

IMPLEMENTATION OF DECISION WHA70(10) 8b)

Terms of Reference

1. Background

As provided in section 7.4.2, the PIP Framework underwent a comprehensive review in 2016 following five years of implementation. The Report of the 2016 PIP Framework Review Group ('PIP Review Group') was submitted to the 70th World Health Assembly in May 2017 through the 140th Executive Board. The PIP Review Group found that “the PIP Framework is a bold and innovative tool for pandemic influenza preparedness, is being well implemented, and that the principle of the PIP Framework of placing virus sharing and benefit sharing on an equal footing remains relevant today.”¹

However, the PIP Review Group noted that “there are key issues that must urgently be addressed for the PIP Framework to remain relevant, including the issue of how [genetic sequence data] should be handled under the PIP Framework, and whether or not the PIP Framework could be expanded to include seasonal influenza.”²

Having considered the PIP Review Group report, the 70th World Health Assembly requested the Director-General, *inter alia*, as follows:

- 8.a) to take forward expeditiously the recommendations of the PIP Framework Review Group's report;
- 8.b) Regarding the Review Group's recommendations on seasonal influenza and genetic sequence data, to conduct a thorough and deliberative analysis of the issues raised, including the implications of pursuing or not pursuing 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 WHO Global Influenza Surveillance and Response System (GISRS).³

Member States also requested the Director-General to report to the 71st World Health Assembly on progress to implement the decision and to make recommendations on further action.

2. The Analysis

This document provides the **Terms of Reference** for the Analysis that the Director-General has been requested to conduct in WHA70(10) par. (8)(b). These Terms of Reference are designed to be read in conjunction with a *Questions and Answers* document available at

http://www.who.int/influenza/pip/WHA70_10_8_b/en.

The Analysis will address:

¹ See Review of the Pandemic Influenza Preparedness Framework, Report by the Director-General, 29 December 2016, at p. 12, available at http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1

² *Ibid.*, p.13

³ 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](http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70(10)-en.pdf)

- A. The implications of pursuing or not pursuing possible approaches to include seasonal influenza viruses in the PIP Framework;
- B. The implications of pursuing or not pursuing possible approaches to genetic sequence data under the PIP Framework.

3. Method of work

The Analysis will be developed by the Director-General who will work closely with the PIP Advisory Group and GISRS, notably the Collaborating Centres. 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. The basis for the analysis will be evidence and views gathered through transparent consultations with Member States and stakeholders. This will include the considerable body of evidence generated by the PIP Review Group. Additional qualitative and quantitative data will be gathered and validated through close work with GISRS, notably the GISRS Collaborating Centres. In conducting the GSD portion 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 the handling GSD under the PIP Framework.

4. Consultations

In order to ensure opportunities for Member States, GISRS laboratories, notably GISRS Collaborating Centres, 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 will be undertaken in several forms, as appropriate and necessary:

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

5. Timeline

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. A detailed timeline of the work, including dates for consultations, will be developed and shared with Member States, GISRS laboratories, notably Collaborating Centres, and stakeholders.