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

Report on the Member States consultation 2023-2024
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Acknowledgements

This report was written by Erika Dueñas (technical officer) and Dzintars Gotham (consultant).
1 Background

The Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA-PHI) was originally developed and approved by the World Health Assembly in 2008 (1), and continued to guide WHO’s work in these areas. The time frame for the implementation of the GSPA-PHI was extended at the Seventy-fifth World Health Assembly (2022), with a new mandate in place until 2030 (2). The 75th WHA urged Member States (MS) to reinforce the implementation, as appropriate and taking into account national contexts, of the recommendations of the review panel that are addressed to Member States to the extent they are consistent with the GSPA-PHI, and to identify and share through informal consultations to be convened by the WHO Secretariat at least every two years, best practices related to the implementation of actions within the GSPA-PHI.

Responding to the request made in resolution WHA75.14 (2022) (2), WHO undertook in 2023 and early 2024 a review of the indicators included in the overall programme review of the GSPA-PHI (3), in consultation with Member States, as well as WHO regional offices and relevant teams in WHO headquarters, and developed proposed revisions to align indicators with the new term of validity of the plan of action, alongside a new implementation plan for GSPA-PHI for the 2024–26 biennium. This document outlines responses to a consultation process conducted between November 2023 and April 2024 to gather Member State priorities for the GSPA-PHI implementation plan for the 2024–26 biennium (an initial deadline for responses of 1 December 2023 was extended in order to accommodate requests for later submissions made by some Member States).

The part of the consultation outlined here was based on the circulation of a consultation document containing 53 questions covering the 8 Elements of the GSPA-PHI (Box 1), and the 30 Recommendations made by the overall programme review panel of the GSPA-PHI and agreed by Member States in 2017. Questions were designed to be forward-looking and create minimal administrative burden. Questions took different forms: binary (yes/no), multiple options, or open questions allowing free-text responses.


1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of intellectual property to contribute to innovate and promote public health
6. Improving delivery and access
7. Promoting sustainable finance mechanisms
Responses to the consultation document

Responses were received from 22 Member States, from the African Region, Region of the Americas, European Region, and Eastern Mediterranean Region (Table 1).\(^1\) Inputs from an additional 7 Member States\(^2\) in a recent regional consultation on GSPA-PHI in the South-East Asia Region were also incorporated.

**Table 1. Breakdown of Member States contributing inputs to this analysis.**

<table>
<thead>
<tr>
<th>Country group</th>
<th>Number of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO Region</strong></td>
<td></td>
</tr>
<tr>
<td>African Region</td>
<td>2</td>
</tr>
<tr>
<td>Region of the Americas</td>
<td>12</td>
</tr>
<tr>
<td>South-East Asia Region(^a)</td>
<td>7</td>
</tr>
<tr>
<td>European Region</td>
<td>4</td>
</tr>
<tr>
<td>Eastern Mediterranean Region</td>
<td>4</td>
</tr>
<tr>
<td>Western Pacific Region</td>
<td>0</td>
</tr>
<tr>
<td><strong>World Bank income category(^b)</strong></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>5</td>
</tr>
<tr>
<td>Upper-middle</td>
<td>11</td>
</tr>
<tr>
<td>Lower-middle</td>
<td>11</td>
</tr>
<tr>
<td>Low</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total responses</strong></td>
<td>29</td>
</tr>
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\(^a\)Inputs from a recent regional consultation on GSPA-PHI in the South-East Asia Region are incorporated in terms of qualitative descriptions of current activities, suggestions, and proposals. However, statistics reported in this summary under each of the 8 Elements refer only to the 22 Member States that responded directly to the consultation document.

\(^b\)The World Bank does not provide an income class for Venezuela in the most recent update, pending release of revised national accounts statistics. Therefore, the most recent available classification (upper-middle income; based on 2019 GNI per capita) was used.

### 2.1 Element 1: Prioritizing research and development needs

68% countries reported having undertaken an analysis of national R&D needs. However, only 45% of countries reported having an inter-ministerial (interdepartmental) R&D priority agenda. Some countries identified the need for increased interdepartmental coordination as a near-term priority.

Member States gave numerous suggestions for needs that WHO could address to strengthen collaboration between stakeholders in identifying health research and development priorities, in order to promote access to medical products. These included: the need for national networks between agencies funding research; the need for intersectoral collaboration; the need for mapping of key actors; the need for

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1. Argentina, Belize, Bolivia (Plurinational State of), Bulgaria, Cabo Verde, Colombia, Costa Rica, Czechia, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Lebanon, Oman, Pakistan, San Marino, Switzerland, Uganda, Uruguay, Venezuela (Bolivarian Republic of), Yemen.

multistakeholder platforms for discussing priorities; the need to involve the full range of actors working in the supply chain for health products; and the need for accessible platforms for publishing clinical trial results.

2.2 Element 2: Promoting research and development

36% of countries reported that national data on investments in health R&D is available, which could be contributed to an international information-sharing mechanism. 45% of countries reported that there would be national capacity to share data on public health R&D investments with WHO through a mechanism such as an online database.

Countries made suggestions for how WHO can support the collection and analysis of national-level data on health R&D investments. One country asked for WHO to support in the development of norms and methods for collecting nationally relevant data on R&D investments, as well as to offer technical assistance for analysing national data. One country suggested that WHO could provide a standardized format for concise reporting of national R&D investment data, in order to provide decision-makers with easily digestible summaries. Relatedly, some countries called for WHO to provide or support governments in establishing data repository systems for collecting and sharing this data. It was suggested that some data collection could be automated. Some countries endorsed WHO centralized analysis of national-level R&D investments.

One Member State suggested that WHO should expand its work in creating and hosting scientific journals in various languages, in order to support the publication of high-quality research in less widely spoken languages.

Only 14% of countries indicated high infrastructure and human resources for undertaking clinical trials (41% reported moderate capacity, 41% reported low capacity). 27% of countries reported highly developed clinical trials regulations, 36% reported moderately well-developed clinical trials regulations, and 32% reported that clinical trials regulations are less well-developed. Only 14% of countries indicated high involvement of national researchers in regional clinical trial expert networks.

Other priorities highlighted by countries included R&D to support pandemic preparedness.

2.3 Element 3: Building and improving innovative capacity

Across different areas of focus for regulatory capacity strengthening, the most commonly identified area of high need (73% of countries) for WHO support was for human resources, financial infrastructure, equipment, and information management systems. High needs for WHO support were reported by 41% of countries or more in all areas, including legal provisions, regulations, and guidelines; organization and governance; policy and strategic planning; leadership and crisis management; transparency, accountability, and communication; quality and risk management systems; regulatory review process; regulation of clinical trials; and monitoring progress and assessing impact. 73% of countries reported that there is a high need for WHO support in increasing the availability of training programmes and materials for people working in health R&D.
Other priorities highlighted by countries included ensuring that standard operating procedures and ethics guidelines are available for clinical research, as well as supporting R&D on traditional medicines. Some MS noted near-term objectives of sharing R&D resources between their national research funding agency and neighbouring countries.

2.4 Element 4: Transfer of technology

41% of countries reported having a national policy to increase local production of health products. Several Member States noted that active national government efforts are underway to identify opportunities for local production of biologics and anti-cancer drugs, under a new industrial policy directed at increasing technology transfer. Several countries identified local manufacturing capacity for vaccines, including with new vaccine platform technologies (e.g. mRNA), as a priority. Several Member States noted near-term plans for technology transfer to and from regional neighbours.

Numerous countries highlighted that obtaining WHO ML3 for local regulator and improving local capacity for manufacturing aligned with Good Manufacturing Practices (cGMP) as high priorities and WHO technical assistance would be welcome in this area. Countries mentioned that virtual workshops are a good tool for supporting improved national capacity.

73% of countries reported that there is a need for strengthened global mechanisms to facilitate technology transfer for health product development and manufacture. Member States identified a range of actions that WHO could take to support technology transfer. Countries called for continued WHO development of relevant guidance and international norms, technical assistance on legal aspects of regulation, and regulatory harmonization, highlighting the need for harmonization for vaccines and advanced therapeutic medical products. The creation of regional technology transfer hubs was suggested.

Countries called for WHO support in identifying channels for access to low-cost financing for investments in technology transfer and increased manufacturing capacity, emphasising that strengthened regional manufacturing capacity is a priority due to its role in pandemic preparedness. Countries called for WHO support in increasing the use of patent pools.

Countries called for WHO technical assistance on intellectual property issues, technology transfer for manufacturing, technical assistance on clinical trial ethics procedures.

Countries highlighted that WHO can facilitate the sharing of experiences and best practices in technology transfer, including through model technology transfer agreements. One proposed mechanism was for WHO to identify and match willing industry partners in the Global North and South for technology transfer. Countries called for WHO to support national efforts in mapping baseline manufacturing capacity and key actors that could contribute to technology transfer to strengthen regional manufacturing capacity, thereby strengthening regional health sovereignty. One Member State proposed establishing a “central organization as representative of SEA association to negotiate incentives for technology transfer agreements that address local public health
needs”. Other suggestions included that WHO could support technology transfer by fostering networking and partnerships with international organizations, advocating for conducive policies, facilitating information sharing, organizing conferences and workshops, providing technical assistance with regard to the manufacturing of medicines, and assisting in the development of a model strategy and action plan.

2.5 Element 5: Application and management of intellectual property to contribute to innovation and promote public health

Member States recognized the WHO COVID-19 Technology Access Pool database (C-TAP database) as an important resource for countries. However, some Member States reported limited awareness of this tool.

Countries suggested several ways in which the database can be improved, including by adding national registration status, data on prices and access, data on clinical effectiveness data on manufacturers and quality, data on global supply chains and stockouts, and pharmacovigilance data and regulatory alerts. Countries suggested that WHO should provide mechanisms for countries to contribute these data, which could be done through regional consultations, online systems, and partnerships with regional and national regulators. One Member State suggested that guidelines for compiling data to be submitted to the database and a dedicated national focal person to assist in this process may be helpful.

Several countries called for WHO to publicize the C-TAP database more, in order to ensure relevant national agencies are aware of the database and able to use it at the national level. It was suggested that WHO could provide training on the use of the C-TAP database and demonstrate use cases.

68% of countries reported that the WHO-WIPO-WTO COVID-19 Technical Assistance Platform is a useful tool. However, countries emphasised that efforts should be made to ensure that the Platform is more widely known. It was suggested that the platform could offer technical assistance for implementing the decision of the 12th WTO Ministerial Conference with regard to the grant of waivers on COVID-19 vaccine patents (4).

50% of countries assessed voluntary licensing as a moderately effective mechanism for enabling affordable access, while 14% assessed voluntary licensing as highly effective. Countries made suggestions for how voluntary licensing can be improved: Expanding their geographic scope, specifically to include upper-middle-income countries; increasing transparency; including provisions for technology transfer; expanding the use of voluntary licenses beyond medicines, to diagnostics, medical devices, and vaccines; and including beneficiary countries in the negotiation and administration of licences. Countries suggested that broader familiarization of countries and manufacturers with the voluntary licensing model is needed.

73% of countries recommended that new innovative incentive mechanisms should be explored to promote voluntary licensing. One country argued that “[e]xperience has shown that voluntary licensing does not work for upper-middle-income countries, which still face great difficulties in guaranteeing timely access to technologies. This has been the situation in [the responding Member State] and in most Latin American
countries. The limited impact of voluntary licenses [in some countries] has been one of the reasons why the Waiver initiative emerged during the Covid-19 pandemic, as a proposal to streamline access to technologies”. In order to promote technology transfer to developing countries, countries suggested approaches including: tax incentives, regulatory incentives, public-private, partnerships. Other enabling actions that WHO could support were proposed: making available model contracts for technology transfer, regulatory harmonization, streamlining and expediting the regulatory approval of products developed through technology transfer, promoting the use of open-source technologies, and strengthening relevant human resources to increase absorptive capacity.

Some countries noted that tailored technology transfer programs supported by UN organizations may be particularly useful. One country suggested the establishing of an international fund to finance technology transfer projects.

55% of countries reported implementing flexibilities in Article 27, 50% reported implementing flexibilities in Articles 30 and 31, 45% reported implementing flexibilities in Article 31bis, 36% reported implementing flexibilities related to Article 6, 32% reported implementing flexibilities related to Articles 7 and 8, and 9% reported implementing flexibilities related to Article 66.1 (Extension period for least-developed countries). 9% reported other legislative provisions related to public health safeguards.

One Member State highlighted that they had instituted a policy of “mandatory reporting of public-funded research outcomes”.

2.6 Element 6: Improving delivery and access

Countries provided proposals for how WHO can support national staff to develop or strengthen national/regional collaboration programmes in the evidence-based selection and health technology assessments (HTA) for health products.

Several Member States highlighted the development of HTA processes as a high national priority, under this Element. Specific suggestions for WHO actions that could support national and regional HTA strengthening mentioned by countries included: the development of guidelines, development of standards and tools for HTA, collection and dissemination of best practices, technical assistance for HTA evaluations, technical assistance for legislative changes and other legal instruments necessary to enable HTA, provision of training in HTA, facilitation of exchanges of staff between countries with less developed HTA and countries with better developed HTA institutions, facilitation of bilateral and regional cooperation in HTA, and the creation of a platform for sharing HTA evaluations of health products. Some countries suggested WHO could host a public database of HTAs.

50% of countries reported that they collect data on prices of essential medicines, and 45% reported that they have a mechanism for monitoring out-of-pocket expenditures on health products. 29% of countries reported a high need for WHO support in undertaking analyses of out-of-pocket expenditures, while 41% reported a moderate need.
With regard to regulatory capacity strengthening, countries highlighted the need for training to develop an expert workforce, as well as the need for exchange of experiences and best practices. Some countries called for WHO to continue to expand the portfolio of WHO guidance on regulatory procedures, and to continue expanding the work of the WHO Prequalification Programme on newer essential medicines and biosimilars. Some countries called for technical assistance for implementing cGMP (both quality assurance and quality control), Global Clinical Practice (GCP), and pharmacovigilance systems.

Several countries identified mutual regulatory reliance networks that they participate in. Several countries noted that, although they do not participate in formal mutual recognition systems, they do recognise certain regulatory decisions taken in other jurisdictions, for example, GMP certificates. Some countries noted that, although reliance procedures do not currently exist, they are being developed. Several countries encouraged WHO to promote regulatory harmonization and reliance, emphasising the potential for regional reliance procedures.

Other near-term priorities identified by Member States included establishing emergency procurement mechanisms for use during pandemics or other public health emergencies.

2.7 Element 7: Promoting sustainable finance mechanisms

23% of countries reported that there is national data available on the percentage of GDP spent on health research.

41% of countries reported that there is a high need for WHO support in developing schemes to delink product prices from research and development costs, while 32% of countries reported there is a moderate need.

Countries made suggestions on how WHO can provide country-level support to encourage the increasing and diversification of funding for product development partnerships (PDPs): countries could sign agreements with established international PDPs such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the International AIDS Vaccine Initiative (IAVI); WHO could facilitate an exchange of best practices regarding PDPs; WHO could facilitate connecting relevant partners; WHO could connect research organizations to relevant funders; and WHO could support in mobilizing funders for PDPs.

One Member State recommended that “WHO should initiate a process of negotiating global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D convention to promote access to good health for all. As a preparatory step, governments should form a working group to begin negotiating a code of principles for biomedical R&D.”

Several countries described national or regional initiatives focused on the development of new health products, including initiatives to develop new vaccines and therapeutics for COVID-19 and animal vaccines. In some cases, these initiatives are part of broader industrial policy: one country responded that “the health sovereignty policy is being
coordinated with the reindustrialization policy to add resources that make R&D initiatives viable that respond to local health needs”.

2.8 Element 8: Establishing monitoring and reporting systems

82% of countries recommended that dedicated regional meetings, convened by WHO, would be helpful in enabling country-level reporting of progress in GSPA-PHI implementation.

Some Member States highlighted a near-term objective of developing new IT systems to monitor national health research activity.
3 Summary

Significant needs remain for strengthening the prioritization of health research and development, with Member States giving suggestions for how WHO can support work on this at the national, regional, and international levels. Among others, Member States reported a lack of data and data collection systems on national investments in R&D, deficiencies in clinical trial infrastructure, and needs for WHO support in strengthening regulatory capacity. A minority of Member States reported having a national policy to increase local production of health products, while a majority of Member States noted a need to strengthen global mechanisms to facilitate technology transfer, which could be supported by WHO. While countries noted that the C-TAP database and WHO-WIPO-WTO COVID-19 Technical Assistance Platform are useful resources, several suggestions were made for how WHO can improve their utilization, including by publicizing the tools more. Member States made proposals for how voluntarily licensing systems could be strengthened. Several Member States reported not implementing TRIPS flexibilities. Several Member States reported a lack of data on medicine prices, cost of production, and overall pharmaceutical expenditures. Several Member States made suggestions on how WHO can support increased and diversified funding for product development partnerships. 82% of countries recommended that dedicated regional meetings, convened by WHO, would be helpful in enabling country-level reporting of progress in GSPA-PHI implementation.
4 References


