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# Global strategy and plan of action on public health, innovation and intellectual property

## Report by the Director-General

1. In decision WHA71(9) (2018), the Seventy-first World Health Assembly requested the Director-General to implement the recommendations of an overall programme review panel, as defined in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property, and to report on progress in implementing the decision.

2. By the same decision, the Health Assembly decided to urge Member States also to further discuss the recommendations of the review panel not emanating from the global strategy and plan of action on public health, innovation and intellectual property.[1]

3. This report presents progress made in implementing the decision. An implementation plan for 2020–2022 is under development, and a draft version is available online.[2] The draft plan will be further refined with inputs from Member States through the questionnaire circulated by the Secretariat in October 2019, and will be completed before the 73rd World Health Assembly.

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

### Prioritizing research and development needs

4. Since the biennium 2014–2015, implementation of the global strategy and plan of action, in particular element 1 (Prioritizing research and development needs) and element 2 (Promoting research and development), has been harmonized with implementation of the WHO strategy on research for health, and particularly the work on the Global Observatory on Health Research and Development (hereinafter the "Observatory").[3] Therefore, reports on progress are also available in related documents.[4] During the biennium 2018–2019, the Observatory received funding from three sources: the European Commission, the Government of France and the Government of Switzerland. As at 9 October 2019, total gross earmarked funds received or pledged for the biennium 2018–2019 was US$ 1.12 million. A new grant of US$ 456 244 from the European Commission will continue to support the Observatory in 2020–2021. As at 9 October 2019, no other funding had been provided or pledged to cover the

[1] Recommendations 4, 27 and 28 in the annex to document A71/13.

[2] See https://www.who.int/medicines/innovation/gspa-review/en/, accessed 16 December 2019.

[3] For further information, see the Global Observatory on Health Research and Development website (https://www.who.int/research-observatory/en/, accessed 7 November 2019).

[4] See document A71/41 Rev.2.

projected budget of the Observatory from 2020 onwards. The funding gap for 2020, 2021 and 2022 is US$ 330 818, US$ 781 094 and US$ 781 094, respectively.

5. The Observatory, in collaboration with the WHO Global Malaria Programme, has developed a methodology for the prioritization of research and development for malaria (a Type III disease). A wide range of input has been obtained, including from the Malaria Policy Advisory Committee, and a public consultation was held from 15 December 2018 to 28 February 2019. The WHO Global Malaria Programme is processing feedback received on a draft report on research and development priorities for malaria,[1] which will inform decisions about how best to monitor product development pipelines and prioritize public health needs as well as research and development activities for malaria, and regarding other priority-setting processes.

6. The establishment of an Expert Committee on Health Research and Development was suspended with the view of reviewing and expanding its original scope to be consistent with the priorities and goals set forth in WHO's Thirteenth General Programme of Work, 2019–2023. The Committee's form and ways of working will also be taken into consideration to best suit the expanded scope. In the meantime, the Observatory is working with WHO technical units to identify global strategic directions and research priorities for each disease or health-related field. As of June 2019, such information has been available and regularly updated for malaria, tuberculosis, HIV, neglected tropical diseases, WHO research and development blueprint pathogens, antimicrobial resistance, mental health, target product profiles and digital health research.[2]

## Promoting research and development

7. The Observatory has expanded its mandate and scope to serve as the authoritative WHO 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 analyses on health research and development investments, activities and capacities, and to help to coordinate efficient and equitable priority-setting for new investments in health research based on public health needs. This, together with the Secretariat's active engagement with various stakeholder groups, serves to promote evidence-informed decisions on new investments in health research based on public health needs in a coordinated and equitable manner.

8. WHO introduced its open access policy in 2014 to ensure that research publications authored or coauthored by WHO staff members or by researchers funded by the Organization were freely available in Europe PubMed Central.[3,4] The policy was extended in 2016 to ensure that all WHO publications were freely available in the WHO Institutional Repository for Information Sharing (IRIS). In 2019, WHO joined cOAlition S, an initiative that provides full and immediate open access to research publications. cOAlition S is built around Plan S, which consists of 10 principles to ensure that the results

[1] Analysis of research and development priorities for malaria – working paper. Geneva: World Health Organization; 2018 (https://www.who.int/research-observatory/analyses/malaria_rd_priorities_working_paper.pdf?ua=1, accessed 7 November 2019).

[2] Information on analyses and syntheses on health research and development is available at https://www.who.int/research-observatory/analyses/en/, (accessed 7 November 2019).

[3] Information on WHO's policy on open access is available at https://www.who.int/publishing/openaccess/en/, (accessed 7 November 2019).

[4] Europe PubMed Central can be consulted at https://europepmc.org/, (accessed 7 November 2019).

from publicly funded research are published in open-access journals, on open-access platforms, or made immediately available through open-access repositories without embargo. Therefore, by 2021 all research supported or published by WHO will be available for immediate access and reusable under the terms of a free public copyright licence.[1] WHO will use its position to encourage all Member States to adopt a similar approach for the dissemination of publicly funded research.

## Building and improving research capacity

9. The WHO research and development blueprint has facilitated collaboration between research and development centres in all regions of the world so that they can be better prepared for and more rapidly respond to serious outbreaks of high-threat pathogens. Regional networks are being strengthened to address blueprint priority pathogens and to focus on preparedness for outbreaks with previously unknown pathogens. WHO has developed a mapping visualization tool to promote further communication and collaboration among various stakeholders and networks engaged in research to address the blueprint priority pathogens.[2] The tool presents parties that are involved in research and development for priority pathogens or for specific products as well as information about collaborations.

10. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases has supported research capacity strengthening for over 40 years through a variety of training programmes, fellowships and its six regional training centres, and as a direct outcome of the research projects it supports. For the Programme to reach a wider audience, additional online tools have been developed including videos, online training tools and massive open online courses on implementation research, research costing and ethics in implementation research, as well as an implementation research toolkit.[3] The Programme also now tracks the career development of all recipients of its funding through an online platform, TDR Global, which encourages networking and mentoring between Programme alumni.[4] Various training programmes are being developed by the Programme's six regional training centres (one in each of the WHO regions). These centres offer short-term courses that are intended for researchers, policy-makers and implementers working in countries, and that cover good practices in research, including laboratory research, ethics in health research, implementation research and research management. In addition, a set of training materials that support country researchers and research institutions has been developed under the Programme and is available for adaptation and use in countries.

11. The WHO global report on traditional and complementary medicine released in May 2019 traces global trends in traditional and complementary medicine over the past two decades, from 1999 to as recent as 2018.[5] It presents knowledge on best practices and developments in traditional and complementary medicine across the globe and supports countries in generating evidence-based policies and strategic plans to strengthen the role that traditional and complementary medicine plays in their

[1] Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo, accessed 2 December 2019).

[2] Consult the mapping tool at http://who-blueprint-mapping-tool.surge.sh/ (accessed 7 November 2019).

[3] Further information on research capacity strengthening is available at https://www.who.int/tdr/capacity/en/, (accessed 7 November 2019).

[4] For more information, see the TDR Global website (https://www.who.int/tdr/partnerships/tdr-global/en/, accessed 7 November 2019).

[5] WHO global report on traditional and complementary medicine 2019. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/312342/9789241515436-eng.pdf?ua=1, accessed 7 November 2019).

health systems. To provide continuous support in the future, the WHO Secretariat also asked Member States to define their collaboration needs. Responses included requests for support and general technical guidance for research and evaluation of traditional and complementary medicine, information sharing on regulatory issues, workshops on national capacity-building and the provision of research databases. Since 2018, two annual WHO interregional training workshops have been conducted to build the capacities of government officials regarding the appropriate integration of traditional and complementary medicines in health services and health systems. WHO also published two guideline documents on the safety and quality of traditional and complementary medicine products.[1] For the first time, a chapter on traditional medicine was included in the International Classification of Diseases, eleventh revision (ICD-11), to enable the counting of traditional medicine services and encounters; the measurement of their form, frequency, effectiveness, safety, quality, outcomes and cost; a comparison with mainstream medicine; and research owing to standardized terms and definitions nationally and internationally.

## Promoting transfer of technology

12. In some instances, WHO has been directly involved in technology transfer projects and has used innovative mechanisms to facilitate the transfer of technology. Mechanisms have included: facilitating contact between potential partners; maintaining a presence during negotiations, mapping and review of technologies; supporting the development of business plans; providing funding and technical cooperation; creating technology transfer hubs or centres to facilitate technology transfer; and establishing public–private partnerships. WHO identified a mechanism whereby a hub or shared technology platform is created and functions to provide a working pilot plant process with all standard operating procedures, documentation and training on all aspects of the production process to numerous manufacturers, and to train national medicine regulatory authorities in order to facilitate the registration process. WHO also has a normative role in setting guidelines or best practices to aid in technology transfer for heath products.

13. During the Seventy-second World Health Assembly, WHO, UNCTAD, UNIDO, UNICEF, UNAIDS and the Global Fund launched the first inter-agency statement on promoting local production of medicines and other health technologies. The inter-agency statement signals the six organizations' aim to work in a strategic, holistic and collaborative manner in partnership with governments and other stakeholders in the promotion of sustainable local production of quality-assured medicines and other health technologies. WHO and UNCTAD, through their ongoing, active and intensified collaboration on local production, have coordinated efforts to support the Government of Ethiopia regarding intellectual property-related policies for the country's national strategy and plan of action for pharmaceutical manufacturing development (2015–2025), among other joint activities aimed to promote policy coherence for local production.

[1] WHO guidelines on good herbal processing practices for herbal medicines. Annex 1 to the WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-second report. Geneva: World Health Organization; 2018 (WHO Technical Report Series, No. 1010; http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf?ua=1, accessed 7 November 2019); and Guidelines on good manufacturing practices for the manufacture of herbal medicines. Annex 2 to the WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-second report. Geneva: World Health Organization; 2018 (WHO Technical Report Series, No. 1010; http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf?ua=1, accessed 7 November 2019).

## Managing intellectual property to contribute to innovation and public health

14. In collaboration with relevant international organizations, WHO provided technical advice and policy support through its headquarters, regional and country offices in the framing of national policies, laws and regulations to favour the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and services. Such support was provided upon request to help Member States to devise ways to safeguard public health interests, while adhering to their obligations under international trade agreements and taking into account the impact on public health of adopting provisions that go beyond the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

15. Within a framework of trilateral cooperation, WHO works with WIPO and WTO to foster a better understanding of the linkage between public health and intellectual property policies and to enhance a mutually supportive implementation of those policies. Each year, the WTO TRIPS Council invites WHO to submit a report on its technical cooperation activities relating to the implementation of the TRIPS Agreement. The most recent communication summarizes the activities of WHO in the area of public health, innovation and intellectual property that have taken place since October 2018. The overall objective of WHO's technical cooperation is to strengthen the capacity of developing countries in the areas of health innovation, access to medicines and management of intellectual property.

16. Since 2017, WHO has requested and strongly promoted the further development of patent status information and licensing databases for health products and facilitated greater access to such information by public health actors, in particular, procurement agencies. MedsPaL, the Medicines Patents and Licences Database of the Medicines Patent Pool, for example, has expanded its scope to include all patented essential medicines in the 21st WHO Model List of Essential Medicines (2019).

17. In 2016, WHO encouraged the Medicines Patent Pool to expand beyond its core remit of HIV, hepatitis C and tuberculosis and to promote public health-oriented voluntary licenses on all patented medicines on the WHO Model List of Essential Medicines. Following a feasibility study exploring an increased remit, the Medicines Patent Pool launched a new five-year strategy in May 2018 to expand its activities to cover all patented essential medicines, which requires engagement with many new stakeholders.

## Improving delivery and access

18. The WHO Secretariat has provided support to three countries in the African Region, three countries in the European Region and one country in the South-East Asia Region in developing national lists of essential medicines and frameworks for coverage and prioritization systems for benefit packages. Furthermore, the WHO Model List of Essential Medicines formed the basis for pooled procurement mechanisms to improve affordability.

19. The WHO Secretariat is undertaking work to update the 2015 WHO guideline on country pharmaceutical pricing policies, which is planned for publication in 2020.[1] The update aims to include evidence-informed recommendations for the promotion of price transparency of pharmaceutical products. The Secretariat has also implemented a digital tool and methodology for measuring the

[1] Information on the WHO guideline on country pharmaceutical pricing policies is available at https://www.who.int/medicines/areas/access/guide-country-pharm-price-policies/en/ (accessed 8 November 2019).

availability and affordability of medicines more efficiently.[1] This has enabled the Secretariat to provide technical support to several Member States in monitoring the prices of medicines, assessing the conformity of policy implementation with policy scopes, and formulating appropriate policy responses. Medicines-pricing databases have also been established in two WHO regions with a view to promoting and monitoring transparency in medicines prices and availability.

20. The WHO Secretariat has established mechanisms to monitor patient out-of-pocket expenditure on health services and products by consolidating information from nationally representative household surveys (selected regions), facility surveys and national health accounts.[2] Work is under way to expand data coverage through household surveys to all Member States by 2021.

## Promoting sustainable financing mechanisms

21. G-Finder[3] tracks public, private, and philanthropic funding of basic research and product development for global health priorities. The core focus of the project is funding for neglected disease research and development. For fiscal year 2018, G-Finder reported that a total of 11 Member States provided funding to product development partnerships, accounting for 56% of total funding for such partnerships (US$ 308 million out of US$ 553 million). This was an increase in both Member State and total funding for product development partnerships compared to fiscal year 2017 (when Member States contributed US$ 293 million out of US$ 526 million in total), but the Member State share of total funding for product development partnerships (56%) and the number of Member States providing funding (11) remained unchanged.

## Establishing a monitoring and accountability mechanism

22. In September 2019, the Secretariat launched a questionnaire to gather baseline information from Member States to monitor progress on implementing decision WHA71(9). The responses to the questionnaire will be analysed by the Secretariat for inclusion in the report on progress to be submitted to the Seventy-third World Health Assembly. The responses will also inform the further development of the draft implementation plan for 2020–2022.

23. A total of 30 Member States reported fiscal year 2018 data to G-Finder. A further seven Member States did not participate but were identified as funders by the funding recipients. This was an increase from the 28 Member States who reported fiscal year 2017 data to G-Finder, and from the four additional Member States previously identified by funding recipients.

[1] Information on the tool is available at https://www.who.int/medicines/areas/policy/monitoring/empmedmon/en/, (accessed 8 November 2019).

[2] For further information, see the WHO Global Health Expenditure Database at https://apps.who.int/nha/database (accessed 8 November 2019).

[3] The G-Finder public search tool can be consulted at https://gfinder.policycuresresearch.org/PublicSearchTool/, (accessed 8 November 2019).

## ACTION BY THE EXECUTIVE BOARD

24. The Board is invited to take note of the report. In its discussions, the Board is invited to:

- comment on progress reported herewith, including the development of the draft implementation plan for 2020–2022;[1]

- take stock of further discussions and actions that have taken place to implement decision WHA71(9), in particular operative paragraph (2) in which Member States were urged to further discuss the recommendations of the review panel not emanating from the global strategy and plan of action on public health, innovation and intellectual property.[2]

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[1] https://www.who.int/medicines/innovation/gspa-review/en/ (accessed 16 December 2019).

[2] Recommendations 4, 27 and 28 in the annex to document A71/13.