

ANNEXⁱ

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)

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 recognizes research and development of and access to affordable essential medicines and vaccines for the communicable and non-communicable diseases that primarily affect developing countries as a global public health challenge.^{1,2} Adopted in 2008, the aim of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) is to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries.³
2. Although progress has been made in certain aspects of both innovation and access since 2008, many of the challenges that motivated formulation of the GSPA-PHI 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. Concerned about the pace of implementation of the GSPA-PHI, the Sixty-eighth World Health Assembly (2015) decided, inter alia, to undertake an overall programme review of the GSPA-PHI.⁴ 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 GSPA-PHI, until 2022.⁵ The review panel considered that the eight elements of the GSPA-PHI remain 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.⁶ The recommendations were directed to the WHO Secretariat and/or Member States, rather than the multiplicity of relevant stakeholders, it being the role of the WHO Secretariat and Member States to encourage appropriate involvement of the broader range of stakeholders.

¹ Support the research and development of vaccines and medicines for the communicable and non-communicable 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

² <https://www.un.org/sustainabledevelopment/health/>

³ https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf

⁴ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R18-en.pdf

⁵ <https://www.who.int/medicines/areas/policy/GSPA-PHI3011rev.pdf?ua=1>

⁶ https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_13-en.pdf

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 of an overall programme review panel 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.”⁷

5. The resulting implementation plan outlines the aim, scope and guiding principles of the plan, consistent with the GSPA-PHI. It also defines the actions needed by the Secretariat to implement the relevant recommendations, drawing on the “Road Map for Access to Medicines, Vaccines and Other Health Products, 2019–2023,” which outlines the programming of WHO’s work on access to medicines and vaccines, including activities, actions and deliverables.

AIM AND SCOPE

6. This implementation plan builds on the recommendations addressed to the Secretariat as prioritized by the overall programme review panel of the GSPA-PHI and covers the period 2020–2022. It brings together in one place the actions needed to implement the relevant recommendations, drawing from the “Road Map for Access to Medicines, Vaccines and Other Health Products, 2019–2023,” which outlines the programming of WHO’s work on access to medicines and vaccines, including activities, actions and deliverables.

7. The aim of the GSPA-PHI, “to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries,” is in alignment with the objectives of the 2030 Agenda for Sustainable Development, notably targets 3.8 and 3.B.^{8,9}

THE PRINCIPLES

8. 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”. 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 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.

⁷ [https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71\(9\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(9)-en.pdf)

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

⁹ Support the research and development of vaccines and medicines for the communicable and non-communicable 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

- 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

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

9. The overall programme review considered that the eight elements of the GSPA-PHI remain broadly valid.
10. The elements and their corresponding actions were designed to: set, prioritize and promote research; foster and build innovation capacity; promote technology transfer and local production of medical products; promote the management and application of intellectual property rights to improve public health; improve access to medical products; mobilize

resources for research and development relevant to this area and monitor and evaluate the progress in all these areas.

11. 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.

PRIORITIZED RECOMMENDATIONS OF THE REVIEW PANEL ADDRESSED TO THE SECRETARIAT

12. An overall programme review panel prioritized 33 actions, rather than the 108 actions in the original GSPA-PHI. To ensure feasibility, many of the prioritized actions build on existing activities by, or with support from, the Secretariat and other partners.

13. The panel formulated a set of actions, indicators and deliverables, which, if achieved by 2022, would constitute real progress. A necessary condition for success is adequate, sustainable funding by Member States, including for activities that are 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 GSPA-PHI. Although the activities of stakeholders are integral to its success, it is for the Secretariat and Member States to encourage their appropriate involvement; furthermore, there is no mechanism for holding stakeholders directly to account. Member States and stakeholders should be fully involved in early planning of the implementation of the GSPA-PHI. A communications strategy and materials should be produced to raise awareness of the GSPA-PHI.

14. 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 estimated 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 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.

I. Prioritize Research and Development Needs

Rationale

Health research and development policies of developed countries need to reflect adequately 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 need to be identified urgently. A better understanding of the developing countries'

health needs and their determinants is essential to drive sustainable research and development on new and existing products.

Table 1.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p><u>Recommendation 2:</u> 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. <i>(Indicator: Methodology for the prioritization of research and development needs developed by 2018.)¹⁰</i></p>	<ul style="list-style-type: none"> Analyse feedback received on draft report of prioritization framework for the R&D of malaria health products.¹¹ Deliberation on malaria R&D priorities methodological approach and outputs by expert panel in consultative step.
<p><u>Recommendation 3:</u> 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. <i>(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.)¹²</i></p>	<ul style="list-style-type: none"> Expand the Global Observatory on Health Research and Development's analysis and synthesis of health R&D, including defining global strategic directions, for specific diseases, pathogens and conditions, drawing on information from WHO specialized departments, the Global Observatory on Health Research and Development and published online information and resources.¹³ Establish an approach to convening an advisory group to advise 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, medical devices (including personal protective equipment).

¹⁰ * High-priority action.

¹¹ <https://www.who.int/research-observatory/analyses/malaria/en/index1.html>

¹² * High-priority action.

¹³ <https://www.who.int/research-observatory/analyses/en/>

	<ul style="list-style-type: none"> • Updated analysis of the R&D pipeline for new antibiotics prepared. • Expand annual pipeline report to include antifungals. • Develop R&D priority list for in vitro diagnostics for antimicrobial resistance. • Update WHO Priority Pathogens List.
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II. Promote Research and Development

Rationale

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.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p><u>Recommendation 5:</u> 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.</p> <p><i>(Indicator: Establishment of an information-sharing mechanism to improve collaboration and coordination of resource allocation in accordance with research and development priorities by 2020.)¹⁴</i></p>	<ul style="list-style-type: none"> • Strengthen 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 a diversity of stakeholder groups to promote evidence-informed decisions on new investments in health research based on public health needs.
<p><u>Recommendation 7:</u> 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.</p> <p><i>(Indicator: Report by 2022 on new initiatives by funders of research and development to ensure that the resulting</i></p>	<ul style="list-style-type: none"> • Provide guidance and support, upon request, to funders of research and development to make all resulting publications open access immediately. • Ensure, by 2021, that all research supported or published by WHO is available for immediate access and

¹⁴ * High-priority action.

<i>publications in peer-reviewed journals are open access.)</i>	reusable under the terms of a Creative Commons licence. <ul style="list-style-type: none"> • 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.
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III. Build and Improve Research Capacity

Rationale

There is a need to frame, develop and support effective policies that promote the development of capacities in developing countries related to health innovation. 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.

Recommendation of the review panel	Steps to be taken by the Secretariat
<u>Recommendation 8:</u> 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. <i>(Indicator: Report on new collaboration programmes developed and supported by 2021.)¹⁵</i>	<ul style="list-style-type: none"> • Develop tools and standards for national research capacity strengthening. • Prepare a report on new collaboration programmes developed and supported.
<u>Recommendation 9:</u> 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. <i>(Indicator: Report on national and regional initiatives for strengthening clinical trial regulatory capacity in developing countries by 2019 and 2021.)¹⁶</i>	<ul style="list-style-type: none"> • Hold the International Conference of Drug Regulatory Authorities and issue recommendations. • Establish and maintain global regulatory networks. • Develop a regulatory framework and expand harmonized guidelines through the African Medicines Regulatory Harmonization Initiative for all health products. • Strengthen facilitated pathways for product registration: collaborative registration procedure. • Provide technical assistance to manufacturers of medical devices and/or other stakeholders to ensure

¹⁵ * High-priority action.

¹⁶ * High-priority action.

	<p>product development, testing and production facilities are in line with WHO norms and standards.</p> <ul style="list-style-type: none"> • Develop WHO certification and proficiency schemes. • Finalize competencies framework and self-assessment tools. • Establish training modules, training centres, mentorship platforms, global competencies framework and curriculum, 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 distribution of poisonous snakes and regulatory capacity building delivered for selection, importation and appropriate use of selected antivenoms. • Prepare a report on national and regional initiatives for strengthening clinical trial regulatory capacity in developing countries.
<p><u>Recommendation 10:</u> 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.)</p>	<ul style="list-style-type: none"> • Organize consultation with Member States to promote the development of a database on relevant training programmes and materials.
<p><u>Recommendation 12:</u> 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</p>	<ul style="list-style-type: none"> • Provide technical guidance to support Member States in providing safe, qualified and effective Traditional Complementary and Integrative (TCI) services. • Develop a series of “Benchmarks for Practice” in traditional and

<i>strategies and strengthening capacity in research and development for traditional medicine by 2022.)</i>	<p>complementary medicine (T&CM).</p> <ul style="list-style-type: none"> • Prepare technical documents on: training and practice of TCI (traditional, complementary and integrative medicine); clinical research in T&CM, and; “Key technical issues for the safe use of herbal medicines with reference to interaction with other medicines.” • Develop a tool package to support Member States in identifying models and approaches for integration of T&CM into their health systems and UHC plans more comprehensively. • Build institutional capacity by developing capacity building tools, including a series of “Benchmarks for Training” and through annual interregional training workshops for government officials. • Prepare a report on national and regional programmes for developing strategies and strengthening capacity in research and development for traditional medicine.¹⁷
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IV. Promote transfer of technology

Rationale

North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights states that the protection and the 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.

Recommendation of the review panel	Steps to be taken by the Secretariat
<u>Recommendation 13</u> : The WHO Secretariat to identify mechanisms to	<ul style="list-style-type: none"> • Prepare a report in relation to the specific mechanisms that were

¹⁷ <https://www.who.int/traditional-complementary-integrative-medicine/activities/en/>

<p>increase health technology transfer in the context of the Technology Facilitation Mechanism established by the Sustainable Development Goals.</p> <p><i>(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.)¹⁸</i></p>	<p>identified as examples to increase health technology transfer.</p> <ul style="list-style-type: none"> • Organize technology transfer and local production conference. • Experience sharing. • Promote technology transfer and local production through partnerships. • Provide recommendations and develop action plan.
<p>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.</p> <p><i>(Indicator: Report on progress on health technology transfer related to implementation of Article 66(2) of the TRIPS Agreement by 2021.)¹⁹</i></p>	<ul style="list-style-type: none"> • Continue to promote and encourage technology transfer to LDCs, including through international collaboration, that is consistent with Article 66(2) of the TRIPS Agreement. • Prepare a report on progress of health technology transfer activities related to Article 66 (2) of the TRIPS Agreement.
<p>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.</p> <p><i>(Indicator: Inter-organizational report on national technology transfer programmes developed and disseminated by 2022.)</i></p>	<ul style="list-style-type: none"> • Develop a tool to conduct holistic situational analyses to assist Member States to identify gaps and provide evidence-based recommendations for promoting technology transfer and sustainable local production. • Convene meetings and seek collective actions with UN organizations and international partners for promoting technology transfer and local production to address public health needs in developing countries in the context of the 1st interagency statement on promoting local production launched in the 72nd WHA. • Develop, in collaboration with partners, a model strategy and plan of action for Member States and regions interested in quality local production. • Organize technology transfer and local production conference. • Experience sharing.

¹⁸ * High-priority action.

¹⁹ * High-priority action.

	<ul style="list-style-type: none"> • Promote technology transfer and local production through partnerships. • Provide recommendations and develop an action plan.
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V. Manage intellectual property to contribute to innovation and public health

Rationale

The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific research and development needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

Table 5.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p>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 31bis of the TRIPS Agreement.</p> <p><i>(Indicator: Inter-organizational report on national legislation and patenting guidelines that include the flexibilities provided in the TRIPS Agreement prepared by 2021.)²⁰</i></p>	<ul style="list-style-type: none"> • In collaboration with other relevant international organizations, including WIPO, WTO and other UN 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 implementation of the TRIPS flexibilities into national legislation. • Provide technical support to Member States as appropriate, upon request, in collaboration with other competent organizations, including on policy processes for the implementation of the TRIPS flexibilities. • In collaboration with other competent international organizations, including WIPO

²⁰ * High-priority action.

	and WTO, prepare a report on national legislation and patenting guidelines that include the flexibilities provided in the TRIPS Agreement, in line with action 5.2(a,b) of the Plan of Action.
<p>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. <i>(Indicator: Monitor coverage and use of existing and new databases of patent and licence information.)</i></p>	<ul style="list-style-type: none"> • Collect information on existing user-friendly databases containing publicly available patent status and licensing information. • Promote further development and use of existing and new publicly available databases containing useful and reliable information for public health actors and procurement agencies.
<p>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. <i>(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.)</i></p>	<ul style="list-style-type: none"> • In line with action 4.3 (a) examine the feasibility of voluntary patent pools (e.g. the MPP) 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, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining 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 MPP and other competent organizations to develop patent landscapes to promote further development of products and access to needed medicines or technologies for all.

VI. Improve delivery and access

Rationale

Support for and strengthening of health systems is 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. International agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Declaration on the TRIPS Agreement and Public Health, that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

Table 6.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p>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.</p> <p><i>(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.)²¹</i></p>	<ul style="list-style-type: none"> • Encourage health authorities to improve domestic management capacities in order to improve delivery of and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines • Promote operational research to maximize 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.
<p>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. <i>(Indicator: Guidance developed and disseminated in countries by 2020.)²²</i></p>	<ul style="list-style-type: none"> • Publish policy guidelines for improving access to affordable health products. • Revise manuals on how to develop, implement and monitor national medicines and health products. • Monitoring and publishing pricing information.
<p>Recommendation 22: The WHO Secretariat, in cooperation with Member</p>	<ul style="list-style-type: none"> • Develop tools for monitoring the availability and predictors of

²¹ * High-priority action.

²² * High-priority action.

<p>States and other partners, to establish mechanisms to monitor patient out-of-pocket expenditure on health products. <i>(Indicator: Monitoring patient out-of-pocket expenditure on health products.)</i>²³</p>	<p>access to medicines, vaccines, and health products including country profiles, house hold surveys and health facility assessments.</p> <ul style="list-style-type: none"> • Develop tools and policy guidance on monitoring affordability along the supply and distribution chain when delivering health products to patients.
<p>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. <i>(Indicator: Report on progress of national and regional regulatory capacity-building efforts in developing countries by 2021.)</i></p>	<ul style="list-style-type: none"> • Hold the International Conference of Drug Regulatory Authorities and issue recommendations. • Establish and maintain global regulatory networks. • Develop a regulatory framework and harmonized guidelines expanded through the African Medicines Regulatory Harmonization Initiative for all health products. • Facilitate pathways for product registration, for example, by strengthening collaborative registration procedures. • Provide technical assistance to manufacturers of medical devices and/or other stakeholders to ensure product development, testing and production facilities are in line with WHO norms and standards • Develop WHO certification and proficiency schemes. • Finalize competencies framework and self-assessment tools. • Establish training modules, training centres, mentorship platforms, global competencies framework and curriculum, 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.

²³ * High-priority action.

	<ul style="list-style-type: none"> • Map distribution of poisonous snakes and deliver regulatory capacity building for selection, importation and appropriate use of selected antivenoms. • Prepare a report on progress of national and regional regulatory capacity-building efforts in developing countries.
<p><u>Recommendation 25:</u> 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. <i>(Indicator: Best practices developed and capacity-building programmes implemented in countries by 2021.)</i></p>	<ul style="list-style-type: none"> • Revise manuals on how to develop, implement and monitor a national medicines and health products policy. • Develop guidance on sales, labelling and promotion of antimicrobial medicines. • Update the access, watch and reserve (AWaRe) categorization of antibacterials. • Develop guidance documents and implementation tools on how and why to adopt the access, watch and reserve categorization. • Establish a hospital stewardship certification initiative to certify hospital adherence to certain antimicrobial resistance stewardship standards. • Develop guidance document on safe use of medical devices. • Pilot, in two countries, a training package on provision of assistive technology products. • Conduct survey on priority assistive technology needs in emergencies and crisis situations. • Support development of disease commodity packages for emergencies and outbreaks. • Conduct landscape analysis of priority assistive products needed for emergency health response. • Assess critically needed medical products candidates for emergency use. • Update guidelines for donations of medicines.

	<ul style="list-style-type: none"> • Update the criteria for solicitation and provision of donations of medical devices. • Update interagency emergency health kit. • Update list of medical devices for emergencies • Update guidance on the safe disposal of unused medicines (including antimicrobials). • Publish manual of priority assistive products needed for emergency health response. • Support countries in their selection and prioritization processes when updating their own National Essential Medicines List.
<p><u>Recommendation 26:</u> The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement.</p> <p><i>(Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)</i></p>	<ul style="list-style-type: none"> • Develop concepts for pooled procurement of health products, including medical devices. • Encourage increased investment to health delivery infrastructure and financing of health products in order to strengthen the health system and facilitate competitive procurement practices. • Develop guidelines on joint procurement of health products. • Update model quality assurance system for procurement of health products. • Ensure that e-training for effective vaccine procurement is available to countries. • Support development of South Eastern European Health Network strategic procurement options for improved access to vaccines within network countries. • Provide services to support the sustainable local production of safe, efficacious and quality medical products, including a model strategy and plan of action, guidance, tools and training packages, a global knowledge repository, and direct and coordinated assistance to Member States.

	<ul style="list-style-type: none"> • Roll out of new wastage rate calculator to decrease vaccine wastage towards more efficiency • Develop guidelines on good pharmaceutical procurement. • Update guidance on procurement of medical devices (including in vitro diagnostics).
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VII. Promote sustainable financing mechanisms

Rationale

In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in financing for health products and research and development covered by this strategy need to be identified and analysed. It is important to make maximum use of, and complement as appropriate, feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.

Table 7.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p><u>Recommendation 31</u>: Member States, with the WHO Secretariat's support, to encourage an increase and diversification of funding for product development partnerships.</p> <p><i>(Indicator: increased and diversified funding for product development partnerships and progress as reported by G-Finder by 2022.)</i></p>	<ul style="list-style-type: none"> • Provide technical and political support for the Global Antibiotic Research and Development Partnership.

VIII. Establish a monitoring and accountability mechanism

Rationale

Systems should be established to monitor performance and progress of this strategy. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.

Table 8.

Recommendation of the review panel	Steps to be taken by the Secretariat
<p><u>Recommendation 32</u>: 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. (<i>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.</i>)</p>	<ul style="list-style-type: none"> • Present an implementation plan for 2020-2022 and mechanism for monitoring of the global strategy and plan of action. • Prepare progress reports in 2020, 2021, and 2022.

CONCLUSIONS

This implementation plan defines the actions to be carried out by the Secretariat to implement the relevant overall programme review recommendations, drawing on 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 necessary condition for the success of the GSPA-PHI.

ⁱ EB146/15 Report by Director-General on progress on implementation of the GSPA-PHI