EXECUTIVE BOARD
148th session
Provisional agenda item 8

EB148/10
11 January 2021

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

Report by the Director-General

1. This report responds to the Seventy-third World Health Assembly's request for a report on progress made in implementing its decision WHA73(11) (2020). The accompanying document annexed to this report sets out the final version of the implementation plan to guide further action on the prioritized recommendations of the review panel, established at the request of the Sixty-eighth World Health Assembly (resolution WHA68.18 (2015)) to conduct an overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.

GLOBAL REPORT ON PROGRESS: RESULTS OF A MEMBER STATE SURVEY

2. Paragraph 1 of decision WHA71(9) (2018), urged Member States to implement, as appropriate and taking into account national contexts, the recommendations of the review panel that are addressed to Member States and consistent with the global strategy and plan of action on public health, innovation and intellectual property. Paragraph 1 of decision WHA73(11) urged Member States to reinforce such implementation. To assess progress in that regard, the Secretariat produced a questionnaire to gather baseline information from Member States.[1]

3. In October 2019, WHO Member States were invited to nominate a focal point to coordinate the collection and reporting of their Governments' intersectoral responses to the questionnaire (responses came from all relevant government authorities relating to public health, innovation, and intellectual property). The questionnaire, which was intended to support implementation and monitoring, was structured around the eight elements of the global strategy and plan of action on public health, innovation and intellectual property. It also included questions by which the Secretariat could collect useful information for developing the implementation plan requested in WHA71(9). The questionnaire was available in the six official languages of the United Nations. A link with a unique token code to the online questionnaire was sent directly to each focal point, with a deadline for completion of 10 January 2020. At the request of Member States, the deadline was extended to 10 February 2020 and subsequently to 24 February 2020.

4. The Secretariat has analysed the responses and will present its findings in a report to be published online by the end of January 2021. The report will describe the progress made across WHO regions in implementing the recommendations of the review panel that are addressed to Member States and

[1] https://www.who.int/medicines/innovation/gspa-review/en/ (accessed 15 December 2020).

consistent with the global strategy and plan of action on public health, innovation and intellectual property.

INFORMAL CONSULTATIONS CONVENED BY THE DIRECTOR-GENERAL IN 2020

5. The Secretariat convened an informal consultation of Member States on 3 December 2020 to discuss the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (2018) as "not emanating from the global strategy and plan of action on public health, innovation and intellectual property" and the "recommendations of the review panel on promoting and monitoring transparency of medicines prices and actions to prevent shortages" referred to in paragraph 3 of decision WHA73(11). The results of the consultation are summarized in a report available online.[1]

IMPLEMENTATION PLAN TO GUIDE FURTHER ACTION BY THE SECRETARIAT

6. The final version of the implementation plan 2020–2022 to guide further action on the prioritized recommendations of the review panel addressed to the Secretariat was published online in December 2020.[2]

7. Following a discussion during the 146th session of the Executive Board, Member States were invited, by a communication dated 4 February 2020, to comment on the draft by 24 February 2020. The information session announced by the Secretariat during that session of the Executive Board was cancelled as a result of the COVID-19 pandemic. The final implementation plan, which is annexed to this report, has been further refined taking into account Member States' comments as well as the responses to the questionnaire circulated by the Secretariat in October 2019. It was presented by the Secretariat during the informal consultation of Member States that was held on 3 December 2020.

ACTION BY THE EXECUTIVE BOARD

8. The Board is invited to take note of this report and provide guidance on the way forward.

[1] https://www.who.int/medicines/innovation/gspa-review/en/ (accessed 15 December 2020).

[2] https://www.who.int/medicines/innovation/gspa-review/Final_Implementation-Plan-GSPA-PHI-2020-2022-30-November-2020.pdf?ua=1 (accessed 5 January 2021).

ANNEX

IMPLEMENTATION PLAN 2020–2022 TO GUIDE FURTHER ACTION ON THE PRIORITIZED RECOMMENDATIONS OF THE REVIEW PANEL ADDRESSED TO THE SECRETARIAT

1. The 2030 Agenda for Sustainable Development identifies research and development of and access to affordable essential medicines and vaccines for the communicable and noncommunicable diseases that primarily affect developing countries as a global public health challenge.[1] Adopted in 2008, the aim of the global strategy and plan of action on public health, innovation and intellectual property is to promote new thinking on innovation and access to medicines and, based on the recommendations of the report of the Commission on Intellectual Property Rights, Innovation and Public Health, to provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development, relevant to diseases that disproportionately affect developing countries.[2]

2. Despite the progress made in certain aspects of both innovation and access since 2008, many of the challenges that first led to the development of the global strategy and plan of action persist. New challenges have also emerged. These include a lack of sustainable financing and new health products in areas of need, the unaffordable price of many new medicines, the inappropriate use and shortage of essential health products, the ineffectiveness of existing delivery and supply chain infrastructure, and the absence of robust regulatory frameworks and trained personnel, mainly but not exclusively in developing countries.

3. Concerned about the pace of implementation, the Sixty-eighth World Health Assembly decided, in resolution WHA68.18 (2015), to undertake an overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.[3] 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 of the global strategy and plan of action, until 2022.[4] The review panel considered that the eight elements of the global strategy and plan of action remained broadly valid. The panel made recommendations that were more focused in terms of scope and scale, and included a set of specific, feasible priority actions for each element, with established indicators and deliverables that could be monitored.[5] The recommendations were directed at the WHO

[1] Sustainable Development Goal 3, target 3.b: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." (https://www.un.org/sustainabledevelopment/health/, accessed 27 November 2020).

[2] https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf (accessed 27 November 2020).

[3] Resolution WHA68.18 (https://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R18-en.pdf, accessed 27 November 2020).

[4] https://www.who.int/medicines/areas/policy/GSPA-PHI3011rev.pdf?ua=1 (accessed 27 November 2020).

[5] Document A71/13 (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_13-en.pdf, accessed 27 November 2020).

Secretariat and/or Member States rather than the multiplicity of relevant stakeholders, it being deemed the role of the former to encourage appropriate involvement of the latter.

4. In May 2018, the Seventy-first World Health Assembly adopted decision WHA71(9), in which it requested the Director-General to implement the recommendations addressed to the Secretariat as prioritized by the review panel, 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.[1]

IMPLEMENTATION PLAN

Aim and scope

5. This implementation plan builds on the recommendations addressed to the Secretariat as prioritized by the overall programme review panel of the global strategy and plan of action on public health, innovation and intellectual property, and covers the period 2020–2022. It provides a comprehensive summary of the steps to be taken by the Secretariat to implement the relevant recommendations, and draws on the provisions of the road map for access to medicines, vaccines and other health products, 2019–2023 that outlines the programming of WHO's work on access to medicines and vaccines.

6. The aim of the global strategy and plan of action on public health, innovation and intellectual property to promote new thinking on innovation and access to medicines and to support needs-driven essential health research and development aligns with the objectives of the 2030 Agenda for Sustainable Development, notably targets 3.8 and 3.b.[2,3]

Guiding principles

7. The global strategy and plan of action on public health, innovation and intellectual property identified the following principles, which underpin this implementation plan.

(a) WHO's Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health".[4] Accordingly, WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant Health Assembly resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, WHO, including its regional and, when appropriate, country

[1] Decision WHA71(9) (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(9)-en.pdf, accessed 27 November 2020).

[2] Sustainable Development Goal 3, target 3.8: 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.

[3] Sustainable Development Goal 3, target 3.b: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

[4] WHO Constitution (https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf, accessed 27 November 2020).

offices, needs to strengthen its institutional competencies and relevant programmes in order to play its role in implementing this global strategy with its plan of action.

(b) The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

(c) The promotion of technological innovation and the transfer of technology should be pursued by all States and supported by intellectual property rights.

(d) Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.

(e) International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.

(f) The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.

(g) Research and development of developed countries should better reflect the health needs of developing countries.

(h) The global strategy and the plan of action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:

- developed in an ethical manner;
- available in sufficient quantities;
- effective, safe and of good quality;
- affordable and accessible;
- used in a rational way.

(i) Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.

(j) Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.

ACTIONS NEEDED TO PROMOTE INNOVATION, BUILD CAPACITY, IMPROVE ACCESS AND MOBILIZE RESOURCES

8. The overall programme review concluded that the eight elements of the global strategy and plan of action on public health, innovation and intellectual property remain broadly valid.

9. The elements and their corresponding actions were designed to: (i) prioritize research and development needs; (ii) promote research and development; (iii) foster and build innovation capacity; (iv) encourage technology transfer and local production of medical products; (v) promote the management and application of intellectual property rights to improve public health; (vi) improve access to medical products; (vii) mobilize resources for research and development relevant to this area; and (viii) monitor and evaluate the progress made in all these areas.

10. The review panel found that the main issue concerning the global strategy and plan of action on public health, innovation and intellectual property had been its lack of impact in implementation. The panel therefore decided that the review could add most value by making recommendations that were more focused in terms of scope and scale, and by including a set of priority actions for each element of the global strategy and plan of action to address the 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 easily monitored.

PRIORITIZED RECOMMENDATIONS OF THE REVIEW PANEL ADDRESSED TO THE SECRETARIAT

11. The overall programme review panel recommended the adoption of 33 priority actions, rather than the 108 actions originally proposed in the global strategy and plan of action on public health, innovation and intellectual property. To ensure feasibility, many of the priority actions had been selected so as to build on existing activities involving the Secretariat and other partners.

12. The panel formulated a set of actions, indicators and deliverables, which, if achieved by 2022, would constitute real progress. Adequate, sustainable funding by Member States remained a key element for success, including for activities that fell under the responsibility of WHO. The panel took the view that the recommendations should be directed to the WHO Secretariat and/or Member States rather than to all the stakeholders addressed by the global strategy and plan of action on public health, innovation and intellectual property. Although the activities of stakeholders would be integral to the global strategy and plan of action's success, the panel concluded that it should be the Secretariat and Member States that encouraged the appropriate stakeholder involvement. Furthermore, the panel noted that no mechanism existed for holding stakeholders directly to account. Member States and stakeholders should therefore be fully involved in the early planning stages for the implementation of the global strategy and plan of action on public health, innovation and intellectual property. A communications strategy and materials should also be produced to raise awareness of the provisions under the global strategy and plan of action.

13. The tables below outline the actions that the WHO Secretariat will undertake to implement the recommendations of the review panel if adequate, sustainable funding by Member States is secured. The Secretariat estimates that the budget for full implementation of the review panel's recommended actions would 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 the appropriate implementation and monitoring of the global strategy and plan of action on public health, innovation and intellectual

property, and enable it to provide technical guidance and support to Member States in the implementation of the review panel's recommendations for the period 2018–2022.

1. Prioritize research and development needs

Rationale

14. Health research and development policies of developed countries should adequately reflect the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases should be identified urgently. A better understanding of the health needs of developing countries and their determinants is essential to driving sustainable research and development on new and existing products.

Table 1. Recommendations 2 and 3 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 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.)*[1]	• Analyse the feedback received on the draft report of the prioritization framework for the research and development of malaria health products[2] • Hold deliberations on malaria research and development priorities, methodological approach, and outputs by the expert panel as a consultative step.
Recommendation 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.)*[1]	• Build on the Global Observatory on Health Research and Development's analysis and synthesis of health research and development, including by defining global strategic directions for specific diseases, pathogens and conditions, based on information from WHO specialized departments, the Global Observatory on Health Research and Development, and published online information and resources.[3] • Define an approach to convening an advisory group to guide the WHO Director-General on the Organization's constitutional function to promote and conduct research in the field of health. • Develop target product profiles for missing antibiotics and in vitro diagnostics for priority pathogens, missing diagnostics for sepsis, and

[1] High-priority action.

[2] https://www.who.int/malaria/news/2018/malaria-research-development-priorities/en/ (accessed 5 January 2021).

[3] https://www.who.int/research-observatory/analyses/en/ (accessed 30 November 2020).

Recommendation of the review panel	Steps to be taken by the Secretariat
	medical devices (including personal protective equipment). • Perform an updated analysis of the research and development pipeline for new antibiotics. • Expand the annual pipeline report to include antifungals. • Develop the research and development priority list of in vitro diagnostics for antimicrobial resistance. • Update the WHO global priority pathogens list.

2. Promote research and development

Rationale

15. There are many determinants of innovation capacity. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential.

Table 2. Recommendations 5 and 7 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 5: 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.)*[1]	• Promote the further development of the Global Observatory on Health Research and Development as an information-sharing mechanism and authoritative WHO source of global information and strategic direction on research for health. • Engage with a diverse range of stakeholders to promote evidence-informed decisions on new investments in health research, based on public health needs.
Recommendation 7: 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.)*	• Provide guidance and support, upon request, to funders of research and development to make all resulting publications open access immediately. • Ensure that, by 2021, all research supported or published by WHO is available for immediate access and reusable under the terms of a Creative Commons licence. • Prepare a report on new initiatives by funders of research and development to ensure that the resulting publications in peer-reviewed journals are open access.

[1] High-priority action.

3. Build and improve research capacity

Rationale

16. Effective policies that promote the development of capacities in developing countries related to health innovation should be framed, developed and supported. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property, and traditional medicine.

Table 3. Recommendations 8, 9, 10 and 12 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 8: 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.)*[1]	• Develop tools and standards to strengthen national research capacity. • Prepare a report on new collaboration programmes that have been developed and supported.
Recommendation 9: 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.)*[1]	• Hold the International Conference of Drug Regulatory Authorities and issue an outcome document containing recommendations. • Establish and maintain global regulatory networks. • Develop a regulatory framework and expand harmonized guidelines for all health products through the African Medicines Regulatory Harmonization initiative. • Strengthen facilitated pathways for product registration, including by strengthening collaborative registration procedures. • Provide technical assistance to manufacturers of medical devices and/or other stakeholders to ensure that product development, testing and production facilities are in line with WHO norms and standards. • Develop WHO certification and proficiency schemes. • Finalize the competencies framework and self-assessment tools. • Establish training modules, training centres, mentorship platforms, a global competencies framework and curriculum, a roster of international experts, rotations within WHO and other agencies, and workshops on WHO regulatory guidelines.

[1] High-priority action.

Recommendation of the review panel	Steps to be taken by the Secretariat
	• Provide technical assistance on training course design and delivery. • Map the distribution of poisonous snakes and offer regulatory capacity-building for the selection, importation and appropriate use of antivenoms. • Prepare a report on national and regional initiatives for strengthening clinical trial regulatory capacity in developing countries.
Recommendation 10: 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.)*	• Organize consultations with Member States to promote the development of a database containing relevant training programmes and materials.
Recommendation 12: 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.)*	• Provide technical guidance to support Member States in providing safe, qualified and effective traditional complementary and integrative services. • Develop a series of benchmarks for practice in traditional and complementary medicine. • Prepare technical documents on: training in and practice of traditional, complementary and integrative medicine; clinical research in traditional and complementary medicine; and key technical issues for the safe use of herbal medicines, including reference to interaction with other medicines. • Develop a tool package to support Member States in identifying models and approaches for the integration of traditional and complementary medicine into their health systems and universal health coverage plans more comprehensively. • Build institutional capacity by developing capacity-building tools, including through the publication of a series of benchmarks for training and by holding annual interregional training workshops for government officials. • Prepare a report on national and regional programmes aimed at developing strategies and strengthening capacity in research and development for traditional medicine.[1]

[1] https://www.who.int/traditional-complementary-integrative-medicine/activities/en/ (accessed 30 November 2020).

4. Promote transfer of technology

Rationale

17. North–South and South–South development cooperation, partnerships and networks should be supported in order to build and improve the transfer of technology related to health innovation. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.

Table 4. Recommendations 13, 14 and 15 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 13: 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.)*[1]	• Prepare a report in relation to the specific mechanisms that were identified as examples to increase health technology transfer. • Organize a technology transfer and local production conference. • Facilitate knowledge-sharing. • Promote technology transfer and local production through the building of partnerships. • Provide recommendations and devise an action plan.
Recommendation 14: 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.)*[1]	• Continue to promote and encourage technology transfer to least developed countries, including through international collaboration, pursuant to Article 66(2) of the TRIPS Agreement. • Prepare a report on the progress of health technology transfer activities related to Article 66(2) of the TRIPS Agreement.
Recommendation 15: 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.)*	• Develop a tool for conducting holistic situational analyses to assist Member States in identifying gaps, and provide evidence-based recommendations for promoting technology transfer and sustainable local production. • Convene meetings with United Nations organizations and international partners and take collective action to promote technology transfer and local production with a view to addressing public health needs in developing countries, in accordance with the first inter-agency statement on

[1] High-priority action.

Recommendation of the review panel	Steps to be taken by the Secretariat
	promoting local production of medicines and other health technologies launched at the Seventy-second World Health Assembly.[1] • Develop, in collaboration with partners, a model strategy and plan of action for Member States and regions interested in guaranteeing quality local production. • Organize a technology transfer and local production conference. • Facilitate knowledge-sharing. • Promote technology transfer and local production through the building of partnerships. • Provide recommendations and develop an action plan.

5. Manage intellectual property to contribute to innovation and public health

Rationale

18. One of the aims of international regimes on intellectual property is to provide incentives for the development of new health products. Incentive schemes should therefore be explored and implemented, where appropriate, for research and development into Type II and Type III diseases and the specific research and development needs of developing countries in respect of Type I diseases. Innovation capacity as well as capacity to manage and apply intellectual property in developing countries should be strengthened, particularly with respect to the full use of the provisions in the TRIPS Agreement and the instruments related thereto, which provide flexibility in taking measures to protect public health.

Table 5. Recommendations 16, 17 and 18 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 16: 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 31*bis* of the TRIPS Agreement. *(Indicator: Inter-organizational report on national legislation and patenting guidelines that include the*	• In collaboration with other relevant international organizations, including the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and other United Nations agencies working in intellectual property, collect information related to intellectual property legislation, in particular patent legislation and patentability guidelines. • Collect and publish information from Member States on the incorporation into national legislation of the flexibilities provided in the TRIPS Agreement.

[1] https://www.who.int/phi/implementation/tech_transfer/Interagency-statement-on-promoting-local-production.pdf?ua=1 (accessed 3 December 2020).

Recommendation of the review panel	Steps to be taken by the Secretariat
flexibilities provided in the TRIPS Agreement prepared by 2021.)[1]	• Provide technical support to Member States, as appropriate and upon request, in collaboration with other competent organizations, including on policy processes for the implementation of the flexibilities provided in the TRIPS Agreement. • In collaboration with other competent international organizations, including WIPO and WTO, prepare a report on national legislation and patenting guidelines that includes the flexibilities provided in the TRIPS Agreement, in accordance with action 5.2(a) and (b) of the global strategy and plan of action on public health, innovation and intellectual property.
Recommendation 17: 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.)*	• Collect information on existing user-friendly databases containing publicly available patent status and licensing information. • Promote the further development and use of existing and new publicly available databases containing useful and reliable information for public health stakeholders and procurement agencies.
Recommendation 18: 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.)*	• In line with action 4.3(a) of the global strategy and plan of action on public health, innovation and intellectual property, examine the feasibility of voluntary patent pools (e.g. the Medicines Patent Pool) of upstream and downstream technologies to promote innovation of and access to health products and medical devices. • Facilitate widespread access to, and promote further development of, including, where necessary, the compiling, maintaining and updating of, user-friendly global databases that contain public information on the administrative status of health-related patents, and support existing efforts to determine the patent status of health products in order to strengthen national capacities for analysis of the information contained in those databases. • Work in collaboration with the Medicines Patent Pool and other competent organizations to develop patent landscapes aimed at promoting further development of products and access to needed medicines or technologies for all.

[1] High-priority action.

6. Improve delivery and access

Rationale

19. Support for and strengthening of health systems are vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system. As such, international agreements that may have an impact on access to health products in developing countries should be regularly monitored with respect to their development and application. Bearing in mind country specificities, national authorities should consider implementing any flexibilities in such agreements that provide for improved access to medicines and other health products, including those contained in the TRIPS Agreement and recognized by the Doha Declaration on the TRIPS Agreement and Public Health. The impact on innovation of taking such action should be monitored.

Table 6. Recommendations 20, 21, 22, 23, 25 and 26 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 20: 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.)*[1]	• Encourage health authorities to improve domestic management capacities in order to improve the delivery of and affordable access to safe, effective and quality medicines and other health products, and where appropriate, to develop strategies to promote the rational use of medicines. • Promote operational research aimed at maximizing the appropriate use of new and existing products, including cost-effective and affordable products in settings with a high disease burden. • Prepare a report on bilateral and regional collaboration programmes.
Recommendation 21: 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.)*[1]	• Publish policy guidelines for improving access to affordable health products. • Revise manuals on how to develop, implement and monitor national medicines and health products. • Monitor and publish pricing information.
Recommendation 22: 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.)*[1]	• Develop tools for monitoring the availability and predictors of access to medicines, vaccines, and health products, including country profiles, household surveys and health facility assessments. • Develop tools and policy guidance on monitoring affordability along the supply and distribution chain when delivering health products to patients.

[1] High-priority action.

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 23: 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.)*	• Hold the International Conference of Drug Regulatory Authorities and issue an outcome document containing recommendations. • Establish and maintain global regulatory networks. • Develop a regulatory framework and expand harmonized guidelines for all health products through the African Medicines Regulatory Harmonization initiative. • Facilitate pathways for product registration, including by strengthening collaborative registration procedures. • Provide technical assistance to manufacturers of medical devices and/or other stakeholders to ensure that product development, testing and production facilities are in line with WHO norms and standards. • Develop WHO certification and proficiency schemes. • Finalize a competencies framework and self-assessment tools. • Establish training modules, training centres, mentorship platforms, a global competencies framework and curriculum, a roster of international experts, rotations within WHO and other agencies, and workshops on WHO regulatory guidelines. • Provide technical assistance on training course design and delivery. • Map the distribution of poisonous snakes and offer regulatory capacity-building for the selection, importation and appropriate use of antivenoms. • Prepare a report on progress of national and regional regulatory capacity-building efforts in developing countries.
Recommendation 25: 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.)*	• Revise manuals on how to develop, implement and monitor a national medicines and health products policy. • Develop guidance on the sale, labelling and promotion of antimicrobial medicines. • Update the Access, Watch and Reserve (AWaRe) classification of antibiotics. • Develop guidance documents and implementation tools on how and why to adopt the AWaRe classification. • Establish a hospital stewardship certification initiative to certify hospital adherence to certain antimicrobial resistance stewardship standards.

Recommendation of the review panel	Steps to be taken by the Secretariat
	• Develop a guidance document on the safe use of medical devices. • Pilot a training package on the provision of assistive technology products in two countries. • Conduct a survey on priority assistive technology needs in emergencies and crisis situations. • Support the development of disease commodity packages for emergencies and outbreaks. • Conduct a landscape analysis of the priority assistive products required for health emergency response. • Assess critically needed medical product candidates for emergency use. • Update the guidelines for medicine donations. • Update the criteria for the requesting and provision of medical device donations. • Update the inter-agency emergency health kits. • Update the list of medical devices for emergencies. • Update guidance on the safe disposal of unused medicines (including antimicrobials). • Publish a manual of priority assistive products required for health emergency response. • Support countries in the selection and prioritization of processes when updating their respective national essential medicines list.
Recommendation 26: 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.)*	• Develop concepts for the pooled procurement of health products, including medical devices. • Encourage increased investment into health delivery infrastructure and the financing of health products in order to strengthen the health system and facilitate competitive procurement practices. • Develop guidelines on the joint procurement of health products. • Update the model quality assurance system for procurement of health products. • Ensure that e-training for effective vaccine procurement is made available to countries. • Support the development of South Eastern European Health Network strategic procurement options for improved access to vaccines within the respective network countries. • Provide services to support the sustainable local production of safe, effective and quality medical products, including a model strategy and plan of action, guidance, tools and training packages, a

Recommendation of the review panel	Steps to be taken by the Secretariat
	global knowledge repository, and direct and coordinated assistance to Member States. • Roll out a new wastage rate calculator to decrease vaccine wastage and increase efficiency. • Develop guidelines on good pharmaceutical procurement. • Update guidance on the procurement of medical devices (including in vitro diagnostics).

7. Promote sustainable financing mechanisms

Rationale

20. In recent years, donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional funding has also been secured for research and development activities linked to the control and treatment of the diseases covered by the global strategy and plan of action on public health, innovation and intellectual property. Nonetheless, further sustainable funding will be essential to support the long-term research and development efforts towards identifying products that meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by the global strategy and plan of action should be identified and analysed. It is important to make the best use of, and complement where appropriate, existing viable initiatives, thereby contributing to a flow of resources into innovation and implementation.

Table 7. Recommendation 31 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
Recommendation 31: 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.)*	• Provide technical and political support for the Global Antibiotic Research and Development Partnership.

8. Establish a monitoring and accountability mechanism

Rationale

21. Systems should be established to monitor the performance and progress of the global strategy and plan of action on public health, innovation and intellectual property. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the global strategy and plan of action will be undertaken after four years.

Table 8. Recommendation 32 of the review panel and steps to be taken by the Secretariat

Recommendation of the review panel	Steps to be taken by the Secretariat
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.)*[1]	• Present an implementation plan for 2020–2022 and a mechanism for monitoring the global strategy and plan of action. • Prepare progress reports in 2020, 2021, and 2022.

CONCLUSIONS

22. This implementation plan defines the actions to be carried out by the Secretariat to implement the relevant overall programme review recommendations, drawing on the provisions of the road map for access to medicines, vaccines and other health products, 2019–2023. The overall programme review recommendations, if achieved by 2022, would constitute real progress; however, adequate, sustainable funding by Member States, including for steps to be taken by the Secretariat, is a prerequisite for the success of the global strategy and plan of action on public health, innovation and intellectual property.

= = =

[1] High-priority action.