SPECIAL SESSION OF THE PANDEMIC INFLUENZA PREPAREDNESS (PIP) FRAMEWORK ADVISORY GROUP

13-14 OCTOBER 2015, GENEVA, SWITZERLAND

Report to the Director-General

Organization and process of the Special Session on the first review of the PIP Framework (PIP Framework)

1. The Advisory Group met with Member States on the morning of 13 October, then with Member States and stakeholders in the afternoon of 13 October, at World Health Organization (WHO) in Geneva, with further deliberations by the Advisory Group on 14 October 2015.

2. Of the 18 members of the Advisory Group, 14 were present. A range of Member States and stakeholders attended the open sessions. In addition, there were WHO staff from four Regional offices. The list of participants is found at Annex 1.

3. The Chair of the Advisory Group, Professor William Kwabena Ampofo, opened the Special Session and welcomed participants. The Assistant Director-General for Health Security made introductory remarks on the structure, function, and governance of the PIP Framework and its implementation to date. He stressed that the PIP Framework is still early in its implementation and challenges remain. He noted nonetheless that much has been accomplished in improving pandemic preparedness in many areas. The PIP Framework should be reviewed by October 2016 in order to submit a report to the World Health Assembly in 2017 through the Executive Board. The Advisory Group Special Session marks the start of the process. He outlined that the purpose of the Special Session is to harvest the views of Member States and other stakeholders. He explained that the Advisory Group would deliberate and provide advice and recommendations to the Director-General on how to take the 2016 Review forward.

Sessions I and II – PIP Framework Advisory Group Members, Member States, and Stakeholders

4. Member States and stakeholders recognized that the Special Session will be crucial in shaping the 2016 Review, and that the PIP Framework is an innovative mechanism that is still in its early stages of implementation. Participants indicated that the PIP Framework has been a successful model that may offer lessons for other public health endeavors. The PIP Framework creates a unique relationship between public and private sectors. The PIP Framework is a mechanism that is functioning well at present and progress has

been made to implement its many and complex components. The 2016 Review should set a process to advance progress made and help define the way forward.

5. Many comments were provided on implementation of the PIP Framework.

    a. The matter of how to handle genetic sequence data under the PIP Framework was raised by participants. This was considered an area of work that requires particular attention to ensure that the objectives and spirit of the PIP Framework continue to be effective as science progresses, to allow the use of genetic sequence data rather than physical virus to produce vaccines and other benefits. Participants pointed out that genetic sequence data is part of the PIP Framework, covered under its virus sharing and access to benefit mechanisms. Some participants stated that genetic sequence data should be open access without undue restrictions on the use of genetic sequence data that would hinder scientific research; it was also underlined that use of genetic sequence data should trigger benefit sharing when it results in products.
    b. The linkages between the PIP Framework and the International Health Regulations (2005) were raised. Discussions highlighted that developing countries need support from WHO to strengthen their national laboratory capacity, and surveillance and monitoring capacity. Strengthening the synergies between PIP Framework and International Health Regulations (2005) could assist Member States to achieve the core capacities in the International Health Regulations (2005).
    c. Participants appreciated the regular communication with the Member States (briefing sessions following Advisory Group meetings) and requested further consultations and communications in the implementation of the 2016 Review to ensure participation and transparency.
    d. There was a broad call for harnessing new technologies, including genetic sequence data, to increase global influenza vaccine production capacity and innovative vaccines.
    e. Participants discussed the synergies between the PIP Framework and the Global Action Plan to Increase Vaccine Supply (the Global Action Plan). The Global Action Plan, a WHO program that started in 2006, has focused on supporting 14 developing countries to develop influenza vaccine production capacity through access to technology. The Global Action Plan will close in 2016 and there are activities that could continue under the PIP Framework, notably the conduct of influenza disease burden studies that assist countries to develop appropriate influenza vaccine policy.
    f. Notwithstanding achievements to date, participants noted that the conclusion of Standard Material Transfer Agreements 2 with vaccine manufacturers has not progressed as quickly as desired. Participants indicated that manufacturers should be strongly encouraged to conclude these agreements more speedily. Additionally, some participants questioned whether benefit sharing by academic/research institutions was adequate.

6. Participants supported the view that the 2016 Review should be independent and have experts with a range of competencies that cover all aspects of the PIP Framework. The Review Group should have balanced regional representation. The participants discussed possible options for the Review Group itself.

7. Participants also stressed that the 2016 Review must be transparent and inclusive, using an iterative approach that includes active consultation, including briefings with Member States and stakeholders in a timely manner. Suggestions for engagement included: teleconferences, regular progress reports, meetings, opportunities for submission of written input, audiovisual links to meetings, media conferences, survey-type questionnaires and working through Regional Offices to brief Member States.

8. The 2016 Review of the PIP Framework should be comprehensive. The Review should explore what has and has not been implemented, with the aim of strengthening. Areas of work specifically mentioned included:

    a. GSD and how it should be handled under the PIP Framework.
    b. The conclusion of Standard Material Transfer Agreements 2, in particular those with vaccine manufacturers.
    c. The status of virus sharing through WHO Global Influenza surveillance and response system.
    d. The Partnership Contribution mechanism, including the level of the yearly amounts to be collected, the collection process, and the use of the funds.
    e. Participants stressed the need for more information about the role of Regional Offices in the selection of countries to receive support through the PC.
    f. The possible synergies with the International Health Regulations (2005) and other programs, and the relationship with other international instruments including the Nagoya Protocol.

9. The Assistant Director-General underscored the need for the 2016 Review to be completed by October 2016, in order for it to be translated into all six official languages so that it is ready to be considered by the Executive Board in January 2017 and the World Health Assembly in May 2017.

Session III – Advisory Group closed meeting

10. Of the 18 members of the Advisory Group, 14 were present. In addition, there were WHO representatives from Eastern Mediterranean Regional Office, European Regional Office, South-East Asian Regional Office, and Western Pacific Regional Office. The list of participants in the meeting is found at Annex 1.

11. The Chair opened the meeting followed by introductions by all Advisory Group members.

12. The findings from a workshop on the PIP Framework in Bangkok were presented. The workshop goal was to improve international communication and collaboration in support of pandemic influenza preparedness and to discuss the 2016 Review.

13. The Advisory Group discussed the possible structure, Review Group composition, and terms of reference for the 2016 Review.

14. ***Recommendations to the Director-General***

Advice to the Director-General on scope and terms of reference for the 2016 Review:

15. *Guiding principles for the Review:* The 2016 Review should be guided by the following principles:

    a. Independence and impartiality
    b. Transparency
    c. Engagement with Member States & stakeholders
    d. Iterative process

16. *Scope of the Review:* The Review should be comprehensive on all aspects of the PIP Framework and assess whether implementation of the PIP Framework is meeting its objectives in accordance with its provisions to: "Improve pandemic influenza preparedness and response, and strengthen the protection against pandemic influenza by improving and strengthening the WHO Global Influenza surveillance and response system "WHO GISRS", with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:

    a. the sharing of H5N1 and other influenza viruses with human pandemic potential;
    b. access to vaccines and other benefits"

17. *The 2016 Review should focus on the following questions:*

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

18. *The 2016 Review should pay particular attention to*:

a. Virus Sharing (section 5), including:
    i. Genetic Sequence Data
b. Benefit Sharing (section 6), including:
    i. Standard Material Transfer Agreements 2
    ii. Partnership Contribution
    iii. Interactions with manufacturers and other stakeholders
c. Governance (section 7)
d. Linkages with other instruments (the Global Action Plan, International Health Regulations (2005), Nagoya Protocol, etc.)

19. *Considerations*

a. The Review Group should engage with Member States and stakeholders through an iterative process to ensure that information about the Review is regularly shared.
b. Communication of information could be provided through:
    i. Meetings /Telcons for the Review Group to receive input
    ii. Reports to WHO Governing Body meetings (e.g. Executive Board, World Health Assembly)
    iii. Web consultations
    iv. Regional consultations
    v. Debriefs following Review Group meetings
c. The Review Group should be a group of 6-12 independent experts, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza;
d. The Chair should combine good knowledge of the PIP Framework and independence from its implementation
e. The Review Group could be supported by or could include a small number of former members of the PIP Framework Advisory Group
f. Membership of the Review Group should reflect regional and gender balance
g. Membership should be made public
h. The Review Group should be supported by a dedicated WHO team
i. Adequate resources should be made available for the Review
j. Complete Review by October 2016
k. The Review Group should provide the final report directly to the Director-General, independent of the Advisory Group, for submission to the World Health Assembly through the Executive Board.

Annex 1

World Health Organization

SPECIAL SESSION OF THE PIP FRAMEWORK ADVISORY GROUP

Geneva, 13-14 October 2015

List of participants

List of Advisory Group participants

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

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Dr Huma Qureshi, Executive Director, Pakistan Medical Research Council, Pakistan

Dr P V Venugopal, Former Director of International Operations, Medicines for Malaria Venture, Public Health Specialist, India

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Representatives from Stakeholders

Ms Atika Abelin, Sanofi Pasteur and representing International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Mr Peter Bogner, GISAID

Mr Edward Hammond, Third World Network

Dr Alan Hay, GISAID

Mr Sam Lee, Sanofi Pasteur, representing IFPMA

Dr Philippe Le Mercier, Swiss Institute of Bioinformatics

Dr John McCauley, Francis Crick Institute

Ms Tharini Sathiamoorthy, AdvaMedDx

Ms Sangeeta Shashikant, Third World Network

Ms Cody Taylor, GSK, representing IFPMA

Live Streaming was also available through WebEx.

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