

# **MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP**

**1-4 April 2025**

## **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, 1-4 April. There were 17 AG members that participated in the AG meeting, 14 in person and 3 virtually. The list of AG members who participated in the meeting is available at Annex 1.
2. The Chair opened the meeting and welcomed all participants. The AG welcomed two new members, Professor Mai Le Thi Quynh (Viet Nam) and Dr. Anna Erika Lindh (Finland). The AG acknowledged and thanked Elizabeth Ferdinand (Barbados) who is finishing her term with the AG.
3. Declarations of Interest were reviewed by the Secretariat and relevant interests were disclosed. The Statement of Declarations of Interest is available at Annex 2.
4. The agenda of the AG meeting was adopted and is available at Annex 3.
5. Four representatives from the WHO Global Influenza Surveillance and Response System (GISRS) participated in relevant technical sessions of the AG meeting.<sup>1</sup>
6. In accordance with its standard practice, the AG convened a consultation with stakeholders on 2 April 2025. The list of participants in both the AG meeting and consultation is available at Annex 4.

### **Public health and multilateralism in the current context**

7. Senior management from the Health Emergencies, Preparedness and Response division provided the AG with an update on the current context within WHO in terms of public health and multilateralism. The AG was also updated on the ongoing work of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB).
8. The AG acknowledged the seriousness of recent events and the implications for WHO, public health and pandemic influenza preparedness and response. The AG noted the positive impact the PIP Framework has had in recent pandemic planning efforts and urges the WHO Director-General to take the necessary steps to maintain the functionality and sustainability of its work in influenza.

### **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 whereby influenza vaccine, diagnostic and pharmaceutical manufacturers that use the GISRS make an annual contribution to WHO for improving global pandemic influenza preparedness and response.

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<sup>1</sup> See [gisrs-representation-20171010.pdf](#) (who.int)

10. The Secretariat updated the AG that as of 25 March 2025, a total of US\$ 329.4 million has been collected through the PC since 2012. The proportion of the invoice amount received by WHO is on average 97% of the US\$ 28M invoiced each year.
11. The PC High-Level Implementation Plan III (HLIP III) outlines how the PC funds are to be used to improve global pandemic preparedness during 2024–2030. The Secretariat informed the AG that implementation for the first twelve months of the 2024-2025 biennium was at 49% across the four outputs of HLIP III. The Secretariat presented recent implementation highlights and stories from the field. PIP Focal Points for the Regional Offices of the Americas and Eastern Mediterranean Region presented progress on implementation of PIP activities in their regions, and WHO Headquarters provided an update on initiatives in regulatory capacity building.
12. The final report of the independent external evaluation of the High-Level Implementation Plan II, which covered implementation of the PC preparedness funds from 2018-2023, has been shared with the AG. The AG was pleased that the evaluation concluded that the PIP preparedness funds have been implemented efficiently and effectively, with significant progress achieved across the six key output areas of HLIP II. The Secretariat updated the AG that the publication of this report and the management response is currently underway, as is a roadmap to implement the recommendations.
13. The AG was encouraged by the updates on HLIP III implementation but also noted, with concern, the current funding challenges reported by WHO implementing teams, notably at the country and regional levels. The AG supports the reprioritization, as necessary, of existing 2024-25 biennial workplans by implementing teams to address the challenges they are facing.
14. The AG suggested that the impact of current funding issues on national, regional and global pandemic influenza preparedness capacity building efforts be considered by WHO implementing teams when developing workplans for the 2026-27 biennium. The AG also encouraged coordinated advocacy efforts to ensure the sustainability of the capacities being strengthened through implementation of the PIP Framework.

#### **Update on the process to adjust the PC Level and PC Formula**

15. The PIP Framework states that the PC Level is to be equivalent to 50% of the running costs of GISRS, and the PC level was initially set at US\$ 28M per year based on the 2010 GISRS running cost estimates. The PIP Framework also acknowledges that these running costs may change over time and that the PC will change accordingly. The AG was pleased that the process to adjust the PC Level has been completed with a PC Level of US\$ 33.7M adopted for the period 2025-2029.
16. The PC Formula is used to determine each contributor's individual payment each year. The current formula, which has been used since 2013, includes 2009 pandemic sales to determine the average annual influenza product sales (AAIPS), which are used to calculate companies' individual payments.
17. At the October 2024 AG meeting, IFPMA and BIO proposed to remove the use of 2009 sales from the formula to calculate each company's individual payment. The Secretariat informed the AG that, based on subsequent discussions with the industry associations, AdvaMeDx agreed with the proposal to remove reference to 2009 sales, whereas DCVMN expressed

concerns and suggested that consideration be given to companies that operate on a nonprofit basis.

18. The AG discussed the proposal to remove 2009 sales, noting that the distribution of PC among companies is to be based on transparency and equity, based on the companies' nature and capacities (PIP Framework Section 6.14.3). The AG agreed that removing 2009 sales from the PC Formula calculation is consistent with these PIP Framework bases and suggested that the Secretariat works with industry associations to explore options to recognize the different nature of companies that operate on a nonprofit basis. The AG also supported the idea that sales from future pandemic years be included in the calculation for a time bound period after a pandemic.

#### **19. Recommendation to the Director-General**

*The AG, with reference to PIP Framework Section 6.14.3, recommends to the Director-General that 2009 sales be removed from the PC Formula from the 2025 collection cycle onwards.*

*The AG also recommends that due consideration be given to companies that operate on a nonprofit basis, to ensure that the distribution of PC among companies remains equitable and reflects the different nature and capacities of companies.*

#### **SMTA2 update**

20. Standard Material Transfer Agreements 2 (SMTA2) are legally binding agreements through which WHO secures real-time access to specific percentages of future production of pandemic response products from non-GISRS recipients of PIP Biological Materials.
21. The Secretariat updated the AG that two new SMTA2s have been signed with academic and research institutes, and that there are five ongoing negotiations with vaccine manufacturers and six more academic and research entities that have recently received PIP Biological Materials. A new agreement was also concluded with a company that has an existing SMTA2, pursuant to Section 6.10 of the PIP Framework, for access to vaccines in the inter-pandemic period for developing countries.
22. The Secretariat summarised the steps GISRS laboratories follow when transferring PIP Biological Materials to non-GISRS entities that do not yet have an SMTA2 to inform them of their obligations under the PIP Framework. The Secretariat is developing a webinar to refresh GISRS laboratories understanding of this process, including notification, shipment and recording in IVTM.
23. Each SMTA2 concluded with manufacturers of pandemic influenza products should be reviewed by the Parties at least every four years, and the Secretariat informed the AG that there are currently 13 agreements with vaccine manufacturers and two with diagnostic manufacturers due for this review. The Secretariat intends complete these reviews in a cascading manner and has commenced the process with three vaccine manufacturers. The Secretariat will also conduct a briefing session with industry associations to further explain the nature and expectations for the review process.
24. The Secretariat informed the AG that it is developing its approach to improve engagement with the influenza diagnostic sector, as recommended in previous AG meetings. The aim is to engage more broadly, with other relevant teams in WHO, and to focus on diagnostic

platforms that are relevant both during and beyond health emergencies. The AG supported the new approach, acknowledging that it builds on the Secretariat's continued efforts to increase engagement with the influenza diagnostic sector.

### **Operationalization of PIP Framework Response Benefits**

25. The Secretariat updated the AG on its work to prepare for operationalization of the benefits secured through the PIP Framework, when an influenza pandemic emerges.
26. The Secretariat continues to develop a high-level implementation plan for use of PIP PC Funds for pandemic influenza response, when the time comes.
27. The Secretariat updated the AG on progress to develop the next version of the PIP Framework Benefits Dashboard (previously referred to as the SMTA2 dashboard), based on the request made by the AG at its previous meeting, to present a more holistic view of PIP Framework benefit sharing. The new version is to include additional categories of information and a public-facing component. The AG looks forward to seeing version 2 of the Dashboard.
28. The AG was briefed on the progress to develop the Global Allocation Framework for medical countermeasures for pandemic response, which was highlighted as an urgent priority by the AG at its last meeting. A summary of potential objectives and scope, principles and criteria for allocation was provided, and a timeline was presented.
29. The AG noted that allocation of PIP-secured products is the main component of the global allocation approach, and that any subsequent product secured by WHO will be allocated in line with the allocation framework that will be developed for the PIP products. The AG also noted that the PIP Framework Section 6.0.2 (iii), which describes the principles for prioritization of PIP secured products, has been considered in the approach and that allocation of product in the interpandemic period is also being explored. The AG was pleased to have the opportunity to discuss the criteria for access being considered and looks forward to an update at the next meeting.

### **Influenza virus sharing**

30. Using data in the Influenza Virus Traceability Mechanism (IVTM) and other sources, the WHO Global Influenza Programme (GIP) provided an overview of the sharing of PIP Biological Materials under WHO guidance for the reporting period of 1 March 2024 to 28 February 2025.
31. There were 121 human cases of infection with an influenza virus with pandemic potential (IVPP) reported from eight countries, areas and territories, with most of these being influenza A(H5N1) cases from the United States of America (USA). Of these, 109 viruses were shared timely, as per the WHO guidance on the sharing of IVPPs,<sup>2</sup> three were shared but not in a timely manner, and nine were not shared. The specific reasons for each of the viruses that were not shared were reported as being due to depletion of clinical sample due to low viral load and repeated testing/virus isolation for confirmation of the case, and for the viruses not

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<sup>2</sup> <https://www.who.int/publications/i/item/operational-guidance-on-sharing-influenza-viruses>

shared in a timely manner, the reasons were reported as being due to long approval and shipping processes.

32. For this reporting period, IVPP sharing continued as per the WHO guidance despite few late sharing or not sharing due to reasons mentioned above.
33. The AG appreciated the additional analysis by GIP which categorised non-GISRS recipients according to the PIP Framework SMTA2 categories, as previously requested by the AG.

#### **Update on influenza H5 situation**

34. GIP gave an update on human cases of influenza A(H5N1). To date, these cases were sporadic and mostly due to direct or indirect exposure to infected animals or contaminated environments. Meanwhile the virus has continued to spread geographically and to new animal species. Avian influenza A(H5N1) viruses, especially those of clade 2.3.4.4b, continue to diversify genetically and spread geographically.
35. The AG noted the risk assessments that were shared with them, including that at this point in time the global public health risk of influenza A(H5N1) viruses is low, while the risk of infection for occupationally exposed persons is low to moderate depending on the risk mitigation measures in place and the local avian influenza situation in animals, but that influenza A(H5N1) outbreaks remain a concerning, evolving situation. The AG recognised the current H5 situation as an opportunity to enhance pandemic influenza readiness.

#### **36. Recommendation to the Director-General**

*Recognising the ever-present threat of an influenza pandemic, especially in view of the current H5 situation, the AG recommends that the Director-General urge each Member State to proactively:*

- *ensure and enhance influenza surveillance and laboratory capacities, with particular focus on rapid reporting of all cases, the timely sharing of virus materials with WHO CCs consistent with PIP Framework section 5.1.1, and associated information including genetic sequence data when available, and to conduct risk assessments at local levels*
- *ensure that appropriate measures for the H5 situation are in place, including using a One Health approach, as appropriate, and consider regulatory approvals for influenza vaccines (e.g., H5) to be used in the interpandemic period.*

#### **Discussion with GISRS representatives**

37. The representatives from GISRS gave a presentation in response to a request by the AG that stressed the importance of GISRS continuing to be a well-functioning, global surveillance system for influenza risk assessment and preparedness. The GISRS representatives indicated that GISRS functions has started being compromised due to recent restrictions of funding and technical expertise. GISRS representatives requested revisiting the priorities of HLIP III, which was developed under the assumption of continued stable funding for core functions of GISRS to bridge the immediate gap and mitigate risks to the functioning of GISRS.
38. The AG acknowledged the critical and new challenges identified by GISRS with regards to funding and technical support.
39. However, the AG does not consider PIP PC funds an option for increasing financial support for the functioning of GISRS. For the 2024-25 biennial workplans, the AG confirmed with the Secretariat that funds have already been allocated across all six Regions and WHO

Headquarters, and that urgent needs for reprioritization should be addressed through existing change request processes.

40. In the interim, the AG strongly suggests that that WHO explore new and innovative ways of working and alternate funding sources to address the current uncertainty in the operations of the GISRS.

#### **Consultation with Stakeholders**

41. The Chair of the PIP AG welcomed stakeholders and provided an update on the AG's work during the meeting.
42. The Secretariat provided an update on SMTA2, the collection of PC funds, implementation of the first twelve months of HLIP III and the evaluation of HLIP II. The PIP Focal Points for the Regional Offices of the Americas and Eastern Mediterranean Region presented progress on implementation of PIP activities in their regions, and WHO Headquarters provided an update on initiatives in regulatory capacity building.
43. The Secretariat provided four questions to the stakeholders prior to the meeting which guided the discussion between stakeholders and the AG. The topics of the questions included: how influenza vaccine, diagnostic and antiviral manufacturers are preparing for the next influenza pandemic; clarification regarding previous requests for greater transparency in the use of PIP PC Funds; input from stakeholders on how to improve the timeliness and predictability of PC payments from contributors; and suggestions to enhance the preparation for, and interaction during, stakeholder consultations.
44. The AG appreciated the interactions from stakeholders on these four topics, including the guidance provided on additional reporting requirements that would address the request for greater transparency in the use of PIP PC Funds and feedback on pandemic preparedness activities. The AG also welcomed the interventions from stakeholders on the proposed changes to the PC Formula.
45. The AG thanked the stakeholders for their interactions and welcomed suggestions on topic questions for next meeting.

#### **Next AG meeting**

46. The next meeting of the AG is to be held during the week of 20 October 2025.

**Meeting of the Pandemic Influenza Preparedness Framework Advisory Group  
1-4 April 2025**

**List of Advisory Group participants**

**Dr Roberto Eduardo Arroba Tijerino**, Ministerio de Salud, Costa Rica  
**Dr Farida Ismail Al Hosani**, Deputy CEO, Global Institute for Disease Elimination (GLIDE), UAE  
**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  
**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, Republic of Korea  
**Dr Gulay Korukluoglu**, Public Health General Directorate, Ankara, Turkiye  
**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 Thi Quynh Mai Le**, Senior Expert, National Influenza Center, Vietnam National Institute of Hygiene and Epidemiology, Hanoi, Vietnam  
**Dr Erika Lindh**, Virologist, Virology and Epidemiology of Influenza A and other Respiratory and Zoonotic Viruses Helsinki, Finland  
**Dr Muhammad Tariq**, Health Emergencies Supply Chain Technologist, Adjunct Faculty at the School of Mechanical and Manufacturing Engineering, NUST.  
**Dr Enrique Tayag**, Department of Health, Philippines  
**Dr Vivi Setiawaty**, Director of Human Resources, Education and Research, Directorate General Medical Services Ministry of Health Republic of Indonesia, Jakarta, Indonesia  
**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

**Meeting of the Pandemic Influenza Preparedness Advisory Group  
1-4 April  
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 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 Erika Lindh (Finland)

**South-East Asia**

- Dr Vivi Setiawaty (Indonesia)
- Dr Sonam Wangchuk (Bhutan)

**Western Pacific**

- Dr Eun Jin Kim (Republic of Korea)
- Dr Enrique Tayag (Philippines)
- Professor Thi Quynh Mai Le (Viet Nam)

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:

<b>Name</b>	<b>Interest declared</b>
Dr Anne von Gottberg	Research Support, Public Position

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.

**Meeting of the Pandemic Influenza Preparedness Framework Advisory Group  
1-4 April 2025  
Agenda**

1. Welcome remarks
2. Declarations of Interest
3. Adoption of agenda
4. Public Health and Multilateralism in the current context
5. Partnership Contribution Update
6. Update on the process to adjust the PC level
7. SMTA2 update
8. Influenza virus sharing and update on H5 situation
9. Interactions with GISRS representatives
10. Consultation with Stakeholders
11. Operationalization of PIP Response Benefits
12. Close of meeting

**Meeting of the Pandemic Influenza Preparedness Framework Advisory Group  
1-4 April 2025  
List of Participants**

**GISRS representatives<sup>3,4</sup>**

- Dr Othmar Engelhard, Principal Scientist, National Institute for Biological Standards and Control, Herdforshire, UK
- Dr Ndongo Dia, Respiratory Viruses group Research, Department of Virology, Pasteur Institute of Dakar, Senegal
- Dr Ruth Harvey, Assistant Director, Worldwide Influenza Centre, The Francis Crick Institute, London, UK
- Olav Hungnes, Director, National Influenza Centre, Norwegian Institute of Public Health, Norway

**Civil society organizations<sup>2</sup>**

- Sangeeta Shashikant, Third World Network (TWN)
- James Packard Love, Knowledge Ecology International

**Manufacturers and industry associations<sup>2</sup>**

- Paula Barbosa, IFPMA
- Chloe Chepigin, Novavax
- Praneel Jadav, BIO
- Hisham Fyyaz, Sanofi
- Simon Schmid, F. Hoffmann-La Roche Ltd
- Rajinder Kumar Suri, DCVMN International
- Jun Hyong Kwon, SK Bioscience
- John Billington, GSK
- Beverly Taylor, CSL Seqirus
- Yusuke Ichikawa, Denka Co.

**WHO Staff<sup>5</sup>**

***WHO regional offices***

**AFRO**

- Lionel Nizigama, AF/RGO/EMP

**AMRO**

- Maria Clari Yaluff, AM/PAHO

**EMRO**

- Amal Barakat, EM/RGO/WHE

**EURO**

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

**SEARO**

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

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3 Participated virtually in relevant technical sessions of the meeting.

4 Participated in the 2 April 2025 consultation with stakeholders

5 Participated in some or all of the meeting.

**WPRO**

- Phuong Nam Nguyen, WPR/RGO/WHE

**WHO headquarters**

- Esther Awit, HQ/WHE/EPP/PIP
- Jennifer Barragan, HQ/WHE/EPP/PIP
- Supriya Bezbaruah, HQ/WHE/CRS/CRR
- Hitesh Chugh, HQ/WHE/EPP/PIP
- Ioana Ghiga, HQ/WHE/EPP/IEP
- Shoshanna Goldin, HQ/WHE/EPP/PGP
- Aspen Hammond, HQ/WHE/EPP/GIP
- Jean-Michel Heraud, HQ/WHE/EPP/GIP
- Sarah Hess, HQ/WHE/EPP/PGP
- Daniel Hougendobler, HQ/HEP/HPR/LAW
- Poonam Huria, HQ/WHE/EPP/PIP
- Anne Huvos, HQ/WHE/EPP/PIP
- Sandra Jackson, HQ/WHE/EPP/GIP
- Fiona Kee, HQ/WHE/EPP/GIP
- Olga Kim, HQ/WHE/EPP/GIP
- Sasha Kontic, HQ/WHE/EPM/PIP
- Alaa Magdy, HQ/MHP/MPQ/REG/RSS
- Jouad Mahjour, HQ/WHE/HEO
- Holly Moore, HQ/ DGO/DGD/LEG
- Claudia Nannini, HQ/DGO/DGD/LEG
- Sergejs Nikisins, HQ/WHE/EPP/GIP
- Tim Nguyen, HQ/WHE/EPM/IEP
- Razieh Ostad, HQ/MHP/MPQ/REG/RSS
- Dmitriy Pereyaslov, HQ/WHE/EPP/GIP
- Kate Rawlings, HQ/WHE/EPP/PIP
- Mike Ryan, HQ/WHE/HEO
- Magdi Samaan, HQ/WHE/EPP/GIP
- Olla Shideed, HQ/WHE/EPA
- Maria Van Kerkhove, HQ/WHE/EPP
- Sebastian Zielinski, HQ/WHE/EPP/GIP
- Wenqing Zhang, HQ/WHE/EPP/GIP