

Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

The Executive Board, having considered the report contained in document EB144/23 on implementation of decision WHA71(11) (2018)¹ decided to recommend to the Seventy-second World Health Assembly the consideration of the following decision:

[The Seventy-second World Health Assembly, having considered the report **contained in document EB144/23 [EU]** on implementation of decision WHA71(11) (2018), decided:

OP (1) consistent with the PIP Advisory Group's recommendations to the Director-General,² to request the Director-General:

- (a) to urgently work with the Global Influenza Surveillance and Response System and other partners to **identify and [EU]** address the challenges and uncertainties related to the sharing of seasonal influenza viruses that have emerged as countries implement the Nagoya Protocol;
- (b) to closely monitor instances where **influenza virus sharing is affected, including due to the** implementation of the Nagoya Protocol **[EU] OR** to closely monitor instances where influenza virus sharing is affected, including due to **countries' domestic measures in implementing** the Nagoya Protocol **[USA] and/or for other reasons, and to present findings thereon to the next meeting of the PIP Advisory Group. [EU]** ~~may be affecting the sharing of seasonal influenza viruses and collect, analyse and present data on virus sharing in time for the next Advisory Group meeting, to allow a deeper understanding of potential problems that exist with influenza virus sharing; [EU] and to share these findings with the WHO's broader effort referenced below regarding the public health implications of the Nagoya Protocol; [USA]~~
- (c) to assess the ~~utility~~ **usefulness [EU]** of the prototype search engine developed to identify products that ~~potentially [EU]~~ have made use of genetic sequence data of influenza viruses with pandemic potential ~~and have not been subject to the benefit-sharing system; [EU]~~

¹ Document EB144/23.

² Meeting of the Pandemic Influenza Preparedness Framework Advisory Group. 17–19 October 2018, Geneva, Switzerland. Geneva: World Health Organization; 2018 (http://www.who.int/influenza/pip/AGMR_Oct2018.pdf?ua=1, accessed 3 December 2018).

(d) to explore **in consultation with Member States [USA]** ~~the [EU] possible next steps in implementing the principle of acknowledgment of the contributions of data providers and active collaboration between~~ **raising awareness of the PIP Framework among databases and initiatives, [EU] data providers and data [EU] users-, and to present such possible steps to the next meeting of the PIP Advisory Group. [EU]** ~~In particular, the Director-General is requested to develop appropriate language for consideration by relevant databases to inform potential users of genetic sequence data of influenza viruses with pandemic potential about the PIP Framework. [EU]~~

OP (2) to work quickly with Member States and relevant stakeholders to explore and evaluate approaches to address concerns regarding the issues raised in paragraph 23 to EB144/23 [USA] ~~to amend footnote 1 in the Standard Material Transfer Agreement 2, in Annex 2 to the PIP Framework,¹ as set out in the report of the Director-General on implementation of decision WHA71(11) (2018),² with effect from the closure of the Seventy-second World Health Assembly, in order to address a loophole that has arisen in connection with indirect uses of PIP biological materials by companies with the result that they do not provide fair and equitable benefit sharing for the use of PIP biological materials; [USA]~~

OP (3) to work collaboratively across WHO to raise awareness among Member States of the implications for public health of implementation of the Nagoya Protocol, particularly given the cross-cutting nature of relevant issues: [EU]

OP (3 4) [EU] to further request the Director-General to report on progress to implement the foregoing to the Seventy-third World Health Assembly in 2020 through the 146th session of the Executive Board.

¹ Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/resources/pip_framework/en/, accessed 3 December 2018).

² The relevant document for consideration by the Seventy-second World Health Assembly in 2019 will reflect the amendments to footnote 1 in Annex 2 to the PIP Framework contained in the Annex to document EB144/23.

ANNEX

**PROPOSED AMENDMENT TO FOOTNOTE 1 OF ANNEX 2 OF
THE PIP FRAMEWORK¹**

Current version	Proposed amended version
Recipients are all entities that receive “PIP Biological Materials” from the WHO global influenza surveillance and response system (GISRS), such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.	Recipients are all entities that receive “PIP Biological Materials” from the WHO global influenza surveillance and response system (GISRS), such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions and entities that engage with recipients of PIP Biological Materials for the purpose of supporting development, testing or regulatory processing of an influenza-related product. Each recipient shall select options based on its nature and capacities.

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Fourteenth meeting, 31 January 2019

EB144/SR/14

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¹ Proposed new text is shown in bold.