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Global strategies and plans of action that are scheduled to expire within one year

Global strategy and plan of action on public health, innovation and intellectual property, for the period 2008-2022

Report by the Director-General

1. Following a two-year negotiation process, the Sixty-first World Health Assembly in May 2008 adopted in resolution WHA61.21 the global strategy and plan of action on public health, innovation and intellectual property for the period 2008–2015. In the following year, the Health Assembly adopted resolution WHA62.16 (2009), in which it finalized the list of stakeholders responsible for the implementation of each element and sub-element, established progress indicators for each element, and proposed time frames in which the specified actions should be accomplished.

2. Concerned about the pace of implementation, the Sixty-eighth World Health Assembly in 2015 decided in resolution WHA68.18 to extend the time frame of the plan of action from 2015 until 2022 and to undertake an overall programme review. In 2017, the report of the review panel recommended a way forward, including details of what elements or actions should be added, enhanced or concluded in the next stage of implementation until 2022.

3. This report responds to the request to the WHO Secretariat to draw up a detailed implementation plan and establish a mechanism to support implementation and monitoring of the global strategy and plan of action.[1] Additionally, in 2020, in decision WHA73(15), on WHO reform: governance, the Health Assembly requested that the Director-General systematically include as substantive items on the provisional agendas of meetings of WHO's governing bodies any global strategies or action plans that are scheduled to expire within one year in order to allow Member States to consider whether the global strategies or action plans have fulfilled their mandates, should be extended and/or need to be adjusted; this is the case for the global strategy and plan of action on public health, innovation and intellectual property in 2022.

[1] See document A71/13, Annex, recommendation 32: The WHO Secretariat to draw up a detailed implementation plan and establish a mechanism to support implementation and monitoring of the global strategy and plan of action. *(Indicator: Implementation plan published and a mechanism for implementation and monitoring of the global strategy and plan of action established in 2018, and progress reports published at least once a year.)*

PROGRESS MADE IN IMPLEMENTING THE RECOMMENDATIONS OF THE OVERALL PROGRAMME REVIEW PANEL

Prioritizing research and development needs

4. WHO's Global Observatory on Health Research and Development (hereinafter the "Observatory") and Global Malaria Programme have developed and implemented an approach to prioritize research and development for malaria (a Type III disease, namely one that is overwhelmingly or exclusively incident in developing countries). The experience gained and the feedback received on the report related to this prioritization approach informed the development of new initiatives for monitoring and prioritization of research and development by the Global Malaria Programme, such as those related to the review and analysis of products in the pipeline and the development of desired product profile characteristics for new products in several areas, including vaccines, therapeutics and vector control.[1,2]

5. The Observatory continues to provide up-to-date information and analyses to support the prioritization of research needs and to identify gaps, and regularly updates its narrative reports on research and development priorities.[3] In 2021, it published two new reviews of antibacterial products in the preclinical and clinical phases of development.[4,5] In addition, it continues to add newly developed WHO target product profiles, such as those for products and diagnostics that target resistant pathogens and coronavirus disease (COVID-19).[6] In April 2021, the Director-General established WHO's Science Council, comprising international experts from a broad range of disciplines to provide guidance on WHO's science and research strategy and facilitate the adoption of new ideas and opportunities in research and innovation to improve global health.[7]

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[1] WHO. Analysis of research and development priorities for Malaria – working paper. Geneva: World Health Organization; 2018 (https://www.who.int/publications/m/item/analysis-of-research-and-development-priorities-for-malaria-working-paper, accessed 23 November 2021).

[2] Global Observatory on Health Research and Development. WHO preferred product characteristics and clinical development considerations for malaria vaccines: draft for public consultation. Geneva: World Health Organization; 2021 (https://cdn.who.int/media/docs/default-source/malaria/ppcs-etc/who-ucn-gmp-2021.03-eng.pdf?sfvrsn=b07d12ef_10, accessed 23 November 2021).

[3] Global Observatory on Health Research and Development/Analyses and syntheses. Geneva: World Health Organization; 2021 (https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses, accessed 23 November 2021).

[4] Global Observatory on Health Research and Development. Antibacterial products in clinical development for priority pathogens. Geneva: World Health Organization; 2021 (https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/antibacterial-products-in-clinical-development-for-priority-pathogens, accessed 23 November 2021).

[5] Global Observatory on Health Research and Development. WHO antibacterial preclinical pipeline review. Geneva: World Health Organization; 2021 (https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/who-antibacterial-preclinical-pipeline-review, accessed 23 November 2021).

[6] Global Observatory on Health Research and Development. Links to WHO target product profiles (TPPs) and product profile characteristics (PPCs). Geneva: World Health Organization (https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs, accessed 23 November 2021).

[7] WHO. Science Council. Geneva: World Health Organization (https://www.who.int/groups/science-council, accessed 23 November 2021).

Promoting research and development

6. The Observatory continues to serve as WHO's authoritative source of global information and strategic direction on research for health. It does so by serving as a global analytical and information-sharing mechanism to promote and disseminate relevant information and the results of analyses on health research and development, and to help to coordinate efficient and equitable priority-setting for new investments in health research based on public health needs. This activity, supported by the active engagement of groups of diverse stakeholders, including the Science Council, serves to promote evidence-informed decisions on new investments in health research based on public health needs in a coordinated and equitable manner.

7. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases commissioned a streamlined "end-to-end approach" to support product development for poverty-related and neglected diseases. The research project aims to develop a new strategic approach to prioritizing and selecting candidate products, evaluating their health and economic impact, estimating resource needs, and matching needs to different financing instruments. To demonstrate the value of this approach, the project is focusing on Chagas disease and hookworm and other soil-transmitted helminths, two of the most neglected diseases based on the very low number of product candidates currently in the pipeline. Once developed, the approach could be applied to a larger group of poverty-related and neglected diseases and conditions.

Building and improving research capacity

8. The Secretariat provides support to national and regional regulatory networks, such as the African Vaccine Regulatory Forum, in order to strengthen vaccines regulatory functions and systems in Africa. The Forum, an informal capacity-building platform aimed also at improving the regulatory oversight of interventional clinical trials being conducted in Africa, received support from the Secretariat for implementation of its joint reviews guideline including a training manual for inspection of clinical trial sites, and for development of its compassionate use guide.[1] The Secretariat also provided specific support to the Forum for COVID-19 response activities, including the development of training material for the use of its MedNet and DataForm platforms for joint reviews. In December 2019, the Secretariat reactivated the Paediatric Regulatory Network, a global network providing a platform for exchange of regulatory information on paediatric medical products to support the availability of quality-assured medical products for children.[2] The membership in the network grew from 13 national regulatory authorities in 2019 to 35 in 2020.

9. In 2020, the WHO-National Control Laboratory Network for Biologicals successfully pursued membership agreements and gained new members, thereby increasing the number of participating national regulatory authorities and national control laboratories to 45.[3] WHO e-learning courses on the basics of vaccine safety allowed the training of 1877 professionals from Member States. Three

[1] WHO. African Vaccine Regulatory Forum (AVAREF). Geneva: World Health Organization (https://www.afro.who.int/health-topics/immunization/avaref, accessed 23 November 2021).

[2] WHO. WHO Paediatric Regulatory Network. Geneva: World Health Organization (https://www.who.int/initiatives/gap-f/who-paediatric-regulatory-network#:~:text=The%20Paediatric%20Regulatory%20Network%20is,communication%2C%20collaboration%2C%20training%2C%20and, accessed 23 November 2021).

[3] WHO. Regulation and prequalification. Geneva: World Health Organization; 2016 (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/laboratory-networks-and-services/regulatory-harmonization/who-nnb, accessed 23 November 2021).

additional national regulatory authorities agreed to participate in the Collaborative Procedure for Accelerated Registration for prequalified products, for both medicines and vaccines, for a total of 44 participating countries and one regional network. The Collaborative Procedure is designed by the Secretariat to facilitate assessments and accelerate national registration of WHO's prequalified products. In 2020, 94 products were registered under the Procedure in 16 countries.

10. In May 2021, WHO published a technical document on key technical issues of herbal medicines with reference to interaction with other medicines.[1] It also published two benchmarks for training and two benchmarks for practice of traditional, complementary and integrative medicine.[2,3,4,5] Membership of national/regional regulatory agencies in WHO's International Regulatory Cooperation for Herbal Medicines network increased from 35 in 2019 to 46 in 2020. The Secretariat facilitated capacity-building of 41 government officials through virtual interregional training in 2020 and a follow-up workshop was planned for November 2021. The Regional Office for Africa established the Regional Expert Advisory Committee on Traditional Medicine for COVID-19.[6] The Secretariat provided technical support to Member States in the Western Pacific Region to develop a regional framework for harnessing traditional and complementary medicine to achieve health and well-being. A study on successful models and tools for the integration of traditional and complementary medicine into health systems was conducted in 20 countries.

Promoting transfer of technology

11. The Secretariat updated guidelines on the transfer of technology in pharmaceutical manufacturing and will present them for endorsement to the forthcoming meeting of the Expert Committee on Specifications for Pharmaceutical Preparations. WHO-UNCTAD joint webinars were organized on investing in high-quality local vaccine production for COVID-19.[7]

12. WHO supported the efforts of the Secretariat of the World Trade Organization (WTO) on more effective implementation of Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on health related technology transfer. Discussions took place with least-developed countries and the report on progress on health-related technology transfer will be uploaded onto the WHO website.

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[1] WHO. Key technical issues of herbal medicines with reference to interaction with other medicines. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240019140, accessed 23 November 2021).

[2] WHO. WHO benchmarks for the practice of tuina. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240016903, accessed 23 November 2021).

[3] WHO. WHO benchmarks for the practice of acupuncture. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/rest/bitstreams/1342685/retrieve, accessed 23 November 2021).

[4] WHO. WHO benchmarks for the training of acupuncture. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240017962, accessed 23 November 2021).

[5] WHO. WHO benchmarks for the training of tuina. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/341724, accessed 23 November 2021).

[6] WHO, Regional Director for Africa. Launch of the Regional Expert Advisory Committee on Traditional Medicine for COVID-19. Geneva: World Health Organization (https://www.afro.who.int/regional-director/speeches-messages/launch-regional-expert-advisory-committee-traditional-medicine, accessed 23 November 2021).

[7] UNCTAD-WHO Global Webinar: Investment in quality local production to address supply bottlenecks related to the pandemic. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/unctad-who-global-webinar-quality-local, accessed 23 November 2021).

13. In May 2020, WHO launched the Solidarity Call to Action in order to realize equitable global access to COVID-19 health technologies through the pooling of knowledge, intellectual property and data.[1] At the same time it also launched the COVID-19 Technology Access Pool to facilitate timely, equitable and affordable access of COVID-19 health products by boosting their production worldwide.[2] To date, the voluntary initiative has engaged several manufacturers and has received offers for diverse COVID-19 technologies, offers which are currently being assessed.

Managing intellectual property to contribute to innovation and public health

14. WHO works in collaboration with the World Intellectual Property Organization (WIPO), WTO and other international organizations to promote the development or improvement of national legislation to reflect fully the public health flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health. WHO submits an annual report on its technical cooperation activities to WTO's Council for TRIPS. In July 2021, WHO, WIPO and WTO launched an update of the trilateral study on promoting access to medical technologies and innovation, which includes a special insert that maps myriad challenges posed by the COVID-19 pandemic in relation to the interface between health, trade and intellectual property.[3] The WHO Secretariat is working on a report related to the use of flexibilities under the TRIPS Agreement that will be published soon on the WHO website.

15. WHO monitors coverage and use of existing and new user-friendly databases of patent status and licensing information for key health technologies. Since May 2021, in collaboration with partners in the COVID-19 Technology Access Pool, WHO has encouraged the further development of such databases according to needs, covering areas including COVID-19 vaccines, therapeutics, diagnostics and other health technologies. As a result, the Medicines Patent Pool expanded its Medicines Patents and Licences Database (MedsPaL) to include COVID-19 products and launched the COVID-19 Vaccines Patent Landscape (VaxPaL). The COVID-19 Technology Access Pool is also developing a global one-stop shop, a database that will include relevant information to be used to promote sharing of COVID-19 health technologies and scale-up of manufacturing to realize equitable global access.

Improving delivery and access

16. The Secretariat has developed and shared good practices on evidence-based methodology for selection of all major health product types. WHO launched a digital version of the Model List of Essential Medicines and the Model List of Essential in vitro Diagnostics.[4,5] In March 2020, WHO

[1] WHO. Making the response to COVID-19 a public common good: Solidarity Call to Action. Geneva: World Health Organization (https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action, accessed 23 November 2021).

[2] WHO. WHO COVID-19 Technology Access Pool. Geneva: World Health Organization; 2020 (https://www.who.int/initiatives/covid-19-technology-access-pool, accessed 23 November 2021).

[3] WHO, WIPO, WTO. Promoting access to medical technologies and innovation – second edition: intersections between public health, intellectual property and trade. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240008267, accessed 23 November 2021).

[4] WHO. WHO model list of essential medicines. Geneva: World Health Organization; 2021 (https://list.essentialmeds.org/, accessed 23 November 2021).

[5] WHO. Second WHO model list of essential in vitro diagnostics. Geneva: World Health Organization; 2019 (https://edl.medevis.test.evidenceprime.com/, accessed 23 November 2021).

published a guidance manual on how to update a national essential medicines list.[1] It also published, in July 2021, a guidance document for countries on methods for developing and updating national lists of essential in vitro diagnostics.[2] A webinar to help countries to develop national essential diagnostics lists was held in October 2021.[3] WHO has also published a how-to guide on institutionalizing health technology assessment mechanisms.[4] A global survey on health technology assessment processes in Member States has been developed, pilot-tested, and implemented. The survey website, with detailed methods and a database of country results, will be available by the end of 2021. The final survey report will be released in early 2022.

17. In September 2020, WHO published an update of the WHO guideline on country pharmaceutical pricing policies.[5] The guideline includes evidence-informed recommendations for the promotion of price transparency of pharmaceutical products. In April 2021, WHO convened the third Fair Pricing Forum, with promoting and monitoring transparency in medicine prices being a major theme.[6]

18. The Secretariat provided support to Member States for strengthening national regulatory capacity and regional harmonization activities. Since 2019, seven additional national regulatory authorities have been benchmarked (total of 28 to date) while 40 additional national regulatory authorities completed self-benchmarking (total of 58 to date) using the WHO Global Benchmarking Tool.[7] To date, 53 (27%) of WHO's 194 Member States are operating at either Maturity Level 3 (stable, well-functioning and integrated regulatory system) or Maturity Level 4 (advanced level of performance and continuous improvement). In accordance with resolution WHA67.20 (2014) on regulatory system strengthening for medical products, the Director-General finalized and approved terms of the reference of a WHO network for regulatory systems strengthening named the Coalition of Interested Parties.[8]

19. In April 2021, WHO published guidelines on Good Reliance Practices and Good Regulatory Practices following their adoption by WHO's Expert Committee on Specifications for Pharmaceutical

[1] WHO. Selection of essential medicines at country level: using the WHO Model List of Essential Medicines to update a national essential medicines list. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/bitstream/handle/10665/330898/9789241515443-eng.pdf, accessed 23 November 2021).

[2] WHO. Selection of essential in vitro diagnostics at country level: using the WHO model list of essential in vitro diagnostics to develop and update a national list of essential in vitro diagnostics. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/343385, accessed 23 November 2021).

[3] WHO. Webinar: How to develop a national list of essential in vitro diagnostics, 13 October 2021. Geneva: World Health Organization; 2021 (https://www.who.int/news-room/events/detail/2021/10/13/default-calendar/webinar-how-to-develop-a-national-list-of-essential-in-vitro-diagnostics, accessed 23 November 2021).

[4] Bertram M, Dhaene G, Tan-Torres Edejer T, Eds. Institutionalizing health technology assessment mechanisms: a how to guide. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/340722, accessed 23 November 2021).

[5] WHO. WHO guidelines on country pharmaceutical pricing policies. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/bitstream/handle/10665/335692/9789240011878-eng.pdf, accessed 23 November 2021).

[6] WHO. Fair pricing forum 2021: meeting report. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/348331, accessed 2 December 2021).

[7] WHO. WHO Network for Regulatory Systems Strengthening: Terms of Reference for the Coalition of Interested Parties. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/348331, accessed 2 December 2021).

[8] WHO. Terms of reference of the Coalition of Interested Parties: WHO Network for Regulatory Systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/m/item/terms-of-reference-for-the-coalition-of-interested-parties, accessed 24 November 2021).

Preparations in October 2020.[1] Both policy documents will help to streamline and support regulatory practices at global, regional and national levels. In June 2021, WHO issued a policy on the evaluation and designation of regulatory authorities as WHO-listed authorities.[2] When operational in 2022, the WHO-listed authorities framework will replace the current concept of stringent regulatory authorities.

20. The Access, Watch and Reserve (AWaRe) classification of antibiotics and the associated database were updated in 2021 in the context of the 23rd meeting of the Expert Committee on the Selection and Use of Essential Medicines.[3] This update includes an additional 78 antibiotics not previously classified, bringing the total to 258. The WHO essential medicines list antibiotic book provides guidance on antibiotic treatment for more than 30 syndromes.[4] A draft version was released for public comment during World Antimicrobial Awareness Week (18-24 November 2021).

21. The Secretariat has provided technical support to nine Member States to integrate the provision of assistive products into their health services, with a focus on training of the primary health care workforce using WHO's training in priority assistive products, which is due to be formally launched by the WHO Academy in 2022. The Secretariat surveyed the needs and priorities for assistive products within humanitarian response and is developing an essential assistive products list and manual for emergency response. In October 2021, WHO published 30 training videos for medical devices needed for oxygen-delivery systems; they will be uploaded shortly in the OpenWHO platform.[5] The list of priority medical devices and its associated technical specifications as well as technical specifications for personal protective equipment for COVID-19 have been updated and translated into all six official languages of the United Nations.[6,7]

Promoting sustainable financing mechanisms

22. The G-FINDER project[8] tracks and reports global funding for neglected disease research and development, and Member States should commit to providing information to G-FINDER. A total of 28 Member States provided their neglected disease research and development funding data in fiscal year 2020, either directly or via public databases, a decrease from the 33 Member States who reported fiscal year 2019 data. An additional three Member States did not participate in the fiscal year 2020 survey but

[1] WHO. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report (WHO Technical Report Series, No. 1033). Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf, accessed 24 November 2021).

[2] WHO. A Framework for evaluating and publicly designating regulatory authorities as WHO-listed authorities (WLA). Geneva: World Health Organization; 2021 (https://www.who.int/initiatives/who-listed-authority-reg-authorities, accessed 24 November 2021).

[3] WHO. 2021AWaRe classification: WHO access, watch, reserve, classification of antibiotics for evaluation and monitoring of use. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/2021-aware-classification, accessed 24 November 2021).

[4] WHO. The WHO Essential Medicines List Antibiotic Book. Geneva: World Health Organization; 2021 (https://www.who.int/news-room/events/detail/2021/11/18/default-calendar/the-who-essential-medicines-list-antibiotic-book, accessed 24 November 2021).

[5] WHO. Welcome to OpenWHO. Geneva: World Health Organization; 2021 (https://openwho.org/, accessed 24 November 2021).

[6] WHO. Priority medical devices list for the COVID-19 response and associated technical specifications. (https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2, accessed 24 November 2021).

[7] WHO. COVID-19 Technical Specifications for personal protective equipment, list of standards and checklists. (https://www.who.int/publications/m/item/technical-specs-PPE-Covid19-07082020, accessed 24 November 2021).

[8] G-FINDER (http://www.policycuresresearch.org/g-finder/, accessed 3 December 2021).

were identified by recipients of their funding. In fiscal year 2020, 11 Member States provided funding to product development partnerships to support neglected disease research and development, accounting for 57% of total funding to such partnerships (US$ 287 million out of US$ 499 million). The number of Member States providing funding, and their funding level, remained unchanged from fiscal year 2019.

Establishing a monitoring and accountability mechanism

23. The Board at its 148th session noted the implementation plan 2020–2022 to guide further action on the prioritized recommendations of the review panel addressed to the Secretariat.[1] To assess progress in implementation of the recommendations addressed to Member States, the Secretariat conducted a questionnaire to gather baseline information from Member States.[2] The Secretariat presented preliminary results of the analyses of the responses during an informal consultation with Member States in December 2020. A second survey is planned for 2022 to provide further information on Member States' progress in the implementation of the review panel recommendations.

ACTION BY THE EXECUTIVE BOARD

24. The Board is invited to note the report and provide guidance on the possibility of extending the time frame of the plan of action beyond 2022, taking stock of further discussions and actions that have taken place to implement the plan of action.

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[1] See document EB148/2021/REC/2, summary record of the ninth meeting, section 2.

[2] WHO. Member State questionnaire: global strategy and plan of action on public health, innovation and intellectual property. Geneva: World Health Organization (https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/member-state-questionnaire-gspa-phi.pdf?sfvrsn=4712b12_5, accessed 24 November 2021).