Report of the Third Meeting of the Pandemic Influenza Preparedness (PIP) Framework 2016 Review Group

ORGANIZATION AND PROCESS OF THE MEETING

1. The third meeting of the PIP Framework Review Group was held at WHO Headquarters from 30 March to 1 April 2016, and included in its agenda:

    - Consultation with Member States and Stakeholders
    - PIP Framework technical team presentations
    - Interviews with key WHO informants
    - Closed deliberations
    - Webcast of key messages from the meeting, led by the Chair

2. The eight members of the Review Group attended the meeting (names and affiliations of the members are in Annex 1).

30 MARCH 2016

OPENING OF THE MEETING

3. Dr Christine Kaseba-Sata, Chair of the Review Group, opened the meeting by welcoming Members, explaining the purpose of the PIP Framework Review, and outlining the agenda for the meeting.

PIP REVIEW GROUP CONSULTATION WITH MEMBER STATES

4. Dr Sylvie Briand, Director of the Pandemic and Epidemic Disease department, welcomed participants to the meeting and provided a brief overview of the history of the PIP Framework and its achievements to date.

5. The Chair presented a summary of the review process to date and emphasized the main focus areas for the Review Group, which include: virus sharing, including the handling of genetic sequence data (GSD), benefit sharing, governance and linkages with other instruments. She also emphasized the three main questions contained in the Review Group's terms of reference:

- What are the achievements since the PIP Framework was adopted?
- Has implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond?
- What are the challenges, and possible ways of addressing them?

6. Around 35 Member States provided comments to the Review Group. Various themes emerged, including:

    - The importance of enhancing and improving the PIP Framework.
    - The principle of the equal footing between virus sharing and benefit sharing as a cornerstone of the Framework.
    - The need for greater cooperation between the International Health Regulations 2005 (IHR) and the PIP Framework, while ensuring the PIP Framework's independence is preserved.
    - That the process of the Advisory Group, in its iterative nature of engaging stakeholders, is a good model of governance.
    - The vital role of transparency and information sharing for building support among the public and Member States.
    - The importance of preparedness for pandemic response, including vaccine production capacity, and ensuring progress made by GAP is not lost when the programme ends.
    - The need for a better understanding of what potential impact the implementation of the Nagoya Protocol will have on the PIP Framework and on the sharing of samples and GSD.
    - The need for clarity over the strategy for conclusion of SMTA 2s thus far.
    - The challenge of addressing the sharing of GSD under the PIP Framework.
    - Better understanding, through better communication, of the impact of Partnership Contribution.

7. The Secretariat described the challenges faced with concluding additional SMTA 2s with small and medium sized vaccine manufacturers, such as a lack of experience with and understanding prequalification and export requirements.

8. The Secretariat also provided information about a forthcoming WHO study on the impact of Nagoya implementation on public health, as requested by Member States in the January 2016 Executive Board; the report of this study will be presented to the 2017 Executive Board.

9. Dr Sylvie Briand provided an explanation of the antiviral stockpile. Dr Briand also explained why work toward establishing a vaccine stockpile was no longer deemed necessary given the conclusion of SMTA2s to ensure early availability of vaccine in case of a pandemic, and the revised recommendations of the Strategic Advisory Group of Experts (SAGE) on Immunization.

10. Members of the Review Group asked a number of questions to Member States on issues such as the cost-benefit calculation regarding the remaining SMTA 2s, the implication of GSD on pandemic influenza, and the extent to which GSD is already contained within GISAID.

OPEN CONSULTATION WITH MEMBER STATES AND STAKEHOLDERS

11. Dr Sylvie Briand welcomed participants to the meeting and provided a brief overview of the history of the PIP Framework and its achievements to date.

12. Dr Margaret Chan, WHO Director-General, extended her thanks to the Review Group and stakeholders, and emphasized the importance of broad engagement in the Review Group's work.

13. The Chair gave a summary of the review process to date and emphasized the main focus areas for the Review Group.

14. Stakeholders provided a number of comments, from which the following themes emerged:

- The possibility of considering expanding the PIP Framework to include seasonal influenza.
- The importance of fully incorporating GSD into the PIP Framework.
- The importance of building capacity and capability within the GISRS system and concern about the capacity of the GISRS network to handle a surge of viruses in case of a pandemic.
- The need for WHO to develop a trigger for the switch from seasonal to pandemic vaccine production.
- The role of databases, and the advantages and disadvantages of different options available for storing and sharing GSD.
- The need for clarity over the strategy to expedite the conclusion of SMTA2s, and the lack of royalty-free licenses.
- The possibility of reconsidering the total amount of Partnership Contribution, including delinking it from GISRS running costs and linking it instead to an economic indicator, and imposing a cap.
- The possibility of re-evaluating the way in which the Partnership Contribution is distributed.
- The need to understand the benefits on preparedness from Partnership Contribution.
- The question of how intellectual property developed using PIP biological materials should be treated.
- The importance of visibility and transparency to building stakeholder support.

31 MARCH 2016

PIP FRAMEWORK TECHNICAL TEAM PRESENTATIONS

15. The Review Group members received technical briefings on various aspects of the PIP Framework including: (1) SMTA 2 negotiations, (2) GISRS and virus sharing, (3) Partnership Contribution collection and implementation, (4) GSD.

CLOSED SESSION

16. The Review Group conducted a SWOT (strengths, weaknesses, opportunities and threats) analysis of various aspects of PIP Framework implementation, including virus sharing

and GSD, SMTA2s, Partnership Contribution collection and implementation, governance, and linkages with other instruments such as the Nagoya Protocol.

17. While the Review Group's analyses are preliminary, some key questions and issues discussed in its deliberative sessions include:

    - How to improve stakeholders' understanding of key aspects of the PIP Framework, for instance the misconception that slow progress in signing SMTA2s delays the access and sharing of benefits with countries.
    - The significant progress made by the Secretariat in signing SMTA2s with the largest manufacturers of influenza vaccines.
    - The potential expansion of the Framework to include seasonal influenza viruses
    - The importance of clarifying a trigger mechanism to switch from seasonal to pandemic vaccine production in the event of a pandemic.
    - How to address a perception by some stakeholders that Partnership Contribution funds are being utilised too slowly.
    - Whether the 2010 costing of GISRS running costs needs to be updated, and the implications for potentially recalculating the Partnership Contribution.
    - The PIP Framework Advisory Group's work in addressing the challenge of sharing of GSD, given that the mechanisms for sharing, and implications for benefit sharing, are not identical to those for sample-sharing.
    - Whether the principle of equitably balancing virus and data sharing with benefit sharing, can be applied to other pathogens, and to what extent the PIP Framework can act as a model or template for new agreements.
    - How to measure collateral benefits from the PIP Framework's capacity building, such as whether it has improved IHR core capacities in surveillance and detection.

18. The Review Group noted and welcomed that the Secretariat was taking actions to implement the EB request to WHO on the Nagoya Protocol through the production of a study. The Group underscored the importance of the study to examine how the objectives of the Framework (virus sharing and benefit sharing) are supportive of, and consistent with, the objectives of the Nagoya Protocol. The Review Group further recommended that the Secretariat take forward the EB's request on Nagoya as expeditiously as possible so that it meets the deadlines requested by the Executive Board.

1 APRIL 2016

INTERVIEWS WITH KEY WHO INFORMANTS

19. The Review Group conducted three interviews with WHO key informants:

    - Dr Guénaël Rodier, Director of the Department of Global Capacity, Alert & Response, which includes the IHR;
    - Dr Sylvie Briand, Director of the Pandemic and Epidemic Diseases Department, which includes the PIP Framework;
    - Dr Bruce Aylward, Executive Director ad interim of the Outbreaks and Health Emergencies Cluster, which includes the PIP Framework;

20. Jakob Quirin, Legal Officer, provided an overview of the relationship between the PIP Framework and the Nagoya Protocol.

CLOSED SESSION

21. The Review Group discussed their schedule and plan of work for the remainder of their work. The Review Group planned to meet again in face-to-face sessions in May, June, and August, supplemented by interaction via email and teleconferences. In an effort to maintain strong interaction with Member States, the Chair will present an update of the Review Group's work to the World Health Assembly in May and the meeting in June will include a webcast mission briefing. The final face-to-face meeting in August will include a meeting with Member States and other stakeholders. Ahead of this August meeting, Member States will be provided with a preview document that contains the Review Group's draft recommendations.

22. Further interviews with key informants will be conducted by teleconference by the Review Group in intersessional periods, and potentially during meetings.

WEBCAST OF KEY MESSAGES FROM THE MEETING

23. The Chair held a webcast briefing, summarizing the key outcomes of the meeting and inviting further participation by Member States and stakeholders in the process.

ANNEX 1

MEMBERS OF THE REVIEW GROUP

Review Group Members	Affiliation
Professor William Kwabena Ampofo	Head of Virology Department, Noguchi Memorial Institute for Medical Research, University of Ghana, Accra, Ghana
Dr Christine Mwelwa Kaseba-Sata (Chair)	Former WHO Goodwill Ambassador against Gender-based Violence, Zambia
Dr Frances McGrath	Chief Advisor, Clinical Leadership, Protection and Regulation, Ministry of Health, New Zealand
Dr Talat Mokhtari-Azad,	Director, Iranian National Influenza Center
Ms Johanne Newstead	Head of Food Policy, Public Health Directorate, Department of Health, United Kingdom
Dr Theresa Tam	Deputy Chief Public Health Officer of the Public Health Agency of Canada
Dr Viroj Tangcharoensathien	Senior Adviser, International Health Policy Program, Ministry of Public Health, Thailand
Prof Dr Makarim Wibisono	Chairman, Governing Board of Indonesia Council of World Affairs