MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP

28-31 March 2023

Report to the Director-General

Organization and process of the meeting

1. The Pandemic Influenza Preparedness (PIP) Framework Advisory Group (AG) met at World Health Organization (WHO) headquarters in Geneva, Switzerland, 28-31 March 2023. 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. Prior to the AG meeting, a technical briefing was held virtually for the new members of the AG on 13 March 2023.

3. Dr Sylvie Briand, the Director of the Department of Epidemic and Pandemic Preparedness, 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.

4. The AG welcomed five new members, Dr Eun Jin Kim (Republic of Korea), Dr Gulay Korukluoglu (Türkiye), Dr Muhammad Tariq (Pakistan), Dr Sonam Wangchuk (Bhutan) and Dr Rhoda Wanyenze (Uganda).

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

6. The Chairperson informed the AG that four observers from the WHO Global Influenza Surveillance and Response System (GISRS) would attend relevant technical sessions of the AG meeting.1

7. In accordance with its standard practice, the AG convened a consultation with stakeholders on 29 March 2023. The list of participants in the AG meeting and consultation is available at Annex 4.

Presentation of the Health Emergency Context

8. A representative for WHO Health Emergencies Programme updated the AG 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).

9. The INB has progressed with its inclusive Member State led process and has to date included four meetings of the INB, as well as public hearings, informal focused consultations, informal

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1 See https://www.who.int/influenza/gisrs_laboratory/GISRS_representation_20171010.pdf
intersessional briefings, and regional consultations. A Zero Draft of the WHO CA\textsuperscript{2} was presented to the INB at their fourth meeting from 27 February to 3 March 2023.

10. The mandate of the WGIHR is to consider proposed targeted amendments to the International Health Regulations (2005), in accordance with decision WHA75(9) and consistent with the decision EB150(3). More than 300 proposed amendments have been received addressing 33 of the 66 articles of the International Health Regulations (2005).

**PIP ‘Pandemic Operational Playbook’**

11. The Partnership Contribution (PC) is a key benefit sharing mechanism of the PIP Framework with the funds used for two purposes: pandemic preparedness and response.

12. In 2014 the AG developed the Guiding Principles for use of PIP Partnership Contribution Response Funds as they recognized that during the initial stage of an influenza pandemic there would be limited opportunity to convene the AG and/or interact with stakeholders. The Guiding Principles provided the basis for the Director-General to make decisions on the use of the PC response funds, without further advice from the AG.

13. As the operational landscape has changed significantly since 2014, especially considering the COVID-19 pandemic, the AG has agreed to review the Guiding Principles to ensure they remain relevant. The Secretariat will facilitate the process to ensure that the AG can have an informed discussion at its next meeting. The AG also noted that prioritizing the use of the PC response funds and allocating them based on public health needs should be further elaborated.

14. The PIP Secretariat has started developing a PIP ‘Pandemic Operational Playbook’ to provide a catalogue of the response elements available to WHO for the next influenza pandemic through the PIP Framework. This will describe, *inter alia*, the resources (e.g., funds, diagnostics, vaccines, therapeutics, syringes), criteria for use of such resources and the roles and responsibilities of WHO and external partners. The Playbook is also to include the Guiding Principles.

15. The AG welcomes the development of the PIP Pandemic Operational ‘Playbook’ and looks forward to it being presented at the next AG meeting by the Secretariat.

**PRET – Preparedness and Resilience for Emerging Threats**

16. The Secretariat presented Preparedness and Resilience for Emerging Threats (PRET) initiative to the AG, which is a new organizing framework to improve pandemic preparedness for groups of pathogens based on their modes of transmission. PRET encourages strengthening of pandemic preparedness in a three-tiered approach: all/multi hazard systems (e.g., the International Health Regulations 2005 core capacities), capacities and systems for pathogen groups (e.g., respiratory) and pathogen specific components (e.g., the PIP Framework for influenza).

17. PRET builds on existing systems and plans and is tailored to fill identified gaps in the core capacities for respiratory pathogen prevention, preparedness, response and recovery. PRET will have modules for specific pathogen groups, e.g., Module 1 for respiratory pathogens, which provide the operational framework.

\textsuperscript{2} WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response
18. The AG noted the connections between PRET, the PIP Framework and GISRS but highlighted that these linkages are often difficult to understand. The AG suggested that an overarching schematic that shows these linkages be developed.

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

19. The Secretariat provided an update on the collection of the annual PC amount of US$ 28 million paid by influenza vaccine, diagnostic and pharmaceutical manufacturers who use GISRS. As of 22 March 2022, the proportion of the invoiced amount of the US$ 28 million per year received was 97% in 2021 and 68% in 2022, which is in keeping with what has occurred in previous years.

20. The Secretariat provided an update on implementation of the HLIP II, which included highlights from the upcoming annual report for 2022. The plan for the HLIP II evaluation, to be conducted between April to October 2023, was also presented by the Secretariat. As previously recommended by the AG, the evaluation will reflect five years of implementation from 2018 through 2022. The evaluation is to be conducted by independent external evaluator(s) and comprise quantitative and qualitative analyses including interviews with key informants and stakeholders.

**Update of HLIP III**

21. The Secretariat provided an update on the finalised content of HLIP III (2024-2030), which builds on HLIP II. In addition to new areas of work, HLIP III realigns the six outputs of HLIP II to four new outputs in HLIP III.

22. The Monitoring and Evaluation framework for the HLIP III comprises 27 indicators, of which 16 are from the HLIP II and 11 are new. The full Monitoring and Evaluation Framework, including baselines and targets for the indicators is to be available by late 2023 to enable implementation of the HLIP III starting in January 2024. To account for the final year outputs of the HLIP II, the baselines may be updated in 2024, as necessary.

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

23. According to the PIP Framework, the sum of the annual PC shall be equivalent to 50% of the running costs of GISRS. The current amount of US$ 28 million is based on the 2010 estimate of the GISRS running costs, and this amount has not been adjusted since the PIP Framework was adopted in 2011. The PC amount is divided among influenza vaccine, diagnostic and pharmaceutical manufacturers who use GISRS using a mathematical equation (the PC formula) that was developed in 2013 in close consultation with stakeholders. The Secretariat updated the AG on the current processes to adjust the PC level and revise the PC formula.

24. Based on a previous recommendation of the AG, the Secretariat developed a tool to adjust the PC level for inflation. The PC Adjustment Tool was presented to the AG in October 2022. The AG recommended, and the Director-General accepted, that the tool be implemented from 1 January 2024 onwards. The AG also requested that the PIP Secretariat, in consultation with stakeholders, develop standard operating procedures (SOPs) for using the tool to adjust the PC level.

25. To guide the development of the SOPs, the Secretariat developed a survey that was sent to stakeholders in January 2023. The survey asked about which of the two proposed indices
should be used in the tool (the Federal Reserve Bank of St. Louis Economic Data [FRED] or the World Bank), which year(s) to use as the basis of the calculation and how often the level should be adjusted. The Secretariat summarised the survey results received from various stakeholders.

26. The Secretariat also updated the AG on discussions held with industry associations to address comments received from industry on the process used to develop the PC Adjustment Tool. The Secretariat reported that the discussions had been constructive and that they are in the process of agreeing on the details of a simulation exercise to determine the impact on individual company payments if the PC Level is adjusted using the Tool and/or the proposed new PC Formula is used. The results of the simulations are to be provided to the AG prior to the next AG meeting.

Influenza virus sharing

27. The AG received an overview of influenza virus sharing, including through the influenza virus traceability mechanism (IVTM), up until 28 February 2023. Of the 305 influenza viruses of pandemic potential (IVPPs) that have been shared since 1 January 2017, 75% of these were shared in a timely manner, in accordance with the relevant WHO guidelines on the sharing of IVPPs.3

28. A representative from the Global Influenza Program (GIP) explained that where there have been some issues in the timely sharing of IVPPs, these were principally due to a range of clinical and administrative reasons. This included the depletion of clinical specimens for confirmatory testing, low viral loads in clinical specimens, and/or relevant national and international regulations on the transport of such viruses.

29. The AG discussed the challenges in communicating about the importance of influenza and how to advocate that there is already a well-established system for influenza pandemic preparedness and response through the PIP Framework and GISRS.

Q&As with GISRS representatives

30. GISRS representatives provided the AG with some key messages for advocacy. This included that there is an imminent threat of an influenza pandemic, that the laboratory and surveillance capacity of GISRS must continue to be strengthened at national, regional and global levels, and that the integrated GISRS surveillance system (GISRS Plus) is a platform to strengthen global surveillance of other respiratory viruses, including those with pandemic potential. The AG acknowledged and appreciated that GISRS is a surveillance system that includes both epidemiological and laboratory components and that both components are to be strengthened in HLIP III.

31. GISRS representatives also stressed that in their view, a priority of HLIP III should be the development and designation or recognition of new National Influenza Centres (NICs) in those countries that currently do not have a NIC. The AG noted that this, as well as the sustainability of the existing network, is a priority for GISRS.

32. GIP provided an update on the process to revise the GISRS NIC Terms of Reference (TORs) for seasonal influenza viruses. This was one of the recommendations made by the AG during

3 https://www.who.int/publications/i/item/operational-guidance-on-sharing-influenza-viruses
their October 2022 meeting to address concerns related to the use of seasonal candidate vaccine viruses for vaccine production and commercialization. GIP informed the AG that they have prepared the updated draft NIC TORs and developed the process for piloting the TORs in 20 NICs.

33. GIP also provided an update of GISRS Plus, in that a Technical Advisory Group for GISRS Plus development is currently being devised with the aim to have a GISRS Strategic Action Plan drafted in 2023.

Recommendation to the Director-General

The AG recommends that the Director-General raise Member States’ awareness of the ever-present threat of an influenza pandemic, urge them to maintain vigilance, strengthen influenza surveillance, and update and exercise their national pandemic preparedness plans.

SMTA2 update

34. The Standard Material Transfer Agreement 2 (SMTA2), the second PIP Framework benefit sharing mechanism, secures real-time access by WHO to future pandemic response products through legally binding agreements. The Secretariat updated that there are two negotiations in process with an influenza vaccine manufacturer and an antiviral manufacturer that have not signed an SMTA2 before.

Consultation with Stakeholders

35. The Chair welcomed stakeholders, thanked them for their ongoing contributions, and provided a brief update on the AG’s work.

36. The Secretariat provided a presentation which covered PC collection and proportional distribution of funds, progress in implementing and evaluating HLIP II, and the upcoming launch of HLIP III. The Regional Office for Africa and the Regional Office for the Americas both presented progress on implementation of PIP activities in their regions, with the WHO Headquarters providing an update on initiatives in laboratory and surveillance.

37. Two stakeholders provided presentations to the AG:

- A representative from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and BIO provided feedback that the HLIP III needs to be focused on influenza pandemic preparedness, queried the relationship between the PIP Framework and the “pandemic accord” that is being discussed in the context of the INB and summarised the discussion with WHO on the revisions to the PC level and formula.

- A representative from Third World Network (TWN) provided feedback on the recommendations from the October 2022 AG meeting with regards to the options to address concerns related to the use of seasonal Candidate Vaccine Viruses (CVVs) for vaccine production and commercialization. This included that Option 1 to revise the GISRS NIC TORs in their view, does not provide any additional benefits and may not be consistent with some national access and benefit sharing (ABS) laws/regulations and that only a multilateral system would provide legal certainty on the use of the seasonal CVVs.
The TWN representative also requested feedback on the status of the AG recommendations from the October 2022 AG meeting report.

38. The AG welcomed the presentations and responded with the following:

- The Director-General has considered the recommendations from the AG for addressing concerns related to the use of seasonal influenza viruses for commercial purposes. The review of the NIC TORs related to seasonal influenza viruses is in progress with a pilot to assess if the relevant national authority would be ready to accept the amended NIC TORs and if the TORs are consistent with their national laws/regulations, including those for ABS.

- Questions about the potential interplay between the PIP Framework and the draft “pandemic accord” would be most suitably addressed by the INB in its deliberations and discussions, as appropriate.

- The high knowledge of the PIP Framework reported within industry association members was reassuring.

39. It was also discussed that generic manufacturers of antivirals, who are not members of the industry associations, are not required to conclude SMTA2s under the PIP Framework as they do not need to access PIP biological materials. Production capacity surveys are currently being conducted for antiviral companies.

40. The next meeting of the AG is to be the week of 23 October 2023.
Annex 1

Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
28-31 March 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 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, Public Health General Directorate, Ankara, 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
Professor Soe Lwin Nyein, Department of Public Health, Ministry of Health and Sports, Myanmar
Dr Vivi Setiawaty, Center for Research and Development of Biomedical and Basic Health Technology, Ministry of Health, Indonesia
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

4 Dr Mbayame Ndiaye Niang (Senegal) was 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 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 Vivi Setiawaty (Indonesia)
- Dr Sonam Wangchuk (Bhutan)

Western Pacific
- Dr Eun Jin Kim (Republic of Korea)

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5 Dr Mbayame Ndiaye Niang (Senegal) was unable to attend.
- 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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<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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<tr>
<td>Dr Roberto Arroba</td>
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<td>Dr Soe Lwin Nyein</td>
<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.
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. PIP Pandemic Operational Playbook
6. Preparedness and Resilience for Emerging Threats (PRET)
7. Partnership Contribution (PC) collection and High-Level Implementation Plan (HLIP-II) implementation
8. Update on HLIP-III
9. Adjusting the PC Level and revising the PC Formula
10. Influenza virus sharing
11. Q&As with GISRS representatives
12. SMTA2 update
13. PIP AG 2022 Annual report
14. Consultation with Stakeholders
15. Close of meeting
Meeting of the Pandemic Influenza Preparedness Framework Advisory Group
28-31 March 2023
List of Participants

GISRS representatives\(^1\,^2\)
- Dr Hector Chiparelli, Depto. de Laboratorios de Salud Pública, Montevideo, Uruguay
- Dr Summer Galloway, Centers for Disease Control and Prevention, Influenza Division, Atlanta, USA
- Dr Ruth Harvey, Assistant Director, Worldwide Influenza Centre, The Francis Crick Institute, London, UK
- Dr Erik Karlsson, Deputy Head, Virology Unit, Director, National Influenza Center of Cambodia and H5 Reference Laboratory, Phnom Penh, Cambodia

Civil society organizations\(^2\)
- Thirukumaran Balasubramaniam, Knowledge Ecology International (KEI)
- Matthieu Chevallier, Médecins Sans Frontières (MSF)
- Yuanqiong Hu, MSF
- James Packard Love, KEI
- Sangeeta Shashikant, Third World Network (TWN)
- Wenzhen Jen Zuo, World Medical Association - Junior Doctor Network

Manufacturers and industry associations\(^2\)
- Phyllis A Arthur, Biotechnology Innovation Organization (BIO)
- Paula Barbosa, IFPMA
- Manish Bhankhodiya, Zydus lifesciences limited
- Alexandre Bimbo, Instituto Butantan
- Felipe Carvilhe, Butantan
- Emily Chavez, Pfizer
- Melchior Kuo, IFPMA
- Chloe Chepigin, Novavax
- Paulo Lee Ho, Instituto Butantan
- Pham Thi Bich Hong, International Vaccine Access Center (IVAC)
- Aeron Hurt, Roche
- Melchior Kuo, IFPMA
- Lyn Morgan Marsden, Sanofi Pasteur
- Débora Botéquio Moretti, Instituto Butantan
- Lauren Parker, AstraZeneca
- Zach Rothstein, AdvaMedDx
- Kaori Shinoda, Daiichi Sankyo Co., Ltd
- Kristina Shultz, AdvaMedDx
- Beverly Taylor, Seqirus Vaccines
- TeChloe Chepigin Tsai, Takeda
- Sogo Yamamoto, DaiichiSankyo
- Shuyan Zuo, China National BioTec Group

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\(^1\) Participated in relevant technical sessions of the meeting.
\(^2\) Participated in the 29 March 2023 consultation with stakeholders
Other organizations
- Audrey Wong, International Pharmaceutical Students Federation (IPSF)
- Yansonghe Li, Shanghai Institute of Biological Products Co., Ltd. Sinopharm
- Matthew Downham, Coalition for Epidemic Preparedness Innovations (CEPI)
- Nicole Lurie, CEPI
- Freya Hopper, CEPI

WHO Staff

WHO regional offices
AFRO
- Belinda Herring, AF/RGO/WHE/EPP

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
- Francis Yesurajan Inbanathan, SE/RGO/WHE/IHM

WPRO
- Phuong Nam Nguyen, WPR/RGO/WHE

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
- Chadi Fayad, HQ/WPE/EPP/IPR
- 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/IPR
- Sandra Jackson, HQ/WPE/EPP/GIP
- Fiona Kee, HQ/WPE/EPP/GIP
- Maja Lievre, HQ/WPE/EPP/GIP

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3 Participated in some or all of the meeting.
- 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
- Kenneth Piercy, HQ/DGO/DGD/LEG
- Magdi Samaan, HQ/WPE/EPP/GIP
- Gina Samaan, HQ/WPE/EPP/PGP
- Shideed Olla, HQ/WPE/EPA
- Siddhivinayak Shriram Hirve, HQ/WPE/EPP/GIP
- Hiiti Sillo, HQ/MHP/RPQ/REG/RSS
- Katelijn Vandemeule, HQ/WPE/EPP/GIP
- Anne Yu, HQ/WPE/EPP/GIP
- Wenqing Zhang, HQ/WPE/EPP/GIP