

**SECOND MEETING OF THE REVIEW PANEL ON THE  
OVERALL PROGRAMME REVIEW OF THE GLOBAL  
STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH,  
INNOVATION AND INTELLECTUAL PROPERTY.  
14-16 June 2017, Geneva, Switzerland.**

**16 June 2017**

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**Report of the Second Meeting of the Review Panel on the Overall Programme  
Review of the Global Strategy and Plan of Action on Public Health,  
Innovation and Intellectual Property**

**ORGANIZATION AND PROCESS OF THE MEETING**

1. The second meeting of the review panel took place at a hotel in Geneva, 14-15 June 2017, and at WHO Headquarters in Geneva, 16 June 2017, with the following provisional agenda:

Closed session with review panel members:

1. Welcome remarks
2. Review of progress so far
3. Introduction to Chapter One: outline, scope, findings and gaps discussion
4. Introduction to Chapter Two: outline, scope, finding and gaps discussion
5. Presentation of research results on:
  - a. Medicines research and development (R&D) initiatives
  - b. Initiatives to promote access to medicines in countries
6. Principles for prioritization of health R&D initiatives- WHO Observatory
7. Discussion
8. Review of Chapter Three: outline, scope, findings, and gaps discussion
9. Group work: Comments on the three chapters, identify strengths and gaps and agree on recommendations on the way forward
10. Reports of group work from day one: findings and recommendations
11. Discuss and agree on an outline for Chapter Four: GSPA-PHI: 'the way forward'
12. Discuss and agree on an outline for Chapter Five: roadmap for implementation
13. Presentation of stakeholders survey
14. Preparation of information sessions with Member States and Stakeholders on 16 June: content of presentation; roles and responsibilities
15. Agreement on next steps of the overall programme review process: further engagement with stakeholders; commissioning more research; timelines and deliverables; next meeting dates

Open session with Member States and stakeholders

16. Assistant Director General's opening remarks

17. Presentation of process, findings so far, challenges and the way forward
18. Questions and answers with stakeholders
19. Director of the Essential Medicines and Health Products' opening remarks
20. Presentation of process, findings so far, challenges and the way forward
21. Questions and answers with Member States

2. Of the 18 members of the review panel (Annex 1), 16 were present and two were unable to attend the meeting.

3. The co-chairs made a number of introductory remarks. They welcomed the members and thanked them for their attendance, as well as for their contributions to date. They then set out the members' schedule for the next three days.

4. All members introduced themselves.

5. A member of the GSPA-PHI review secretariat gave an update on the progress thus far, noting the following:

- The first review panel meeting on the 23-24 March 2017 provided the panel an opportunity to define its methods of work, identify deliverables and timelines, and structure the working groups and first three chapters of the review report.
- Since the first meeting, information has been collected, chapters one to three have been drafted and the on-line survey questionnaire for stakeholders and Member States on the relevance and future of the strategy has been finalized and sent out and results returned.
- The objectives of the second review panel meeting are to present and discuss the first three chapters, discuss the results of the survey questionnaire, develop outlines for the two subsequent chapters and prepare for the open session with Stakeholders and Member States.

## **SUMMARY OF CHAPTER REVIEW PROCEEDINGS**

6. The chair of working group one presented Chapter One which provides an overview of key developments in the global health landscape since 2008, including: the transition from the MDGs to the SDGs; increased focus on UHC; increased focus on human rights; epidemiological change; developments in the intellectual property landscape; developments in innovation; changes in the funding landscape; and developments within WHO. Subsequent discussion focused on the challenges and opportunities these changes represent in the context of the GSPA-PHI.

7. A co-chair of working group two presented an overview of the data that had been gathered to support the drafting of Chapter Two, which presents a landscape analysis of current activities related to R&D and access to medicines. A member of the secretariat stated that a draft Chapter Two had been generated based on the notes produced by working group two, and on telephone conversations with the group, and was available for the review panel's perusal. The members of group two requested that the draft be circulated.

8. A member of the WHO technical team gave a presentation on the prioritization of health R&D initiatives and provided an update on the progress of the WHO Global Observatory on Health R&D, which was launched in response to World Health Assembly resolution WHA66.22. He highlighted a potential common approach for priority setting across diseases and provided useful insights into current gaps in policy adherence as it relates to reporting results of clinical trials.

9. The chair of working group three presented Chapter Three, which assessed the comprehensive evaluation of the strategy implementation. He discussed the strengths and weaknesses of the evaluation itself, then discussed the implications of the evaluation results (notably in regard to lack of awareness and

lack of implementation) for the overall programme review. This led to a discussion of how best to prioritize the different elements, sub-elements and actions of the strategy.

## **SUMMARY OF PANEL DISCUSSIONS**

10. The co-chair thanked the review panel members for their presentations. The panel went on to discuss normative issues as well as missing information to be added to the first three chapters. The members decided to divide Chapter Two into two separate chapters and to combine both the recommendations and the way forward section into Chapter Five.

11. A member of the secretariat presented the preliminary results of the stakeholders survey, noting that submissions were still being received.

12. The panel reviewed the process and goals of the June 16 open session with stakeholders and Member States. They also proposed three standard questions that could be used to generate feedback.

13. The co-chairs led a discussion focused on developing an approach to writing Chapter Five. The review panel decided as a group to retain the eight elements and twenty-five sub-elements of the GSPA-PHI but to establish priorities for implementation based on relevance, and feasibility.

14. The second day of the meeting began with a review of the previous day's discussions and an explanation of how the group would be prioritizing the elements, and sub-elements.

15. The review panel spent the majority of the second day reviewing the following elements and prioritizing and adding to the corresponding sub-elements: Element 1- Prioritizing research and development needs; Element 4 - Transfer of technology; Element 5 – Application and management of intellectual property to contribute to innovation and promote public health; Element 7- Promoting sustainable financing mechanisms; Element 8 – Establishing monitoring and reporting systems. Sub-elements were ranked by relevance in both the medium- and long-term.

16. A member of the review panel proposed three new principles to inform the addition of elements to the GSPA-PHI:

- The strategy should be compatible and synergistic with other related global health policies.
- Capacity building is a prerequisite for the implementation of this strategy.
- Awareness of the strategy must be enhanced through increased engagement with stakeholders and the incorporation of an effective communication strategy.

17. The Panel discussed a tentative timeline for the continued drafting of chapters one to five, with specific deadlines to be determined after collection of availability is completed. Chapter five is to focus on clear recommendations and will outline future steps pertinent for the strategy's improvement.

## **SUMMARY OF OPEN SESSIONS WITH STAKEHOLDERS AND MEMBER STATES**

18. The third day began with an open information session with Stakeholders followed by an open session with Member States (Annex 2 & 3).

19. The open sessions for both stakeholder groups began with opening remarks thanking the participants for their attendance, providing an overview of the GSPA-PHI and wishing all participants a fruitful meeting. The participants were then asked to introduce themselves.

20. A co-chair presented an Overall Programme Review of the GSPA-PHI explaining the strategy's background, the mandate and purpose of the evaluation and review as well as a review of the progress to date (Annex 4).

21. Participants were encouraged to make initial comments and provide feedback. When all comments had been discussed, the review panel posed the following three questions to participants in both meetings:

- In the context of the GSPA-PHI, how can R&D for medicines be improved? (Please feel free to comment on any aspect of R&D for medicines, from issues relating to intellectual property to possible funding models).
- In the context of the GSPA-PHI, how can access to medicines be improved?
- Are there any issues not addressed by the GSPA-PHI and that you consider relevant to R&D and access to medicines? Are there elements, sub-elements or actions you would drop?

22. The participants responded, making a range of valuable comments, and asking the review panel for clarification on different issues.

23. The co-chairs thanked the participants for the comprehensive feedback and asked for specific input to be sent in writing. The co-chairs also reminded the participants of the July 15<sup>th</sup> deadline for submitting answers to the survey or further comments or submissions relevant to this review.

23. The co-chairs concluded the meeting.

## **Annex 1: List of Members of the Review Panel on 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 Christine Ardal, 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 (absent the first half of day two)

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, Vice President of 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. (absent first day)

Dr Bitá 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 (absent second half of day two)

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 (absent both days)

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

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. (absent first day)

**Annex 2: List of Stakeholder Participants in the Open Session of the Second Meeting of the Overall Programme Review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**

Drugs for Neglected Tropical Diseases Initiative (DNDi)

Health Action International (HAI)

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

International Pharmaceutical Federation (FIP)

Knowledge Ecology International (KEI)

Médecins sans Frontières (MSF)

Medicines Patent Pool (MPP)

OXFAM (remote)

Bio Farma Indonesia (remote)

South Centre

Third World Network (TWN) (remote)

United Nations Conference on Trade and Development (UNCTAD)

Universities Allied for Essential Medicines (UAEM)

World Trade Organization (WTO)

**Annex 3: List of Member State Participants in the Open Session of the Second Meeting of the Overall Programme Review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**

Australia

Belgium

Brazil

Ecuador

EU Delegation

France

Germany

Japan

Malta (remote)

Mexico (remote)

Mozambique

Netherlands

Peru

Switzerland

Thailand

United Kingdom

United States of America

Zambia

**Annex 4: Open Session Presentation for the Overall Programme Review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**

**OVERALL PROGRAMME REVIEW**

**GLOBAL STRATEGY AND PLAN OF  
ACTION ON PUBLIC HEALTH,  
INNOVATION AND  
INTELLECTUAL PROPERTY (GSPA-PHI)**

**OPEN SESSION**

GSPA-PHI Background

- The GSPA-PHI has been developed through an inter-governmental working group and endorsed at the 61<sup>st</sup> WHA in 2008 - (WHA 61.12).
- The aim of the GSPA-PHI is to promote new thinking on innovation and access to medicines
- and to secure an enhanced and sustainable basis/framework for needs-driven essential health research and development, relevant to diseases that disproportionately affect developing countries.
- GSPA-PHI timeframe has been extended to 2022

### GSPA-PHI: 8 Elements

- 1-Prioritizing research & development needs
- 2-Promoting research and development
- 3-Building and improving innovative capacity
- 4-Transfer of technology
- 5-Application and management of IP to contribute to innovation and promote Public Health
- 6-Improving delivery and access
- 7-Promoting sustainable financing mechanisms
- 8-Establishing monitoring and reporting systems

### GSPA –PHI Evaluation and Review

- WHA 68.18, requested WHO DG to initiate a comprehensive evaluation of the implementation of GSPA-PHI - documenting achievements, challenges, recommendations for addressing gaps – Evaluation was presented at 70<sup>th</sup> WHA
- Member States requested WHO DG to carry out an overall programme review (WHA68.18) - the mission of the Review is to look forward, in the current broad policy context and recommend improved policies and actions for the next stages of GSPA-PHI
- A panel was established with 18 experts with diverse and complementary expertise covering the 8 elements of the GSPA-PHI, taking into account gender balance and equal regional representation; endorsed by 140<sup>th</sup> EB Officers, in January 2017

### Terms of reference of the Review

- (a) assess the continued relevance of the aim and objectives and the eight elements of the GSPA-PHI;
- (b) consider the evaluation of the implementation 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 appropriate input and comment from WIPO, WTO, and UNCTAD and other relevant intergovernmental organizations;
- (e) recommend a way forward, including elements/actions to be added, enhanced or concluded in the implementation until 2022
- (f) submit a final report to the Health Assembly in 2018, including the assessment of the GSPA-PHI and recommendations on the way forward

### Proposed Method of Work

- Face to face meetings of the Review panel held in March, June and September at WHO headquarters.
- A half-day open session organized at each panel meeting to allow input from Member States, United Nations specialized agencies and all categories of non-State actors in line with FENSA
- The GSPA-PHI Review secretariat will make all necessary arrangements to ensure that the review is conducted at “arm’s length” and with full attention to avoid conflicts of interests.
- The review shall be carried out in accordance with principles such as:
  - independence,
  - impartiality,
  - inclusiveness, and
  - transparency.

### Review of progress

- First review panel meeting, 23 and 24 March 2017 to define its method of work, identify deliverables and timelines, as well as the structure of the review report.
- 3 sub-groups established and outlines of first 3 chapters drafted
  - Chapter 1: Setting the scene, overview of the situation of R&D and access to medicines;
  - Chapter 2: Mapping of current activities related to R&D and access to medicines;
  - Chapter 3: Lessons learnt and implementation of the recommendations of the GSPA evaluation report.
- Sub-group calls held to monitor drafting of chapters & to ensure involvement of group members
- Chapters 1 & 3 drafted and commissioning of research work for Chapter 2
- On-line survey questionnaire developed to consult with Member States and stakeholders from private sector, inter and non-governmental organizations, academics etc. on the relevance of the GSPA-PHI elements and sub-elements & way forward.

### Objectives of the second experts panel meeting 14 & 15 June

- Presentation and review of Chapter 1 and 3 and of data for Chapter 2 in plenary and in group work
- Identify gaps and additional work and research needed
- Review of Member States and stakeholders surveys results
- Develop outline for the final chapter (the way forward and implementation plan)
- Timelines and objectives of next meeting and expected deliverables

### Next Steps and Timelines

- Drafting of the final chapter (June - July)
- Finalize all chapters and transmission of draft report to the experts panel for comments (first week of September)
- Editing of report (1<sup>st</sup> week of September)
- Third and final meeting, endorsement of report by panel, (14-15 September)
- Submission of report to DG and to translation (2 October)
- The final report will be presented to the Seventy-first World Health Assembly in 2018 (May 2018) through the Executive Board at its 142nd session (January 2018).

### Questions for the open session

- In the context of the GSPA-PHI, how can R&D for medicines be improved? (please feel free to comment on any aspect of R&D for medicines, from issues relating to intellectual property to possible funding models)
- In the context of the GSPA-PHI, how can access to medicines be improved?
- Are there any issues not addressed by the GSPA-PHI and that you consider relevant to R&D and access to medicines? Are there elements, sub-elements or actions that you would drop ?