Member State Information Session

16 December 2019 | Division of Medicines & Health Products | GSPOA@WHO.INT
Information Session for Member States

1. **Background information**
   - GSPA-PHI
   - Overall Review Panel
   - Progress report and implementation plan 2020-2022

2. **About the Questionnaire**
   - Purpose
   - Content (Health + IP)
   - WHA71(9) Paragraph 2
   - Process and timelines

3. **Related activities in the Global Agenda**
   - GSPA-PHI Draft Implementation plan 2020-2022
   - 146th Executive Board and 73rd WHA (2020)
   - Implementation Resolution on Improving the Transparency of Markets for Medicines, Vaccines and other Health Products
   - Road map on Access to Medicines, Vaccines, and other Health Products

4. **Questions/Clarifications**
   Further clarifications: gspoa@who.int
Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPA-PHI)

GSPA-PHI document (GSPA) was agreed by Member States (IGWG 2008) several recommendations and progress indicators to foster innovation and improve access for people in developing countries. (WHA61.21 and WHA62.16)

8 Elements GSPA-PHI:
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
6. Improving delivery and access
7. Promoting sustainable financing mechanisms
8. Establishing and monitoring reporting systems
GSPA-PHI
Overall programme review

WHA62.16 requested an overall programme review of the GSPA-PHI in 2014 (achievements, remaining challenges and recommendations)

WHA68.18 decided “to extend the time frames of the plan of action on public health, innovation and intellectual property from 2015 until 2022.” (composition of the Overall review panel)

- Expert review panel (document A71/13) presented at the 71st WHA in May 2018.
- Panel report considered that the 8 elements of the GSPA remain broadly valid, noting that the main problem is the lack of its implementation.
- Prioritized 33 recommendations and indicators for implementation and monitoring.
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.”

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”

“submit a report on progress made in implementing this decision to the Seventy-third WHA in 2020, through the Executive Board at its 146th session.”
Member State Questionnaire

The purpose

- **To gather baseline information** from Member States to monitor progress on implementing decision WHA71(9)*.

- The responses to this questionnaire will be compiled in aggregate form. Country names will not be attributed to the information provided.

- To complement the 2020 report on progress and implementation plan prepared by WHO Secretariat for next EB (Currently includes recommendations addressed to the Secretariat).

- Country responses will also be used to guide follow-up actions and provision of assistance and support.

* Note: The Questionnaire was prepared with the inputs and support of several departments in WHO (Including new Science Division, Traditional Medicines, Regulatory, Pricing and Procurement, EML, EDL, Technology transfer, Vaccines, IP and other teams)
Member State Questionnaire
The content

- Questions are based on the 8 elements of the GSPA-PHI

- According to 30 of the recommendations made by the Expert review panel and approved by Member States.

- Some related additional questions are included to collect useful information for the Secretariat to further develop the implementation plan and for the implementation of other related resolutions, such as recently approved WHA72.8.

- Questions related to IP are included in particular in elements: 4. Transfer of technology and 5. Application and management of intellectual property

ABOUT THE QUESTIONNAIRE
The questionnaire is organized in the following way:

- Section A on Member State information
- Section B on statement of policy on data sharing
- Section C on GSPA elements
  - Prioritize research and development needs
  - Promote research and development
  - Build and improve research capacity
  - Promote transfer of technology
  - Manage intellectual property to contribute to innovation and public health
  - Improve delivery and access
  - Promote sustainable financing mechanisms
  - Establish a monitoring and accountability mechanism
- Section D on other aspects
Member State Questionnaire
Content: Decision WHA71(9) –Paragraph 2

“to urge Member States also to further discuss the recommendations of the review panel not emanating from the global strategy and plan of action on public health, innovation and intellectual property;”

The Member States Questionnaire does not include questions related to:

**Recommendation 4**: Member States to support the WHO Secretariat in promoting transparency in, and understanding of, the costs of research and development.

**Recommendation 27**: Member States to identify essential medicines that are at risk of being in short supply and mechanisms to avoid shortages, and disseminate related information accordingly.

**Recommendation 28**: Member States to commit to dedicating at least 0.01% of their gross domestic product to basic and applied research relevant to the health needs of developing countries.

Member State Questionnaire
Process and timelines

✓ **Circular Letter** was sent to Member States explaining process.

✓ **Focal Point Nominations:**
  - **Purpose:** To coordinate the collection and reporting of the Government’s intersectoral response to the questionnaire.
  - **Nomination Timeframe:** 16 December 2019 (extended)
  - **Process:** Upon receipt of nomination to gspoa@who.int, Secretariat sends invitation to online questionnaire which includes a unique token code link.

✓ Questionnaire **translated in all official languages** to facilitate responses, however **English answers strongly encouraged**.

✓ If unable to submit questionnaire online, contact the Secretariat.

✓ **Final deadline:** **Friday, 10 January 2020**
146\textsuperscript{th} Executive Board (2020)
GSPA-PHI Agenda Item

- Report on progress made in implementing WHA71(9): \textbf{EB146/15 Report by Director-General on progress on implementation of the GSPA-PHI}

- \textbf{Draft Implementation Plan 2020-2022}
  https://www.who.int/medicines/innovation/gspa-review/en/

- Recommendation 32 of the review panel (document A71/13) requires: “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.”
Final Implementation Plan 2020-2022 will be presented by the WHO Secretariat, as an annex of the Report on Progress of the Implementation of the GSPA-PHI, containing inputs from Member States received through the MEMBER STATE QUESTIONNAIRE.
Other related activities in the global health agenda

GSPA-PHI

- Related/similar activities to the prioritized recommendations in the GSPA-PHI are included in the following documents:
  - WHA72.8 Resolution on Improving the Transparency of Markets for Medicines, Vaccines and other Health Products (e.g. promoting user-friendly patent status databases)
  - Road map on Access to Medicines, Vaccines, and other Health includes activities, actions and deliverables for 2019–2023 (e.g. R&D; Pricing policies; Application and management of IP)

- The questionnaire intends to collect some information for the connected activities

- The GSPA-PHI Implementation Plan 2020-2022 is an attempt to map some of the connected activities.
Thank you