MEETING OF THE PANDEMIC INFLuenZa PREPAREDNESS
FRAMEWORK ADVISORY GROUP

12-15 March 2019, GENEVA, SWITZERLAND

Report to the Director-General

Organization and process of the meeting


2. Of the 18 members of the AG, 15 were present. The list of AG members who participated in the meeting is available at Annex 1.

3. On behalf of the Director-General, the Chief, Influenza Preparedness and Response, welcomed the AG members and thanked them for their invaluable work and support.

4. Declarations of Interest were reviewed by the Secretariat and relevant interests were disclosed. The Statement of Declarations of Interest is available at Annex 2.

5. Following the completion of Professor Mahmudur Rahman’s (Bangladesh) term as Chair, Dr Kerri-Ann Jones (United States of America) was selected as the Chair of the AG and Dr Huma Qureshi (Pakistan) as Vice-Chair. The AG expressed its gratitude to Professor Rahman for his excellent work as Chair.

6. The AG welcomed a new member, Dr Heidi Meyer (Germany). The AG thanked outgoing member, Dr Gustavo Aristizabal, for his valuable contributions to the AG.

7. The revised agenda of the AG meeting was adopted and is available at Annex 3.

8. Three representatives from the WHO Global Influenza Surveillance and Response System (GISRS) Collaborating Centres (CCs)\(^1\) attended relevant technical meeting sessions in accordance with the arrangement for representation of GISRS at PIP Framework meetings.\(^2\)

9. In accordance with its standard practice, the AG convened a consultation with industry and relevant stakeholders. A list of participants in the AG meeting and consultation is available at Annex 4.

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\(^1\) A GISRS representative from a National Influenza Centre (NIC) was scheduled to attend but was unable to travel for personal reasons.

Decision EB144(6):\(^3\) Review of the Information Session on Decision EB144(6) (11 March 2019) and of EB outcomes

10. Further to the discussions at the 144th Executive Board (EB), WHO organized an Information Session on Decision EB144(6) for Member States and all relevant stakeholders. The Information Session was held on 11 March 2019 at WHO headquarters, Geneva.

11. Fifteen of the eighteen members of the AG attended the Information Session.

12. Following the Information Session, a Member State-only intersessional Informal Consultation was held, during which Member States advanced their work to finalize the text of the draft decision.

13. The Secretariat provided the AG with a summary of the discussions and outcomes related to the EB’s consideration of the Director-General’s Report on the PIP Framework and the draft decision it contained (document EB144/23).\(^4\)

14. Some elements of the draft decision contained in EB144(6), which will be considered by WHA72 (May 2019), were based on the PIP AG’s October 2018 recommendations to the Director-General. This included a proposal — contained in operative paragraph 2 — to amend Footnote 1, Annex 2 of the PIP Framework. The intent of the proposed amendment was to address the use of PIP biological materials (PIP BM) outside of an original Standard Material Transfer Agreement 2 (SMTA 2), in order to promote fair and equitable benefit sharing.

15. The Secretariat relayed to the AG that, during the Informal Consultation on Decision EB144(6) held on 11 March 2019, Member States requested that further guidance and clarity be provided by the Advisory Group regarding the proposed amendment to Footnote 1, Annex 2 of the PIP Framework, to assist Member States in their efforts to finalize the text of the draft decision.

16. In response to this request, the AG developed advice on “Addressing the use of PIP biological materials outside of an original SMTA 2”, as contained in Annex 5.

Actions taken since October 2018 Advisory Group meeting

17. The Secretariat updated the AG on actions taken in response to the AG’s October 2018 recommendations to the Director-General. The AG thanked the Secretariat, noted that the approach to providing a regular summary of actions taken was helpful, and requested that the Secretariat continue to provide these summaries to the AG.

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\(^3\) See http://apps.who.int/gb/ebwha/pdf_files/EB144/B144(6)-en.pdf.

Technical discussions: Update on SMTA 2

18. The Secretariat provided an update on its negotiations with influenza vaccine and antiviral product manufacturers.

19. The Secretariat noted that the terms of the SMTA 2 require that WHO and a manufacturer review the agreement at least once every 4 years after the date of signature, in order to assess if any relevant circumstances or processes have changed for the company or WHO. The Secretariat will determine how best to document these reviews and will report back on this matter to the PIP AG on progress.

20. The Secretariat provided an overview of an updated model for Country Recipient Agreements (CRAs). A CRA is an agreement that must be signed by any country that wishes to receive vaccine or other products supplied by WHO during a pandemic. The agreement outlines the conditions that will apply to the WHO donations of pandemic response products. In some cases, the terms of the CRA proved to be one of the bottlenecks in the 2009 pandemic response, and the document has been updated in order to make it clearer and more user-friendly for countries.

21. The Secretariat will work with WHO, including HQ, regional and country offices, to familiarize countries with the terms of the CRA, and help ensure that, when the time comes, CRAs can be concluded as rapidly as possible.

Technical discussions: Update on implementation of the Partnership Contribution

22. The Final Report for the Partnership Contribution (PC) High Level Implementation Plan I (HLIP I), which summarizes the 2014-2017 achievements, was published and made available online in December 2018.

23. Financial implementation for HLIP II is on track for 2018-19; 71% of the funds distributed in 2018 have been implemented. Progress against HLIP II indicators and sustainability of HLIP II achievements align with WHO 2020-2021 biennial planning and WHO’s Thirteenth General Programme of Work 2019-2023. The HLIP II indicators and outcomes are also aligned with core capacity building investments under the International Health Regulations (IHR) (2005).

24. The PIP Framework Annual Progress Report for 2018 has been completed; it includes the 2018 Interim Certified Financial Statements and progress on 21 HLIP II indicators.6 Following the suggestions of the AG and industry, the Report highlights success stories and first instances of important achievements.

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6 See https://www.who.int/influenza/pip/benefit_sharing/pip_annualreport_31dec2018.pdf
25. The AG noted that these reports contain important evidence and are well-analysed and presented for the various stakeholders and broader audiences.

**Technical discussions: Update on collection of the Partnership Contribution**

26. The Secretariat presented data on the status of PC collection. As of 6 March 2019, US$ 23M has been collected against 2018 invoices compared to US$ 14M in March 2018 against 2017 invoices. The AG noted that a few companies recently were able to catch up on 2017 contributions to the PC.

27. The AG suggested that the Secretariat, in its presentations of current and past PC collection data to the AG, include information on companies that have made partial payments, and stratify data by SMTA 2 categories A, B and C. This will assist the AG in more clearly understanding back contributions and outstanding invoices.

28. The AG was pleased to note that the amount of interest earned in 2018 on the PC Response Fund (US$ 928,587) was credited back to the Response Fund.

**Technical discussions: Update on virus sharing and efforts to improve virus sharing**

29. The Global Influenza Programme (GIP) provided detailed information on virus sharing in reformatted, easier-to-understand graphics in response to the AG’s October 2018 recommendation.

30. In general, the completeness and timeliness of sharing influenza viruses with pandemic potential (IVPP) has improved since the development of the WHO IVPP sharing guidance in July 2017. GIP has enhanced ongoing communications and networking among WHO Collaborating Centres (CCs), National Influenza Centres (NICs) and WHO regional and country offices, which has enabled improvements.

31. GIP is continuing to work with NICs and WHO regional and country offices to improve the understanding of IVPP sharing requirements within countries and across the network, as detailed in the 2017 guidance.

32. GIP is conducting a historical analysis of IVPP that were not shared prior to 1 July 2017 in order to have a full accounting and understanding of why they were not shared.

33. Timely receipt and sharing of PIP BM continue to face challenges as a result of a growing trend of international and national biosecurity and biosafety regulations.

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8 Ibid.
and complex national approval procedures for import and export, which typically involve non-health sectors such as ministries of commerce and agriculture.

34. To raise awareness, especially among non-health sectors, about the importance of timely virus sharing for rapid risk assessment, WHO convened an Informal Consultation in Beijing from 22-23 February 2019 with the countries that host the WHO Influenza CCs. Participants included WHO CCs and Essential Regulatory Laboratories (ERLs); ministries of health, agriculture, and commerce; the veterinary sector; and national quarantine and border control offices. Country working groups identified bottlenecks and challenges to rapid sharing of viruses and information. Participants recommended that additional, similar informal consultations be held in countries that host WHO CCs.

35. The AG commended GIP and the WHO regional and country offices for their efforts and the resultant positive impact on addressing some of the virus sharing challenges.

**Recommendation to the Director General on virus sharing**

36. The AG recommends that:
   a) GIP and GISRS continue and build on the outreach and information processes they have begun; and
   b) The Director-General continue to highlight, during meetings with Member States and in other appropriate forums, the importance of timely influenza virus sharing, emphasizing the complexity given the involvement of multiple ministries outside of the health ministry.

**Technical discussions: Update on the IVTM upgrade**

37. The AG was briefed on the Influenza Virus Traceability Mechanism (IVTM) version 2.0. It is due to be launched in Summer 2019. Improvements include more user-friendly data entry procedures; identification of duplicate data; provision of pop-up instructions; and tracking non-GISRS recipients of PIP BM for SMTA 2 purposes.

**Technical discussions: World Bank Pandemic Emergency Financing Facility (PEF) and WHO Contingency Fund for Emergencies (CFE)**

38. The AG was provided an overview of the PEF and CFE. These funding mechanisms were developed following the 2014-15 Ebola outbreak which revealed systemic failures in global and country financing of the response.

39. The AG had requested this briefing to better understand the broader funding mechanisms currently available for pandemic influenza response, and to provide context for discussions on the PC Response Fund.
Consultation with stakeholders on PIP Framework implementation

40. The Chair opened the Consultation by thanking industry for their contributions to the PC and reiterated industry’s importance to the success of the Framework’s implementation. The AG also recognized that some companies had been able to submit catch-up contributions and it encouraged ongoing timely contributions.

41. The AG informed stakeholders that it had initiated discussions on potential methodologies for updating GISRS running costs, as described in Section 6.14.3, footnote 1. The AG will keep stakeholders apprised of its work.

42. The Secretariat updated industry and other stakeholders on PC implementation activities since the last AG meeting. Representatives (selected on a rotating basis) from WHO regions (Eastern Mediterranean and European) and technical units in headquarters provided updates on PC implementation and highlighted success stories and strengthened capacities.

43. Points that were raised during a discussion of PC implementation included:
   i. Industry commended the PIP Secretariat on its continuing progress in producing high-quality reports with demonstrable impact and achievements; industry noted that these reports are very helpful to maintain companies’ support for the PC.
   ii. Industry representatives offered to share their own collection of information that they suggested could be used to support field training activities that relate to vaccine manufacture and deployment. WHO indicated that it will pursue discussions with industry on this topic.
   iii. Third World Network (TWN) requested clarity on the Global Preparedness Monitoring Board and on the informal group established to coordinate WHO’s work on access and benefit sharing for pathogens.
   iv. TWN requested further information and details on the challenges faced in influenza virus sharing. The Secretariat described some of the challenges facing IVPP sharing and WHO’s ongoing efforts to address them.

44. A representative from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) presented a proposed new model to calculate a company’s individual PC. Development of a new model has been the subject of earlier discussions. IFPMA indicated that it had led some consultations with other associations to arrive at this proposed model.

45. The model is based on a combination of a company’s financial capacity (average seasonal influenza sales) and pandemic manufacturing potential (installed manufacturing capacity). Contributions would be fixed for three years and capped at both the low and high PC bands. Setting contributions for a fixed period could result in a fluctuating annual total PC; i.e. if some companies cease manufacture and “drop out” during the period, the total PC will be less than the current target
PC of US$ 28M as defined in the PIP Framework;⁹ if new companies are added, the total PC could be more.

46. A robust discussion of the proposed IFPMA model ensued among all stakeholders and the AG; major areas of discussion included:
   i. the need to address the potential reduction in receipt of contributions in a given year, should companies drop out, and, in particular, the impact that the uncertainty of a reduced contribution level could have on the implementation of the overall PIP Framework, including HLIP II activities;
   ii. the rationales for a three-year fixed period and “capping”;
   iii. the level of discussion and support for the proposed model by all relevant industry associations;
   iv. how to incorporate companies that do not belong to an industry association;
   v. how to improve identification of companies that use GISRS but have not been recognized as potential PC contributors;
   vi. how to assess non-IFPMA manufacturers’ “installed capacity”; and
   vii. next steps in moving forward on the analysis and potential adoption of a new model.

47. The AG conveyed its appreciation to IFPMA and other industry colleagues for their efforts in developing a proposed model and expects additional analysis, review and discussion of the model at the next AG meeting.

**Recommendation to the Director-General on the proposed industry model for calculation of an individual company’s PC**

48. The AG recommends that the Secretariat work with relevant industry associations to pursue further analysis and testing of the proposed model, and to address questions raised about the proposed model. In addition, the AG recommends that the Secretariat work with relevant industry associations to develop options for ensuring that WHO receives the entire defined PC each year.

**Other matters: Options for updating GISRS running costs**

49. The Secretariat presented an overview of various methodologies and associated advantages and disadvantages that could be considered for updating GISRS running costs, as described in PIP Framework Section 6.14.3, footnote 1.

50. The AG noted the importance of using a methodology that is credible, technically sound, reproducible, and does not provide an undue financial and personnel burden on GISRS or the Secretariat. The AG will continue these discussions — particularly exploring a hybrid methodology that addresses the change over time

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in GISRS running costs (the current PC level was established in 2010) — at its next meeting.

Other matters: Advisory Group Annual Report

51. The AG submits an Annual Report to the Director-General on its evaluation of the implementation of the Framework. The Annual Report covers seven topics as specified in PIP Framework Section 7.2.5

52. It was noted that evidence and information about these topics is contained in other reports and mechanisms including the PIP 6-monthly and Annual Progress Reports which provide regular progress on defined milestones and indicators; and the WHO Programme Budget Web Portal. These reports were developed in response to the 2016 PIP Review Group’s findings and recommendation.\(^\text{10}\) In addition, it was noted that detailed presentations on influenza virus sharing by GIP at each AG meeting and discussions with GISRS Representatives occur at each AG meeting.

53. The AG, to enhance efficiency and avoid duplication, agreed that the format of the 2018 AG Annual Report will be a succinct assessment of the seven topics specified in Section 7.2.5 referencing evidence and information available in the reports cited above.

Presentation: Pandemic Supply Chain Network

54. A presentation about the Pandemic Supply Chain Network was made to the AG to enhance its understanding of other pandemic planning and response mechanisms. This shared asset platform aims to connect the public and private sectors with the humanitarian sector to support a global response to a pandemic. Small-scale pilot testing is being planned.

Presentation: Overview of prototype IVPP GSD search engine

55. In October 2018, the AG recommended that the Secretariat assess the utility of the prototype search engine. The AG requested, and received, a demonstration of the prototype search engine to review its structure, operation and outputs to ensure that all members (including some new members of the AG) had been briefed on the search engine.

Other matters: GISRS Update on the Functioning of GISRS

56. In response to questions by the AG about the functioning of GISRS, GISRS representatives expressed the view that GISRS has never been stronger.

However, they indicated concerns for seasonal virus sharing due to some uncertainties associated with implementation of the Nagoya Protocol.

57. GIP is planning to conduct its next NIC survey to understand and assess these and other challenges and issues.

**Presentation: WHO’s work on access and benefit sharing in the context of public health**

58. An overview of WHO’s work on access and benefit sharing in the context of public health was provided to the AG. This work is cross-cutting and not limited to influenza.

**Next steps**

59. The AG agreed that its next meeting will take place in the week of 7 October 2019.
Annex 1

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
12-15 March 2019

List of Advisory Group participants

Dr Kedar Prasad Baral, Professor of Public Health, Patan Academy of Health Sciences, Nepal

Dr Sulaiman Mohamed Al Busaidi, Former Director, Central Public Health Laboratory, Ministry of Health, Oman

Dr Gustavo Aristizabal Duque, Former Advisor to the Ministry of Health, Ministerio de Salud y Protección Social, Colombia

Dr Hamad Ali Hamad El-Turabi, Associate Professor of Medicine/Consultant Physician and Pneumonologist, Soba University Hospital, University of Khartoum, Sudan

Dr Kerri-Ann Jones (Chair), Former Vice President, Research and Science, The Pew Charitable Trusts; former Assistant Secretary, State Department, United States of America.

Professor Raymond LIN Tzer Pin, Director, National Public Health Laboratory, National Centre for Infectious Diseases, Ministry of Health, Singapore

Dr Cuauhtémoc Mancha-Moctezuma, Deputy Director-General of Preventive Programs, National Center for Preventive Programs and Disease Control (CENAPRECE), Ministry of Health, Mexico

Dr Heidi Meyer, Head of Section, International Coordination / Regulatory Service, Paul-Ehrlich-Institut, Germany

Dr Richard Njouom, Head, Virology Department, Centre Pasteur of Cameroon, Cameroon

Dr Paba Palihawadana, Director, Health Promotion Bureau, Ministry of Health, Sri Lanka

Dr Huma Qureshi (Vice-Chair), Former Executive Director, Pakistan Medical Research Council, Pakistan

1 Dr Jane Ruth Aceng (Uganda), Professor Chris Baggoley (Australia) and Dr Janneth Maridadi Mghamba (United Republic of Tanzania) were unable to attend.
Professor Mahmudur Rahman, Former Director, Institute of Epidemiology, Disease Control and Research (IEDCR) & National Influenza Centre, Bangladesh

Professor Lokman Hakim Bin Sulaiman, Professor of Public Health, International Medical University, Malaysia

Dr Liana Torosyan, Head of Department of Epidemiology of Special Dangerous and Airborne Diseases, National Center of Disease Control and Prevention, Ministry of Health, Armenia

Professor John M Watson, Former Deputy Chief Medical Officer for England, Health Protection Directorate, Public Health England, United Kingdom
Annex 2

Meeting of the Pandemic Influenza Preparedness Advisory Group
12-15 March 2019

Summary of Declarations of Interests by members

In accordance with WHO policy, in advance of the meeting, all PIP Framework Advisory Group members were asked to provide a duly completed Declaration of Interests form to inform WHO about real, potential or actual conflicts of interests that they might have in relation to the subject matter of the meeting. Over the course of the meeting, the Advisory Group discussed, reviewed, or was provided updates on the implementation of the Framework, including: a) virus sharing, b) SMTA 2 negotiations, c) handling of seasonal influenza and genetic sequence data under the PIP Framework, and d) Partnership Contribution collection and implementation.

During the meeting, the Advisory Group also interacted with manufacturers and other stakeholders regarding the implementation of the PIP Framework.

Members, in the exercise of their functions on the Advisory Group, serve in their individual capacity acting as international experts serving WHO exclusively. The experts participating in the Advisory Group meeting were, by WHO region:¹

Africa
- Dr Richard Njouom (Cameroon)

Americas
- Dr Gustavo Aristizabal Duque (Colombia)
- Dr Kerri-Ann Jones (United States of America)
- Dr Cuahtémoc Mancha-Moctezuma (Mexico)

Eastern Mediterranean
- Dr Sulaiman Mohamed Al-Busaidi (Oman)
- Professor Hamad El-Turabi (Sudan)
- Dr Huma Qureshi (Pakistan)

Europe
- Dr Heidi Meyer (Germany)
- Dr Liana Torosyan (Armenia)
- Professor John Watson (United Kingdom)

¹ Dr Jane Ruth Aceng (Uganda), Professor Chris Baggoley (Australia) and Dr Janneth Maridadi Mghamba (United Republic of Tanzania) were unable to attend.
South-East Asia
  • Dr Kedar Baral (Nepal)
  • Dr Paba Palihawadana (Sri Lanka)
  • Professor Dr Mahmudur Rahman (Bangladesh)

Western Pacific
  • Professor Raymond LIN Tzer Pin (Singapore)
  • Dr Lokman Hakim Bin Sulaiman (Malaysia)

Given that discussions in the meeting were on the use or allocation of Partnership Contribution resources, and in the interest of transparency, the following interests and/or affiliations are relevant to the subject of work and are hereby disclosed:

<table>
<thead>
<tr>
<th>Name</th>
<th>Interest declared</th>
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<tbody>
<tr>
<td>Dr Gustavo Aristizabel Duque</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Sulaiman Al-Busaidi</td>
<td>Former Civil Servant</td>
</tr>
<tr>
<td>Professor Raymond LIN Tzer Pin</td>
<td>Civil Servant and affiliated with a GISRS laboratory</td>
</tr>
<tr>
<td>Dr Cuahtémoc Mancha-Moctezuma</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Richard Njouom</td>
<td>Affiliated with a GISRS laboratory</td>
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<td>Civil Servant</td>
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<tr>
<td>Dr Liana Torosyan</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Professor John Watson</td>
<td>Civil Servant</td>
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</table>

No comments were received as a result of the Public Notice and Comment period. No other interests declared by members of the Advisory Group were deemed relevant to the work of the group. In consultation with the Compliance and Risk Management and Ethics unit, it was determined that there is no conflict in respect of these members.
Annex 3

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
12-15 March 2019

Agenda

In accordance with the arrangements for GISRS representation in PIP Framework meetings, GISRS representatives are invited to participate in relevant technical sessions from Tuesday, 12 March, 11:00 to Wednesday, 13 March, 16:00.

1. Welcome remarks
2. Declarations of Interest
3. Selection of Chair and Vice-Chair
4. Adoption of agenda
5. Any other business
6. Review
   • Outcomes of EB144
   • Actions since last meeting
7. Technical discussions
   • Update on SMTA 2
   • Update on implementation of the Partnership Contribution
   • Update on collection of the Partnership Contribution
   • Update on virus sharing
   • Update on IVTM upgrade
8. Advisory Group consultation with industry and other stakeholders
   • Updates on PIP Framework implementation
   • Presentations from stakeholders
   • Discussion
9. Technical discussions
   • Overview of World Bank PEF and WHO CFE in the context of the PIP Response Fund
   • Efforts to improve virus sharing

1 See http://www.who.int/influenza/gisrs_laboratory/GISRS_representation_20171010.pdf.
10. Q&A with GISRS representatives

11. Other matters
   • Options for updating GISRS running costs
   • Advisory Group Annual Report

12. Presentations
   • Pandemic Supply Chain Network
   • Overview of prototype IVPP GSD search engine
   • Overview of WHO’s work on access and benefit sharing in the context of public health

13. Development of recommendations to the Director-General and Meeting Report

14. Finalization of the Meeting Report

15. Next steps
   • Next meeting of the Advisory Group
   • Any other business

16. Close of meeting
Annex 4

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group  
12-15 March 2019  

List of Participants  

GISRS representatives\(^1,2\)

- Summer Galloway, WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza, US Centers for Disease Control and Prevention (CDC), United States of America  
- Jacqueline Katz, WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza, US CDC, United States of America  
- John McCauley, WHO Collaborating Centre for Reference and Research on Influenza, Crick Worldwide Influenza Centre, The Francis Crick Institute, United Kingdom  

Databases & initiatives\(^2\)

- Peter Bogner, GISAID Initiative  

Manufacturers and industry associations\(^2\)

- Atika Abelin, Sanofi Pasteur  
- Paula Barbosa, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)  
- John Billington, GSK  
- Matthew Downham, AstraZeneca  
- Sam Lee, Sanofi Pasteur  
- Sharon Mchale, Seqirus Vaccines  
- Tamara Schudel, F. Hoffman-La Roche  
- Koert Stittelaar, Viroclinics Biosciences BV  
- Beverly Taylor, Seqirus Vaccines  

Civil society organizations\(^2\)

- Edward Hammond, TWN  

WHO Staff\(^3\)

WHO regional offices  

- Belinda Herring, AF/RGO/WHE/IHM  
- Angella Smith, AM/PAHO/PHE  

\(^1\) Participated in relevant technical sessions of the meeting.  
\(^2\) Participated in 13 March 2019 consultation with stakeholders.  
\(^3\) Participated in all or part of the meeting.
• Amgad Elkholy, EM/RGO/WHE/IHM
• Bhagawan Shrestha, EM/RGO/WHE/IHM
• Michala Hegermann-Lindencrone, EU/RGO/WHE/IHM
• Philip Gould, SE/RGO/WHE/IHM
• Hitesh Chugh, WP/RGO/WHE/IHM

WHO headquarters

• Claudia Alfonso, HQ/WHE/IHM/IPR/GIP
• Esther Awit, HQ/WHE/IHM/IPR/PIP
• Jennifer Barragan, HQ/WHE/IHM/IPR/PIP
• Luisa Belloni, HQ/WHE/IHM/IPR/PIP
• Isabel Bergeri, HQ/WHE/IHM/IPR/GIP
• Christopher Chadwick, HQ/WHE/IHM/IPR
• Katherine Deland, External Consultant
• Julia Fitzner, HQ/WHE/IHM/GIP
• Martin Friede, HQ/FWC/IVB/IVR
• Melinda Frost, HQ/WHE/IHM
• Iona Ghiga, HQ/WHE/IHM/PAT
• Shoshanna Goldin, HQ/WHE/IHM/IPR
• Michael Griffin, HQ/WHE/EMO/OSL
• Aspen Hammond, HQ/WHE/IHM/IPR/GIP
• Payman Hemmati, HQ/WHE/IHM/IPR/GIP
• Daniel Hougendobler, HQ/WHE/IHM/IPR/PIP
• Poonam Huria, HQ/WHE/IHM/IPR/PIP
• Anne Huvos, HQ/WHE/IHM/IPR/PIP
• Sasha Kontic, HQ/WHE/IHM/IPR/PIP
• Awandha Mamahit, HQ/WHE/IHM/IPR/GIP
• Ann Moen, HQ/WHE/IHM/IPR
• Claudia Nannini, HQ/DGO/DGD/LEG/GBI
• Tim Nguyen, HQ/WHE/IHM/ENI
• Tatiana Resnikoff, HQ/WHE/IHM/IPR/PIP
• Amélie Rioux, HQ/WHE/IHM/IPR/PIP
• Gina Samaan, HQ/WHE/IHM/IPR/PIP
• Magdi Samaan, HQ/WHE/IHM/IPR/GIP
• Hiiti Sillo, HQ/HIS/EMP/RHT/RSS
• Steven Solomon, HQ/DGO/DGD/LEG/GBI
• Katelijn Vandemaele, HQ/WHE/IHM/IPR/GIP
• Wenqing Zhang, HQ/WHE/IHM/IPR/GIP
Annex 5

Addressing the use of PIP biological materials outside of an original SMTA 2

At the Informal Consultation on Decision EB144(6) that took place on 11 March 2019, Member States requested that the PIP AG provide further guidance and clarity regarding the proposed amendment to the Footnote to assist in their efforts to finalize the text of the draft decision. The PIP AG has developed the following additional information, presented below:

1. Guiding Principles

   a) Equal footing of access and benefit sharing on IVPP
   b) SMTA2s are a key tool for supporting access and benefit sharing. Under the PIP Framework, all who receive PIP BM, are required to enter into an SMTA2 with WHO. There are three categories of SMTA2s:
      a. Category A: vaccine and antiviral manufacturers – SMTA 2 has defined contributions
      b. Category B: manufacturers of diagnostics and other products – SMTA 2 has defined contributions
      c. Category C: other recipients, such as academic and research institutions – SMTA 2 asks for consideration of contributing a benefit.
   c) Ensuring fairness and equity in the PIP Benefit Sharing System strengthens the PIP Framework in the interest of all Member States and stakeholders.

2. Background regarding modifications to Annex 2, footnote 1

   a) All SMTA2s require the signing entity to inform WHO of any further transfer of PIP biological materials.
   b) Some SMTA2s in Category A and B include partners (contractors or affiliates of the signing entity) who are not required to sign an SMTA2 when handling or using PIP biological materials on behalf of the signing entity, subject to conditions including those which limit product development.
   c) Entities which make use of PIP biological materials (e.g. sending research or commercial products for testing to a signatory of an SMTA 2) have the potential to receive benefits from this use. This use, outside of the original SMTA 2, which may result in benefits, should be subject to the conditions of the PIP Framework.
3. Overview of options for addressing the indirect benefits generated

To address this need, the AG has identified three approaches:

1. First, the requirement to report to WHO for this use of PIP biological materials that could result in benefits can be assigned to the original recipient of the PIP biological material;

   Comment: As WHO is already in a contractual relationship with the original recipient, this approach helps WHO to identify outside entities.

2. Second, a requirement can be established so that the outside entity that uses PIP biological materials and potentially benefits from that use signs an SMTA 2; or,

   Comment: This approach avoids placing a burden on the original recipient of PIP biological materials. Further, the requirement for benefit sharing is especially flexible, consistent with SMTA 2 Category C, for entities that are not manufacturers.

3. Third, this responsibility can be assigned to both the original recipient of the PIP biological material and to the outside entity which uses it outside of the original SMTA 2.

   Comment: This approach maximizes the opportunity to identify the outside entities and is most comprehensive.

It appears that the simplest way to address these options would be through the footnote process. The current footnote could be amended or a new footnote could be added. In addition, it is important to include in whatever footnote approach is used, language that will reassure research and other relevant institutions that the need to sign an SMTA 2 will not hinder research.

4. Possible footnote modifications/additions

Modifying existing footnote 1

“Recipients are all entities that receive ‘PIP Biological Materials’ from the WHO global influenza surveillance and response system (GISRS), such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.”

There is the potential for a benefit when an entity which is not the original recipient and not an SMTA 2 signatory, benefits from the use, on its behalf, of the PIP biological material by the original recipient.
Followed by (a), (b) or both:

a) The original recipient who signed the SMTA 2 must inform WHO of the use of PIP BM on behalf of the outside entity. The original recipient is also required to inform the outside entity.
b) These outside entities are required to sign an SMTA 2. It is noted that the requirement for benefit sharing is especially flexible, consistent with SMTA 2 Category C, for entities that are not manufacturers.

Adding an additional footnote (footnote 2) in Annex 2 of the PIP Framework

There is the potential for a benefit when an entity which is not the original recipient and not an SMTA 2 signatory, benefits from the use, on its behalf, of the PIP biological material by the original recipient.

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a) The original recipient who signed the SMTA 2 must inform WHO of the use of PIP BM on behalf of the outside entity. The original recipient is also required to inform the outside entity.
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The Director-General may wish to facilitate consideration by Member States of this matter by bringing these observations to the attention of Member States and relevant stakeholders, including GISRS.