MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK
ADVISORY GROUP

24-27 October 2023

Report to the Director-General

Organization and process of the meeting

1. The Pandemic Influenza Preparedness (PIP) Framework Advisory Group (AG) met at the World Health Organization (WHO) headquarters in Geneva, Switzerland, 24-27 October 2023. There were 17 AG members that participated in the AG meeting, 13 in person and 4 virtually. The list of AG members who participated in the meeting is available at Annex 1.

2. Dr Maria van Kerkhove, the Director of the Department of Epidemic and Pandemic Preparedness, ad interim starting 1 November 2023, opened the meeting and welcomed all participants. Declarations of Interest were reviewed by the Secretariat and relevant interests were disclosed. The Statement of Declarations of Interest is available at Annex 2.

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

4. Four representatives from the WHO Global Influenza Surveillance and Response System (GISRS) participated in relevant technical sessions of the AG meeting.

5. In accordance with its standard practice, the AG convened a consultation with stakeholders on 25 October 2023. The list of participants in both the AG meeting and consultation is available at Annex 4.

Presentation of the Health Emergency Context

6. The AG was updated on the status of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB), and the Working Group on Amendments to the International Health Regulations (WGIHR).

7. The AG noted the latest developments in the Member State-led processes to strengthen pandemic prevention, preparedness and response, with equity as a key guiding principle. The AG acknowledged the importance given to the PIP Framework as a model for building a global pathogen access and benefit sharing system (PABS). In light of this, and mindful of the limited timeframe remaining to conclude negotiations, the AG would welcome the opportunity to meet with the INB or its Bureau, as appropriate, to share its experience, lessons learned, and contribute to the ongoing process.

8. The AG was also briefed on the United Nations High Level Meeting on Pandemic Prevention, Preparedness and Response and the resultant Political Declaration that was adopted at the 78th General Assembly of the United Nations. The political declaration reinforced the global mandate of the WHO in pandemic prevention, preparedness and

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1 See https://cdn.who.int/media/docs/default-source/influenza/gisrs-representation-20171010.pdf?sfvrsn=d76661a1_4.
response, stressed the importance of equity as a priority and encouraged the timely conclusion of the INB and WGIHR processes.

**Partnership Contribution collection and High-Level Implementation Plan (HLIP) implementation**

9. The PIP Partnership Contribution (PC) is a key benefit sharing mechanism of the PIP Framework with the funds used for two purposes: pandemic influenza preparedness and response. According to the PIP Framework, the annual PC amount is to be paid by influenza vaccine, diagnostic and pharmaceutical manufacturers who use GISRS, with the total amount equivalent to 50% of the running costs of GISRS. The current PC amount of US$ 28 million is based on the 2010 estimate of the GISRS running costs.

10. The Secretariat updated the AG on the collection of the annual PC amount of US$ 28 million. As of 18 October 2023, collection for the years 2022 and 2023 stands at 88% and 29% respectively.

11. The AG recognised that only a few diagnostic companies are participating in the PIP Framework. The Secretariat summarised their past interactions with an industry association of diagnostic manufacturers (AdvaMedDx) to encourage the involvement of the diagnostic sector. The AG brainstormed new ideas for further engagement with this sector and several useful suggestions were made for the Secretariat to consider. The Secretariat will report to the AG on actions taken to engage with the diagnostic sector at the next AG meeting.

12. The Secretariat provided an update on the final year of HLIP II implementation, which is on track. Highlights from the 18-month progress report from 1 January 2022 to 30 June 2023 were presented. An independent external evaluation of HLIP II commenced in August 2023 and will cover the full six years of HLIP II implementation.

13. The Secretariat also summarized the HLIP III operational planning process for implementation in 2024-25. The Secretariat provided an overview of the Partnership Contribution Independent Technical Expert Mechanism meeting which was held in October 2023 to review and provide technical advice on the proposed pandemic preparedness activities for HLIP III. Country, regional and global biennial workplans for 2024-25 are currently being finalized for approval in November 2023, distribution of funds in December, and commencement of activities in January 2024.

14. The AG noted that HLIP III promotes the broad PIP Framework objectives of increasing fairness and equity and supports the PIP Framework objective of improving pandemic influenza preparedness globally, regionally and at country-level, with appropriate prioritization of countries for each output. The AG welcomed the implementation of a broad range of activities through HLIP III that will continue to support strengthening pandemic influenza preparedness in line with the overall objective of the PIP Framework.

**Adjusting the PC Level and revising the PC Formula**

15. The current PC level of US$ 28 million has not been adjusted since the PIP Framework was adopted in 2011. Based on a previous AG recommendation, the Secretariat developed the PC Adjustment Tool to adjust the PC level for inflation. In October 2022, the tool was endorsed by the AG and the Director-General accepted the AG’s recommendation that it be used starting in 2024. The AG also requested that the PIP Secretariat, in consultation with
stakeholders, finalize the development of standard operating procedures (SOPs) for using the tool to adjust the PC level.

16. The PC formula is used to determine the specific amount of PC that is to be paid by each influenza vaccine, diagnostic and pharmaceutical manufacturers that use GISRS. The current PC formula was developed in 2013 in close consultation with stakeholders. Industry associations, led by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and Biotechnology Industry Organization (BIO), have proposed a revised PC formula.

17. The Secretariat updated the AG on their work with the four industry associations to run a simulation exercise to understand the impact of the adjusted PC level and of the proposed changes to the PC formula on payments of individual companies. The results of the simulations should inform the development of the SOPs to determine the new PC level and the potential adoption of a new and/or revised PC formula for 2024 PC collection process, and for future years.

18. The AG welcomed the progress made on adjusting the PC level and revising the PC formula between the Secretariat and relevant stakeholders, including manufacturer associations and civil society organisations. The AG looks forward to reviewing the outcome of the simulations at its next meeting, and to see the SOPs for using the PIP PC Adjustment tool starting in 2024, as previously recommended.

PC Response Fund Guiding Principles

19. In 2014 the AG developed Guiding Principles for use of PIP Partnership Contribution Response Funds. These guiding principles were developed to provide the basis for the Director-General to make decisions on the use of the PC response funds at the time of a pandemic. At their March 2023 meeting, the AG agreed to review the Guiding Principles, with the support of the Secretariat, to incorporate new learnings and developments.

20. A revised version of the Guiding Principles was provided to the AG for discussion. Key changes included a more streamlined structure, and inclusion of an overarching aim, some new principles, and a section on the release and use of PC Response funds.

21. The AG reviewed the draft, focusing on the principles for the release and use of PC response funds at the time of a pandemic. The AG agreed that the Guiding Principles should undergo consultation with manufacturers and other relevant stakeholders, and the AG undertook to consider the inputs received in the development of the final version of the document.

SMTA2 update

22. Standard Material Transfer Agreements 2 (SMTA2) are legally binding agreements between non-GISRS recipients of PIP Biological Materials and WHO through which secures real-time access to future pandemic response products. The Secretariat informed the AG that there are two ongoing negotiations – one with an influenza vaccine manufacturer and one with an antiviral manufacturer.

23. Each SMTA2 requires a review at least every four years, and the Secretariat informed the AG that 14 of the current 16 agreements with category A and B manufacturers are due for this review. The Secretariat will prioritise this area of work.
24. The Secretariat also updated the AG on its work to operationalise the SMTA2 commitments. This includes creating an internal dashboard containing relevant information on what has been secured through the SMTA2s concluded to date. The dashboard will include information on the nature of the commitments (percentages and products secured), location of manufacturing facilities, and vaccine technology that will be used.

25. The Secretariat is also working to ensure that manufacturers are ready to supply, and that WHO and countries are ready to receive, the products secured through the SMTA2s.

**Influenza virus sharing**

26. The WHO Global Influenza Programme (GIP) provided an overview of the sharing of PIP Biological Materials through 31 August 2023. During the reporting period of 1 September 2022 to 31 August 2023, 45 IVPP cases were reported from 10 countries; 11 IVPPs were shared in a timely manner as per the WHO guidelines on the sharing of IVPPs,\(^2\) 17 were shared but not in the timeframe required by the guidelines, and 18 were not shared. GIP reported that since 2017, when the WHO guidelines were developed, material from 278 of the 331 reported cases were shared, of which 76% were shared in a timely manner.

27. The AG noted that the reasons for not sharing included that there was no clinical sample left to share due to low viral load in the clinical specimens or that further testing was being conducted in the originating laboratory. Some sharing is also in progress at the time of reporting to PIP AG. The delay in sharing was mainly due to transport logistics and in some countries, the need to comply with national requirements for the transport of dangerous pathogens.

**Q&As with GISRS representatives**

28. GISRS representatives presented an overview of the operations of GISRS to the AG and emphasized that the PIP Framework objective includes improving and strengthening GISRS. They stressed to the AG that in their view, a priority of HLIP III should be strengthening the laboratory and surveillance capacity of GISRS, with a focus on the development and recognition of new National Influenza Centres (NICs) in those countries that currently do not have a NIC.

29. The AG affirmed that GISRS is the foundation of the PIP Framework and agreed that strengthening GISRS remains a priority. During rich discussions about potential approaches, it was recognised that in some WHO Regions it may not be practical or feasible to have a NIC in every country, and that existing sub-regional and regional mechanisms may provide the sufficient support to ensure influenza surveillance and laboratory testing.

30. The AG also acknowledged that many of the systems used for influenza are also used for other respiratory diseases, and suggested that recent scientific and technological advances, as well as new tools developed for COVID, be considered for existing influenza systems.

31. GIP provided an update on the process to revise the GISRS NIC Terms of Reference (TORs) for seasonal influenza viruses. GIP informed the AG that the revised TORs were piloted in 20 NICs from all WHO regions and are being revised based on the pilot outcomes.

**Recommendation to the Director-General**

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\(^2\) [https://www.who.int/publications/i/item/operational-guidance-on-sharing-influenza-viruses](https://www.who.int/publications/i/item/operational-guidance-on-sharing-influenza-viruses)
Recognising the ever-present threat of an influenza pandemic, the AG recommends that the Director-General urge each Member State to:

- periodically update their influenza pandemic preparedness plans, building on the experience of COVID-19, and exercise them, for example, through outbreak response and simulations
- continue to strengthen capacities for influenza preparedness and response, making the best use of available resources and leveraging scientific and technological advances.

Consultation with Stakeholders

32. Dr Sylvie Briand, the outgoing Director of the Department of Epidemic and Pandemic Preparedness welcomed stakeholders and thanked them for their ongoing contributions. The Chair provided a brief update on the AG’s work.

33. The Secretariat provided a short update on collection of PC funds, progress in implementing and evaluating HLIP II, and the operational planning for activities under HLIP III, due to commence in 2024. The Regional Office for the Eastern Mediterranean and the Regional Office for South-East Asia both presented progress on implementation of PIP activities in their regions, and WHO Headquarters provided an update on initiatives in influenza pandemic preparedness planning.

34. Three stakeholders provided presentations to the AG.

A representative from the Coalition for Epidemic Preparedness Innovations (CEPI) gave a presentation of their proposal of their 100 Day Mission to enable the development and delivery of a pandemic vaccine in 100 days.

A representative from IFPMA and BIO provided the following feedback:
- that the HLIP III needs to be focused on influenza pandemic preparedness.
- whether the adjustment of the PC level should be paused while the new pandemic accord is being negotiated.
- that they appreciated the support from the Secretariat in the simulation exercise to test a new and/or revised PC Formula against current and adjusted PC level.
- whether there would be any impact of the INB outcomes on the PIP Framework and if PIP had engaged with the INB process.

A representative from Third World Network (TWN) presented the following:
- reiterated that the revision of the GISRS NIC TORs for seasonal influenza does not provide any additional benefits.
- queried what steps are being taken to recover unpaid PC contributions.
- supported that the adjustment to the PC level should commence in 2024 as previously recommended by the AG.
- commented on the IPFMA suggestion to pause the PC level update, stating that the INB process is still in the initial stage with the negotiation text only just released.
- queried how the challenge of the new global initiatives on preparedness, as identified by the HLIP II implementation, is to be addressed.
- that further discussions on the option of technology transfer in the SMTA2 is required.

35. The AG welcomed the presentations and responded with the following:
• The HLIP III focuses on influenza pandemic preparedness and has been endorsed by the DG after much consultation with stakeholders. The HLIP III factored in the many aspects required to adequately respond to a pandemic of influenza and remains fully within the remit of the PIP Framework.
• The INB process is ongoing, with the recent release of the negotiating text. As Member State led processes, the PIP AG has not been involved in the INB or WGIHR to date.
• As recommended in October 2022, the adjusted PC level is to be implemented from 2024 onwards.
• Appreciation to the companies that have paid their PC, and that the Secretariat continues to follow-up with companies that have not paid their PC.

**PIP Advisory Group 2022 Annual Report to the Director-General**

36. The AG reviewed and approved its 2022 Annual Report, which will be submitted to the Director-General as required by PIP Framework Section 7.2.5.

**Next AG meeting**

37. The next meeting of the AG is to be the week of 4 March 2024.
Annex 1

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
24-28 October 2023

List of Advisory Group participants

Dr Roberto Eduardo Arroba Tijerino, Ministerio de Salud, Costa Rica
Dr Farida Ismail Al Hosani, Executive Director Communicable Diseases Sector, Abu Dhabi Public Health Center, United Arab Emirates
Dr Dragana Dimitrijevic, Institute of Public Health of Serbia, Belgrade, Serbia
Dr Elizabeth Ferdinand, former Chief Medical Officer, Ministry of Health, Barbados
Dr Mohammad-Mehdi Gouya, Assistant Professor, Faculty of Medicine, Iran University of Medical Sciences, Islamic Republic of Iran
Dr Anne Margareta von Gottberg, Lead, Laboratory, Centre for Respiratory Diseases and Meningitis, Johannesburg, South Africa
Dr Eun Jin Kim, Korea Disease Control and Prevention (KDCA), Cheongju-si, Republique of Korea
Dr Gulay Korukluoglu, University of Health Sciences, Ministry of Health, Türkiye
Dr Heidi Meyer, Head of Section, International Coordination / Regulatory Service, Paul-Ehrlich-Institut, Germany
Dr Howard Njoo, Deputy Chief Public Health Officer, Public Health Agency of Canada, Ottawa, Canada
Dr Mbayame Ndiaye Niang, former Director of the National Influenza Center at Pasteur Institute of Dakar, Senegal
Professor Soe Lwin Nyein, Department of Public Health, Ministry of Health and Sports, Myanmar
Dr Muhammad Tariq, Country Director, USAID Global Health Supply Chain Islamabad, Pakistan
Dr Enrique Tayag, Department of Health, Philippines
Dr Sonam Wangchuk, Programme Director, Royal Centre for Disease Control Serbithang, Ministry of Health, Thimphu, Bhutan
Dr Rhoda Wanyenze, Professor and Dean, School of Public Health, College of Health Sciences, Makerere University, Kampala, Uganda
Dr Phonepadith Xangsayarath, Director of National Center for Laboratory and epidemiology, Ministry of Health, LAO
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 implementation of the Framework, including: a) virus sharing; b) Standard Material Transfer Agreement 2, and c) Partnership Contribution 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:

Africa
- Dr Mbayame Ndiaye Niang (Senegal)
- Dr Anne Margareta von Gottberg (South Africa)
- Dr Rhoda Wanyenze (Uganda)

Americas
- Dr Elizabeth Ferdinand (Barbados)
- Dr Howard Njoo (Canada)
- Dr Roberto Eduardo Arroba Tijerino (Costa Rica)

Eastern Mediterranean
- Dr Mohammad Mehdi Gouya (Iran)
- Dr Farida Al Hosani (United Arab Emirates)
- Dr Muhammad Tariq (Pakistan)

Europe
- Dr Dimitrijevic Dragana (Serbia)
- Dr Gulay Korukluoglu (Türkiye)
- Dr Heidi Meyer (Germany)

South-East Asia
- Dr Soe Lwin Nyein (Myanmar)
- Dr Sonam Wangchuk (Bhutan)

Western Pacific
- Dr Eun Jin Kim (Republic of Korea)
- Dr Enrique Tayag (Philippines)
- Dr Phonepadith Xangsayarath (Lao People's Democratic Republic)
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 Elizabeth Ferdinand</td>
<td>Former Civil Servant</td>
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<tr>
<td>Dr Enrique Tayag</td>
<td>Civil Servant</td>
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<td>Dr Mohammad Mehdi Gouya</td>
<td>Civil Servant</td>
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<td>Dr Roberto Arroba</td>
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<td>Civil Servant</td>
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<tr>
<td>Dr Howard Njoo</td>
<td>Civil Servant</td>
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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
28-31 March 2023
Agenda

1. Welcome remarks
2. Declarations of Interest
3. Adoption of agenda
4. Presentation of the Health Emergency Context
5. PC Response Fund Guiding Principles
6. Partnership Contribution (PC) collection and High-Level Implementation Plan (HLIP-II) implementation
7. Adjusting the PC Level and revising the PC Formula
8. Influenza virus sharing
9. Q&As with GISRS representatives
10. SMTA2 update
11. Consultation with Stakeholders
12. PIP AG 2023 Annual report
13. Close of meeting
Annex 4

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
24-28 October 2023
List of Participants

GISRS representatives3,4
- Dr Hector Chiparelli, Depto. de Laboratorios de Salud Pública, Montevideo, Uruguay
- Dr Charles Davis, Centers for Disease Control and Prevention, Influenza Division, Atlanta, USA
- Dr Ruth Harvey, Worldwide Influenza Centre, The Francis Crick Institute, London, UK
- Dr Olav Hungnes, National Influenza Center, Norwegian Institute of Public Health, Norway

Civil society organizations2
- Thirukumaran Balasubramaniam, Knowledge Ecology International (KEI)
- Sangeeta Shashikant, Third World Network (TWN)
- Magda Mihaila, World Medical Association - Junior Doctor Network

Manufacturers and industry associations2
- Paula Barbosa, IFPMA
- Alexandre Bimbo, Instituto Butantan
- Felipe Carvilhe, Butantan
- Melchior Kuo, IFPMA
- Chloe Chepigin, Novavax
- John-Kenneth Billingsley, Seqirus Vaccines
- Kaori Shinoda, Daiichi Sankyo Co., Ltd
- Erica Dueger, Sanofi Pasteur
- Lyn Morgan Marsden, Sanofi Pasteur
- Zach Rothstein, AdvaMedDx
- Kristina Shultz, AdvaMedDx
- Wang Tianping, Sinovac
- Seema Sharma, Cadila Pharmeceuticals Ltd
- Caroline Mendy, Roche
- Verna Welch, Pfizer
- John Billington, GSK
- Fernando Lobos, Sinergium Biotech S.A.
- Charles Reynard, Pfizer
- Constantina Boikos, Pfizer
- Sunil Gairola, Serum Institute of India Pty Ltd
- Sogo Yamamoto, DaichiSankyo
- Katarina Ilie, Institute of Virology, Vaccines and Serw “Torlak”
- Theoore Tsai, Takeda
- Phyllis A Arthur, Biotechnology Innovation Organization (BIO)

Other organizations2
- Matthew Downham, Coalition for Epidemic Preparedness Innovations (CEPI)

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3 Participated in relevant technical sessions of the meeting.
4 Participated in the 25 October 2023 consultation with stakeholders
• Freya Hopper, CEPI
• Ilene Mizrachi, National Institutes of Health (NIH)

**WHO Staff**

**WHO regional offices**

**AMRO**
- Carolina Serrano, AM/PAHO

**EMRO**
- Ruba Kawafha, EM/RGO/WHE/IHM

**EURO**
- Michala Hegermann-Lindencrone, EU/RGO/WHE/IHM

**SEARO**
- Pushpa Ranjan Wijensinghe, SE/RGO/WHE/IHM

**WHO headquarters**
- Esther Awit, HQ/WPE/EPP/PIP
- Jennifer Barragan, HQ/WPE/EPP/PIP
- Luisa Belloni, HQ/WPE/EPP/PIP
- Isabel Bergeri, HQ/WPE/EPP/GIP
- Sylvie Briand, HQ/WPE/EPP
- Christopher Chadwick, HQ/WPE/EPP/IPR
- Hitesh Chugh, HQ/WPE/EPP/PIP
- Julia Fitzner, HQ/WPE/EPP/GIP
- Ioana Ghiga, HQ/WPE/EPP/IEP
- Shoshanna Goldin, HQ/WPE/EPP/IPR
- Sarah Hamid, HQ/WPE/EPP/GIP
- Aspen Hammond, HQ/WPE/EPP/GIP
- Sarah Hess, HQ/WPE/EPP/IEP
- Poonam Huria, HQ/WPE/EPP/PIP
- Anne Huvos, HQ/WPE/EPP/PIP
- Sandra Jackson, HQ/WPE/EPP/GIP
- Fiona Kee, HQ/WPE/EPP/GIP
- Olga Kim, HQ/WPE/EPP/GIP
- Maja Lievre, HQ/WPE/EPP/GIP
- Alaa Magdy, HQ/MHP/RPQ/REG/RSS
- Bikram Maharjan, HQ/WPE/EPP/GIP
- Holly Moore, HQ/DGO/DGD/LEG
- Josh Mott, HQ/WPE/EPP
- Claudia Nannini, HQ/DGO/DGD/LEG
- Tim Nguyen, HQ/WPE/EPP/IEP
- Razieh Ostad, HQ/MHP/RPQ/REG/RSS
- Dmitriy Pereyaslov, HQ/WPE/EPP/GIP
- Michelle Quaye, HQ/WPE/EPP/GIP
- Kate Rawlings, HQ/WPE/EPP/PIP

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5 Participated in some or all of the meeting.
• Magdi Samaan, HQ/WPE/EPP/GIP
• Gina Samaan, HQ/WPE/EPP/PGP
• Olla Shideed, HQ/WPE/EPA
• Siddhivinayak Shriram Hirve, HQ/WPE/EPP/GIP
• Hiiti Sillo, HQ/MHP/RPQ/REG/RSS
• Katelijn Vandemaele, HQ/WPE/EPP/GIP
• Maria Van Kerkhove, HQ/WPE/EPP/EZD
• Wenqing Zhang, HQ/WPE/EPP/GIP