

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

Implementation of decision WHA71(11) (2018)

Report by the Director-General

1. Following the course of action agreed by the Executive Board at its 144th session in January 2019, the Secretariat convened informal consultations, facilitated by Australia and South Africa, during the intersessional period in respect of the bracketed draft decision contained in decision EB144(6) (2019). Five consultations took place on 11 March, 2 May, 9 May, 14 May and 16 May. *Ad referendum* agreement within the informal consultation was reached on the revised draft decision reproduced below, which remains bracketed in full to clarify the *ad referendum* status. One Member State requested an indication that its reservations with respect to footnote 1 of Annex 2 of the Pandemic Influenza Preparedness (PIP) Framework be recorded following the footnote.
2. The Health Assembly is invited to consider the following bracketed draft decision, which is the outcome of the informal consultations.

[The Seventy-second World Health Assembly, having considered the report on implementation of decision WHA71(11) (2018),¹ and taking note of the PIP Advisory Group's recommendations to the Director-General,² decided:

OP(1) to request the Director-General:

- (a) to work with the Global Influenza Surveillance and Response System (GISRS) and other partners, such as Other Authorized Laboratories and relevant institutions, to collect, analyse, and present data on influenza virus sharing in a way that enables a deeper understanding of challenges, opportunities, and implications for public health associated with virus sharing under the GISRS, including by identifying

¹ Document A72/21.

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).

specific instances where influenza virus sharing has been hindered and how such instances may be mitigated;

(b) to prepare a report, with inputs from Member States¹ and stakeholders, as appropriate, on the treatment of influenza virus sharing and the public health considerations thereof by existing relevant legislation and regulatory measures including those implementing the Nagoya Protocol, in consultation with the Secretariat of the Convention on Biological Diversity as appropriate;

(c) to provide more information on the functioning, usefulness, and limitations of the prototype search engine;

(d) to explore, including through soliciting input from Member States, possible next steps in raising awareness of the PIP Framework among relevant databases and initiatives, data providers and data users, and in promoting the acknowledgment of data providers and collaboration between data providers and data users;

(e) to continue providing information on new challenges posed and opportunities provided by new technologies in the context of the *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* and possible approaches to them;

OP(2) to revise Footnote 1 in the SMTA2, in Annex 2 to the PIP Framework, as set out in the Annex to this decision with effect from the closure of the Seventy-second World Health Assembly;

OP(3) 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.

ANNEX

PROPOSED AMENDMENTS TO FOOTNOTE 1 OF ANNEX 2 OF THE PIP FRAMEWORK²

Recipients are ~~all entities that receive~~ **receivers of** “PIP Biological Materials” from the WHO global influenza surveillance and response system (GISRS), such as ~~influenza vaccine, diagnostic and pharmaceutical~~ **manufacturers of influenza vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic preparedness and response**, as well as biotechnology firms, research institutions and academic institutions. ~~Each recipient shall select options based on its nature and capacities.~~

¹ And, where applicable, regional economic integration organizations.

² Additions are shown in **bold**, deletions are shown in strikethrough.

Any entity that enters into any contracts or formal agreements with recipients for the purpose of using PIP Biological Materials by such recipients on the entity's behalf for commercialization, public use or regulatory approval of that entity's vaccines, diagnostics, or pharmaceuticals is also considered a recipient.

All the above recipients are included by the Director-General in implementing section 5.4.2 of the Framework.

Recipients that are manufacturers shall select from among the commitments identified in SMTA2 Article 4.1.1 (a) to (c) based on their nature and capacities; those that are not manufacturers shall only have to consider contributing to the measures set out in SMTA2 Article 4.1.1(c).

[Reserve Switzerland]¹

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¹ Only relates to the Annex of the draft decision.