Sep_2016.pdf, accessed 19 February 2018).

[3] Responding to industry initiatives to increase access to medicines and other health technologies in countries. Essential Medicines and Health Products Policy Brief Series No. 2.0. Geneva: World Health Organization; 2017 (http://apps.who.int/iris/bitstream/10665/259359/1/WHO-EMP-2017.04-eng.pdf, accessed 19 February 2018).

[4] The pharmaceutical system transparency and accountability assessment tool is scheduled for publication in June 2018.

[5] For further information on National Immunization Technical Advisory Groups, see http://www.nitag-resource.org/ (accessed 19 February 2018).

13. Country support for governance has been provided through WHO's Good Governance for Medicines programme, which aims to: raise awareness of the impact of corruption in the pharmaceutical sector; increase transparency and accountability of pharmaceutical systems; and institutionalize good governance in pharmaceutical systems. The Regional Office for the Eastern Mediterranean has been particularly active in the Good Governance for Medicines programme, and support has been provided to countries in the Region to: establish policies for implementing codes of conduct; manage conflicts of interest; increase public availability of information; develop membership guidelines for committees; develop standard operating procedures for decision-making processes; establish independent complaints mechanisms to improve protection for whistle-blowers; and increase civil society engagement.

14. Key considerations are as follows.

- More work is required to engender and facilitate the development of political will at the national and regional levels to ensure access to medicines and vaccines, particularly with regard to the implementation of pricing policies and domestic financial investment in coverage schemes.

- Strategies for reducing undue influence and tackling vulnerabilities to corruption need to be included in support provided to countries for developing and implementing medicines and vaccines policies.

(b) Workforce

15. Although population changes and growth are expected to create 40 million new health worker jobs by 2030, there is currently an estimated shortfall of 18 million health workers required in order to achieve the health-related Sustainable Development Goals.[1] The development, production, procurement, distribution and appropriate use of medicines, as well as the supportive functions of regulation, all require a competent, equitably distributed pharmaceutical workforce. However, low- and lower-middle-income countries continue to have a very low density of pharmacists compared to high- and upper-middle-income countries.[2] It has been found that countries with a lower number of pharmacists per capita are more likely to have reduced access to medicines, as pharmacists are needed at every stage of the pharmaceutical supply chain.[3]

16. WHO's Global Strategy on Human Resources for Health: Workforce 2030[4] sets out four strategic objectives and policy options to improve the health workforce (applicable to all occupations) including: the optimization of the existing workforce; anticipating and planning for future workforce requirements; strengthening institutional capacity to plan and manage the workforce;

[1] 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://apps.who.int/iris/bitstream/10665/250047/1/9789241511308-eng.pdf?ua=1, accessed 19 February 2018).

[2] Global pharmacy workforce intelligence: trends report. The Hague: International Pharmaceutical Federation; 2015 (http://www.fip.org/files/fip/PharmacyEducation/Trends/FIPEd_Trends_report_2015_web_v3.pdf, accessed 19 February 2018).

[3] Bates I, John C, Bruno A, Fu P, Aliabadi S. An analysis of the global pharmacy workforce capacity. Human Resources for Health. 2016;14(1):61. doi: 10.1186/s12960-016-0158-z.

[4] Global strategy on human resources for health: workforce 2030. Geneva: World Health Organization; 2016 (http://www.who.int/hrh/resources/pub_globstrathrh-2030/en/, accessed 19 February 2018).

and building and utilizing data and evidence to drive workforce policies and strategies. The International Pharmaceutical Federation's Pharmaceutical Workforce Development Goals,[1] 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.

17. WHO, in partnership with African, Caribbean and Pacific island countries and the European Union, has trained more than 3500 health workers since 2012 to strengthen pharmaceutical systems and improve access to quality medicines.[2] The training has covered a broad range of topics, from the acquisition of additional skills to assess and register medicines to training on how to conduct surveys of consumption of antimicrobial medicines. Over 250 regulatory authority personnel from all WHO regions have been trained on a range of regulatory issues. Support from donors such as the European Commission has allowed the continuation of the work of a network of WHO national professional officers, particularly in Africa, with expertise in medicines and health technologies, which is key to supporting this work effectively in country offices. Numerous training and capacity-building efforts have also been carried out at the regional and country levels on all topics, as reported throughout this document.

18. Key considerations are as follows.

- A more systematic approach to providing technical support for improving the skills of the pharmaceutical workforce and monitoring the size, composition, skill sets, training needs and performance of the pharmaceutical workforce could be developed.

- National professional officers with expertise in medicines and health technologies play a key role in WHO country offices and should be supported.

(c) Needs-based research, development and innovation

19. The shortcomings of the current market-driven innovation system have been the subject of intensive discussion. The problem of commercial research and development not meeting public health needs was first highlighted in 2001 with respect to neglected diseases.[3] Today, it is widely acknowledged that there is a similar problem with the research and development pipeline for pathogens with pandemic potential such as Ebola virus or Middle East respiratory syndrome

[1] Pharmaceutical workforce development goals. The Hague: International Pharmaceutical Federation; 2016 (https://fip.org/files/fip/PharmacyEducation/2016_report/2016-11-Education-workforce-development-goals.pdf, accessed 12 March 2018).

[2] Annual report 2016: WHO essential medicines and health products. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/annual-reports/WHO_EMP_Report_2016_Online.pdf?ua=1, accessed 19 February 2018).

[3] Médecins Sans Frontières Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group. Fatal imbalance: the crisis in research and development for drugs for neglected diseases. Geneva: MSF Access to Essential Medicines Campaign; 2001 (http://www.msf.org/sites/msf.org/files/old-cms/source/access/2001/fatal/fatal.pdf, accessed 19 February 2018).

coronavirus,[1] as well as for antibiotic treatments.[2] Research and development investments in neglected diseases have shown an annual decline of 2–3% since 2012 (US$ 3.3 billion).[3] In addition, advancements in vaccine formulations have increased the need for innovative technologies that simplify vaccine delivery.

20. A lack of sharing of clinical trial data can not only create unnecessary duplication, but also introduce publication bias that can potentially distort regulatory and public health decision-making.[4] In addition, a lack of regulatory capacity and/or inadequate regulatory pathways for clinical trials has an impact on the development of new medical products, for example for emergency preparedness and/or for specific populations, such as medicines for children.

21. The global strategy and plan of action on public health, innovation and intellectual property and the Consultative Expert Working Group on Research and Development: Financing and Coordination[5] have provided the overarching framework guiding the work on research and development by the Secretariat and Member States. The Secretariat has reviewed the recommendations from the overall programme review of the global strategy and plan of action[6] and has reviewed the recommendations from the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines[7] (see also section (d) below and Appendix 3) and compared them with progress made by WHO on needs-based research and development and innovation.

22. Key progress made by the Secretariat on research and development priority-setting includes the establishment of the Global Observatory on Health Research and Development.[8] A mechanism is in the process of being established to highlight critical research priorities, knowledge gaps and identify solutions and innovations in line with the General Programme of Work outcomes and impact framework. Progress on strategic work to promote innovation, research and development and product development includes the establishment of the research and development blueprint for action to

[1] WHO publishes list of top emerging diseases likely to cause major epidemics. Geneva: World Health Organization; 2015 (http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en/, accessed 19 February 2018).

[2] Organisation for Economic Co-operation and Development, World Health Organization, Food and Agriculture Organization of the United Nations, World Organisation for Animal Health. Tackling antimicrobial resistance: ensuring sustainable R&D. Paris: Organisation for Economic Co-operation and Development; 2017 (http://www.oecd.org/g20/summits/hamburg/Tackling-Antimicrobial-Resistance-Ensuring-Sustainable-RD.pdf, accessed 19 February 2018).

[3] R&D funding flows for neglected diseases (G-FINDER), by disease, year and funding category. Geneva: World Health Organization, Global Observatory on Health Research and Development; 2017 (http://www.who.int/research-observatory/monitoring/inputs/neglected_diseases/en/, accessed 19 February 2018).

[4] Hudson KL, Collins FS. Sharing and reporting the results of clinical trials. JAMA. 2015;313(4):355-6. doi: 10.001/jama.2014.10716.

[5] Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Geneva: World Health Organization; 2012 (http://www.who.int/phi/CEWG_Report_5_April_2012.pdf, accessed 19 February 2018).

[6] See document A71/13.

[7] Report of the United Nations Secretary-General's High-level Panel on Access to Medicines: promoting innovation and access to health technologies. Geneva: United Nations High-Level Panel on Access to Medicines; 2016 (http://www.unsgaccessmeds.org/final-report, accessed 19 February 2018).

[8] For further information on the Global Observatory on Health Research and Development, see http://www.who.int/research-observatory/en/ (accessed 19 February 2018).

prevent epidemics which publishes annually updated lists of priority diseases.[1] Applying the blueprint to Zika virus vaccine development has allowed research and development to progress at an unprecedented speed.[2] For Middle East respiratory syndrome coronavirus, WHO has developed a global research and development road map as well as vaccine target product profiles, and a vaccine is now in clinical testing. WHO has collaborated on numerous product development partnerships. For example, WHO has established jointly with the Drugs for Neglected Diseases initiative the Global Antibiotic Research & Development Partnership[3] and provides support for the Coalition for Epidemic Preparedness Innovations,[4] among others.

23. WHO has made progress on normative work to guide product development and has recently published several major reports on: antibacterial agents in clinical development;[5] prioritization of pathogens to guide discovery, research and development of new antibiotics for drug-resistant bacterial infections, including tuberculosis;[6] and a proposal for financing and operation of a health product research and development fund.[7] The Secretariat is actively engaged in a number of ongoing activities to promote research availability and transparency, such as through the WHO International Clinical Trials Registry Platform,[8] the publication of a formal position on the timing of reporting,[9] and a statement on public disclosure of clinical trial results.[10] To foster an enabling environment for research on vaccines, medicines and diagnostics for outbreak response, several tools have been developed,

[1] An R&D blueprint for action to prevent epidemics: funding & coordination models for preparedness and response. Geneva: World Health Organization; 2016 (http://apps.who.int/medicinedocs/documents/s22472en/s22472en.pdf, accessed 19 February 2018) and List of Blueprint priority diseases (http://www.who.int/blueprint/priority-diseases/en/, accessed 23 February 2018).

[2] Current Zika product pipeline. Geneva: World Health Organization; 2016 (http://www.who.int/blueprint/priority-diseases/key-action/zika-rd-pipeline.pdf?ua=1, accessed 19 February 2018).

[3] For further information, see the Global Antibiotic Research & Development Partnership website (https://www.gardp.org/, accessed 19 February 2018).

[4] For further information, see the Coalition for Epidemic Preparedness Innovations website (http://cepi.net/, accessed 19 February 2018).

[5] Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline, including tuberculosis. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/news/2017/IAU_AntibacterialAgentsClinicalDevelopment_webfinal_2017_09_19.pdf, accessed 19 February 2018).

[6] Prioritization of pathogens to guide discovery, research and development of new antibiotics for drug-resistant bacterial infections, including tuberculosis. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/areas/rational_use/PPLreport_2017_09_19.pdf?ua=1, accessed 19 February 2018).

[7] Health product research and development fund: a proposal for financing and operation. Geneva: World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases; 2016 (http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1, accessed 19 February 2018).

[8] For further information on the WHO International Clinical Trials Registry Platform, see http://www.who.int/ictrp/en/ (accessed 19 February 2018).

[9] Moorthy VS, Karam G, Vannice KS, Kieny M-P. Rationale for WHO's new position calling for prompt reporting and public disclosure of interventional clinical trial results. PLoS Med. 2015;12(4):e1001819. doi: 10.137/journal.pmed.1001819.

[10] WHO statement on public disclosure of clinical trial results. Geneva: World Health Organization; 2015 (http://www.who.int/ictrp/results/reporting/en/, accessed 19 February 2018).

including Material Transfer Agreements[1] for sample sharing, and an agreement with stakeholders for rapid sharing of data.

24. The Secretariat provides technical support to countries to enhance clinical trial oversight, especially in low- and middle-income countries. This includes facilitating the acceleration of clinical trial and market approvals through work with national regulatory authorities and regulatory and other networks such as the African Vaccine Regulatory Forum (see section (e) below). Other regional activities include the establishment by the Regional Office for the Western Pacific of a health research portal,[2] national health research/clinical trial registries[3] and an Ethics Review Committee[4] to provide ethical review of research involving human participants.

25. Key considerations are as follows.

- The Global Observatory on Health Research and Development and the research and development blueprint for action to prevent epidemics will play a key role in contributing to priority-setting mechanisms for product development.

- WHO could strengthen the understanding of its own role in product development partnerships and scale up successful approaches.

- A standardized approach to target product profile development may be useful to improve efficiencies in the use of time and resources, ensure alignment of objectives, accelerate product development timelines, minimize product development risks, and lead to an optimal product.

- The recommendations resulting from the overall review of the global strategy and plan of action on public health, innovation and intellectual property[5] are in line with WHO's work in this area.

- The work of the Secretariat covers many of the recommendations in the report of the United Nations Secretary-General's High-Level-Panel on Access to Medicines.

- WHO could support the development of a code of principles for research and development in order to provide a public health target for funders of research and development.

[1] For further information on the Standard Material Transfer Agreements 2 (SMTA2), see http://www.who.int/influenza/pip/benefit_sharing/smta2/en/ (accessed 19 February 2018).

[2] For further information on the health research portal of the Regional Office for the Western Pacific, see http://researchportal.wpro.who.int/index.php/whorrp (accessed 19 February 2018).

[3] For further information on national health research registries, see http://www.wpro.who.int/health_research/nhrr/en/ (accessed 19 February 2018).

[4] For further information on the Ethics Review Committee of the Regional Office for the Western Pacific (WPRO-ERC), see http://www.wpro.who.int/health_research/ethics/wproresearchethics/en/ (accessed 19 February 2018).

[5] See document A71/13.

(d) Public health-oriented intellectual property and trade policies

26. Since the adoption of the TRIPS Agreement in 1994, the implications of the WTO intellectual property regime for access to medicines in developing countries have been the subject of robust discussion. Countries have implemented and used the flexibilities provided in the TRIPS Agreement, as restated by the 2001 Doha Declaration on the TRIPS Agreement and Public Health, to varying extents. In addition, the use of compulsory licences has been limited. Concerns remain that "TRIPS-plus" provisions in trade agreements that further strengthen and prolong patent regimes beyond the TRIPS Agreement standards create additional challenges for ensuring the availability of, and access to, medicines and other health products.[1]

27. The report of the High-Level Panel on Access to Medicines echoes the conclusions of previous reports prepared under the auspices of WHO (in particular the reports of the Commission on Intellectual Property Rights, Innovation and Public Health[2] and the Consultative Expert Working Group on Research and Development: Financing and Coordination[3]). It also reiterates elements of WHO's global strategy and plan of action on public health, innovation and intellectual property, in particular the call for greater policy coherence between public health, development and trade.[4] The Secretariat has reviewed the recommendations from the report of the High-Level Panel on Access to Medicines and compared them with progress made by WHO (see also section (c) above and Appendix 3).

28. The global strategy and plan of action on public health, innovation and intellectual property constitutes the basic mandate for WHO's work in this area. WHO closely collaborates on this topic with other relevant international and regional organizations, in particular through the trilateral collaboration with WIPO and WTO,[5] as well as with other organizations, including UNCTAD and UNDP.

29. Highlights regarding recent progress in normative work on the relationship of innovation, intellectual property and access to medical products include the publication of the report on access to hepatitis C treatments,[6] and the report on the role of intellectual property in local production in

[1] WHO, International Centre for Trade and Sustainable Development. Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2010 (http://apps.who.int/medicinedocs/documents/s21391en/s21391en.pdf, accessed 19 February 2018).

[2] Commission on Intellectual Property Rights, Innovation and Public Health. Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva: World Health Organization; 2006 (http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, accessed 19 February 2018).

[3] For further information, see the webpage of the Consultative Expert Working Group on Research and Development: Financing and Coordination (http://www.who.int/phi/cewg/en/, accessed 19 February 2018).

[4] See document A71/13.

[5] For further information on the trilateral cooperation, see http://www.who.int/phi/implementation/trilateral_cooperation/en/ (accessed 19 February 2018).

[6] Global report on access to hepatitis C treatment: focus on overcoming barriers. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1, accessed 19 February 2018).

developing countries.[1] In addition, WHO published the patent situation for all new hepatitis treatments[2] as well as for other treatments, including for noncommunicable diseases. WHO has published two guides: one on trade and health,[3] which provides guidance on how to harness and maximize opportunities to promote public health and minimize the risks and threats of trade policies; and another for negotiators and implementers on TRIPS-plus provisions in the Eastern Mediterranean Region.[4] WHO supports innovative approaches to overcoming patent barriers such as the Medicines Patent Pool.

30. Training and technical support has been provided by the Secretariat, in collaboration with other relevant international organizations, to numerous Member States and regions on how to facilitate access to affordable treatments, including on the appropriate use of the flexibilities provided in the TRIPS Agreement and the effective promotion of health production innovation.[5]

31. Key considerations are as follows.

- The recommendations of the overall review of the global strategy and plan of action on public health, innovation and intellectual property are in line with WHO's work in this area.
- The work of the Secretariat covers many of the recommendations in the report of the High-Level Panel on Access to Medicines.
- The Medicines Patent Pool should be expanded to include all patented medicines on the WHO Model List of Essential Medicines.
- The Secretariat should continue to provide technical support and training to Member States in this area.

(e) Regulation to ensure quality, safety and efficacy

32. Despite significant investment over the past decade by many partners, it is estimated that only 60 regulatory authorities in all WHO regions have well-functioning and integrated regulatory systems. Weak regulatory capacity limits the ability of national regulatory agencies to ensure the quality, safety and efficacy of medicines and vaccines and regulate new products such as biological products and cell

[1] The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 (http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf, accessed 19 February 2018).

[2] For further information on patent information on treatments for hepatitis C, see http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/ (accessed 19 February 2018).

[3] Smith R, Blouin C, Mirza Z, Beyer P, Drager N Eds. Trade and health: towards building a national strategy. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/183934/1/9789241565035_eng.pdf?ua=1, accessed 19 February 2018).

[4] El Said MK. Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2010 (http://apps.who.int/medicinedocs/documents/s21391en/s21391en.pdf, accessed 19 February 2018).

[5] For further information on technical cooperation programmes relating to the implementation of the TRIPS Agreement, see http://www.who.int/phi/wto_communications/en/ (accessed 19 February 2018).

and gene therapies,[1] thus delaying advancements in research and market entry of these products. Long lead times and differing regulations among countries also cause delays in market entry of new products, as evidenced in a study reporting a delay of four to seven years between the first regulatory submission (in a high-income country) and the final regulatory approval in sub-Saharan Africa.[2] Weak national regulatory capacity creates a risk that poor-quality or substandard and falsified medical products enter markets. In 2011–2012, more than 200 people died and around 1000 became seriously ill in Pakistan after taking a contaminated cardiac medicine.[3] As at November 2017, 100 Member States had reported more than 1500 suspect substandard and falsified medical products in their supply chains through the WHO Global Surveillance and Monitoring System.[4]

33. WHO develops international norms and standards, so that countries worldwide can consistently regulate health products and technologies. The Secretariat supports countries to strengthen regulation, including post-market surveillance, and eliminate substandard and falsified medicines. It also facilitates access to quality-assured, safe and effective health products by assessing medicines, vaccines and medical devices for priority diseases.

34. Progress by the Secretariat on normative work includes: the recent development of draft good regulatory practices, consisting of a compendium of international standards, guidelines and "smart" legislation (that delivers results in the least burdensome way) to establish effective regulatory systems;[5] the publication of good data and record management practices,[6] which helps regulators to identify insufficient or false data about health products; and the publication of the global model regulatory framework for medical devices,[7] including in vitro diagnostic medical devices, which recommends guiding principles and harmonized definitions for effective regulation of medical devices. In 2016 and 2017, WHO further developed the national regulatory authority global benchmarking tool that will be used to evaluate regulatory systems that oversee medical products in Member States. The Secretariat is also working to revise the WHO emergency use assessment and listing procedure developed in 2015,[8] which is used in the event of a public health emergency to assess the quality, safety and efficacy of the available products with fewer data than usual regarding potential use.

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[1] Milstien J, Belgharbi L. Regulatory pathways for vaccines for developing countries. Bulletin of the World Health Organization 2004;82(2):128-33.

[2] Ahonkhai V, Martins SF, Portet A, Lumpkin M, Hartman D. Speeding access to vaccines and medicines in low- and middle-income countries: a case for change and a framework for optimized product market authorization. PLoS One. 2016;11(11):e0166515. doi: 10.1371/journal.pone.0166515.

[3] Deadly medicines contamination in Pakistan. Geneva: World Health Organization; 2013 (http://www.who.int/features/2013/pakistan_medicine_safety/en/, accessed 19 February 2018).

[4] WHO Global Surveillance and Monitoring System. Geneva: World Health Organization (http://www.who.int/medicines/regulation/ssffc/surveillance/en/, accessed 19 February 2018).

[5] To be presented to the Expert Committee on Specifications for Pharmaceutical Preparations in October 2018.

[6] Guidance on good data and record management practices. Annex 5 to the WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016 (WHO Technical Report Series, No. 996; http://apps.who.int/medicinedocs/documents/s22402en/s22402en.pdf, accessed 19 February 2018).

[7] WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. (WHO medical device technical series). Geneva: World Health Organization; 2017 (http://apps.who.int/medicinedocs/documents/s23213en/s23213en.pdf, accessed 19 February 2018).

[8] For further information on the WHO emergency use assessment and listing procedures for medical products during public health emergencies, see http://www.who.int/medicines/news/public_consult_med_prods/en/ (accessed 19 February 2018).

35. The Secretariat has provided support to countries for regulatory system capacity strengthening, targeting specific areas such as registration, inspections, good manufacturing practices, reviews of legislation and pharmacovigilance, and has provided support on the development of regulatory authority institutional development plans. Intensive support has been provided to regulatory authorities in major producing countries to enhance regulatory oversight of products exported to the global market and to countries with strategic development plans for local production. Support has also been provided to strengthen networks and in the convergence and harmonization of medicines regulation at the international, regional and subregional levels. Technical support has been provided at all levels of the Organization. The Regional Office for South-East Asia supported the establishment of the South-East Asia Regulatory Network and the Regional Office for Africa has been supporting countries with collaborative initiatives such as the African Vaccine Regulatory Forum, which has been expanded to include medicines, and the African Medicines Regulatory Harmonization initiative. In the Eastern Mediterranean Region, WHO held a regional meeting on strengthening pharmacovigilance systems, in which harmonization and strengthening of post-market and vigilance regulatory functions for medicines, vaccines and medical devices were specifically promoted. Consultation workshops with national tuberculosis programmes, national medicine regulatory authorities and technical partners were also organized in the Western Pacific Region to establish priorities and strategies for strengthening and harmonizing the regulation of tuberculosis medicines. Progress has also been made on the creation of regulatory networks for work-sharing to enhance smart regulation (the delivery of results in the least burdensome way) and disseminate good regulatory practices.

36. WHO's Prequalification of Medicines programme has helped to ensure access to quality-assured products for global procurement. In 2014 alone, it enabled sales of medicines and vaccines worth more than US$ 3 billion. In addition, the programme provides capacity-building activities for regulatory systems strengthening that include rotating staff fellowships and joint reviews of products with the regulatory authorities of collaborating Member States. Following requests from Member States and procurement agencies as well as current donors, the Secretariat is developing a strategic plan to expand the programme to include many of the products on the WHO Model List of Essential Medicines: vector control products, medicines for hepatitis C, diagnostic tests for hepatitis C virus infection and biological products. The Secretariat is also planning to devolve the assessment of as many products as possible to benchmarked and well-functioning national regulatory authorities. Similarly, the Secretariat is working with Member States and regional networks to promote reliance on products included in the WHO list of prequalified medicinal products as another pathway to regulatory approval.

37. To support Member States in improving the quantity, quality and analysis of accurate data concerning substandard and falsified medical products, the Secretariat established the Global Surveillance and Monitoring System and has provided training for Member States on detection and reporting. The Regional Office for the Western Pacific worked with Interpol on annual campaigns to identify substandard and falsified medical products and strengthen enforcement to curb the sale of such products. The Regional Office for Africa developed a regional plan of action (2014–2017) to minimize the spread of substandard and falsified medical products, which included the establishment of a regional working group on substandard and falsified medical products. The Regional Office for South-East Asia also provided strategic policy support to countries in that Region for setting up the pharmacovigilance systems required for implementing the use of bedaquiline, which is used specifically to treat multidrug-resistant tuberculosis.

38. WHO continues to gather information on suspected adverse events resulting from medicinal products through the VigiAccess global database for reporting on adverse drug reactions,[1] which is currently used by 127 countries and contains more than three million reports.

39. Key considerations are as follows.

- Political will at the national and regional levels is required to ensure access to safe, effective and quality products through effective regulation.
- The success of the Prequalification of Medicines programme can be built upon through strategies such as expansion to other products and promoting reliance on programme-listed products.
- The increasing number of substandard and falsified medical products requires additional efforts to detect, prevent and respond to such products effectively.
- There is also much scope for improving regulation by pooling resources among Member States, for example by pursuing regional harmonization initiatives.

(f) Strategic and sustainable local production

40. Many middle-income countries have established sizeable pharmaceutical industries, built vaccine production capacity and are diversifying into other areas of health technology manufacturing. As at June 2017, the number of vaccine-producing countries was 43, of which 36 have a functional national regulatory authority. Local production is also being pursued in low-income countries, as demonstrated for example by the Pharmaceutical Manufacturing Plan for Africa and the ASEAN vaccine security and self-reliance initiative for improving vaccine security.

41. The current interest in local production of medicines and vaccines is significant both as a strategy to improve access and for industrial and economic development. Nevertheless, the success of industrial development that has been experienced in larger economies is difficult to replicate in smaller markets. Many countries may lack a sufficient market that could justify such investments in terms of economies of scale.[2] In some settings, the economic and development agendas are currently overwhelming the capacity of the health system, especially the ability of countries' national regulatory authorities to respond effectively. Major barriers to developing local production include: a lack of fundamental infrastructure; the lack of a well-trained workforce; lack of access to appropriate and long-term sustainable financing; a lack of collaborative linkages and policy coordination between ministries and institutions; high costs of finance; and low production standards.[3]

42. The Secretariat, with support from the European Commission and the Bill & Melinda Gates Foundation, has undertaken several studies on local production, in collaboration with UNIDO,

[1] For further information on the VigiAccess database, see http://www.vigiaccess.org/ (accessed 19 February 2018).

[2] The changing landscape on access to medicines. Geneva: International Federation of Pharmaceutical Manufacturers & Associations; 2012 (https://www.ifpma.org/wp-content/uploads/2016/01/ChangingLandscapes-Web.pdf, accessed 19 February 2018).

[3] Local production for access to medical products: developing a framework to improve public health. Geneva: World Health Organization; 2011 (http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf, accessed 19 February 2018).

UNCTAD and other partners. The lessons learned from this work are outlined in a report[1] and include the need for greater consideration of the long-term investments (over a period of 15–20 years) involved in increasing local production.

43. Progress on normative guidance in this area includes publication of the report on the role of intellectual property in local production in developing countries.[2] An inter-agency consultation on local production is planned for June 2018. The Secretariat is also enhancing inter-agency collaboration between WHO, UNCTAD, UNIDO and other partners to define roles and responsibilities for supporting local production.

44. The Secretariat has provided technical support to strengthen manufacturing capacity in countries. For example, in 2015, under the leadership of the Government of Ethiopia, the Secretariat supported the development and launch of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025), and is now facilitating the implementation of this strategy. In addition, the Secretariat has provided support to the ASEAN vaccine security and self-reliance initiative to develop a strategy for vaccine security through guaranteed production and financing. Support has also been provided to countries to improve regulatory capacity (as described in section (e) above) and to individual manufacturers through the Prequalification of Medicines programme. The Secretariat has also worked on supporting local production capacity for influenza vaccine manufacturing in several Member States, as well as supporting technology transfer initiatives for biological products such as monoclonal antibodies.[3]

45. Key considerations are as follows.

- Strong regulatory capacity is essential before investing in local production.
- Increasing local production to improve access to medicines requires the alignment of countries' development agendas with health plans and an understanding of the conditions under which such local production could lead to improved access.

(g) Pricing policies

46. Inadequate domestic or government financing of medicines is a major contributor to lack of access to medicines and vaccines and high out-of-pocket expenditure. The extent to which health care systems cover pharmaceutical expenditure is a crucial measure of the adequacy of the benefits package offered under universal health coverage.[4] One particular concern at present is the evolving donor

[1] Report of the interagency consultation on local production of essential medicines and health products. Geneva: World Health Organization; 2017 (http://apps.who.int/medicinedocs/documents/s23255en/s23255en.pdf, accessed 19 February 2018).

[2] The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 (http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf, accessed 19 February 2018).

[3] Improving access to safe blood products through local production and technology transfer in blood establishments. Geneva, World Health Organization; 2015 (http://www.who.int/phi/publications/blood-prods_technology_transfer.pdf, accessed 19 February 2018).

[4] WHO, The World Bank. Tracking universal health coverage: first global monitoring report. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977_eng.pdf?ua=1, accessed 19 February 2018).

priorities for funding. As countries transition away from donor support for globally purchased quality products, the question is how to implement sustainable financing mechanisms to avoid disruptions in medicine and vaccine availability, particularly in middle-income countries that no longer receive support but do not have the required resources.

47. Ineffective policy interventions and processes to manage expenditure also contribute to a lack of access and high out-of-pocket expenditure. Medicines and vaccines need to be selected through a rigorous selection process based on clinical evidence of safety, efficacy and cost-effectiveness, in order to avoid risks of higher expenditure, poor procurement practice and irrational use of medicines that result from the high variety of available products.[1] As much as 70% of all medicines currently on the market are duplicative or non-essential, and newer medicines are nearly always more expensive than existing ones.[2]

48. Owing to their lower prices, generic medicines and vaccines offer an opportunity for significant savings for health budgets and for lowering out-of-pocket expenditure. However, developing and implementing policies for the procurement and use of generic medicines is complex and requires many different policy components to be in place, such as: the establishment of systems that facilitate market entry of generic medicines; the existence of a functioning and transparent medicines regulatory agency; and adequate training of prescribers and dispensers.

49. Countries need additional capacity to negotiate prices effectively, or to take better advantage of their position to negotiate with manufacturers. A lack of transparency regarding costs of production, research and development, and prices paid by other Member States and procurement agencies results in a lack of power to negotiate and a reliance on mechanisms for comparison such as international reference pricing, which is likewise opaque. Capacity to effectively negotiate prices is limited even in some high-income countries. As a result, countries are forced to limit access to high-priced but effective medicines and vaccines, the most well-described example being the direct-acting antiviral medicines for the treatment of hepatitis C. Collaborative approaches for strategic procurement offer possibilities to improve negotiation, as discussed in section (h) below.

50. Supply chain mark-ups are uncontrolled in many countries, resulting in the price-to-patient being many times that of the ex-manufacturer price. There have been several well-documented examples of rapid and extreme price rises leading to reduced access. There are also challenges in collecting and monitoring pricing information that could inform policy-setting.

51. WHO is working closely with national and global immunization partners to advocate increased domestic financing to sustain immunization gains once donor support ends. In 2016–2017, an assessment for new immunization financing was added as a module in the new WHO guidance on conducting a national immunization assessment review.[3] This module has been tested in several countries over the past five years: in low-income countries; countries transitioning from support from the GAVI Alliance; and middle-income countries that are not eligible for support from the GAVI

[1] Laing R, Waning B, Gray A, Ford N, 't Hoen E. 25 years of the WHO essential medicines lists: progress and challenges. Lancet. 2003;361(9370):1723-9. doi: 10.1016/S0140-6736(03)13375-2.

[2] Olson C. Managing medicine selection. In: Managing access to medicines and health technologies, third edition. Arlington, VA, United States of America: Management Sciences for Health; 2012 (http://apps.who.int/medicinedocs/documents/s19630en/s19630en.pdf, accessed 19 February 2018).

[3] For WHO's information and publications on guidance and tools, see http://www.who.int/immunization/programmes_systems/financing/tools/en/ (accessed 19 February 2018).

Alliance. The additional module will allow countries to assess immunization financing and financial sustainability bottlenecks prior to the development of a comprehensive multiyear plan for immunization.

52. The Secretariat has contributed for many years to normative work on medicine selection, for instance through the development of standard treatment guidelines and the WHO Model List of Essential Medicines. In 2017, the Expert Committee on the Selection and Use of Medicines undertook an important review of antibiotics for treatment of infectious diseases, sexually transmitted infections and paediatric indications, as well as medicines for treatment of noncommunicable diseases such as cancer and diabetes.[1]

53. The Secretariat has started collecting evidence for a fair-pricing[2] model that could be adapted by countries according to the national context. The Secretariat has made substantial progress on the vaccine product, price and procurement initiative, which now provides access to procurement prices of vaccines across more than 80% of countries, with the goal of increasing price transparency and informing vaccine introduction and procurement. Through the use of a smartphone application, the Secretariat is building on the work carried out in collaboration with Stichting Health Action International on the tool for measuring and monitoring medicine price and availability.[3] The Secretariat is also providing support to Member States to collect data on medicine price and availability and explore methods for price negotiation.

54. Detailed regional-level discussions on how to manage the complex process of selection and pricing of medicines and health products in the context of universal health coverage have taken place over the past three years. In the Region of the Americas, a Health Technology Assessment Network of the Americas (Red de Evaluación de Tecnologías en Salud de las Américas) has been established to strengthen and promote the evaluation process of technologies and enable the exchange of information. In the South-East Asia Region, the Secretariat has helped countries to revise essential medicines lists as part of the revision of the package of essential health services and has helped countries to introduce health technology assessments as a routine part of the decision-making process for adding medicines to their national benefit packages. In the Western Pacific Region, the Secretariat has supported countries with evidence-based revisions of national essential medicines lists and the selection of new cost-effective therapeutic options based on health technology assessments. Regional efforts by the regional offices for Africa and South-East Asia include assessments of medicine pricing policy, best practices and lessons learned for price control. The Regional Office for the Western Pacific relaunched the Price Information Exchange for Selected Medicines to provide comparative information across the region on procurement prices for medicines. In the European Region, the Secretariat conducted a technical briefing in 2016 that resulted in recommendations calling on the Regional Office to promote collaboration among Member States and support the development of regional and subregional networks to address topics such as horizon scanning (that is, examining how

[1] WHO updates Essential Medicines List with new advice on use of antibiotics, and adds medicines for hepatitis C, HIV, tuberculosis and cancer. Geneva: World Health Organization; 2017 (http://www.who.int/mediacentre/news/releases/2017/essential-medicines-list/en/, accessed 19 February 2018).

[2] 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. In this context, fairness implies positive incentives/benefits for all stakeholders, including purchasers and those involved in the research and development and manufacture of medicines.

[3] WHO, Health Action International. Measuring medicine prices, availability, affordability and price components, second edition. Geneva: World Health Organization; 2008 (http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf?ua=1, accessed 20 February 2018).

emerging trends and developments might affect current policy and practice), health technology assessment, the willingness to pay for innovation, and the delinking of medicine prices from research and development costs.

55. Platforms for price information exchanges (such as the Price Information Exchange for Selected Medicines) and for discussions on strategies to facilitate sustainable access to essential medicines (such as the Asia Pacific Network on Access to Medicines) have been established. In the European Region, best practices for pricing and reimbursement policies were shared during a summer school and two pharmaceutical pricing and reimbursement information network meetings were held for Member States.

56. Key considerations are as follows.

- There is a need for greater political will and support to enable countries to develop domestic financial investment in coverage schemes and implement policies that reduce out-of-pocket payments, such as generic policies, control of supply chain mark-ups and other pricing control methods, as well as reviewing intellectual property legislation, and implementation and use of the flexibilities provided in the TRIPS Agreement.

- Support is needed in countries to improve evidence-based selection of medicines, including selective use of health technology assessment techniques in order to achieve universal health coverage.

- There is a need to establish a fair-pricing model that ensures sustainability for health systems and access for patients as well as sufficient profit for industry to sustain the production of quality products.

- Support to countries is needed to facilitate the transition away from donor support for globally-purchased quality products in order to implement sustainable financing mechanisms and avoid disruptions in medicine availability.

- Platforms for sharing procurement price information, including WHO's Global Price Reporting Mechanism and Vaccine Product, Price and Procurement initiative, offer opportunities for better price negotiation.

- Routine monitoring of data on medicine prices and availability is essential in order to inform decision-making.

(h) Procurement and supply chain management

57. Good procurement practices play a key role in securing competitive prices, ensuring adequate supply of quality products and contributing to appropriate use. Three main challenges to good procurement practice are: limited negotiating power (also discussed in section (g) above); inaccurate quantification of the demand for medicines; and corrupt procurement practices and procedures. Limited negotiating power stems from a lack of information on how prices are derived and on what price other Member States and procurement agencies are paying, and from small economies of scale. Inaccurate quantification is common in the absence of reliable data on needs, stocks and usage, while corruption occurs in the absence of transparent procurement processes. In the light of several notable cases of failure of governance, such as the theft and resale on the black market of malaria medicines purchased with donor funds and accounts of donations from pharmaceutical companies during

emergency relief operations that fail to meet recipients' real needs, there has been recognition by global health partners and donors of a need for change.

58. Good supply chain management ensures the availability of quality products at all levels of the health system and encompasses storage and inventory management, physical distribution and tracking of products. The supply chain is frequently weakened by inadequate infrastructure and the lack of effective management information systems. As immunization programmes expand to include new vaccines and strive to reach more people, they are increasingly constrained by outdated supply chains. This is of particular concern for the delivery of new vaccine formulations, as it is projected that by 2020, four times the cold-chain capacity will be needed compared with 2010.[1] The information systems for tracking stock and associated documentation may also be poorly managed, leading to the oversupply of unnecessary products, the undersupply or stock outs of medicines and vaccines, the inability to monitor supply chain leaks, and the infiltration of substandard and falsified medical products into the supply chain.

59. Normative work by the Secretariat has mainly focused on providing guidance to countries to improve coordination and quality of donations and on the development of pre-packaged medical kits (for example, the Interagency Emergency Health Kit and the piloting and expanding use of noncommunicable diseases kits). To determine which vaccines are needed for crisis-affected populations, in 2013 WHO published a framework for vaccination in acute humanitarian emergencies.[2] WHO, UNICEF, Médecins Sans Frontières International and The Save the Children Fund also jointly developed and launched a Humanitarian Mechanism[3] in May 2017 for more effective and efficient vaccine procurement during emergencies.

60. WHO has also played a role in the coordination of the Interagency Supply Chain Group, an informal coalition of partners, which was established following the work of the United Nations Commission on Life-Saving Commodities for Women and Children with the aim of coordinating and collaborating at the global level to strengthen countries' supply chains.

61. Support has been provided to Member States for the establishment of appropriate policies and good practices, as well as capacity-building for improving governance, efficiency and the quality of procurement and supply-chain management, both in ordinary and emergency situations. In the Eastern Mediterranean Region, the Secretariat has collaborated closely with countries to strengthen good governance and tackle vulnerabilities to corruption through the Good Governance for Medicines programme (see section (a) above).

62. At the regional and country levels there have been enhanced efforts to: increase intercountry collaboration on procurement of medicines and vaccines to enhance transparency; facilitate cross-country learning; strengthen bargaining power; and mitigate high transaction costs. For example,

[1] For further information on the immunization supply chain, see the GAVI Alliance website (http://www.gavi.org/support/hss/immunisation-supply-chain/, accessed 20 February 2018).

[2] Vaccination in acute humanitarian emergencies: a framework for decision making. Geneva: World Health Organization; 2013 (http://www.who.int/hac/techguidance/tools/vaccines_in_humanitarian_emergency_2013.pdf, accessed 20 February 2018).

[3] Accessing affordable and timely supply of vaccines for use in humanitarian emergencies: the Humanitarian Mechanism. WHO working document. Geneva: World Health Organization; 2017 (http://www.who.int/immunization/programmes_systems/sustainability/The_Humanitarian_Mechanism_ToRs.pdf?ua=1, accessed 20 February 2018).

PAHO's Revolving Fund for Strategic Public Health Supplies[1] was used by 41 Latin American and Caribbean countries and territories in 2015 to purchase goods worth more than US$ 70 million. The Organisation of Eastern Caribbean States reported an average cost saving of 37% for buying 25 selected medicines over a five-year period by using a regional pooled procurement mechanism.[2] The Nordic Forum, the BeNeLuxA Initiative, the European Union's Joint Procurement Agreement to Procure Medical Countermeasures, and the Baltic Partnership Agreement are examples of joint procurement efforts that have helped to facilitate procurement in the European Region. In May 2017, eight European countries signed the Valletta Declaration on cooperation in the health sector as a commitment to explore areas for cooperation in procurement such as information sharing, joint procurement and price negotiations. The Regional Office for South-East Asia held a regional consultation in August 2017 with 11 countries in the region, United Nations bodies and international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria to discuss options for intercountry and regional collaboration on public procurement and pricing.

63. WHO regional offices have also been providing technical support to Member States to: improve the accuracy of national vaccine forecasts; enhance demand-consolidation activities (such as the harmonization of product requirements across countries); and improve procurement legislation and practices. Several countries have introduced more strategic public procurement practices such as longer-term contracts, central bargaining and e-procurement, which have contributed to lower prices and fewer stock outs. Countries that currently self-procure vaccines have been supported to consider procuring through alternative mechanisms, such as that developed by UNICEF, for enhanced access to affordable vaccines. Following a call for action as a result of the review in 2016 by the Strategic Advisory Group of Experts on immunization of the global vaccine action plan[3] to redesign supply chains and information systems, WHO and UNICEF have been working in collaboration with other partners to support countries to improve their vaccine supply and cold-chain systems with transformative solutions through the WHO/UNICEF Effective Vaccine Management initiative.[4]

64. Key considerations are as follows.

- Joint or pooled procurement at the national, regional and global levels has proved an effective means to secure lower prices and offers promise for expansion. The scaling up of collaborative approaches for strategic procurement should be supported.

- Increased transparency of procurement procedures offers an opportunity to curb corrupt procurement practice.

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[1] For further information on the PAHO Strategic Fund, see http://www.paho.org/hq/index.php?option=com_content&view=article&id=12163%3Apaho-strategic-fund&catid=8775%3Aabout&Itemid=42005&lang=en (accessed 20 February 2018).

[2] Multi-country regional pooled procurement of medicines: identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific island countries. Geneva, Switzerland, 15–16 January 2017, meeting report. Geneva: World Health Organization; 2007 (http://www.who.int/medicines/publications/PooledProcurement.pdf, accessed 20 February 2018).

[3] 2016 Midterm review of the global vaccine action plan. Geneva: Strategic Advisory Group of Experts on immunization, World Health Organization; 2016 (http://www.who.int/immunization/sage/meetings/2016/october/1_Draft_GVAP_Assessment_report_2016_for_Yellow_Book_28_Sep_2016.pdf, accessed 20 February 2018).

[4] For further information on the Effective Vaccine Management initiative, see http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/(accessed 20 February 2018).

(i) Appropriate prescribing, dispensing and use

65. It has been reported that worldwide, more than 50% of all medicines are prescribed, dispensed or sold inappropriately, and 50% of patients fail to take their prescribed medicines correctly.[1] Medicines continue to be inappropriately prescribed and dispensed in many countries owing to an inadequately trained workforce, poor-quality diagnosis and medication errors. The impact of marketing and promotional activities on doctors' prescribing patterns may also be a contributing factor to irrational prescribing and use.[2] On the patient side, the inability to pay and the unavailability of medicines lead to patients not seeking treatment or reverting to harmful treatments.[3] Furthermore, the overuse and misuse of antimicrobial medicines is leading to increased antimicrobial resistance. Challenges remain in establishing a balance between increasing access to palliative care to those who need it and minimizing misuse and abuse of opioids. Improving appropriate prescribing, dispensing and use requires implementing behavioural change policies, monitoring and commitment to quality of care – a series of complex activities that may currently be beyond the capacity of many health systems.

66. In resolution WHA60.16 (2007) on progress in the rational use of medicines the Health Assembly identified the interventions that had been shown to be effective at that time. It also identified some policy approaches, such as national advisory committees on rational use of medicines, that have generally not been implemented over the past decade. However, the commitment to the achievement of the Sustainable Development Goals, the rise of antimicrobial resistance and the move away from vertical disease-management programmes offers an opportunity to re-evaluate what is most likely to be effective in promoting appropriate use of medicines and thus to update WHO's recommendations in this area.

67. For health care workers, WHO has now established robust methods for developing standard treatment guidelines that can be adapted at the national level, but there needs to be greater emphasis on ensuring that these guidelines are implemented.

68. The Secretariat is leading work on surveillance of the consumption and use of antimicrobial medicines. Training and survey implementation began in 2016. The Secretariat developed a protocol for WHO's hospital point prevalence survey on use of antimicrobial medicines on the basis of that issued by the European Centre for Disease Prevention and Control. The pilot phase of surveys on the use of antimicrobial medicines in hospitals took place in late 2017 and the beginning of 2018 in the African Region and the Region of the Americas: the surveys are being scaled up in 2018. When considering antimicrobial resistance, it is important to note the role of diagnostic devices and infection prevention and control measures in health facilities.

69. The Regional Office for the Americas has published guidance on developing, implementing and monitoring national medicines policies to reinforce strategies for the rational use of medicines. In the African Region, 17 countries have worked to improve the selection, prescribing, dispensing and use of medicines. Activities have included: the revision of national essential medicines lists and/or standard

[1] Promoting rational use of medicines: core components. Geneva: World Health Organization; 2002 (http://apps.who.int/iris/bitstream/10665/67438/1/WHO_EDM_2002.3.pdf, accessed 20 February 2018).

[2] Vancelik S, Beyhun NE, Acemoglu H, Calikoglu O. Impact of pharmaceutical promotion on prescribing decisions of general practitioners in Eastern Turkey. BMC Public Health. 2007;7(1):122. doi: 10.1186/1471-2458-7-122.

[3] Global health community slithers away from snakebite crisis as antivenom runs out. Geneva: Médecins Sans Frontières International; 4 September 2015 (http://www.msf.org/en/article/global-health-community-slithers-away-snakebite-crisis-antivenom-runs-out, accessed 20 February 2018).

treatment guidelines; training on prescribing and use; and surveys to assess prescribing and use of medicines. The Regional Office for South-East Asia has provided support to enable countries to establish medicines and therapeutics committees at the health facility level in order to improve rational use of medicines and national medicine supply systems and increase compliance with national essential medicines lists in prescribing. The Regional Office for Europe collaborates with partners in order to support community pharmacists to promote greater engagement in issues related to the responsible use of medicines and has co-convened a course to provide guidance to countries on understanding how multifaceted models can improve adherence to recommendations on quality care with respect to the use of medicines. The Regional Office for the Eastern Mediterranean has provided training for eight countries on addressing barriers to access to opioid medicines and their use, on topics such as conducting surveys on accessibility, availability, affordability and use, and estimation of future needs. More than 115 Member States have formed independent National Immunization Technical Advisory Groups to guide decision-making on vaccine introductions, immunization schedules and immunization policies.

70. Key considerations are as follows.

- WHO's recommendations for improving prescribing, dispensing and use of medicines should be updated to include effective strategies that are within the capacity of health systems.
- Technical support is required to implement and monitor national medicines policies for the appropriate use of medicines.
- Strategies for effective implementation of the ethical criteria for medicinal drug promotion need to be updated.

(j) Monitoring of pharmaceutical systems

71. Routine monitoring of access to medicines and vaccines and other key data such as expenditure on medicines and vaccines, shortages, consumption, immunization, safety and detection of substandard and falsified medical products is essential to inform policy decisions and improve accountability. The lack of methods for collecting immunization data, for example, has created difficulties for locating unimmunized pockets and assessing the success of immunization programmes.[1] The lack of fully computerized systems and variabilities in how data are collected and validated create discrepancies in reporting and limit the ability of countries to conduct analyses and make well-informed decisions.[2] Although survey-based methods such as the service availability and readiness assessment[3] will be used for some time to monitor progress on the indicators of the Sustainable Development Goals, countries need to move towards much more routine data assessment methods.

[1] 2016 Midterm review of the global vaccine action plan. Geneva: Strategic Advisory Group of Experts on immunization, World Health Organization; 2016 (http://www.who.int/immunization/sage/meetings/2016/october/1_Draft_GVAP_Assessment_report_2016_for_Yellow_Book_28_Sep_2016.pdf, accessed 20 February 2018).

[2] Núñez-Núñez M, Navarro MD, Palomo V, Rajendran NB, del Toro MD, Voss A, et al. The methodology of surveillance for antimicrobial resistance and healthcare-associated infections in Europe (SUSPIRE): a systematic review of publicly available information. Clinical Microbiology and Infection, 2017. doi: 10.1016/j.cmi.2017.07.014.

[3] For further information on Service availability and readiness assessment, see http://www.who.int/healthinfo/systems/sara_introduction/en/ (accessed 20 February 2018).

72. WHO has started working on the development of the newly approved Sustainable Development Goal indicator on access to medicines that includes the proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis. This indicator is similar to the one that was selected for target 8.E of the Millennium Development Goals[1] and that, after failure to establish a reliable and consistent data collection and measurement method, was dropped from the formal reporting on the Millennium Development Goals for the years 2009–2014. WHO has already started engaging with relevant international agencies and experts on monitoring indicators of the Sustainable Development Goals to ensure that reliable, measurable and available metrics are developed for this newly approved indicator.

73. The Secretariat's work to strengthen monitoring includes the development of monitoring and reporting mechanisms and the provision of technical support to Member States on data collection and the development of strong information management systems. Key areas of work mentioned throughout this report include: collection of information on suspected adverse events resulting from medicinal products (section (e)); collection of data concerning substandard and falsified medical products through the Global Surveillance and Monitoring System (section (e)); development of a smartphone application for measuring medicine price and availability (section (g)); surveillance of the consumption and use of antimicrobial medicines (section (i)); and development of a global medicine-shortage notification system to track and monitor medicine shortages (summarized in the report on the progress of resolution WHA69.25 – see paragraphs 12–16 of the main report, above). In addition, the WHO/UNICEF joint reporting process[2] provides data on performance, planning, financing and quality indicators for immunization to all Member States on an annual basis and has helped to avoid the publication and dissemination of discrepant immunization system performance data.

74. Key considerations are as follows.

- A new emphasis on data and monitoring is required in order to support policy decisions and improve accountability, particularly for key indicators such as access, expenditure, claims data and usage.

(k) Collaboration

75. The pharmaceutical system includes myriad stakeholders including pharmacists, health care workers, patient groups and consumers, wholesalers, academic institutions, donors, policy-makers, regulatory authorities, bodies in the United Nations system, 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 collaborates with stakeholders in a multitude of ways, some of which are mentioned in this report. A non-exhaustive list of entities working on access to medicines (WHO collaborating centres, bodies in the United Nations system and related organizations, partners and non-State actors in official relations with WHO) is provided in Appendix 4.

[1] Target 8.E of the Millennium Development Goals: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

[2] For further information on the WHO/UNICEF joint reporting process, see http://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/ (accessed 20 February 2018).

76. Key considerations are as follows.

- WHO can use its convening power and advantage compared with other organizations to support increased interorganizational, regional and country collaboration in order to network, share best practices and improve information sharing.

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

[1] Unless otherwise indicated.

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

[1] Unless otherwise indicated.

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

[1] Unless otherwise indicated.

Resolution[1] (year)	**Title**
SEA/RC60/R8 (2007)	Challenges in polio eradication
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
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)

[1] Unless otherwise indicated.

Appendix 2

DOCUMENTS REVIEWED FOR THE PURPOSES OF PREPARING THIS REPORT

A70/17	Review of the Pandemic Influenza Preparedness Framework
A70/20	Addressing the global shortage of, and access to, medicines and vaccines
A70/21	Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property
A70/22	Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
A70/23	Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products
A70/25	Global vaccine action plan
A70/38	Progress reports: Health systems: I. Progress in the rational use of medicines (resolution WHA60.16)
A70/38	Progress reports: Health systems: J. Regulatory system strengthening for medical products (resolution WHA67.20)
A69/22	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
A69/24	Global action plan on antimicrobial resistance
A69/34	Global vaccine action plan
A69/42	Addressing the global shortages of medicines, and the safety and accessibility of children's medication
A69/43	Progress reports: Promoting health through the life course: C. Strengthening of palliative care as a component of comprehensive care throughout the life course (resolution WHA67.19)
A69/43	Progress reports: Health systems: G. Access to essential medicines (resolution WHA67.22)
A68/36	Progress reports: Health systems: N. Progress in the rational use of medicines (resolution WHA60.16)
A68/36	Progress reports: Preparedness, surveillance and response: O. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (resolution WHA64.5)
A67/30	Access to essential medicines
A67/31	Strengthening of palliative care as a component of integrated treatment throughout the life course
A67/32	Regulatory system strengthening
A67/40	Progress reports: Health systems: I. Global strategy and plan of action on public health, innovation and intellectual property (resolution WHA61.21)
A66/19	Global vaccine action plan
A66/27	Progress reports: Health systems: L. Progress in the rational use of medicines (resolution WHA60.16)
AFR/RC67/2	The work of WHO in the African Region 2016–2017: Biennial report of the Regional Director
AFR/RC67/INF. DOC/1	Progress report on implementation of the Regional Strategic Plan on Immunization

AFR/RC66/2	The work of WHO in the African Region, 2015–2016: Report of the Regional Director – illustrative report
AFR/RC66/13	Regional Strategy on Regulation of Medical Products in the African Region, 2016–2025
AFR/RC66/19	Sixty-sixth session of the WHO Regional Committee for Africa: Final report
AFR/RC65/2	The work of WHO in the African Region: Biennial report of the Regional Director, 2014–2015
AFR/RC65/14	Sixty-fifth session of the WHO Regional Committee for Africa: Final report
AFR/RC65/INF. DOC/7	Progress report on the establishment of the African Medicines Agency
AFR/RC64/14	Sixty-fourth session of the WHO Regional Committee for Africa: Final report
AFR/RC63/7	Strengthening the capacity for regulation of medical products in the African Region
AFR/RC63/16	Sixty-third session of the WHO Regional Committee for Africa: Final report
SEA/RC70/2	The work of the WHO in the South-East Asia Region 2016: Report of the Regional Director, 1 January–31 December 2016
SEA/RC70/9	Access to medicines
SEA/RC70/13 Rev.1	Progress reports on selected Regional Committee resolutions: antimicrobial resistance (SEA/RC68/R3)
SEA/RC70/13 Rev.1	Progress reports on selected Regional Committee resolutions: Consultative Expert Working Group on Research and Development (CEWG): Financing and Coordination (SEA/RC65/R3)
SEA/RC69/2	The work of the WHO in the South-East Asia Region: Report of the Regional Director, 1 January–31 December 2015
SEA/RC69/9	Antimicrobial resistance
SEA/RC69/13	The Decade for Health Workforce Strengthening in the SEA Region 2015–2024: the first review of progress, challenges and opportunities
SEA/RC69/18	Progress reports on selected Regional Committee resolutions: 2012: Year of Intensification of Routine Immunization in the South-East Asia Region: Framework for increasing and sustaining coverage (SEA/RC64/R3)
SEA/RC68/2	The work of the WHO in the South-East Asia Region: Report of the Regional Director, 1 January–31 December 2014
SEA/RC68/11	Policy and technical topics: Antimicrobial resistance
SEA/RC68/16	Progress reports on selected Regional Committee resolutions: Effective management of medicines (SEA/RC66/R7)
SEA/RC67/2	The work of the WHO in the South-East Asia Region 2013: Biennial report of the Regional Director, 1 January 2012–31 December 2013
SEA/RC66/15	Progress reports on selected Regional Committee resolutions: National Essential Drug Policy Including the Rational Use of Medicines (SEA/RC64/R5)
EUR/RC67/5	The work of WHO in the European Region in 2016–2017: Interim report of the Regional Director
EUR/RC67/11	Strengthening Member State collaboration on improving access to medicines in the WHO European Region
EUR/RC66/5	Moving from vision to action: Report of the Regional Director on the work of WHO in the European Region in 2014–2015
EUR/RC65/5 Rev.1	The work of WHO in the European Region in 2014–2015: Interim report of the Regional Director
EUR/RC64/5	Realizing our vision: Report of the Regional Director on the work of WHO in the European Region in 2012–2013

EUR/RC64/15 Rev.1	European Vaccine Action Plan 2015–2020
EUR/RC64/19	Progress reports: E. The European strategic action plan on antibiotic resistance
EUR/RC63/5	The work of WHO in the European Region in 2012–2013: Interim report of the Regional Director
EM/RC64/INF. DOC.4	Progress report on the implementation of the Eastern Mediterranean vaccine action plan 2016–2020
EM/RC63/3	The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director 2015
EM/RC62/2	The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director 2014
EM/RC61/4	The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director 2013
EM/RC60/2	The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director 2012
EM/RC59/2	The work of WHO in the Eastern Mediterranean Region: Annual report of the Regional Director, 1 January–31 December 2011
WPR/RC67/2	Report of the Regional Director: The work of WHO in the Western Pacific Region 1 July 2015–30 June 2016
WPR/RC67/10	Progress reports on technical programmes: 15.5 Antimicrobial resistance
WPR/RC67/10	Progress reports on technical programmes: 15.6 Essential medicines
WPR/RC66/2	Report of the Regional Director: The work of WHO in the Western Pacific Region 1 July 2014–30 June 2015
WPR/RC66/9	Progress reports on technical programmes: 14.6 Regulatory systems strengthening
WPR/RC64/9	Progress reports on technical programmes: 15.7 Expanded Programme on Immunization
WPR/RC63/11	Progress reports on technical programmes: (7) Expanded Programme on Immunization

Appendix 3

RECOMMENDATIONS OF THE REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES[1] AND WHO'S ACTIVITIES IN THE AREA OF ACCESS TO MEDICINES

2. INTELLECTUAL PROPERTY LAWS AND ACCESS TO HEALTH TECHNOLOGIES			
No.	**Recommendation[2]**	**Entities concerned[3]**	**WHO's activities, including those carried out in collaboration with WTO and WIPO**
2.6.1	World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on the TRIPS Agreement and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies.	WTO Members	• WHO provides technical support to countries to build capacity to develop and implement intellectual property policies and management, including guidance on how to develop health-sensitive patent legislation and patentability standards. • On request, WHO also provides technical support to countries to improve access to affordable medicines, including through the use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). • WHO also supports initiatives to increase access to patent information. • The Directors-General of WHO, WIPO and WTO have established a trilateral cooperation arrangement that includes annual symposia and training workshops[4] and a trilateral study on promoting access to medical technologies and innovation,[5] which is available in all six official United Nations languages, as well as an online course.

[1] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: promoting innovation and access to health technologies. Geneva: United Nations High-Level Panel on Access to Medicines; 2016 (http://www.unsgaccessmeds.org/final-report, accessed 20 February 2018).

[2] As stated in the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[3] As specified in the recommendation of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[4] For further information, see http://www.wipo.int/policy/en/global_health/events.html (accessed 20 February 2018).

[5] Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2013 (http://www.who.int/phi/promoting_access_medical_innovation/en/, accessed 20 February 2018).

			• WHO has published or co-published a range of guidance documents, including: Global report on access to hepatitis C treatment: focus on overcoming barriers[1] (2016); The role of intellectual property in local production in developing countries: opportunities and challenges[2] (2016); Increasing access to HIV treatment in middle-income countries: key data on prices, regulatory status, tariffs and the intellectual property situation[3] (2014); Using TRIPS flexibilities to improve access to HIV treatment[4] (2011); and Guidelines for the examination of pharmaceutical patents: developing a public health perspective[5] (2007). • WHO contributed to the consideration of the report of the High-Level Panel on Access to Medicines by WTO Members at the WTO TRIPS Council meetings in November 2016 and March 2017.

[1] Global report on access to hepatitis C treatment: focus on overcoming barriers. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1, accessed 20 February 2018).

[2] The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 (http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf, accessed 20 February 2018).

[3] Increasing access to HIV treatment in middle-income countries: key data on prices, regulatory status, tariffs and the intellectual property situation. Geneva: World Health Organization; 2014 (http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf?ua=1, accessed 20 February 2018).

[4] Using TRIPS flexibilities to improve access to HIV treatment. Joint United Nations Programme on HIV/AIDS, World Health Organization, United Nations Development Programme; 2011 (http://apps.who.int/medicinedocs/documents/s18392en/s18392en.pdf, accessed 20 February 2018).

[5] Correa C. Guidelines for the examination of pharmaceutical patents: developing a public health perspective – a working paper. International Centre for Trade and Sustainable Development, World Health Organization, United Nations Conference on Trade and Development; 2007 (http://apps.who.int/medicinedocs/documents/s21419en/s21419en.pdf, accessed 20 February 2018).

2.6.1.(a)	WTO Members must make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.	WTO Members	• WHO provides technical support to countries to build capacity to develop and implement intellectual property policies and management, including guidance on how to develop health-sensitive patent legislation and patentability standards. • On request, WHO provides technical support to countries to improve access to affordable medicines, including through the use of the flexibilities provided in the TRIPS Agreement, and guidance on how to negotiate trade agreements insofar as they have an impact on public health. • WHO has provided technical support and training to numerous countries and regions over the past 10 years.[1] • WHO also supports initiatives to increase access to patent information. • WHO has published a range of guidance documents, including: The role of intellectual property in local production in developing countries: opportunities and challenges[2] (2016); Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade[3] (2013); and Guidelines for the examination of pharmaceutical patents: developing a public health perspective[4] (2007).

[1] For further information, see Overview on technical cooperation programmes relating to the implementation of the TRIPS Agreement (http://www.who.int/phi/wto_communications/en/, accessed 20 February 2018).

[2] The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 (http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf, accessed 20 February 2018).

[3] Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2013 (http://www.who.int/phi/promoting_access_medical_innovation/en/, accessed 20 February 2018).

[4] Correa C. Guidelines for the examination of pharmaceutical patents: developing a public health perspective. International Centre for Trade and Sustainable Development, United Nations Conference on Trade and Development, World Health Organization; 2007 (http://apps.who.int/medicinedocs/documents/s21419en/s21419en.pdf, accessed 20 February 2018).

2.6.1.(a)(i)	The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.	UNCTAD, UNDP, WHO, WIPO, WTO	• The International Centre for Trade and Sustainable Development, UNCTAD and WHO have developed the following guidance for the examination of pharmaceutical patents: The role of intellectual property in local production in developing countries: opportunities and challenges[1] (2016). • A WHO/WIPO/WTO technical workshop on patentability criteria was held in 2015. • WHO and UNCTAD submitted a grant proposal to UNITAID in 2017 to expand work in this area.
2.6.1.(a)(ii)	These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.	UNCTAD, UNDP, WHO, WIPO, WTO	• On request, WHO provides technical support to countries to build capacity to develop and implement intellectual property policies and management, including guidance on how to develop health-sensitive patent legislation and patentability standards. • On request, WHO provides technical support to countries to improve access to affordable medicines, including through the use of the flexibilities provided in the TRIPS Agreement, and in negotiations of relevant chapters of free trade agreements. • WHO also supports initiatives to increase access to patent information. • The International Centre for Trade and Sustainable Development, UNCTAD and WHO have developed the following guidance for the examination of pharmaceutical patents: The role of intellectual property in local production in developing countries: opportunities and challenges[1] (2016).

[1] The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 (http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf, accessed 20 February 2018).

2.6.1.(b)	Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.	Governments	• On request, WHO provides technical support to countries to improve access to affordable medicines, including through the use of the flexibilities provided in the TRIPS Agreement, and in negotiations of relevant chapters of free trade agreements. • WHO has published the following guidance on implementing the flexibilities contained in the TRIPS Agreement: Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade[1] (2013). • An annual Geneva-based training workshop has been organized in collaboration with WIPO and WTO (the WTO annual Workshop on Trade and Public Health). • WHO has also published the following guidance: Guide for the application and granting of compulsory licenses and authorization of government use of pharmaceutical patents[2] (2009); and Remuneration guidelines for non-voluntary use of a patent on medical technologies[3] (2005).
2.6.1.(c)	WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.	WTO Members	• At the TRIPS Council meeting on 30 January 2017, WTO Members took note of the entry into force of the amended TRIPS Agreement. They also requested capacity-building to make the compulsory licensing system work effectively as a procurement tool.

[1] Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2013 (http://www.who.int/phi/promoting_access_medical_innovation/en/, accessed 20 February 2018).

[2] Guide for the application and granting of compulsory licences and authorization of government use of pharmaceutical patents. Geneva: World Health Organization; 2009 (http://apps.who.int/medicinedocs/documents/s19902en/s19902en.pdf, accessed 20 February 2018).

[3] UNDP, WHO. Remuneration guidelines for non-voluntary use of a patent on medical technologies. Geneva: World Health Organization; 2005 (http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf, accessed 20 February 2018).

2.6.1.(d)	Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.	Governments and the private sector	• Not applicable
2.6.1.(e)	Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.	Governments	• WHO advocates for and provides support to countries to align health, development and trade policies with one another and provides technical support on request in collaboration with other relevant United Nations entities. • WHO has published the following guides: Trade and health: towards building a national strategy[1] (2015), which provides guidance on how to harness and maximize opportunities to promote public health and minimize the risks and threats of trade policies; and Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region[2] (2010).
2.6.2.(a)	Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.	Public funders of research	• In May 2017, 20 funders and nongovernmental organizations made a commitment to implement WHO standards on dissemination of research results.[3] These entities have made a commitment to develop a publicly available policy, making specific framework commitments on research registration, methods and results disclosure, and embedding dissemination standards as a quality criterion for future grant-funding decisions.

[1] Smith R, Blouin C, Mirza Z, Beyer P, Drager N Eds. Trade and health: towards building a national strategy. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/183934/1/9789241565035_eng.pdf?ua=1, accessed 20 February 2018).

[2] El Said MK. Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2010 (http://apps.who.int/medicinedocs/documents/s21391en/s21391en.pdf, accessed 20 February 2018).

[3] For further information, see the joint statement on public disclosure of results from clinical trials (http://www.who.int/ictrp/results/jointstatement/en/, accessed 20 February 2018).

2.6.2.(b)	Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.	Universities and research institutions	• Universities Allied for Essential Medicines is publishing scorecards that provide transparency on performance of universities on prioritization of public health objectives. Following input from WHO, Universities Allied for Essential Medicines has included research results metrics in its scorecard.
2.6.2.(c)	Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public.	Universities and research institutions	• Universities Allied for Essential Medicines is publishing scorecards that provide transparency on performance of universities on prioritization of public health objectives. Following input from WHO, Universities Allied for Essential Medicines has included research results metrics in its scorecard.

NEW INCENTIVES FOR RESEARCH AND DEVELOPMENT OF HEALTH TECHNOLOGIES			
No.	**Recommendation[1]**	**Entities concerned[2]**	**WHO's activities**
3.4.(a)	It is imperative that governments increase their current levels of investment in health technology innovation to address unmet needs.	Governments	• WHO will continue research and development prioritization efforts through the Global Observatory on Health Research and Development, the research and development blueprint for action to prevent epidemics and the global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics.[3] • The Secretariat is considering terms of reference for a possible Expert Committee on Health Research and Development

[1] As stated in the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[2] As specified in the recommendation of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[3] Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/, accessed 20 February 2018).

3.4.(b)	Stakeholders, including governments, the biomedical industry, institutional funders of health care and civil society, should test and implement new and additional models for financing and rewarding public health research and development (R&D), such as the transaction taxes and other innovative financing mechanisms.	Governments, the biomedical industry, institutional funders of health care and civil society	• The Consultative Expert Working Group on Research and Development: Financing and Coordination has provided overarching guidance on this work. • WHO and the Drugs for Neglected Diseases initiative have established the Global Antibiotic Research & Development Partnership and WHO has supported the creation of the Coalition for Epidemic Preparedness Innovations.
3.4.(c)	Building on current discussions at the WHO, the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all. Such a Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and antimicrobial resistance and must complement existing mechanisms.	United Nations Secretary-General	• The Consultative Expert Working Group on Research and Development: Financing and Coordination recommended the development of a research and development treaty in 2012. • WHO will continue research and development prioritization efforts through the Global Observatory on Health Research and Development, the research and development blueprint for action to prevent epidemics and the global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. • The Secretariat is considering terms of reference for a possible Expert Committee on Health Research and Development.
3.4.(d)	As a preparatory step, governments should form a Working Group to begin negotiating a Code of Principles for Biomedical R&D. The Principles would apply to public R&D funds and should also be adopted by private and philanthropic funders, product development partnerships, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress in negotiating and implementing a Code of Principles as a preparatory step to negotiating the Convention in the United Nations General Assembly.	Governments	• WHO support for the definition of the scope and requirements needed for the development of a code of principles for biomedical research and development is currently under consideration.

GOVERNANCE, ACCOUNTABILTY AND TRANSPARENCY			
No.	**Recommendation[1]**	**Entities concerned[2]**	**WHO's activities**
4.3.1.(a)	Governments must review the situation of access to health technologies in their countries in light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR) and other relevant United Nations entities. The results of these assessments should be made publicly available. Civil society should be financially supported to submit their own shadow reports on innovation and access to health technologies. Such national reviews should be repeated at regular intervals.	Governments	• Not applicable
4.3.1.(b)	Governments should strengthen national level policy and institutional coherence between trade and intellectual property, the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. Appropriate member/s of the national executive who can manage competing priorities, mandates and interests should convene such bodies. The deliberations and decisions of such groups should operate with a maximum of transparency. Civil society should be financially supported to participate and submit their shadow reports on innovation and access to health technologies.	Governments	• WHO advocates for and provides support to countries to align health, development and trade policies with one another. In that connection, WHO has published the following guidelines for negotiators and implementers on TRIPS-plus provisions: Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region[3] (2010). • Training activities that WHO organizes or to which it contributes, such as the WTO annual Workshop on Trade and Public Health, call for a holistic, coherent and inclusive approach that is based on coordination among all competent government departments.

[1] As stated in the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[2] As specified in the recommendation of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

[3] El Said MK. Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2010 (http://apps.who.int/medicinedocs/documents/s21391en/s21391en.pdf, accessed 20 February 2018).

4.3.2.(a)	The United Nations Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access. Challenges and progress on innovation and access to health technologies under the ambit of the 2030 Agenda, as well as progress made in implementing the recommendations of this High-Level Panel, should be monitored by this body. Membership should comprise of representatives from United Nations and multilateral organizations, civil society, governments, academia and the private sector.	United Nations Secretary-General	• Not applicable
4.3.2.(b)	The United Nations Secretary-General should establish an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organizations like the WTO. The taskforce, charged with overseeing the implementation of the High-Level Panel's recommendations, should be coordinated by the United Nations Development Group and report annually to the United Nations Secretary-General on progress made in enhancing United Nations system-wide coherence.	United Nations Secretary-General	• Extensive cooperation between WTO and the other relevant United Nations entities is already in place, including an annual coordination meeting that is convened by WHO as the United Nations specialized agency for health.
4.3.2.(c)	The United Nations General Assembly should convene a Special Session no later than 2018 on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access as set out in the 2030 Agenda. Civil society should be financially supported to participate and submit their reports on innovation and access to health technologies at this Special Session.	United Nations Secretary-General	• Not applicable
4.3.3.(a)	Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.	Biomedical private sector companies	• WHO will continue research and development prioritization efforts through the Global Observatory on Health Research and Development, the research and development blueprint on action to prevent epidemics and the global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. • The Secretariat is considering terms of reference for a possible Expert Committee on Health Research and Development.

4.3.3.(b)	Private sector companies should implement the following:	Private sector companies	• Not applicable
4.3.3.(b)(i)	A publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures and lines of accountability; and	Private sector companies	• Not applicable
4.3.3.(b)(ii)	A governance system that includes direct board-level responsibility and accountability on improving access to health technologies.	Private sector companies	• Not applicable
4.3.4.(a)	Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to:	Governments	• Not applicable
4.3.4.(a)(i)	The costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and	Governments	• WHO advocates for increased transparency regarding the costs of research and development and production.
4.3.4.(a)(ii)	Any public funding received in the development of the health technology, including tax credits, subsidies and grants.	Governments	• WHO advocates for increased transparency regarding the costs of research and development and production.
4.3.4.(b)	Building on the Global Price Reporting Mechanism, Vaccine Product, Price and Procurement and other initiatives, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.	WHO	• WHO provides support to maintain existing and develop new platforms for sharing procurement price information, including the Global Price Reporting Mechanism and the Vaccine Product, Price and Procurement initiative.
4.3.5.(a)	Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinicaltrials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.	Governments	• In May 2017, 20 funders and nongovernmental organizations made a commitment to implement WHO standards on dissemination of research results.[1] These entities have made specific framework commitments on research registration, methods and results disclosure, and on embedding dissemination standards as a quality criterion for future grant-funding decisions. WHO advocates that all public sector funders of clinical trials sign the WHO joint statement on public disclosure of results from clinical trials.

[1] For further information, see the Joint statement on public disclosure of results from clinical trials (http://www.who.int/ictrp/results/jointstatement/en/, accessed 20 February 2018).

4.3.5.(b)	To facilitate open collaboration, reconstruction and reinvestigation of failures, governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion. Those undertaking clinical trials must not prevent researchers from publishing their findings.	Governments	• WHO advocates for all funders of research and development to align their reporting of clinical trial results with WHO standards. • In May 2017, WHO called for access to methods (in the form of protocols) to be made available at the time of results disclosure in order to assess outcome switching. • WHO is initiating a mapping process of the status of individual participant data sharing from clinical trials as a basis for agreeing on a set of global standards in this area. One focus of the process is to ensure that developing country perspectives are fully addressed in the development of WHO standards.
4.3.6.(a)	Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include: • standard international common names for biological products; • international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and • dates of grant and expiry.	Governments	• WHO supports efforts to establish and maintain publicly accessible databases containing patent information. • WHO has published patent information on the treatment for hepatitis C and other treatments, including for noncommunicable diseases. • WHO has published the following guidelines for conducting patent searches: How to conduct patent searches for medicines: a step-by-step guide[1] (2010).

NA: not applicable.

[1] How to conduct patent searches for medicines: a step-by-step guide. New Delhi: WHO Regional Office for South-East Asia and Manila: WHO Regional Office for the Western Pacific; 2010 (http://apps.who.int/medicinedocs/documents/s17398e/s17398e.pdf, accessed 20 February 2018).

Appendix 4

ENTITIES THAT CARRY OUT WORK ON ACCESS TO MEDICINES[1]

WHO collaborating centres[2]

- WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (Ghana)
- WHO Collaborating Centre for Antimicrobial Resistance (South Africa)
- WHO Collaborating Centre for Biological Standardization (United States of America)
- WHO Collaborating Centre for Clinical Laboratory Standards and Accreditation (United States of America)
- WHO Collaborating Centre for Drug Information (Malaysia)
- WHO Collaborating Centre for Drug Quality Assurance (Australia)
- WHO Collaborating Centre for Drug Quality Assurance (China)
- WHO Collaborating Centre for Drug Statistics Methodology (Norway)
- WHO Collaborating Centre for Evidence Synthesis for Infectious and Tropical Diseases (United Kingdom of Great Britain and Northern Ireland)
- WHO Collaborating Centre for Evidence-Based Research Synthesis and Guideline Development (Italy)
- WHO Collaborating Centre for Gonorrhoea and Other Sexually Transmitted Infections (Sweden)
- WHO Collaborating Centre for Governance, Transparency and Accountability in the Pharmaceutical Sector (Canada)
- WHO Collaborating Centre for Health Technology (Mexico)
- WHO Collaborating Centre for Health Technology Assessment (Argentina)
- WHO Collaborating Centre for International Drug Monitoring (Sweden)
- WHO Collaborating Centre for International Laboratory for Biological Standards (United Kingdom of Great Britain and Northern Ireland)
- WHO Collaborating Centre for Knowledge Translation and Health Technology Assessment in Health Equity (Canada)
- WHO Collaborating Centre for Medicines Quality Assurance (Singapore)
- WHO Collaborating Centre for Monitoring of Anthelminthic Drug Efficacy for Soil-transmitted Helminthiasis (Belgium)
- WHO Collaborating Centre for Pharmaceutical Policies (Brazil)
- WHO Collaborating Centre for Pharmaceutical Policy (United States of America)
- WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (Austria)
- WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting (Netherlands)
- WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services (India)
- WHO Collaborating Centre for Prevention and Control of Chronic Respiratory Diseases (Japan)
- WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy (India)
- WHO Collaborating Centre for Quality Assessment in Haematology (United Kingdom of Great Britain and Northern Ireland)
- WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices (Germany)
- WHO Collaborating Centre for Quality Assurance of Medicines (South Africa)
- WHO Collaborating Centre for Rational Use of Medicines (Argentina)
- WHO Collaborating Centre for Regulatory Control of Pharmaceuticals (Malaysia)

[1] This list is non-exhaustive.

[2] The country of each WHO Collaborating Centre is shown in parentheses.

- WHO Collaborating Centre for Research and Training in Pharmacoepidemiology (Spain)
- WHO Collaborating Centre for Research on Bioequivalence Testing of Medicines (Germany)
- WHO Collaborating Centre for Standardization and Evaluation of Biologicals (Canada)
- WHO Collaborating Centre for Standardization and Evaluation of Biologicals (Japan)
- WHO Collaborating Centre for Standardization and Evaluation of Vaccines (Germany)
- WHO Collaborating Centre for Strengthening Pharmacovigilance Practices (Morocco)
- WHO Collaborating Centre for Training and Policy on Access to Pain Relief (India)
- WHO Collaborating Centre for Training and Research in Essential Medicines and Rational Use of Medicines (India)
- WHO Collaborating Centre for Training on Medical Product Registration and Regulation (Tunisia)

Partners and non-State actors in official relations with WHO

- AMREF Health Africa
- Association Africaine des Centrales d'Achats de Médicaments Essentiels
- Bill & Melinda Gates Foundation
- Council on Health Research for Development
- Drugs for Neglected Diseases initiative
- Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
- Health Technology Assessment International
- International Alliance for Biological Standardization
- International Association for Hospice and Palliative Care Inc.
- International Association for the Study of Pain
- International Diabetes Federation
- International Federation of Pharmaceutical Manufacturers and Associations
- International Insulin Foundation
- International Network for Cancer Treatment and Research
- International Organization for Standardization
- International Pharmaceutical Students' Federation
- International Pharmaceutical Federation
- International Union Against Tuberculosis and Lung Disease
- International Union of Basic and Clinical Pharmacology
- Knowledge Ecology International
- Medicines for Europe
- Medicines for Malaria Venture
- Medicines Patent Pool Foundation
- Médecins Sans Frontières International
- Medicus Mundi International International Network
- OXFAM
- PATH
- Public Services International
- Stichting Health Action International
- The Commonwealth Pharmacists Association
- The Save the Children Fund
- The Worldwide Hospice Palliative Care Alliance
- Union for International Cancer Control
- United States Pharmacopeial Convention
- World Hepatitis Alliance

Bodies of the United Nations system and related organizations
– Organisation for Economic Co-operation and Development – South Centre – UNCTAD – UNDP – UNFPA – UNHCR – UNICEF – UNIDO – UNITAID – UNODC – World Bank – WIPO – WTO

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