

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

Report by the Director-General

1. This report is submitted at the request of the Executive Board in accordance with decision EB140(8) (2017), in which it approved the terms of reference of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.
2. In resolution WHA68.18 (2015), the Sixty-eighth World Health Assembly requested the Director-General to establish a panel of 18 experts to conduct an overall programme review of the global strategy and plan of action as a complement to the comprehensive evaluation to be commissioned by the Secretariat. The executive summary of the evaluation was presented to the Executive Board at its 140th session¹ and the full report of the evaluation is available on the WHO website.²
3. The terms of reference of the overall programme review suggested that it should be a more policy-oriented, forward-looking exercise than the evaluation. Although the expert review panel should be guided by the evaluation, it should take into account other evidence and involve relevant stakeholders.
4. As part of the review process, a survey on the way forward for the global strategy and plan of action was conducted, as well as interviews, with Member States and a wide range of stakeholders, including United Nations bodies, and intergovernmental, civil society and private sector organizations. Information sessions were also held with Member States and relevant stakeholders.
5. The expert review panel held several meetings between March and September 2017 to assess the continued relevance of the aims and objectives of the global strategy and plan of action, review its achievements and weaknesses, identify any remaining challenges and recommend a way forward until 2022. The full report of the overall programme review is available on the WHO website.³
6. In decision EB140(8) (2017), the Executive Board also requested the Secretariat to develop an indication of funding requirements and possible sources of the implementation costs of the

¹ Document EB140/20.

² See http://www.who.int/about/evaluation/gspoa_report_final20dec16.pdf (accessed 18 October 2017).

³ See <http://www.who.int/medicines/areas/policy/overall-programme-review-global-strategy-phi/en/> (accessed 1 December 2017).

recommendations of the programme review. In 2009, the cost of implementing the global strategy and plan of action was estimated at US\$ 350 million over the period 2009–2015.¹

7. Having considered that the number of priority actions recommended by the expert review panel is only 33, compared with the original 108, the Secretariat estimates that the budget for full implementation of the review panel's recommended actions will be US\$ 31.5 million over the period 2018–2022. In addition, the estimated budget for implementation of the high-priority actions identified by the review panel would be US\$ 16.3 million. This indicative budget would allow the Secretariat to ensure implementation and monitoring of the global strategy and plan of action and provide technical guidance and support to Member States in the implementation of the review panel's recommendations for the period 2018–2022.

8. The proposed budget is not covered within existing resources. Additional resources would therefore need to be mobilized from assessed or voluntary contributions. Many of the actions have resource implications for Member States, for which it is not possible to establish accurate estimates of the costs.

9. The priority actions recommended by the review panel are set out in the annex to this report. The executive summary and the full report of the overall programme review of the global strategy and plan of action are available online.

ACTION BY THE EXECUTIVE BOARD

10. The Board is invited to note the report and to consider the draft decision contained in document EB142/14 Add.1.

¹ Document A62/16 Add.1.

ANNEX

ACTIONS RECOMMENDED BY THE EXPERT PANEL FOR THE OVERALL PROGRAMME REVIEW OF THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

1. The terms of reference of the overall programme review requested the expert review panel to “recommend a way forward, including details of what elements or actions should be added, enhanced or concluded in the next stage of implementation of the global strategy and plan of action on public health, innovation and intellectual property, until 2022”.¹
2. Although progress has been made in certain aspects of both innovation and access, many of the challenges that motivated formulation of the global strategy and plan of action on public health, innovation and intellectual property remain, and new challenges have emerged. These include a lack of new health products in areas of need and of sustainable financing, the unaffordability of many new medicines, a lack of essential health products and inappropriate use, ineffective delivery and supply chain infrastructure and the absence of robust regulatory frameworks and trained personnel, mainly but not exclusively in developing countries.
3. The review panel considered that the eight elements of the global strategy and plan of action on public health, innovation and intellectual property remain broadly valid. The main issue concerning the global strategy and plan of action has been its lack of impact in implementation. This suggested that the review could add most value by making recommendations that were more focused in terms of scope and scale and included a set of priority actions for each element of the global strategy and plan of action to address current needs in research and development, and access to medicines. Such priority actions needed to be specific and feasible with established indicators and deliverables that could be monitored.
4. The review panel took the view that the recommendations should be directed to the WHO Secretariat and/or Member States, rather than the multiplicity of relevant stakeholders. Although the contribution of stakeholders is integral to the success of the global strategy and plan of action, it is the role of the WHO Secretariat and Member States to encourage their appropriate involvement.
5. Member States and other key stakeholders should be fully engaged in the implementation of the global strategy and plan of action at an early planning stage. A mechanism for effective governance of the global strategy and plan of action is also required, as well as relevant capacity and tools for implementation and monitoring. A communications strategy and materials should be produced by the WHO Secretariat to raise awareness of the global strategy and plan of action among Member States and other stakeholders.
6. On that basis, the review panel made the following proposals for priority actions between 2018 and 2022. High-priority actions are underlined. The dates proposed for achievement of the actions are indicative.

¹ Decision EB140(8) (2017); and document EB140/2017/REC/1, Annex 6, paragraph 1(e).

RECOMMENDATIONS

Prioritize research and development needs

1. Member States to establish sustainable financing for the Global Observatory on Health Research and Development and the Expert Committee on Health Research and Development. (*Indicator: Funding secured by 2019 to cover the projected budget up to 2022.*)
2. The WHO Secretariat to formulate a methodology for the prioritization of research and development needs for Type II and Type III diseases and the specific research and development needs of developing countries for Type I diseases for use by the Expert Committee on Health Research and Development and by Member States, to enable them to identify, respectively, both global and national research and development priorities. (*Indicator: Methodology for the prioritization of research and development needs developed by 2018.*)
3. Report by the Expert Committee on Health Research and Development identifying health research and development priorities to address unmet medical needs based on evidence from the Global Observatory on Health Research and Development and on information provided by experts and relevant stakeholders. (*Indicator: List of prioritized research and development needs for Type II and Type III diseases established by 2019, with a final list including Type I diseases established by 2020.*)

Promote research and development

1. Member States to support the WHO Secretariat in promoting transparency in, and understanding of, the costs of research and development. (*Indicator: Reports on the costs of research and development for health products prepared in 2019 and 2021.*)
2. The WHO Secretariat to establish an information-sharing mechanism to promote collaboration and coordination in research and development linked to the Expert Committee on Health Research and Development and the Global Observatory on Health Research and Development. (*Indicator: Establishment of an information-sharing mechanism to improve collaboration and coordination of resource allocation in accordance with research and development priorities by 2020.*)
3. Member States to promote programmes for collaboration with (and provision of support to) developing countries to strengthen clinical trial capacity and expert networks regionally and, where relevant, nationally. (*Indicator: Report on mapping of programmes for strengthening clinical trial capacity and expert networks regionally and nationally by 2021.*)
4. Member States and the WHO Secretariat to encourage funders of research and development to make all resulting publications open access immediately or, at the most, within six months after publication. (*Indicator: Report by 2022 on new initiatives by funders of research and development to ensure that the resulting publications in peer-reviewed journals are open access.*)

Build and improve research capacity

1. The WHO Secretariat and Member States to develop and support collaboration programmes between internationally recognized centres for research and development and relevant institutions in developing countries to enable those countries to enhance their capacity across the research and development pipeline. (*Indicator: Report on new collaboration programmes developed and supported by 2021.*)
2. The WHO Secretariat to continue providing support to strengthen the capacity of national and regional regulatory functions and systems, including for improving clinical trial regulatory review and oversight. (*Indicator: Report on national and regional initiatives for strengthening clinical trial regulatory capacity in developing countries by 2019 and 2021.*)
3. The WHO Secretariat, in collaboration with Member States, to construct and promote the use of a database of relevant training programmes and materials for scientists and other experts involved in research and development from the public and private sectors in developing countries. (*Indicator: Database of relevant training programmes and materials established and populated and its use promoted by 2021.*)
4. Member States to promote the availability of training courses of certified quality, including online courses, for personnel involved in research and development. (*Indicator: Monitoring the availability of certified quality training courses on research and development.*)
5. Member States, with the support of the WHO Secretariat, to develop strategies and strengthen their capacity for policy formulation, regulation, research methodology and ethics, and resource preservation in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023. (*Indicator: Report on national and regional programmes for developing strategies and strengthening capacity in research and development for traditional medicine by 2022.*)

Promote transfer of technology

1. The WHO Secretariat to identify mechanisms to increase health technology transfer in the context of the Technology Facilitation Mechanism established by the Sustainable Development Goals. (*Indicator: Report on the identification of mechanisms to increase health technology transfer in the context of activities related to the Technology Facilitation Mechanism by 2020.*)
2. The WHO Secretariat to work with the secretariat of WTO to identify how Article 66(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) could be implemented more effectively in relation to health technology transfer in countries. (*Indicator: Report on progress on health technology transfer related to implementation of Article 66(2) of the TRIPS Agreement by 2021.*)
3. The WHO Secretariat to identify new opportunities for collaboration with other United Nations organizations (e.g. UNIDO, UNCTAD) to promote technology transfer as part of local health technology production programmes in developing countries in line with country needs. (*Indicator: Inter-organizational report on national technology transfer programmes developed and disseminated by 2022.*)

Manage intellectual property to contribute to innovation and public health

1. The WHO Secretariat, in collaboration with other international organizations working in intellectual property, to advocate for the development of national legislation to fully reflect the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement. (Indicator: *Inter-organizational report on national legislation and patenting guidelines that include the flexibilities provided in the TRIPS Agreement prepared by 2021.*)
2. The WHO Secretariat, in collaboration with partners, to promote the further development of databases of patents and non-confidential licence agreements for health products and facilitate greater access to such databases. (Indicator: *Monitor coverage and use of existing and new databases of patent and licence information.*)
3. Member States and other funders, with WHO Secretariat support, to strengthen the Medicines Patent Pool, which may include support for the expansion of its portfolio to cover other diseases or technologies where the Medicines Patent Pool model can have the most impact. (Indicator: *Number of diseases and/or technologies covered by the Medicines Patent Pool’s portfolio and amount of funding committed by new donors by 2020.*)
4. Member States, when negotiating trade agreements, to take into account the impact on public health of adopting provisions that go beyond the requirements of the TRIPS Agreement. (Indicator: *Assessment by 2022 of evidence that negotiators of new trade agreements have taken account of the public health impact of the adoption of such agreements.*)

Improve delivery and access

1. The WHO Secretariat to develop and share good practices on evidence-based selection and health technology assessment for health products for national use, and support bilateral and regional collaboration between countries. (Indicator: *Good practices on evidence-based selection and health technology assessment developed and disseminated by 2019. Report on bilateral and regional collaboration programmes prepared by WHO by 2022.*)
2. The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: *Guidance developed and disseminated in countries by 2020.*)
3. The WHO Secretariat, in cooperation with Member States and other partners, to establish mechanisms to monitor patient out-of-pocket expenditure on health products. (Indicator: *Monitoring patient out-of-pocket expenditure on health products.*)
4. The WHO Secretariat to continue to support Member States in strengthening national regulatory capacity, regional harmonization and other collaborative initiatives for improving access to new and existing quality-assured medicines and health products. (Indicator: *Report on progress of national and regional regulatory capacity-building efforts in developing countries by 2021.*)

5. Member States and funders to support the WHO Prequalification of Medicines Programme to include newer essential health products, encompassing medicines, vaccines, diagnostics or biologicals. (*Indicator: Number of newer health products included in the portfolio of the Prequalification of Medicines Programme by 2020 and 2022.*)
6. The WHO Secretariat to develop best practices and implement capacity-building programmes for more appropriate use of new and existing medicines and health products in national clinical practice. (*Indicator: Best practices developed and capacity-building programmes implemented in countries by 2021.*)
7. The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (*Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.*)
8. Member States to identify essential medicines that are at risk of being in short supply and mechanisms to avoid shortages, and disseminate related information accordingly. (*Indicator: Lists of medicines at risk of being in short supply and information on mechanisms for preventing shortages made available and disseminated by 2020.*)

Promote sustainable financing mechanisms

1. Member States to commit to dedicating at least 0.01% of their gross domestic product to basic and applied research relevant to the health needs of developing countries. (*Indicator: Percentage of gross domestic product dedicated to basic and applied research as reported by G-Finder by 2021.*)
2. Member States to commit to increasing domestic resource mobilization and supporting the Addis Tax Initiative in order to, inter alia, implement the health-related Sustainable Development Goals. (*Indicator: Data from Member States on domestic resource mobilization gathered by 2021.*)
3. Member States to encourage the implementation of schemes which partially or wholly delink product prices from research and development costs, including actions recommended by the Consultative Expert Working Group on Research and Development: Financing and Coordination. (*Indicator: New schemes to partially or wholly delink product prices from research and development costs developed, approved and implemented by 2022.*)
4. Member States, with the WHO Secretariat's support, to encourage an increase and diversification of funding for product development partnerships. (*Indicator: increased and diversified funding for product development partnerships and progress as reported by G-Finder by 2022.*)

Establish a monitoring and accountability mechanism

1. 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.)
2. Member States to commit to providing information to G-Finder. (Indicator: Number of countries that have provided information to G-Finder.)

= = =