

# **Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits**

## **Report of the meeting of the Pandemic Influenza Preparedness Framework Advisory Group**

**Report by the Director-General**

The Director-General has the honour to transmit to the Sixty-seventh World Health Assembly a summary report of the Pandemic Influenza Preparedness Framework Advisory Group, which reflects its deliberations during its meeting in April 2014 (see Annex). The Health Assembly is invited to note this report.

ANNEX

**MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS (PIP)  
FRAMEWORK ADVISORY GROUP**

**9–11 APRIL 2014, GENEVA, SWITZERLAND**

**Summary of the report to the Director-General**

1. The Advisory Group met 9–11 April 2014 and discussed the following as per its adopted agenda.

**Preliminary report of the Technical Expert Working Group on genetic sequence data**

2. The matter under review arises in connection with PIP Framework Section 5.2.4 which directs the Director-General to “consult the Advisory Group on the best process for further discussion and resolution of issues relating to the handling of genetic sequence data from H5N1 and other influenza viruses with human pandemic potential as part of the PIP Framework.”

3. A few manufacturers are using genetic sequence data to make vaccines and other influenza-related products, a trend that is anticipated to increase. During its October 2013 meeting, the Advisory Group agreed that this raised a number of complex issues in relation to benefit sharing. To assist the Advisory Group in developing guidance for the Director-General on this matter, a Technical Expert Working Group was established.

4. The Chair of the Technical Expert Working Group presented the Group’s method of work and summarized the key elements of the preliminary report (use of genetic sequence data, regulatory and intellectual property issues, monitoring and tracing of genetic sequence data, and biosecurity and biosafety issues). The ensuing discussion noted that:

- Genetic sequence data are covered by the PIP Framework. There were different perspectives on whether genetic sequence data are included in the definition of PIP biological materials.
- As genetic sequence data fall within the PIP Framework (e.g. Section 5.2; Annex 4, Point 9; Annex 5 “Guiding Principles”), the spirit of the Framework and the importance of maintaining equal footing for the sharing of viruses and benefits derived therefrom must be kept in mind in considering issues related to the handling of genetic sequence data for H5N1 and other influenza viruses with pandemic potential.
- Given the many ways that genetic sequence data may be disseminated, it is likely that WHO will not be aware of all instances of the use of genetic sequence data arising out of the WHO Global Influenza Surveillance and Response System. The PIP Framework’s objective of benefit sharing, however, must be met. Different approaches are available, including the monitoring and/or tracing of genetic sequence data through electronic databases (e.g. – the Global Initiative on Sharing All Influenza Data or GenBank) or through regulatory approval files and patent applications for influenza-related products. The utility of monitoring to maximize benefit sharing, as well as the feasibility and costs of possible monitoring methods, deserve further investigation.

5. Advice to the Director-General upon the finalization of the report of the Technical Expert Working Group.

*The Advisory Group reaffirmed the spirit of the Framework and the importance of maintaining equal footing for the sharing of viruses and benefits derived therefrom. It noted that genetic sequence data is a rendering of virus material and its use could accelerate the development of pandemic influenza vaccines. The Advisory Group thanked the Technical Expert Working Group for its work and noted that upon submission of its final report it will have concluded its work.*

*The Advisory Group recommended that the Director-General:*

- *post the final report of the Technical Expert Working Group on the WHO website for informational purposes with an attached cover note describing the process;*
- *inform Members States, industry and other stakeholders about the posting of the report; and*
- *inform the World Health Assembly about progress on the issue of genetic sequence data.*

6. The Advisory Group will meet with electronic database managers for genetic sequence data as well as industry and other stakeholders during its meeting in October 2014 to gather further information with a view to developing advice to the Director-General on genetic sequence data-related issues.

### **Partnership Contribution: update on collection of funds for 2013**

7. Through the *PIP PC 2013 Questionnaire*, the Secretariat identified 37 companies as partnership contributors. This extensive process to invoice and follow-up is ongoing and has resulted to date in a total of more than US\$ 26 million for 2013 from 24 contributors. The Secretariat will pursue collection of the remaining funds.

8. Advice to the Director-General on the collection of Partnership Contribution funds.

*The Advisory Group expressed appreciation for the enhanced efforts and success of the Secretariat to secure PIP Partnership Contribution funds in 2013 from all identified contributors.*

*The Advisory Group noted, however, that efforts to collect Partnership Contribution funds continue to be time-consuming and have not been successful in all instances. This is a concern as Partnership Contribution resources are needed to fully implement planned preparedness and response activities.*

*The Advisory Group recommended that the Director-General consider additional methods to improve the completeness of Partnership Contribution funds. These could include:*

- *better communication of the purpose and reasons for benefit sharing;*
- *more specific targeting to encourage partnership contributions by entities that use Global Influenza Surveillance and Response System;*

- *increasing visibility about participation in the Partnership Contribution collection process;*
- *providing companies with an estimate (based on prior contributions) of their annual contribution early in the fiscal year to facilitate budgetary planning; and*
- *feedback on achievements in preparedness activities made possible through the Partnership Contribution.*

### **Partnership contribution: draft guiding principles for use of Partnership Contribution response funds**

9. The Advisory Group reviewed the draft guiding principles and provided a number of comments, including the identification of a clear trigger for the release of funds.

10. The Advisory Group agreed that the draft guiding principles, as revised, should be shared with industry and other stakeholders in accordance with PIP Framework Section 6.14.6, with a view to finalizing them at the October 2014 meeting for submission, as a recommendation, to the Director-General.

### **Partnership Contribution: overview of implementation of preparedness activities**

11. The Secretariat provided an update on the implementation of preparedness activities in the five areas of work: laboratory and surveillance capacity building; burden of disease; risk communications; regulatory capacity building; and planning for deployment of pandemic supplies.

12. Advice to the Director-General on the implementation of preparedness activities.

*The Advisory Group welcomed the significant progress made in developing detailed activity plans by areas of work. The Advisory Group recommended that the Director-General build on this progress by:*

- *actively promoting the Partnership Contribution implementation plan;*
- *immediately releasing funds and implementing activities at the regional and country levels;*
- *assuring added value through synergy with related programmes and activities;*
- *using the Partnership Contribution implementation plan to leverage additional funds, particularly from Member States and other donors; and*
- *regularly communicating achievements and successes to encourage continued flow of Partnership Contribution contributions.*

### **Consultation with industry and other stakeholders**

13. The Advisory Group met representatives of industry associations, manufacturers and other stakeholders in a joint session. Industry and other stakeholder representatives expressed a favourable opinion of the progress achieved. Three main topics were discussed:

(a) Partnership Contribution Implementation Plan: The Secretariat provided an update on the implementation of preparedness activities. A number of comments were expressed, inter alia:

- Progress has been achieved in the development of detailed implementation plans; however, industry and other stakeholders felt that it would have been beneficial to have been regularly informed.
- Established synergies among the PIP, the Global Action Plan for Influenza Vaccines, the International Health Regulations (2005) and other relevant WHO programmes need to be ensured.
- Industry requested that an increased proportion of Partnership Contribution funds and emphasis be directed to regulatory capacity building, risk communications, and planning for deployment, which are critical to deployment of vaccines and antivirals during a pandemic.
- Guidance and training in laboratory biosafety/biosecurity is an essential part of building capacity to produce vaccine and antivirals.

(b) Technical Expert Working Group on genetic sequence data: The Chair of the Technical Expert Working Group summarized the key elements of the preliminary report. A number of comments were expressed, inter alia:

- Other stakeholders noted that excluding genetic sequence data from benefit sharing would undermine the objective of the Framework and create inequity within the Global Influenza Surveillance and Response System.
- Industry stated its concern that placing restrictions on the access/use of genetic sequence data would delay development of pandemic products.
- Industry indicated that assuring the sharing of benefits associated with the use of genetic sequence data might be better approached through the monitoring of products derived from the use of genetic sequence data.
- Industry and other stakeholders raised the issue of potential biosecurity/biosafety risks related to use of genetic sequence data.

(c) Enhancing communications: Industry representatives and other stakeholders commented on the importance of communications and transparency and how this might be improved, inter alia:

- Industry and other stakeholders raised the issue of emphasizing the objectives and spirit of the PIP Framework.
- Industry and other stakeholders indicated that it is beneficial to be regularly informed about the implementation of the PIP Framework using a range of platforms, including annual meetings and conferences.
- Industry requested that the Director-General remind Member States of their responsibilities under the PIP Framework, inter alia:

- strengthening regulatory capacity; and
- ensuring that pandemic products produced on their territories during a pandemic be made available to WHO as per the PIP Framework.

14. Advice to the Director-General on Partnership Contribution resources.

*The Advisory Group recommended that the Director-General consider:*

- *industry's request to increase the priority of regulatory capacity-building, risk communications and planning for deployment. This could be approached in a number of ways for these three areas, including:*
  - *an increase in the Partnership Contribution resources allocated to these areas of work;*
  - *earlier roll-out of implementation;*
  - *focused outreach and communication to industry on achievements and progress; and*
  - *identification of synergies with Global Action Plan for Influenza Vaccines and the International Health Regulations (2005) capacity-building activities*
- *other stakeholders' request that the Director-General increase efforts to ensure that all manufacturers using the Global Influenza Surveillance and Response System contribute to the Partnership Contribution and conclude SMTA 2s as appropriate.*

15. Advice to the Director-General on enhancing communications.

*Regular and effective communication with Member States, industry and other stakeholders and between WHO headquarters, and regional and country offices is essential to the successful implementation of the PIP Framework.*

*Communication of planned implementation activities, spending of Partnership Contribution funds, and achievement of measureable outcomes will facilitate an uninterrupted flow of Partnership Contributions. The Advisory Group was encouraged to learn that the Secretariat is considering options such as a web portal to provide real-time information on implementation of Partnership Contribution activities.*

*The Advisory Group recommended that the Director-General:*

- *increase communication, emphasizing the spirit and objectives of the PIP Framework;*
- *develop a comprehensive communications strategy for the PIP Framework, with particular attention to implementation of Partnership Contribution preparedness activities; and*
- *continue to encourage Member States to support the PIP Framework, including through the provision of resources to supplement the Partnership Contribution.*

16. Advice to the Director-General on strengthening the PIP Secretariat.

*The Advisory Group noted that the Director-General's decision to reinforce the Secretariat has resulted, inter alia, in demonstrable improvements in the collection of Partnership Contribution resources, the development of detailed implementation plans for Partnership Contribution preparedness plans, and the successful conclusion of an additional SMTA 2.*

*The Advisory Group recommended that the Director-General provide for further strengthening of the Secretariat as needed to ensure that the work of implementing the PIP Framework moves forward unimpeded.*

### **Preparations for the 2016 review of the PIP Framework**

17. The Secretariat proposed objectives and a general process for the review. It will take into account developments in science and pandemic preparedness that have affected operationalization of the Framework. The Advisory Group will continue to consider the scope and modalities of the review.

### **Update on SMTA 2s**

18. The Secretariat provided an update on the status of SMTA 2 negotiations.

- Category A: three SMTA 2 agreements have been concluded:
  - Glaxo Group Limited
  - Serum Institute of India
  - Sanofi Pasteur
- Category B: discussions have been initiated with five manufacturers
- Category C: two SMTA 2 agreements have been concluded (University of Florida and Harvard College).

19. The Advisory Group reviewed and noted the recent Sanofi Pasteur agreement under a Supplementary Confidentiality Undertaking, as the agreement included certain propriety information. The Advisory Group welcomed the conclusion of this agreement and emphasized the importance of showcasing such agreements in an appropriate manner.

20. The Advisory Group noted industry's continued concerns about their ability to export vaccines/antivirals from the country of production during a pandemic. The Advisory Group recommended that the Director-General seek periodic assurances from Member States that SMTA 2 agreements would be honoured and products delivered to WHO to be made available to countries in need. The Secretariat proposed that they review this with the Director-General and update the Advisory Group at its next meeting.

21. The Advisory Group noted industry's request for greater clarity on what would trigger pandemic vaccine production.

## Technical matters

22. Global Action Plan for Influenza Vaccines update: The Advisory Group welcomed the update on the Global Action Plan for Influenza Vaccines and noted that the end of the Global Action Plan for Influenza Vaccines initiative in 2016 may present an opportunity to explore the PIP Framework and Partnership Contributions as possible mechanisms to help sustain Global Action Plan-related progress in global influenza vaccine production.

23. Global Influenza Surveillance and Response System self-assessment: The Advisory Group welcomed the preliminary report and provided a number of comments; further discussion is planned upon completion of data collection and finalization of the report.

## Review and approval of meeting report

24. The Advisory Group adopted the Meeting Report after providing comments.

## Next steps

25. Next meeting: The Advisory Group will meet in Geneva on 21–24 October 2014. Agenda items include:

- consultation with genetic sequence data databank representatives, industry and other stakeholders
- review of final Global Influenza Surveillance and Response System self-assessment report
- update on SMTA 2
- update on Partnership Contribution implementation
- update on Global Action Plan for Influenza Vaccines.

26. Process to renew Advisory Group members: The Secretariat outlined a process to renew one third of the members during the October 2014 meeting as required in the PIP Framework (Annex 3, Section 3.2).

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