31 August 2017

IMPLEMENTATION OF DECISION WHA70(10) 8(b)

Questions & Answers

Note

This document aims to explain the WHO Director-General's process to implement decision WHA70(10) paragraph 8(b), and should be read in conjunction with the *Terms of Reference* for the Implementation of Decision WHA70(10) 8b), available at http://www.who.int/influenza/pip/WHA70_10_8_b/en. As new questions arise, this document will be updated. Please feel free to send questions to pipanalysis@who.int.

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I. BACKGROUND

Q1. What is decision WHA70(10)?

In May 2017, following consideration of the Report of the 2016 PIP Framework Review Group[1], the 70th World Health Assembly adopted decision WHA70(10)[2]. This decision requests the Director-General, *inter alia*:

> (8) (a) to take forward expeditiously the recommendations of the PIP Framework Review Group's report;
>
> (8) (b) regarding the PIP Framework Review Group's recommendations concerning seasonal influenza and genetic sequence data, to conduct a thorough and deliberative analysis of the issues raised, including the implications of pursuing or not pursing possible approaches, relying on the 2016 PIP Framework Review and the expertise of the PIP Advisory Group, and transparent consultation of Member States and relevant stakeholders, including the Global Influenza Surveillance and Response System;
>
> (8) (g) to report to the Seventy-first World Health Assembly, on progress in implementing this decision, including indicating the status of the response to the recommendations contained in the report of the PIP Framework Review Group, and to make recommendations on further action.

Q2. How will WHO address paragraph 8(a)?

Decision 70(10)(8)(a) requests the Director-General to take forward expeditiously the recommendations of the PIP Review Group. A plan to implement all PIP Review Group recommendations has been developed. As requested under WHA70(10) paragraph (8)(g), the Director-General will report to the Seventy-First World Health Assembly on progress.

Q3. How will WHO address paragraph 8(b)?

The Director-General will conduct an Analysis of the issues and implications raised by the recommendations of the 2016 PIP Framework Review Group ("the PIP Review Group") concerning seasonal influenza and genetic sequence data. These *Questions and Answers* provide further information about the process to conduct this Analysis, including the method of work, consultations and timeline.

Q4. What are the Review Group recommendations relevant to the Analysis?

REC NUMBER	TEXT OF THE RECOMMENDATION http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf
Rec 3	The Director-General should undertake a study to determine the implications and desirability of including seasonal influenza viruses in the PIP Framework.
Rec 9	Although genetic sequence data do not fully substitute for the physical virus, in cases where it is not possible to ship PIP biological materials rapidly, genetic sequence data should, if available, be shared immediately.

[1] See http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf.
[2] See http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70(10)-en.pdf.

REC NUMBER	TEXT OF THE RECOMMENDATION http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf
Rec 12	The Director-General should request Member States to consider amending the definition of PIP biological materials in section 4.1 of the PIP Framework to include genetic sequence data.
Rec 13	The Director-General should request Member States to consider clarifying Annex 4, section 9, which currently states that "The WHO GISRS laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement", by amending it to: "The WHO GISRS laboratories will submit genetic sequences data to one or more publicly accessible database of their choice in a timely manner consistent with the Standard Material Transfer Agreement".
Rec 14	The Director-General should request Member States to consider updating and correcting the statement in section 5.2.2 of the PIP Framework, which currently states "Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and there is a movement towards the use of public-domain or public-access databases such as Genbank and GISAID respectively;" by amending it to: "Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and use is made of public domain or public-access databases such as GenBank and/or GISAID, respectively;"
Rec 15	It is critical that the PIP Framework adapts to technological developments, and that the Advisory Group produces with urgency recommendations to clarify the handling of genetic sequence data. The Advisory Group should consider asking WHO Collaborating Centres to report on how genetic sequence data are actually handled, with a view to providing information about the operational realities in GISRS in relation to the acquisition, sharing and use of such data, to inform the Advisory Group's recommendations on the optimal handling of genetic sequence data under the PIP Framework.
Rec 16	The Director-General should enlist the support of Member States to ensure that influenza virus genetic sequence data remain publicly accessible in sustainable databases, to enable timely, accurate and accessible sharing of these data for pandemic risk assessment and rapid response.
Rec 17	Noting that genetic sequence data may be generated from many entities outside of GISRS, and that there are diverse views on the optimal traceability and monitoring mechanism, the Advisory Group should give consideration to broadening and deepening engagement with all stakeholders.
Rec 36	The PIP Framework should be considered as a specialized international instrument to clarify the implementation of the Nagoya Protocol in relation to pandemic influenza preparedness and response: - The December 2016 Meeting of the Parties of the Nagoya Protocol provides an opportunity to consider recognizing the PIP Framework as a specialized international instrument for pandemic influenza preparedness and response. In the

REC NUMBER	TEXT OF THE RECOMMENDATION http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf
	view of the Review Group, it would serve the aims of the PIP Framework if the Meeting of the Parties took up this opportunity. - Further, the 2017 World Health Assembly should address the recognition of the PIP Framework as a specialized international instrument under the Nagoya Protocol.

II. ANALYSIS

Q5. What will be the scope of the 8(b) Analysis?

The Analysis requested of the Director-General will have two parts. **Part A** will address the implications of pursuing or not pursuing possible approaches to include seasonal influenza viruses in the PIP Framework. This part of the Analysis ("Seasonal Analysis") will also provide an overview of the context and issues related to influenza risk assessment, virus sharing, and the development of influenza vaccines. Issues that may be considered in the course of the Analysis include:

- the need for rapid and comprehensive sharing of influenza viruses for timely and thorough risk assessment, and the development of effective vaccines for the prevention and control of influenza;
- the impact on the work of GISRS; and
- the potential impact of relevant external factors, such as implementation of the Nagoya Protocol[3].

Part B will address the implications of pursuing or not pursuing possible approaches to genetic sequence data ('GSD') under the PIP Framework. This part of the Analysis ("GSD Analysis") will also provide an overview of the context and issues related to access, sharing and use of GSD for influenza surveillance and risk assessment, and the development of vaccines and other influenza products. Elements that may be considered in the course of the Analysis include:

- the impact of new technologies that use GSD (e.g. synthetic vaccines);
- linkages with the International Health Regulations(2005) and other relevant WHO work, such as the work under the Research and Development Blueprint for action to prevent epidemics;
- synergies with other relevant processes, notably discussions under the Convention on Biological Diversity and the Nagoya Protocol, and in other international forums.

Q6. Will the Analysis address non-influenza pathogens?

World Health Assembly Decision 70(10) paragraph 8(b) requests the Director-General to conduct an analysis of the PIP Review Group recommendations "concerning seasonal influenza and genetic sequence data". The Director-General will therefore limit the scope of the Analysis to these two subjects.

[3] See Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, entered into force 12 October 2014. Text available at: https://www.cbd.int/abs/text/default.shtml

III. OVERVIEW OF PROCESS

Q7. Are there Terms of Reference for the Analysis?

Yes - Terms of Reference are found at http://www.who.int/influenza/pip/WHA70_10_8_b/en.

Q8. Who will conduct the Analysis?

As requested by the Health Assembly, the Director-General will conduct the Analysis, relying on the expertise of the PIP Advisory Group and the Global Influenza Surveillance and Response System (GISRS). As necessary, the Director-General may seek, on an *ad hoc* basis, technical advice and input from former PIP Advisory Group Members and members of the PIP Review Group.

Q9. What will be the process?

As the Analysis must address two different topics (seasonal influenza viruses and GSD), two work streams will be undertaken in parallel. The process to conduct these two work streams will involve three phases:

- Phase I: Scoping (Jun-Oct 2017)
- Phase II: Drafting (Nov 2017- Mar 2018)
- Phase III: Report on progress to WHA 71 (May 2018)

Each phase will ensure opportunities for engagement with, and input from, Member States, GISRS laboratories and stakeholders, including but not limited to, relevant international organizations, manufacturers and associations, civil society organizations, databases and initiatives. A timeline is provided below.

Q10. How will evidence be gathered?

Part A: Seasonal Analysis

Quantitative and qualitative data and evidence on virus sharing and GISRS functions in the handling of both seasonal influenza viruses and influenza viruses with pandemic potential (IVPP), will be gathered and validated through close work with GISRS, notably the GISRS Collaborating Centres. In addition, the Director-General will refer to the significant work undertaken, and information gathered by, the PIP Review Group.

Part B: GSD Analysis

Further to the request in PIP Framework section 5.2.4, the PIP Advisory Group has been conducting work since 2013 to provide guidance to the Director-General on the handling of GSD. In developing Part B of the Analysis, the Director-General will refer to, and rely on the significant body of work and evidence generated by the PIP Advisory Group in its work on handling GSD under the PIP Framework. The Director-General will also rely on the considerable body of evidence generated by the PIP Review Group. Further quantitative and qualitative data and evidence on the access, sharing and use of IVPP GSD will be gathered and validated through close work with GISRS, notably the Collaborating Centres.

Additional input for the Analysis will be obtained through consultations with Member States and stakeholders (including but not limited to relevant international organizations, manufacturers and associations, civil society organizations, databases and initiatives).

IV. ADVISORY GROUP WORK ON GSD

Q11. What is the PIP Advisory Group work on handling IVPP GSD under the Framework?

Recognizing that further work would be needed to resolve the handling of GSD under the Framework, Member States requested that the Director-General consult with the PIP Advisory Group "on the best process for further discussion and resolution of issues relating to the handling of [IVPP GSD] as part of the PIP Framework."[4]

The PIP Advisory Group has been working on the matter since 2013. To support its work, the Advisory Group established two technical working groups, and developed several documents on the handling of GSD under the Framework.[5] These documents have provided the bases for several recommendations to the Director-General. In its most recent meeting of March 2017, the Advisory Group recommended to the Director-General that it continue its work under section 5.2.4 by developing guidance on an approach to operationalize the handling of IVPP GSD under the PIP Framework for both data sharing and benefit sharing[6]. The Director-General accepted this recommendation. At its next meeting (8-10 November 2017), the Advisory Group will discuss how to take forward its work on GSD, taking into account the discussions and outcomes of the consultation of 6-7 November.

More information on the work of the PIP Advisory Group related to GSD is available at http://www.who.int/influenza/pip/advisory_group/gsd/en/.

IV. CONSULTATIONS

Q12. Who will be consulted in the development of the 8(b) Analysis?

To develop the *Analysis*, the Director-General will work closely with the PIP Advisory Group and GISRS, notably the Collaborating Centres. As necessary, former PIP Advisory Group Members and members of the PIP Review Group will be consulted for technical advice and input.

Q13. What consultations are planned?

In order to ensure opportunities for Member States and all interested stakeholders (including but not limited to relevant international organizations, manufacturers and associations, civil society organizations, databases and initiatives) to provide written and oral information, consultations may be undertaken in several forms, as appropriate and necessary:

- Electronic consultations

[4] See PIP Framework section 5.2.4.

[5] Relevant documents produced in the course of the Advisory Group's work on GSD include: the Report of the Technical Expert Working Group (TEWG) on GSD, established in October 2013 to assess the scientific, technical, operational and intellectual property implications of using GSD to develop vaccines, diagnostic and pharmaceutical products; the Report of the Technical Working Group (TWG) on sharing influenza GSD, established in 2015 to identify the optimal characteristics and best practices of a GSD sharing system that best meets the objectives of the Framework; a paper on "Options to monitor the use of genetic sequence data from influenza viruses with human pandemic potential (IVPP GSD) in end-products"; and, a survey of data providers and data users on the "Sharing of Genetic Sequence Data of Influenza Viruses with Human Pandemic Potential". These documents are available at http://www.who.int/influenza/pip/advisory_group/gsd/en/. See also, GSD Timeline July 2017, available at http://www.who.int/influenza/pip/advisory_group/GSD_timeline.pdf.

[6] See March 2017 PIP AG Meeting Report, recommendation 32, available at http://www.who.int/influenza/pip/AG_Mar2017.pdf.

- Consultations with Member States, the PIP Advisory Group, GISRS, and Stakeholders
- Teleconferences
- Interviews with key informants

Q14. Is there a calendar of consultations?

The provisional calendar of consultations is below. Additional consultations may be considered, as necessary.

DATE	CONSULTATION
October 2017	E-Circulation of *Scoping Paper*, for discussion in November 2017
6-7 November 2017	**Consultation with Member States, PIP Advisory Group, GISRS & Stakeholders**
March 2018	E-Circulation of *Analysis* Draft 1, for discussion in April 2018
April 2018	**Consultation with Member States, PIP Advisory Group, GISRS & Stakeholders**
May 2018	Report on progress to implement WHA70(10)

Q15. What documents will be shared for input?

Two documents will be shared with Member States, GISRS and stakeholders for input:

- In October 2017, the Secretariat will circulate the *Scoping Paper*. This document will be discussed during the 6-7 November 2017 Consultation with Member States, PIP Advisory Group, GISRS and Stakeholders.
- In March 2018, the Secretariat will circulate the first draft of the *Analysis*. The draft document will be discussed during the April 2018 Consultation with Member States, PIP Advisory Group, GISRS and Stakeholders.

Q16. What is the *Scoping Paper*?

The *Scoping Paper* will consist of an annotated outline of the *Analysis* and will include an overview of relevant preliminary considerations, as well as a list of questions to guide discussions during the 6-7 November 2017 Consultation.

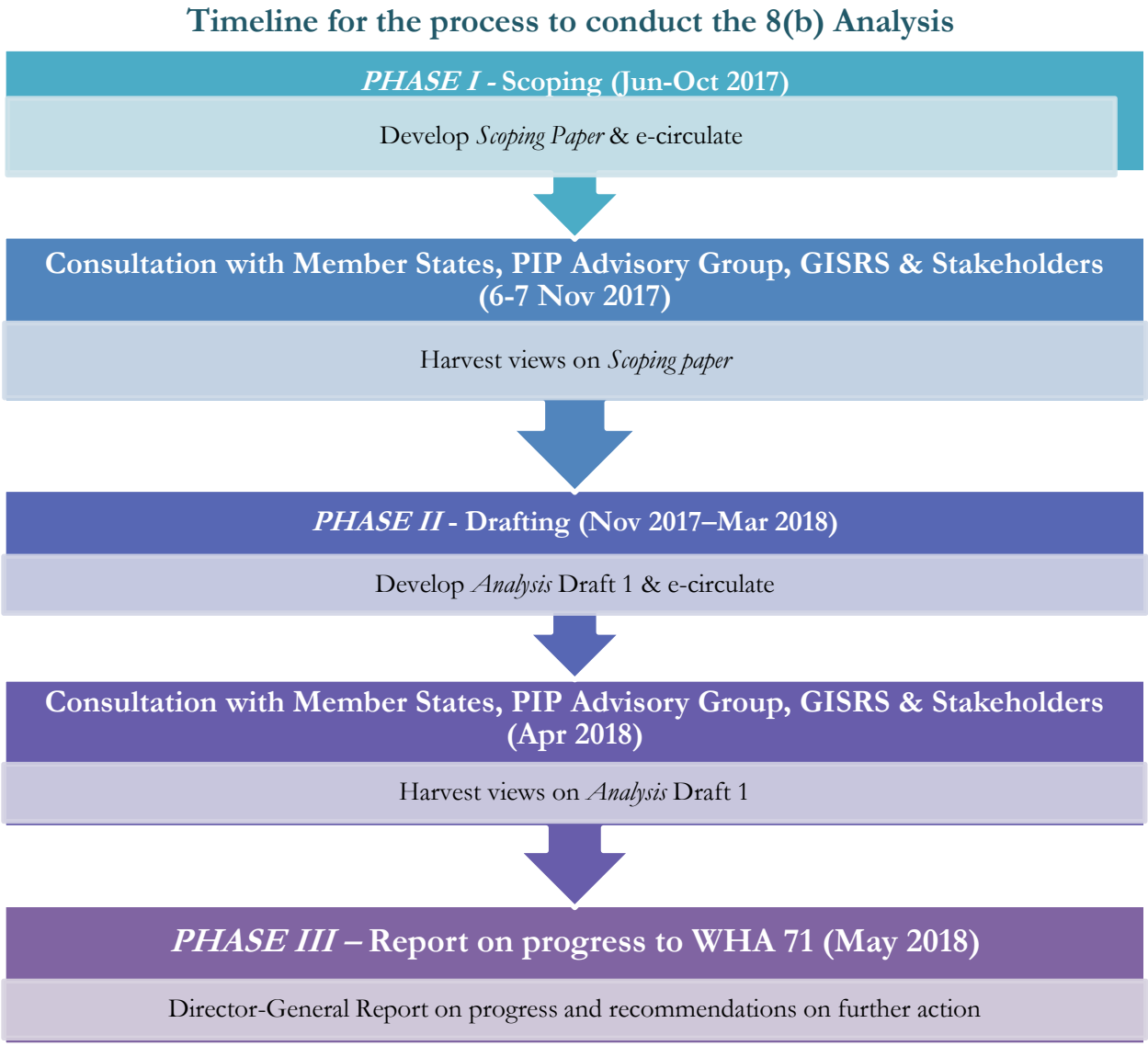
Q17. How can I provide input?

There will be many opportunities to provide input through electronic and in-person consultations. In addition, the Director-General welcomes submissions, comments or questions at any time at pipanalysis@who.int.

V. TIMELINE

Q18. What is the timeline for completing the *Analysis*?

Decision WHA70(10) paragraph (8)(g) requests the Director-General to report on progress to the Seventy-First World Health Assembly in May 2018. A first draft of the *Analysis* will be completed and shared electronically for input in March 2018. Follow-on work and finalization of the Analysis will be guided by the discussions and outcomes of WHA71. The diagram below shows a timeline for the work.



VI. HOW TO STAY INFORMED

Q19. How will information on progress be shared?

The Director-General will provide updates on progress during the two Consultations with Member States, PIP Advisory Group, GISRS and Stakeholders on 6-7 November 2017 and in April 2018, and will report on progress at the Seventy-First World Health Assembly. In addition and as possible, the Director-General will share information on the 8(b) Analysis webpage at http://www.who.int/influenza/pip/WHA70_10_8_b/en.

Q20. Where may I find relevant documents and information?

You will find all relevant documents and information about future consultations on the 8(b) Analysis webpage at http://www.who.int/influenza/pip/WHA70_10_8_b/en.