Implementation of Decision WHA70(10)8b) Guide to Consultations 6-7 November 2017

This document provides practical information regarding the 6-7 November 2017 Consultations on Implementation of Decision WHA70(10)8b). It also contains in annex the Draft provisional agenda and the Questions for discussion during the Consultations.

1. Background

In May 2017, WHO Member States adopted Decision WHA70(10), which in paragraph 8b) requests the Director-General to conduct a thorough and deliberative analysis ('the Analysis') of the issues raised by the Review Group's recommendations on seasonal influenza and genetic sequence data (GSD), including the implications of pursuing or not pursuing possible approaches. In so doing, the Director-General will rely on the 2016 PIP Framework Review and the expertise of the PIP Advisory Group, and transparent consultation of Member States and relevant stakeholders, including GISRS.¹ Decision WHA70(10) paragraph (8)(g) requests the Director-General to report on progress to the Seventy-First World Health Assembly in May 2018.

The diagram below shows a timeline for the Analysis.

Timeline for the process to conduct the 8(b) Analysis

PHASE I - Scoping (Jun-Oct 2017)

Develop Scoping Paper & e-circulate

Consultation with Member States, PIP Advisory Group, GISRS & Stakeholders (6-7 Nov 2017)

Harvest views on Scoping paper

PHASE II - Drafting (Nov 2017–Mar 2018)

Develop Analysis Draft 1 & e-circulate

Consultation with Member States, PIP Advisory Group, GISRS & Stakeholders (Apr 2018)

Harvest views on Analysis Draft 1

PHASE III - Report on progress to WHA 71 (May 2018)

Director-General Report on progress and recommendations on further action

¹ See decision WHA70(10), Review of the Pandemic Influenza Preparedness Framework, 29 May 2017, available at http://apps.who.int/gb/ebwha/pdf files/WHA70/A70(10)-en.pdf

2. Phase I Consultations: November 2017

a) Objectives of the Consultations

The 6-7 November Consultations are the final step of Phase I (see above figure). In anticipation of this meeting, the Secretariat has circulated the *Scoping Paper*, an annotated outline of the Analysis.

The purpose of the consultations will be to harvest views on the Scoping Paper.

b) Date and Place

The Consultations will start on Monday, 6 November 2017 at 9:00 and will close on Tuesday, 7 November 2017 at 17:00. The draft provisional Agenda is provided in Annex 1.

The Consultations will take place in the Executive Board room of the World Health Organization headquarters in Geneva, Switzerland. The address is: Avenue Appia 20, 1211 Geneva 27 Switzerland.

c) Documentation

Documents for the consultation are listed below. All may be found on the PIP webpage at http://www.who.int/influenza/pip/WHA70 10 8 b/en/:

- Scoping paper
- Guide to Evidence
- Compilation I. Seasonal Analysis
- Compilation II. GSD Analysis
- Compilation III. PIP Advisory Group work on GSD under the Framework
- Terms of Reference
- Questions and Answers

d) Conduct of Discussion during Consultations

Discussions will be interactive. Participants should therefore focus their interventions on the questions listed in Annex 2.

Interpretation will be provided in the official languages (Arabic, Chinese, English, French, Russian and Spanish).

e) Online participation

Participants who cannot attend in person will be able to listen in via WebEx. Links will be sent separately to participants the week before the Consultations.

Participants who connect via WebEx will be muted throughout the Consultations. However, remote participants may interact through WebEx's online "chat" function. Instructions for using this function are available at: http://trv.webex.com/meet/pdfs/2ds_mc-sfg-attendee_3.pdf.

The Secretariat will do its best to ensure any questions or comments received through WebEx chat are addressed in the course of the consultation, depending upon time constraints and technological limitations.

f) Submissions

Participants may provide written submissions in advance of the Consultations. Submissions can be made using an online questionnaire available at http://www.who.int/influenza/pip/WHA70_10_8_b/en/ or sent to pipanalysis@who.int.

This questionnaire will remain open following the Consultations. In the interest of transparency, all submissions will be published on the WHO website. However, WHO reserves the right not to publish

comments that are deemed inappropriate due to, e.g., offensive language, advertising or personal promotion.

3. Practical information

a) Registration

Registration is required in advance of the meeting. Please register by sending your name, affiliation, contact information, and sessions you wish to attend to pipanalysis@who.int.

b) Procedure upon arrival

Upon arrival to WHO, participants should present themselves at the main reception to collect their meeting badge. Government-issued photo identification (e.g. a national passport) is required.

c) Badges

Participants will be issued colour-coded meeting badges according to their category. Access to sessions will depend on badge colour, as specified below:

Badge Colour	Participant Categories	Access to Sessions
Blue badges	Member States	6 November 2017
World Health Organization Organization MEETING World Health MEETING SPECIMEN 16-MAY-2011		All sessions
		<u>7 November 2017</u>
		All sessions
Yellow badges World Health MEETING	 PIP Advisory Group WHO GISRS Collaborating Centres 	6 November 2017
		Session I (9:00-12:00)
		Session II (14:00-16:00)
		<u>7 November 2017</u>
		Session IV (9:00-12:00)
		Session V (14:00-16:00)
Green badges	All other stakeholders	6 November 2017
World Health MEETING		Session II (14:00-16:00)
		<u>7 November 2017</u>
		Session V (14:00-16:00)

d) Contact information

For further information, please contact <u>pipanalysis@who.int</u>. For urgent issues, you may contact Cora Cipriano at +41 79 217 34 11 (mobile).

WHO Consultation on the Implementation of Decision WHA70(10)(8)(b)

6-7 November 2017

Executive Board Room, WHO Headquarters, Geneva

Draft provisional Agenda

6 November 2017 - Genetic Sequence Data

- 9:00 12:00 **Session I:** Member States, PIP Advisory Group and WHO GISRS Collaborating Centres
 - Welcome Remarks
 - Discussion on Scoping paper
- 14:00 16:00 **Session II:** Member States, PIP Advisory Group, WHO GISRS, relevant international organizations, databases and initiatives, all interested stakeholders
 - Welcome Remarks
 - Discussion on Scoping paper
- 16:00 16:15 Coffee Break
- 16:15 17:00 **Session III:** Member States
 - Member States conclusions and wrap-up

7 November 2017 - Seasonal influenza

- 9:00 12:00 **Session IV:** Member States, PIP Advisory Group, WHO GISRS Collaborating Centres Discussion on *Scoping paper*
- 14:00 16:00 **Session V:** Member States, PIP Advisory Group, WHO GISRS, relevant international organizations, databases and initiatives, all interested stakeholders
 - Discussion on Scoping paper
- 16:00 16:15 Coffee Break
- 16:15 17:00 **Session VI:** Member States
 - Member States conclusions and wrap-up

Annex 2

Proposed discussion questions for the 6-7 November Consultations

Overarching section (paras 1-19)

Does the overarching section of the Scoping Paper cover all of the overarching issues that are relevant to the Analysis? If not, what other issues should be addressed?

A. Implications of pursuing three possible approaches to seasonal influenza viruses in the context of the PIP Framework

Background to the seasonal influenza section (paras 20-25):

Does the Scoping Paper cover all the issues that are relevant to the analysis of pursuing or not pursuing possible approaches to include seasonal influenza in the Framework? If not, what issues should be addressed?

Approach 1: Expand the PIP Framework to include seasonal influenza viruses (paras 26-27 and Table A)

What would be the implications of including seasonal influenza viruses in the PIP Framework for:

- Pandemic influenza preparedness and response?
- Seasonal influenza prevention and control?
- The work of GISRS?
- The development of influenza vaccines and other influenza products?

Are there other implications to consider?

How should the challenges identified under this approach be addressed?

Approach 2: Do not expand the PIP Framework so that national access and benefit-sharing regimes under the Nagoya Protocol apply to the sharing of seasonal influenza viruses(paras 26-27 and Table A)

With reference to the findings contained in the <u>WHO Nagoya Study</u>, are there other opportunities or challenges that might arise from seasonal influenza viruses being covered by the Nagoya Protocol?

Approach 3: Develop or adapt another instrument to cover seasonal influenza viruses, with a view to that instrument being recognized as an SII under the Nagoya Protocol (paras 26-27 and Table A)

What would be the implications of developing or adapting another instrument to cover seasonal influenza viruses for:

- Pandemic influenza preparedness and response?
- Seasonal influenza prevention and control?
- The work of GISRS?
- The development of influenza vaccines and other influenza products?

Are there other implications to consider?

How should the challenges identified under this approach be addressed?

B. Considerations in relation to GSD under the PIP Framework (paras 28-42 and Table B)

Background to the GSD section (paras 28-40):

Does the Scoping Paper cover all the issues that are relevant to the analysis of pursuing or not pursuing possible approaches to GSD under the PIP Framework? If not, what issues should be addressed?

Considerations in relation to GSD under the PIP Framework (paras 40-42 and Table B)

How would implementation of the Review Group recommendations on GSD ² affect:

- The work of GISRS?
- The development of influenza vaccines and other influenza products?
- The implementation of the PIP Framework?

If the definition of PIP biological materials is not amended to include GSD, are there implications for:

- Pandemic influenza preparedness and response?
- Implementation of the PIP Framework?

Are there additional considerations or implications?

² Report of the 2016 PIP Framework Review Group. Geneva: World Health Organization; 2017 (A70/17; http://apps.who.int/gb/ebwha/pdf files/WHA70/A70 17-en.pdf). Recommendations 12, 13, 14 and 16.