MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP
5 - 8 March 2024
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, 5-8 March 2024. 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 interim Director of the Department of Epidemic and Pandemic Preparedness, opened the meeting and welcomed all participants.
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. Following the completion of Dr Enrique Tayag’s (Philippines) term as Chair and Dr Heidi Meyer’s (Germany) term as Vice-Chair, the AG selected Dr Farida Al Hosani (United Arab Emirates) and Dr Howard Njoo (Canada) to serve as Chair and Vice-Chair, respectively.
5. The agenda of the AG meeting was adopted and is available at Annex 3.
6. Four representatives from the WHO Global Influenza Surveillance and Response System (GISRS) participated in relevant technical sessions of the AG meeting.¹
7. In accordance with its standard practice, the AG convened a consultation with stakeholders on 6 March 2024. The list of participants in both the AG meeting and consultation is available at Annex 4.

Presentation of the Health Emergency Context
8. The AG was updated on the status of discussions in 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). The AG appreciated the update regarding the work towards the Pandemic Agreement and a package of amendments to the International Health Regulations (2005) (“IHR”).
9. The AG appreciated the discussion with the Vice Chair of the INB Bureau that is leading the Article 12 drafting subgroup. The AG welcomed that the PIP Framework has been discussed as a model for building the global pathogen access and benefit sharing system (PABS), noting that the system for influenza viruses with pandemic potential has unique characteristics not shared with all pathogens with pandemic potential.
10. The AG acknowledged that the relationship between the PIP Framework and the future PABS is still under discussion. The AG recognised that the outcomes of the WGIHR and INB may

¹ See gisrs-representation-20171010.pdf (who.int)
have an impact on the PIP Framework going forward, but until such time, the PIP Framework is to continue.

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

11. The PIP Partnership Contribution (PC) is a key benefit sharing mechanism of the PIP Framework with the funds used for two main purposes: pandemic influenza preparedness and response. The annual PC amount as determined in the PIP Framework is equivalent to 50% of the running costs of GISRS and is currently based on the 2010 estimated running costs of US$ 56.5 million. The annual contribution of US$ 28M is to be paid by influenza vaccine, diagnostic and pharmaceutical manufacturers who use GISRS.

12. The Secretariat updated the AG on the collection process. As of 28 February 2024, a total of US$ 303.05 million has been collected through the PC since 2012, The Secretariat continues to follow up on outstanding invoices.

13. The AG appreciates that the Secretariat has pursued many avenues of engagement with the diagnostic sector, but again noted that only a few diagnostic companies are participating in the PIP Framework. The AG requests that the Secretariat continue to engage the diagnostic companies.

14. With HLIP II concluding at the end of 2023, the Secretariat summarised the achievements of the final two years of HLIP II implementation. This included implementation of 90% of funds, which is the highest implementation rate to date, and that many of the indicators had exceeded their biennial targets. The final biennial report of HLIP II is expected to be published in April 2024.

15. An evaluation of HLIP II is underway to review the use of the PC for preparedness activities and to make recommendations to improve the implementation of PC preparedness funds. The independent external evaluator conducting the evaluation of HLIP II informed the AG on the evaluation process with the methodology including document review, plus key informant interviews and an online survey with stakeholder groups. Whilst specific results of the evaluation were not presented, the evaluators commented that the results were overall positive, with many similarities reported across respondents. The full evaluation report is to be submitted at the end of April 2024 to the PIP Secretariat.

16. The Secretariat updated the AG on the commencement of HLIP III in 2024, with 65 budget centres at Headquarters, region and country levels implementing workplans over the 2024-2025 biennium. There are 79 PIP priority countries for 2024-2025 to receive direct or indirect support. The HLIP III monitoring and evaluation framework has been completed and is pending final clearance for publication.

17. The AG welcomed these updates, acknowledging the changeover from HLIP II to HLIP III. The AG looks forward to receiving the HLIP II evaluation report from the PIP Secretariat and discussing it at their next meeting.

**Update on the process to revise the PC level and the PC formula**

18. The current PC level of US$ 28 million has not been adjusted since the PIP Framework was adopted in 2011. As per a previous AG recommendation, the PC Adjustment Tool will be used to adjust the PC level for inflation.
19. The PC formula is used to determine the amount of PC to be paid by each influenza vaccine, diagnostic and pharmaceutical manufacturers that use GISRS. Industry associations, led by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and Biotechnology Industry Organization (BIO), had previously proposed changes to the PC formula.

20. To test the impact of an adjusted PC level and use of the proposed new PC formula on individual companies’ payments, the Secretariat and industry associations conducted a simulation exercise between August and December 2023. Anonymized results of the various simulations were shared with industry associations, and several meetings have been held to discuss the results. The AG noted that the diagnostic association AdvaMedDx was informed of the simulation exercise, but that diagnostic manufacturers did not participate in the exercise.

21. The Secretariat is cooperating with the industry associations to develop SOPs for using the inflation-based PC level adjustment tool for updating the PC level. These are to include the frequency of running the adjustment, which of the two GDP index(es) is(are) to be used and which year(s) to be selected for applying the tool.

22. The AG expects to receive the final SOPs by 30 September 2024 for discussion at their October 2024 meeting, to ensure that the new PC level is applied starting in January 2025.

23. The AG was also informed that no changes have been made to the PC formula, and that the current PC Formula is to continue until further notice. Any changes made to the PC Formula require agreement from all four industry associations.

Operationalization of PIP Framework Response Benefits

24. The PIP Framework, through its benefit sharing mechanisms, secures access to resources that are used to prepare for and respond to an influenza pandemic. Some of these resources will only be available to WHO at the time of the next influenza pandemic. These include the proportion of funds that is set aside for response and the pandemic related products secured through SMTA2s.

25. The Secretariat informed the AG on their work to ensure that WHO is ready to operationalise the PIP Framework response benefits, when required. The three categories of activities in this project include operationalising the PIP PC Funds by updating the Guiding Principles for use of PIP Framework PC Funds for pandemic influenza response, operationalising SMTA2 commitments, and developing a toolkit to support timely and informed decision making by senior management.

Guiding Principles for use of PIP Framework PC Funds for pandemic influenza response

26. The Guiding Principles were developed in 2014 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. The AG reviewed and updated the Guiding Principles at their October 2023 meeting and recommended that a consultation with manufacturers and stakeholders be conducted on these revisions. The Secretariat reported to the AG that this consultation was undertaken in December 2023 and that comments and proposed changes to the text were received from 13 stakeholders.
27. The AG reviewed and considered the inputs received from stakeholders. The AG requests that the Secretariat share the responses received with the stakeholders that indicated that they would be willing for their comments to be shared.

28. The AG further considered the Guiding Principles, introduced some revisions based on the inputs received from stakeholders, and approved the final text for submission to the Director-General.

**Recommendation to the Director-General**

Following broad consultation with stakeholders, consideration of their input, and taking into account lessons learned from the COVID-19 pandemic, the PIP Advisory Group updated and revised the 2014 Guiding Principles for the use of PIP Response funds. The AG submits the “Guiding Principles for use of PIP Framework PC Funds for pandemic influenza response” set forth in Annex 5 to this report, for the consideration and approval of the Director-General.

**SMTA2 update**

29. Standard Material Transfer Agreements 2 (SMTA2) are legally binding agreements between non-GISRS recipients of PIP Biological Materials and WHO, through which WHO secure real-time access to specific percentages of future production of pandemic response products.

30. The Secretariat updated the AG that the two ongoing negotiations – one with an influenza vaccine manufacturer and one with an antiviral manufacturer – are near completion. The AG was encouraged by the latter agreement, which is the first that will be concluded pursuant to Section 6.8 of the PIP Framework. This is an agreement concluded on a voluntary basis, with a legally binding commitment to donate products at the time of a pandemic.

31. The Secretariat is to follow up with several new recipients of PIP biological materials that are recorded in the IVTM. This includes seven influenza vaccine and antivirals manufacturers, 19 research institutes or universities and 22 diagnostics manufacturers. The increase of diagnostics manufacturers receiving PIP biological materials highlights the post-COVID importance of diagnostics and confirms previous AG concerns of diagnostic companies not participating in the PIP Framework. The Secretariat reported that they are working on the previous AG suggestions for engaging the diagnostic sector.

32. The Secretariat informed the AG on the efforts to operationalise the SMTA2. This includes developing the SMTA2 Dashboard, conducting the SMTA2 reviews for agreements that were concluded more than four years ago; establishing the process for countries to sign the Country Recipient Agreement; identifying, mapping and documenting the key activities and stakeholders involved in the process of SMTA2 product development and deployment; and working with manufacturers, WHO colleagues, countries, and stakeholders to develop processes and address gaps.

33. The Secretariat updated the AG on the development of the SMTA2 Dashboard which will consolidate product, manufacturer and SMTA2 agreement information to support the deployment of products secured through the agreements. The Secretariat has been working with WHO technical experts and senior managers to identify categories of information to be included in the dashboard and plan to engage a platform developer to create the dashboard. The AG looks forward to a presentation of the dashboard at its next meeting.
Influenza virus sharing

34. The WHO Global Influenza Programme (GIP) provided an overview of the sharing of PIP Biological Materials through 29 February 2024 as recorded in the Influenza Virus Traceability Mechanism (IVTM). During the reporting period of 1 March 2023 to 29 February 2024, there have been 19 virus isolates and 38 other PIP biological materials including three zoonotic influenza candidate vaccine viruses (CVVs) tracked, 27 shipments of PIP biological materials recorded, four PIP biological materials shared from WHO Collaborating Centre (CC) and Essential Regulatory Laboratories (ERL) to other GISRS laboratories, and three zoonotic candidate vaccine viruses (CVV) shared.

35. During the reporting period, 41 cases due to infection from an influenza virus with pandemic potential (IVPP) were reported from nine countries, areas and territories; 15 IVPPs (37%) were shared in a timely manner as per the WHO guidance on the sharing of IVPPs, 8 (19%) were shared but not in the timeframe required by the guidance, and 18 (44%) were not shared. The AG appreciated the timely reporting and sharing of IVPPs and noted that the reasons for not sharing IVPPs included depletion of clinical specimens for confirmatory testing and low viral load in clinical specimens resulting in no virus isolate and no sequence data being available for sharing. 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 goods.

36. The AG requested that in the future, GIP presentations on influenza virus sharing include the type of non-GISRS entities receiving PIP Biological Materials (i.e. manufacturers of vaccines/antivirals, diagnostic manufacturers, academic and research institutions), in order to provide the AG with an overview of the types of entities that are using PIP biological materials.

Update on amendment to the NIC seasonal influenza TORs

37. GIP provided an update on the process to revise the seasonal component of the GISRS National Influenza Centre (NIC) Terms of Reference (TORs). GIP informed the AG that the revised TORs were piloted in 20 NICs from all WHO regions, which entailed a discussion on the revisions with each NIC and its corresponding national authorities. Adjustment of revision to the TORs has been made based on the pilot outcomes.

38. The AG noted that almost half of the NICs reported either needing a material transfer agreement (MTA) or having in place national legislation for the shipping and use of seasonal influenza CVVs through GISRS. Only a small portion (3 out of 20 NICs) reported potential delays in signing the MTAs. GIP clarified that these issues might have an impact on the time needed to process the shipment, not that the sharing stopped. It was clarified that the initial phase of the pilot did not include asking whether the NICs would accept the revised TORs, as this was to be part of the second phase of the pilot.

39. The AG requested that GIP report at the next AG meeting on the number of NICs from the pilot that have adopted the revised TORs, and whether they subsequently shared seasonal influenza viruses under the new TORs.

2 https://www.who.int/publications/i/item/operational-guidance-on-sharing-influenza-viruses
Discussion with GISRS representatives

40. GISRS representatives made a presentation highlighting the following:

- their goal is to enable effective surveillance of seasonal and zoonotic influenza and assure year-round surveillance of influenza viruses
- that 100% GISRS coverage, defined as having influenza surveillance covered by GISRS, is to be achieved by 2030
- strengthening genomic sequencing and bioinformatics capabilities globally was also a priority.

41. The AG agreed that coverage of influenza surveillance and laboratory capacity was required globally, but suggested that coverage could be achieved through sub-regional or regional; collaboration, noting that it may not be practical or feasible for every country to have their own NIC. The AG requested that GIP provide information on the current coverage of influenza surveillance through GISRS for discussion at the next AG meeting.

42. Genomic surveillance was discussed as another area requiring global strengthening. The AG discussed the need for strengthening financing for sequencing reagents, having adequate bioinformatics capacity, and right-sizing surveillance systems to ensure appropriate sampling and virus sequencing. The sustainability of genomic surveillance systems established during the COVID-19 pandemic that have been expanded to include influenza, was also discussed as a key challenge. The Secretariat confirmed that PC funds will support genomic surveillance capacity building as part of HLIP III.

Recommendation to the Director-General

The AG recommends that the Director-General continue to raise Member States’ awareness of the ever-present threat of an influenza pandemic, enhancing vigilance, as possible, and continuing to strengthen capacities for influenza preparedness, scale up and response, making the best use of available resources and leveraging scientific and technological advances. In this context, ongoing and continuous enhancement of timely sharing of influenza viruses remains a critical component for effective pandemic influenza preparedness and response.

Consultation with Stakeholders

43. The Chair of the PIP AG welcomed stakeholders and provided a brief update on the AG’s work during the meeting.

44. The Secretariat provided a short update on collection of PC funds, the final two years of implementation of HLIP II and its evaluation, the initiation of HLIP III implementation in 2024-25, and the process to adjust the PC level. The Regional Offices of Europe and the Western Pacific presented progress on implementation of PIP activities in their regions, and WHO Headquarters provided an update on initiatives in planning for deployment.

45. During the discussion, which included presentations from three stakeholders, the following information was shared by the AG:

- A new PC level will be applied starting in 2025.
• Information on the use of the PC is found in the regular PIP six-monthly progress reports found online, and on the WHO Programme Budget Web Portal.

• The PIP AG receives updates on the INB and WGIHR processes given their importance to the implementation of the PIP Framework, but the PIP AG has not been involved in the INB or WGIHR as these are Member State led processes.

• The AG would welcome the support of other industry organisations in getting diagnostic companies to engage with PIP and in sharing the name of companies that could be sent the PIP PC questionnaire which is used to identify PC contributors.

General discussions to enhance AG interactions with regions and countries

46. The AG and Secretariat discussed ideas for new mechanisms to enhance the AG’s understanding of implementation of the PIP Framework, particularly implementation at the regional and country levels, in order to enable them to provide more meaningful advice to the Secretariat. The AG specified that any additional mechanisms would need to be within their terms of reference, maintain their independence and contribute to their role in providing advice to the Director-General. The discussion touched on how these regional and country level perspectives could be presented in more detail during the PIP AG meetings.

47. The AG requested that the Secretariat explore the utility and feasibility of such additional mechanisms, including greater analysis and strategic perspectives from the data-derived information currently provided and report back at the next AG meeting.

Next AG meeting

48. The next meeting of the AG is to be the week of 22 October 2024.

---

3 https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/partnership-contribution
4 https://open.who.int/2024-25/our-work/category/14/programme/14.003/about/about
Annex 1

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
5-8 March 2024
List of Advisory Group participants

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 and Director General of Centre for Disease Control, Ministry of Health and Medical Education, 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 Xangsayarith, Director of National Center for Laboratory and epidemiology, Ministry of Health, Lao People’s Democratic Republic

5 Dr Roberto Eduardo Arroba Tijerino (Costa Rica) and Dr Vivi Setiawaty (Indonesia) were unable to attend.
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)

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)

6 Dr Roberto Eduardo Arroba Tijerino (Costa Rica) and Dr Vivi Setiawaty (Indonesia) were unable to attend.
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>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Elizabeth Ferdinand</td>
<td>Former Civil Servant</td>
</tr>
<tr>
<td>Dr Enrique Tayag</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Mohammad Mehdi Gouya</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Soe Lwin Nyein</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Howard Njoo</td>
<td>Civil Servant</td>
</tr>
</tbody>
</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
5-8 March 2024
Agenda

1. Welcome remarks
2. Declarations of Interest
3. Adoption of agenda
4. Presentation of the Health Emergency Context
5. Operationalization of PIP Response Benefits
6. Partnership Contribution collection and High-Level Implementation Plan (HLIP) implementation
7. Update on the process to revise the PC level and the PC formula
8. Influenza virus sharing
9. Update on NIC TORs amendment
10. Q&As with GISRS representatives
11. SMTA2 update
12. Consultation with Stakeholders
13. PC Response Fund Guiding Principles
14. PIP Advisory Group 2023 Annual Report to the Director-General
15. Close of meeting
Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
5-8 March 2024
List of Participants

GISRS representatives

- Dr Larisa Gubareva, WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza, 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
- Dr Fernando Motta, Laboratorio de Virus Respiratorio e Sarampo, Rio de Janeiro, Brazil

Civil society organizations

- Chetali Rao, TWN
- Sangeeta Shashikant, TWN

Manufacturers and industry associations

- Phyllis A Arthur, Biotechnology Innovation Organization (BIO)
- Paula Barbosa, IFPMA
- Luka Dragacevic, Institute of Virology, Vaccines and Serw “Torlak”
- Erica Dueger, Sanofi Pasteur
- Katarina Ilić, Institute of Virology, Vaccines and Serw “Torlak”
- Melchior Kuo, IFPMA
- Fernando Lobos, Sinergium Biotech S.A.; DCVMN
- Caroline Mendy, Roche
- Lyn Morgan Marsden, Sanofi Pasteur
- Kaori Shinoda, Daiichi Sankyo Co., Ltd
- Theoore Tsai, Takeda
- Beverly Taylor, Seqirus Vaccines
- Sogo Yamamoto, Daiichi Sankyo Co., Ltd

Other organizations

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

WHO Staff

WHO regional offices

AFRO
- Belinda Herring, AF/RGO/WHE/EPP

AMRO
- Mark Rondy, AM/PAHO
- Carolina Serrano, AM/PAHO

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

---

7 Participated in relevant technical sessions of the meeting.
8 Participated in the 6 March 2024 consultation with stakeholders
9 Participated in some or all of the meeting.
EURO
- Michala Hegermann-Lindencrone, EU/RGO/WHE/IHM

SEARO
- Pushpa Ranjan Wijesinghe, SE/RGO/WHE/IHM

WPRO
- Phuong Nam Nguyen, WPR/RGO/WHE

WHO headquarters
- Jennifer Barragan, HQ/WPE/EPP/PIP
- Luisa Belloni, HQ/WPE/EPP/PIP
- Isabel Bergeri, HQ/WPE/EPP/GIP
- Hitesh Chugh, HQ/WPE/EPP/PIP
- Ioana Ghiga, HQ/WPE/EPP/IEP
- Aspen Hammond, HQ/WPE/EPP/GIP
- Jean-Michel Heraud, HQ/WPE/EPP/GIP
- 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
- Jouad Mahjour, HQ/WHE/HEO
- Holly Moore, HQ/ DGO/DGD/LEG
- Josh Mott, HQ/WPE/EPP
- Tim Nguyen, HQ/WPE/EPP/IEP
- Razieh Ostad, HQ/MHP/RPQ/REG/RSS
- Dmitriy Pereyaslov, HQ/WPE/EPP/GIP
- Kate Rawlings, HQ/WPE/EPP/PIP
- Magdi Samaan, HQ/WPE/EPP/GIP
- Gina Samaan, HQ/WPE/EPP/PGP
- Olla Shideed, HQ/WPE/EPA
- Shanmugapriya Umachandran, HQ/WPE/EPP/IEP
- Maria Van Kerkhove, HQ/WPE/EPP/EZD
- Wenqing Zhang, HQ/WPE/EPP/GIP
Annex 5

Guiding Principles for use of PIP Framework Partnership Contribution Funds for Pandemic Influenza Response
Revised March 2024

I. Background

1. The Pandemic Influenza Preparedness Framework (“PIP Framework”) Partnership Contribution (PC) is an annual payment to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers using the Global Influenza Surveillance and Response System (GISRS). The PIP Framework specifies that the annual contribution shall be equivalent to 50% of the running costs of GISRS.

2. PIP Framework section 6.14.4 specifies that PC resources “shall be used for improving pandemic preparedness and response […].” (Emphasis supplied.)

3. Consistent with this, the Executive Board has decided that 30% of the PC funds received for preparedness and response activities are to be set aside annually by WHO for use at the time of a pandemic. This is known as the “PIP PC Response Fund”. Since 2018, interest has accrued on the PC Response Fund.

4. To ensure that the proportional division does not hinder necessary response measures during an influenza pandemic, the Executive Board further specified that during such time, the Director-General will be able to temporarily modify the allocation of PC resources as required to respond. The Executive Board specified that the Director-General will report on any such modifications to Member States, and to manufacturers and other stakeholders.

5. These Guiding Principles provide the basis for the Director-General to decide on the use of PC funds, both response funds and any preparedness funds that may still be available, in a timely manner, at the time of a pandemic. At such time, the Director-General will keep the Advisory Group, manufacturers and other stakeholders informed on decisions made on use of the PC Response funds.

6. In 2014, the Advisory Group developed ‘Guiding Principles for use of PIP Partnership Contribution Response Funds’. In 2024, following interaction with manufacturers and other stakeholders, the Advisory Group developed this revised version.

II. Authority

The WHO Director-General shall decide on the allocation and use of PC funds for pandemic influenza response, using the Guiding Principles set out below.

---

10 Approved by the Director-General
11 See PIP Framework Section 6.14.3
12 Upon receipt by WHO, PC funds are allocated as follows: 10% to the PIP Secretariat; of the remaining 90%, 70% is allocated to Preparedness, and 30% is allocated to the PC Response Fund (see decision EB152(22)).
13 Decision EB152(22).
III. Guiding Principles

Guided by the principles below, the overarching aim of the PC funds for pandemic influenza response is to contribute to a rapid and equitable response to pandemic influenza.

1. **Fairness and Equity**: Fairness and equity are at the core of the PIP Framework. Benefits secured through the PIP Framework, including antivirals and other therapeutics, vaccines, ancillary products and diagnostics, will be distributed to countries, particularly developing countries, according to public health risk and need and particularly where those countries do not have their own capacity to produce or access pandemic products. Based on the foregoing, WHO will ensure that any use of PC funds for pandemic response reflects fairness and equity.

2. **Timeliness**: Decisions on the release and use of the PC funds for pandemic response will be made in a manner that recognises that in a pandemic, time is of the essence.

3. **Evidence Based Decisions**: Decisions on the release, use and allocation of the PC funds for pandemic response will be grounded in the most relevant and up-to-date evidence related to the actions to be taken at the time.

4. **Transparency and Accountability**: WHO will be fully accountable for the use of all PC funds for pandemic influenza response activities. Information on the allocation and use of PC funds for pandemic response will be shared in a timely manner with Member States, the PIP Advisory Group, manufacturers, and other stakeholders through WHO’s regular emergency response reporting, and/or through specific reporting by the PIP Secretariat, as appropriate.

5. **Efficient Use of Funds**: PC funds for pandemic response should neither duplicate nor supplant other funds allocated to pandemic influenza response.

IV. Release and Use of PC Funds for Response

1. PC funds for pandemic response will be used to provide the benefits outlined in the PIP Framework, in particular to facilitate access to, effective deployment, and use of pandemic vaccines, antiviral medicines and other therapeutics, ancillary products, diagnostic kits and other pandemic influenza response products.

2. PC funds for pandemic response may be released in connection with the convening of an emergency committee under the IHR regarding the determination of a PHEIC due to the emergence of a human influenza virus with pandemic potential, in as many disbursements as is financially prudent, to ensure that funds are supportive of necessary pandemic influenza response activities. PC funds for pandemic response may be used for a range of pandemic influenza response activities, as determined by the Director-General, including, but not limited to:

   - Shipments of biological materials, including clinical specimens, viruses and virus isolates, and laboratory diagnostic reagents, between or among WHO GISRS laboratories and/or Other authorized laboratories, as well as laboratory and epidemiology activities;

---

14 cf PIP Framework Section 6.0.2(iii)
• The purchase and/or shipping to recipient countries\textsuperscript{15} of pandemic influenza response products, such as vaccines, antivirals and other therapeutics, ancillary products, diagnostic kits, and other products relevant to pandemic influenza response, including those secured under PIP Standard Material Transfer Agreements 2; and

• Supporting countries, including to request and prepare for the receipt, effective deployment, and use of pandemic influenza vaccines, antivirals and other therapeutics, ancillary products, diagnostic kits or other pandemic influenza response products.

\textsuperscript{15} This may be directly or indirectly via procuring or supporting bodies.