Organization and process of the meeting

1. The Advisory Group met at WHO headquarters in Geneva, 14-17 April 2015.

2. The meeting was preceded with a briefing for new Advisory Group members, and the Chair welcomed the new members. The briefing explained the history and mission of the PIP Framework, including the main elements of virus sharing, benefit sharing, and governance. The briefing also included the screening of a new video intended for public communication on the history and objectives of the PIP Framework.

3. Of the 18 members of the Advisory Group, 13 were present. The list of participants in the meeting is found at Annex 1.

4. The Chair made introductory remarks.

5. The Chair welcomed members. The WHO Principal Legal Officer reviewed the process for Declarations of Interest. The summary of Declarations of Interest is found at Annex 2.

6. The Advisory Group selected Dr Frances McGrath as Vice-Chair.

7. The Assistant Director-General for Health Security made some introductory remarks, highlighting the importance of ensuring that the implementation of the PIP Framework continues to accelerate, to strengthen countries’ preparedness for public health emergencies of international concern (PHEIC), such as the recent Ebola Virus Disease (EVD) outbreak. He drew members’ attention to issues such as the pending Review of the PIP Framework, and the implications of the Nagoya Protocol.

8. The Advisory Group adopted the meeting agenda. The agenda is found at Annex 3.

9. As part of the meeting, the Advisory Group held consultations on Day 3 with industry, civil society and other stakeholders as well as representatives of databases\(^1\) for genetic sequence data (GSD) (see Annex 4). The points raised in those conversations have been incorporated throughout the report.

\(^1\) Throughout this report, the term “database” refers to any institute, collaboration, initiative, organization or other entity that houses genetic sequence data.
Update on SMTA2s

10. The PIP Secretariat introduced the pre-negotiation preparatory work that has been undertaken for vaccine manufacturers. The Secretariat explained that the process of reaching out to companies includes awareness-raising of the PIP Framework, through workshops and meetings, but concluding agreements with major manufacturers is a time-consuming process and remains a challenge. The discussions with Category B manufacturers have resumed; these have been facilitated by recommendations from the Advisory Group’s October 2014 meeting.

Update on Partnership Contribution (PC) Collection

11. The Secretariat reviewed progress to collect contributions. The 2015 questionnaire has been published online, and the portal includes a link to a new PC collection video. There has been progress in collection but some issues remain. The Advisory Group discussed with industry the factors that have led to more timely payment of 2014 PC Funds. The response from industry was that it might have been due to the increased familiarization of the PIP Framework process through the Secretariat’s interactions and outreach work.

12. In discussions with industry and other stakeholders, the Secretariat was asked whether companies could receive invoices earlier in the year. The Secretariat noted that the formula used to weight partner contributions requires that all Band Selection Forms (BSFs) be received before it can be run. Industry representatives also noted that over the next 12 months, it would be useful to find another basis for determining average annual influenza product sales, given the concern expressed over the continued use, as previously agreed, of 2009 as a baseline year.

13. Advice to the Director-General on the collection of the 2014 PC funds:

   The Advisory Group recommended that the Secretariat send information about the use of the PC funds to companies along with the BSFs so that they may better understand how the funds are used.

   The Advisory Group encouraged the Secretariat to collaborate with industry to study the appropriate reference years to determine the average annual influenza product sales.

   The Advisory Group also encouraged the Secretariat to increase its interactions with industry associations about implementation of the Framework, for instance by participating in annual general meetings and other fora.

Update on Virus Sharing

14. The Secretariat emphasized the need for a response that encompasses the rapid detection of viruses with human pandemic potential, rapid development of vaccines, and the acceleration of research on vaccines and other interventions.

15. The discussion highlighted that the continued threat of pandemics in view of zoonotic influenza further emphasized the need for timely sharing of viruses and genetic sequence information. It was noted that timeliness in recording of viruses in the Influenza Virus Traceability Mechanism (IVTM) is important.
Update on Global Action Plan for Influenza Vaccines (GAP)

16. The goals of GAP are: to increase evidence-based use of seasonal influenza vaccine; increase vaccine production capacity; strengthen regulatory capacity; and foster the development of new vaccines. The update included these further points:

- Despite policy recommendation, there is a need for more information about implementation of routine maternal immunization.
- Seasonal influenza vaccine uptake in the 2014 winter season was low in some countries.
- Influenza vaccine production has not attained the expected targets, and regional differences in production capacity remain, with a significant lack in the Middle-East and Africa.
- GAP will be closing at the end of 2016.

17. Advice to the Director-General on the Global Action Plan for Influenza Vaccines (GAP)

The Advisory Group took good notice of the interactions between GAP and the PIP Framework. The Advisory Group suggested that the 2016 Review of the PIP Framework should include an analysis of the implications related to the closure of the GAP initiative.

Update on PC Implementation

18. The Secretariat presented a high-level overview of the Partnership Contribution Implementation Plan 2013–2016. Actual implementation began in mid-2014, and was impacted by the Ebola crisis. Of the funds budgeted for preparedness, 40% had been spent by 31 March 2015. The 2014 Annual Report on PC has been published. The ensuing discussion covered these points:

- The PIP Secretariat should consider how to better synergize with other public health programs or initiatives, including but not limited to the IHR (2005), the GAP and the Global Health Security Agenda (GHSA) so as to ensure that efforts are complementary.
- Country capacities to handle increased implementation should be taken into consideration.
- Caution should be exercised in comparing data between regions given that the selection of recipient countries by each region was tailored to country capacities.
- During the interaction with industry and other stakeholders, they expressed concern about the slow rate of disbursement and implementation.

19. Advice to the Director-General on PC Implementation:

The Advisory Group recommended that throughout 2015, WHO accelerate implementation of activities supported with the Partnership Contribution funds. In addition, the Secretariat is urged to work more closely with countries through WHO Regional Offices to better understand and address implementation challenges, including sustainability.
Discussion of 2016 Review

20. The Advisory Group discussed next steps in relation to the upcoming Review of the PIP Framework and its Annexes. Resolution 64.5, which adopted the PIP Framework, requests the Director-General, in consultation with the AG “to monitor and review the operation of the PIP Framework and all of its components, in accordance with its provisions.” The PIP Framework, at section 7.4.2, provides that: “The Framework and its annexes will be reviewed by 2016 with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, through the Executive Board.”

21. The Advisory Group noted that the Review process should start as soon as possible in 2015. It analysed the relevant provisions in the PIP Framework and considered that there were ambiguities regarding the review process. Nevertheless, it discussed options for carrying out this process, such as the role of governing bodies and the Advisory Group, the orientation of the review, the degree of independence of the reviewers, any potential changes in the scope of the Framework, and the changing context in terms of Genetic Sequence Data, closure of the GAP initiative, and the Nagoya Protocol. It was considered necessary to raise this matter with the Director-General in order to have the benefit of her views on the process of the Review, and the options available.

Update on Communications and Outreach

22. The Secretariat updated the Advisory Group and the stakeholders about its activities in outreach and development of user-friendly products, such as newsletters and videos.

23. The Advisory Group, industry and other stakeholders commended the Secretariat for the quality and range of communications and outreach materials now available, including videos on the overview of the Framework and the PC Animation; the PIP Framework website and the Implementation Portal; the e-newsletter; and the 2014 PC Annual Report.

24. Advice to the Director-General on Communications and Outreach.

*The Advisory Group recommended that the Secretariat diversify its involvement with media, especially at the regional level. It also recommended that the Secretariat prepare articles for publications and media outlets, to increase awareness of the PIP Framework.*

Update on progress to implement recommendations on handling of Genetic Sequence Data (GSD)

25. The Secretariat updated the Advisory Group on progress to implement the recommendation to identify the optimal characteristics of a system for handling GSD products under the PIP Framework. On the specific issue of possible mechanisms to monitor the use of GSD in end products, representatives from the World Data Centre for Microorganisms (Chinese Academy of Sciences) (WDCM) and the World Federation of Culture Collections (WFCC) presented a prototype search engine that could be used.

26. The Advisory Group thanked the World Data Centre for Microorganisms (Chinese Academy of Sciences) and the World Federation of Culture Collections for their technical presentation on a prototype search engine.
The Advisory Group noted the need to quantify and increase the accuracy of results, and narrow the focus of searches to checkpoints that allow identification of end products that are relevant to the PIP Framework (e.g. patents, clinical trials, regulatory approval files, and publications presenting clinical trial data results).

The Advisory Group reviewed the next steps for work on GSD sharing systems. Based on discussions with industry, civil society and database representatives, the Advisory Group indicated that the Secretariat should consider initiating discussions with database managers on the possibility of including a statement about the PIP Framework on their website.

The Advisory Group adopted Terms of Reference for a Technical Working Group (TWG) on GSD sharing systems.

Advice to the Director-General on progress to implement recommendations on handling of Genetic Sequence Data:

The Advisory Group recommended that the Secretariat consider initiating discussions with database managers on the possibility of including a statement about the PIP Framework on their website.

The Advisory Group recommended that the Secretariat continue its collaboration with the WDCM and WFCC with a view to using the prototype search engine on a pilot basis.

The Advisory Group recommended that the TWG start work as soon as possible. They also recommended that the TWG have the same Chair as the TEWG in order to have continuity. The Advisory Group also recommended that the composition of the TWG should include two additional PIP Advisory Group Members.

Planning for deployment: preliminary findings from an Informal Technical Workshop

The Secretariat demonstrated progress made to develop a simulation tool for deployment of pandemic products. Industry and other stakeholders provided input into discussions around issues such as data security and the confirmation of product availability. The simulation tool was welcomed as a positive development.

Review and approval of meeting report

The Advisory Group adopted the meeting report after providing comments.

Next steps
The Advisory Group will meet in Geneva from 13 to 16 October, 2015.
Pandemic Influenza Preparedness Framework Advisory Group Meeting
14-17 April 2015

List of Advisory Group participants

Professor Tjandra Y Aditama, Chairman, National Institute of Health Research and Development, Ministry of Health, Indonesia

Professor William Kwabena Ampofo, Head - Virology, Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana

Professor Chris Baggoley, Chief Medical Officer, Department of Health, Australia

Dr Jarbas Barbosa da Silva, Jr, Secretary (Vice Minister) of Health Surveillance, Ministry of Health, Brazil

Dr Rainer Engelhardt, Assistant Deputy Minister, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada, Canada

Professor Didier Houssin, President, French Evaluation Agency for Research and Higher Education (AERES), France

Dr Olav Hungnes, Director, National Influenza Centre, Norwegian Institute of Public Health, Norway

Dr Hama Issa Moussa, National Technical Assistant, Institutional Support Unit, Ministry of Public Health, Niger

Dr Amr Mohamed Kandeel, Chief of Preventive Affairs and Endemic Diseases Sector, First Undersecretary, Ministry of Health and Population, Egypt

Professor Oleg Ivanovich Kiselev, Director, Research Institute of Influenza, Ministry of Public Health and Social Development, National Influenza Centre, Russian Federation

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

Dr Frances McGrath, Deputy Director of Public Health, Clinical Leadership, Protection and Regulation, Ministry of Health, New Zealand

Dr P V Venugopal, Former Director of International Operations, Medicines for Malaria Venture, Public Health Specialist, India
Pandemic Influenza Preparedness Advisory Group Meeting
14-17 April 2015

Summary of Declarations of Interest by members

In accordance with WHO policy, in advance of the meeting, all PIP Framework Advisory Group members were asked to provide a duly completed Declaration of Interests form to inform WHO about real, potential or actual conflicts of interests that they might have in relation to the subject matter of the meeting. Over the course of the meeting, the Advisory Group discussed, reviewed, or was provided updates on the implementation of the Framework, including: 1) the Partnership Contribution, b) SMTA negotiations, c) virus sharing, d) handling of genetic sequence data, and e) other technical matters including communications and outreach, as well as the 2016 review.

During the meeting, the Advisory Group also interacted with manufacturers and other stakeholders regarding the implementation of the Partnership Contribution, the handling of genetic sequence data, the 2016 review, and planning for deployment.

Additionally, Advisory Group members were informed of the following enhancements to the management of the Conflict of Interest process at WHO:

1. The DOI Form now includes language relating to failure by an expert to be forthcoming in his/her disclosure. If an expert does not fully complete and disclose all relevant information on the form then this could potentially lead to the expert no longer being appointed to WHO advisory bodies/functions in the future.
2. The revised policy includes a Confidentiality Undertaking that must be signed by each member once for the duration of the term.
3. A new Public Notice and Comment period was instituted. This is a period of two weeks prior to each meeting where the public can comment on any potential conflicts of interests of members. Prior to this meeting, the Public Notice statement was posted on the Advisory Group Member webpage that includes member biographies and affiliations.

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:
- Professor William Kwabena Ampofo (Ghana)
- Dr Hama Issa Moussa (Niger)

Americas:
- Dr Rainer Engelhardt (Canada)
- Dr Jarbas Barbosa da Silva Jr, (Brazil)
- Dr Cuauhtémoc Mancha-Moctezuma (Mexico)

1 Dr Janneth Mghamba (United Republic of Tanzania), Dr Huma Qureshi (Pakistan), Dr Amr Mohamed Kandeel (Egypt), Professor Mahmudur Rahman (Bangladesh), and Professor Yu Wang (China) were unable to attend.
Eastern Mediterranean:
- Professor Ziad Memish (Saudia Arabia)

Europe:
- Professor Didier Houssin (France)
- Dr Olav Hungnes (Norway)
- Professor Oleg Ivanovich Kiselev (Russian Federation)

South-East Asia:
- Professor Tjandra Y. Aditama (Indonesia)
- Dr P V Venugopal (India)

Western Pacific:
- Dr Frances McGrath (New Zealand)
- Professor Chris Baggoley (Australia)

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>Professor Tjandra Y. Aditama</td>
<td>Civil Servant</td>
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<tr>
<td>Professor William Kwabena Ampofo</td>
<td>Affiliated with a GISRS laboratory</td>
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<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.
Annex 3

Pandemic Influenza Preparedness Framework Advisory Group Meeting
14-17 April 2015

Agenda

1. Registration
2. Briefing for new Advisory Group members
3. Welcome remarks from the Chair
4. Introductions
5. Selection of Vice-Chair
6. Declarations of Interest
7. Adoption of agenda
8. Update on SMTAs 2
9. Update on Partnership Contribution
   - Partnership Contribution collection
   - Implementation
   - Communications and outreach
10. Update on Virus Sharing
11. Update on Global Action Plan for Influenza Vaccines (GAP)
12. Discussion of 2016 Review
13. Update on progress to implement recommendations on handling of Genetic Sequence Data (GSD)
14. Consultation with industry and other stakeholders
   - Welcome remarks from the Chair, PIP Framework Advisory Group
   - Update on Partnership Contribution
   - Review and discussion of progress to implement recommendations on the handling of Genetic Sequence Data
   - Discussion on the 2016 Review of the PIP Framework
   - Planning for Deployment
     - Presentation of preliminary findings from Informal Technical Workshop
     - Discussion
15. Review of outcomes of consultations and drafting of recommendations
16. Review and approve recommendations and meeting report

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

18. Close of meeting
Annex 4

Pandemic Influenza Preparedness Framework Advisory Group Meeting
14-17 April 2015

Civil society organizations and other stakeholders:
Participants

- International Hospital Federation
- Sapienza Università di Roma
- Third World Network
- University Health Network

Manufacturers and industry associations:
Participants

- Adimmune
- AdvaMedDx
- bioCSL
- Biotechnology Industry Organization (BIO)
- Cepheid
- GlaxoSmithKline (GSK)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- KAKETSUKEN
- Kitasato Daiichi Sankyo Vaccine
- QIAGEN Manchester Ltd
- Sanofi Pasteur
- St. Petersburg Scientific Research Institute of Vaccines and Sera
- Takeda
- Viroclinics Biosciences BV

Genetic sequence database:
Representatives

- GISAID Initiative
- Influenza Research Database
- OpenFluDB
- World Federation of Culture Collections (WFCC), World Data Centre for Microorganisms (Chinese Academy of Sciences) (WDCM)