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BACKGROUND

The global strategy on public health, innovation and intellectual property (GSPA-PHI) and the agreed parts of the related plan of action were adopted by the Sixty-first World Health Assembly (WHA)\(^1\), while the final plan of action was adopted by the Sixty-second Health Assembly\(^2\). The 61st WHA requested biennial reporting on implementation, in addition to comprehensive evaluation of the strategy after four years,\(^3\) and the Sixty-second Health Assembly requested that the Director-General “conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward”\(^4\).

The Sixty-eighth WHA decided to extend the time frames of the plan of action on public health, innovation and intellectual property from 2015 until 2022 (WHA68.18).

The WHA requested that the Director-General: initiate the comprehensive evaluation of the implementation of the global strategy and plan of action on public health, innovation and intellectual property in June 2015, pursuant to the terms of reference specified in document A68/35; present the inception report and comments of the evaluation management group to the Executive Board for consideration at its 138th session in January 2016; and submit the final comprehensive evaluation report to the Seventieth World Health Assembly for consideration, through the Executive Board. The WHA also requested that the Director General establish a panel of 18 experts to conduct the overall programme review of the GSPA-PHI.

As directed in resolution WHA68.18, the overall programme review, as distinct from the evaluation, is to be a more policy-oriented, forward-looking exercise. The expert review panel’s conclusions should identify areas of convergence, in line with the 10 principles of the GSPA-PHI (contained in the annex to resolution WHA61.21 (2008)). Guided by the report of the comprehensive evaluation and, where appropriate, taking into account other evidence and involving relevant stakeholders, including public sector entities and all categories of non-State actors in line with FENSA, the programme review will:

(a) assess the continued relevance of the aim and objectives of the eight elements of the global strategy and plan of action;
(b) consider the evaluation of the implementation of the global strategy and plan of action so far and its key barriers;
(c) review achievements, good practices, success factors, opportunities, gaps, weaknesses, unsuccessful efforts, remaining challenges, and value for money;
(d) invite, over the course of the evaluation, appropriate input and comment from WIPO, WTO, and UNCTAD and other relevant intergovernmental organizations;

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1 Resolution WHA61.21.
2 Resolution WHA62.16.
3 See document WHA61/2008/REC/1, resolution WHA61.21, Annex, paragraph 41.
4 Resolution WHA62.16, paragraph 6.
(e) recommend a way forward, including details of what elements or actions should be added, enhanced or concluded in the next stage of implementation of the global strategy and plan of action on public health, innovation and intellectual property, until 2022;

(f) submit a final report to the Health Assembly, including the assessment of the global strategy and plan of action and recommendations on the way forward.

In accordance with resolution WHA68.18, the review panel was established respecting gender balance, equal regional representation and diversity of technical competence and expertise, with a broad and balanced mix or expertise, practical expertise and backgrounds covering the eight elements of the global strategy and including experts from developed and developing countries.

The overall programme review of the GSPA-PHI will be carried out in accordance with the terms of reference approved by the WHO Executive Board in decision 140(8), with resolution WHA68.18 and in general conformity with the principles outlined in the WHO Expert Advisory Panel Regulations and the WHO Regulations for Study and Scientific Groups. In accordance with document A68/35, which provides for the review panel to elaborate its method of work, the panel will carry out the overall programme review in accordance with the following methods of work.

**Methods of work**

**Guiding principles**

The review panel agreed that it will carry out the overall programme review in accordance with the following: independence, impartiality, confidentiality, inclusiveness, and transparency.

**Meetings**

The review panel plans to meet in March, June, and September at WHO headquarters in Geneva. To promote openness and candour during the process, the review panel will hold a mix of open sessions (outlined below) and closed sessions limited to members of the panel and the WHO GSPA-PHI review secretariat. The panel requests that the GSPA-PHI review secretariat invite other WHO staff on an ad hoc basis, for specific parts of its meetings, subject to its request and intended schedules of work for each meeting.

It is currently planned to hold at least one half-day open session during the meeting in June to engage with Member States, the United Nations specialized agencies, public sector entities and all categories of non-state actors in line with the Framework of Engagement with non-State Actors (FENSA) and involved in biomedical research and development. It is also foreseen that, in between its physical meetings, the review panel members will hold teleconferences to discuss further specific technical or strategic issues.

The review panel requests that the GSPA-PHI review secretariat make all necessary arrangements to ensure that the review is conducted at “arm’s length” and with full attention to the avoidance of conflicts of interest in accordance with WHO’s declaration of interest policy for experts, in furtherance of providing an independent and impartial report to the World Health Assembly, through the WHO Director-General and the Executive Board.
Assessment and development of recommendations

The panel agreed that it will gather information in accordance with its mandate as provided by the WHO governing bodies, and, in particular, letters 1. (a) to (d) in its Terms of Reference, as approved by the Executive Board through decision EB140(8). The panel will submit its final report, focusing on the GSPA-PHI’s achievements, remaining challenges, and recommendations on the way forward through the Director-General to the Executive Board at its 142nd session, with a view to presenting it to the Seventy-first World Health Assembly in 2018.

Secretariat’s support

The review panel requested that the GSPA-PHI review secretariat, in supporting its activities, call on technical experts, upon request and as appropriate, to address relevant aspects related to the review of the GSPA-PHI. It is also agreed that a writer appointed by the review secretariat (who attended the meeting) will contribute to drafting and finalizing the report of the review.

ORGANIZATION AND PROCESS OF THE MEETING

The first meeting of the review panel took place at WHO headquarters in Geneva, 23-24 March, 2017, as per the agenda set out in Annex 2.

At the beginning of its meeting the review panel elected Professor Elias Mossialos, and Dr Claudia Chamas as their Co-Chairs. Of the 18 members of the review panel, 17 were present\(^5\). Dr Jaime C. Montoya was unable to attend the initial meeting.

Representatives from the WHO Legal and Compliance, Risk Management & Ethics offices briefed the panel on their task and mandate, and reminded the review panel that all members participate in their personal capacity and are not allowed to take instructions from any government or any other authority. He noted that in accordance with WHO policy, all review panel members attending the meeting were asked to disclose any potential conflicts of interest (i.e. any interest that may affect or may reasonably be perceived to affect an expert’s objectivity and independence) in relation to the subject matter of the meeting. The disclosed interests of three members (Annex 3) were considered by the WHO Secretariat as not in conflict with any issues to be discussed at the meeting.

The Director of Essential Medicines and Health Products welcomed the review panel members and noted that it is time to take stock of the GSPA-PHI, and to explore how it can improve access to medicines in line with WHO’s new vision for 2030 under the Sustainable Development Goals. The evaluation report looked backwards at what GSPA-PHI has achieved and what it did not. The expert panel and formal panel review is now required to determine what WHO should do to take this area of work forward.

The review panel Co-Chairs pointed out there are 5 months to produce a report, and stressed the need to be very focused in order to be successful.

A number of presentations and updates regarding the implementation of the GSPOA-PHI and areas worthy of consideration were made by the WHO technical team, with topics including: the WHO

\(^5\) The members of the review panel are listed in Annex 1.
strategic framework: *Towards access 2030*; intellectual property; sustainable financing mechanisms for R&D; promoting transfer of technology and the production of health products in developing countries; establishing monitoring systems for GSPA-PHI.

In the afternoon the Global Strategy and Plan of Action: Evaluation Report was presented. Key overall findings included: a lack of awareness and engagement of stakeholders; variance in engagement and awareness across income groups; and a lack of connection with/attribution to the GSPA-PHI (Member States are doing GSPA-PHI-related activities but do not attribute them to GSPA-PHI).

The panel acknowledged the thought and energy that had gone into the evaluation, but questioned the lack of quantitative analysis that would have helped assessment of the strategy’s effectiveness. The panel was also of the opinion that there is a need to get some level of data to support the decision-making process for the review.

Among the many issues and observations raised by the review panel, several themes recurred. These included:

- the need to focus on public health as the ultimate goal;
- the lack of awareness of the GSPOA-PHI among local stakeholders in the Member States;
- the lack of quantitative data related to the achievements of GSPOA-PHI;
- the need for recommendations that can be implemented;
- the need to identify policy-orientated priorities established on the basis of cost and feasibility;
- the need for transparency of R&D costs;
- the need to identify R&D priorities and to coordinate funding to support them;
- the need to increase financial and human resources for R&D;
- the need to take into account relevant documents and reports, including the Report of the High Level Panel on access to medicines convened by the UN Secretary General.

On the second day the panel discussed and agreed on a possible structure for the report. Key elements included:

- A brief, scene-setting, overview chapter, stating the situation with regard to R&D and access;
- A mapping exercise of current activities related to R&D and access;
- A response to the Evaluation Report, taking into account presentations from WHO Secretariat presentations in the June meeting and additional information to be analysed;
- Priority setting, defining core priorities, and recommendations;
- Implementation and advocacy.

It was pointed out that it would be important to identify and consult key stakeholders (as recommended by the TORs) as an explicit component of the implementation strategy. The panel agreed that the review is an opportunity to address and involve a range of stakeholders, and that Product Development Partnerships (PDPs) should be a key focus. The panel drew up a list of questions to be put to the stakeholders, and then drafted a stakeholder list.
The decision was taken to focus on the first three chapters ahead of the June meeting, and then address chapters 4 and 5 at the June meeting. It was decided that a division of labour would be helpful. The panel was split into three sub-groups (with two co-chairs each) to address chapters 1, 2, and 3. Each group worked on drafting a list of bullet points that were presented to an approved by the plenary. These points will be expanded to form the body of the first three chapters.

The review panel also agreed that specific inputs will be requested from experts to obtain information needed for the review panel to conduct its analysis and elaborate its recommendations. The TORs for these inputs will be circulated to the sub-groups for approval.

The review panel plans to present a progress report describing how the review is being conducted to the Seventieth World Health Assembly.
Annex 1: List of members of the review panel of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property.

Dr Chutima Akaleephan. Program Manager and Senior Researcher, International Health Policy Program, Ministry of Public Health, Thailand

Dr Salah Nasser Khalfan Al Muzahmi. Assistant DG of Planning and Studies, Ministry of Health, Oman

Dr Ibrahim A. Aljuffali. Executive Vice President for Drug Affairs, Food and Drug Authority, Saudi Arabia

Ms Ardal Christine, Senior Advisor, Institute of Public Health, Norway

Dr Shabir Banoo. Chief Technical Specialist, Pharmaceutical Policy and Programmes, South Africa

Dr Claudia Chamas. IP advisor to the director of the Centre for Technological Development in Health (CDTS), Oswaldo Cruz Foundation, Brazil

Prof Carlos Correa. Director of the Center for Interdisciplinary Studies on Industrial Property and Economics and of the Post-graduate Course on Intellectual Property at the Law Faculty, University of Buenos Aires, Argentina

Prof Jonathan Craig. Associate Dean and Chair, Research and Research Training Committee, Sydney School of Public Health, University of Sydney, Australia

Prof Yan Guo. Professor of School of Public Health, Peking University Health Science Center, China

Dr Martha Gyansa-Lutterodt. Director of Pharmaceutical Services and Chief Pharmacist, Ghana

Dr Harimat Hendrawan. Deputy Director of Health Resources, Center of Health Resources and Services Research and Development, Ministry of Health, Republic of Indonesia

Mr Erik Iverson. Managing Director, Wisconsin Alumni Research Foundation (WARF), United States of America.

Dr Bita Mesgarpour. Director of National and International Affairs at National Institute for Medical Research Development (NIMAD), Islamic Republic of Iran

Dr Jaime C. Montoya. Executive Director, Department of Science and Technology, Council for Health Research and Development, Philippines

Prof Elias Mossialos (Greece). London School of Economics and Political Science and Imperial College London, United Kingdom

Prof Ibrahima Seck Technical Adviser of Minister of Health, Senegal

Dr Soumya Swaminathan. Secretary to the Govt. of India, Department of Health Research, Ministry of Health and Family Welfare & Director General, ICMR, India

Prof Yazdan Yazdanpanah. Head of Infectious Disease department at Bichat Claude Bernard Hospital, head of an Inserm team on decision analysis in Infectious Diseases, and Professor of Medicine at Paris Diderot University, France.
### Annex 2: First experts meeting for the overall programme review of the GSPA-PHI - annotated agenda 23-24 March 2017 WHO HQ, Salle C

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<td>9:00-9:15</td>
<td>Welcome message</td>
<td>Dr HILL (Director Essential Medicines and Health Products Department: EMP)</td>
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<tr>
<td>23 March</td>
<td>9:15-9:30</td>
<td>Panel members’ introduction, area of expertise for the review</td>
<td>Review panel members</td>
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<td>23 March</td>
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<td>WHO Review process rules and regulations Declaration of interests and confidentiality</td>
<td>Legal Office Compliance, Risk Management &amp; Ethics</td>
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<td>GSPA-PHI Programme Review: Background, TOR and timeline</td>
<td>Dr FORTE (EMP Coordinator)</td>
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<td>23 March</td>
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<td>WHO Essential Medicines and Health Products strategic framework 2016-2030</td>
<td>Dr HILL</td>
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<tr>
<td>23 March</td>
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<td>Introduction to GSPA-PHI implementation, achievements and challenges for implementation</td>
<td>Dr BEYER, EMP Mr TERRY, TDR</td>
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<tr>
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<tr>
<td>24 March</td>
<td>9:00-10:30</td>
<td>Identifying gaps and areas of research/work needed to conduct the Programme Review</td>
<td>Chairs &amp; review panel Members</td>
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<td>24 March</td>
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<tr>
<td>24 March</td>
<td>11:00-12:00</td>
<td>Identification of stakeholders and approach for engaging with them</td>
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<tr>
<td>12:00-13:00</td>
<td>Division of work among the experts and commissioning of work</td>
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<td>Role of the secretariat</td>
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<td>14:00-15:30</td>
<td>Structure of the final report; Communication and visibility</td>
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<td>15:30-16:00</td>
<td>Agreement on way forward: work plan, deliverables and timelines – dates of next meeting</td>
<td>Chairs &amp; Review Panel Members</td>
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<tr>
<td>16:00-17:00</td>
<td>Wrapping up and closing of the meeting</td>
<td>Dr KIENY (ADG Health Systems and Innovation)</td>
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Annex 3: Statement on declarations of interest.

In view of the advisory nature of their functions and the personal capacity in which they act, members of advisory committees such as the review panel are required under the Regulations on expert committees to disclose any interest of a financial, personal or professional nature which could be seen as affecting the impartiality of their advice in the sole interest of WHO.

Invited members were requested to fill a declaration of interest form that was assessed by the Secretariat before the invitations could be finalized. All members have duly filled and returned their forms. In accordance with WHO's policy, all declared interests, even if they do not give rise to a conflict of interest that would warrant partial or total exclusion of the expert concerned, will be disclosed within the panel at the beginning of the meeting so that other members are aware of them.

The Secretariat received and disclosed the following interests at the beginning of the meeting to the other members present:

• Prof Yazdan Yazdanpanah from France disclosed that in the past 4 years he received honorarium for being part of advisory boards and for educational presentations for AbbVie, BMS, Gilead, J&J, MSD, Pfizer, Roche and Viiv Healthcare. These were on HIV/HCV testing, treatment and care, and not related to the meeting’s subject matter. It is noted that Professor Yazdanpanah’s collaboration with these boards and companies ended in November 2016.

• Dr Christine Ardal from Norway disclosed that her employer The Norwegian Institute of Public Health received a grant from Europe’s Innovative Medicines Initiative for the DRIVE-AB project, which is to end on September 30, 2017. The grant financing for DRIVE-AB comes from the European Union’s health research framework. The Norwegian Institute of Public Health receives no financing from the pharmaceutical industry for the DRIVE-AB project or any other project. It is noted that the Innovative Medicines Initiative is a collaboration between the EU and the pharmaceutical industry. The pharmaceutical industry finances their own contributions to projects like DRIVE-AB. Additionally, Dr Ardal has advised that she works with GlaxoSmithKline, AstraZeneca, Pfizer, Astellas, Roche and Merck however their contributions are in-kind and the work does not relate to the subject matter of this meeting.

• Dr Erik Iverson from USA disclosed that he is the former President of the Infectious Disease Research Institute (IDRI), a non-profit research institute in Seattle Washington. Currently, he is the Managing Director of Wisconsin Alumni Research Foundation (WARF), a non-profit institute which is a technology transfer organization for the University of Wisconsin-Madison. WARF is responsible for commercialization of some technologies which include federally funded IP associated with potential new drugs and vaccines.

The WHO Secretariat determined that the disclosed interests were not in conflict with the work of the group. Participants were reminded that they are bound by the confidential agreement that was signed.