SEVENTY-SECOND WORLD HEALTH ASSEMBLY A72/21
Provisional agenda item 12.1 11 April 2019

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. In January 2019, the Executive Board, at its 144th session, considered an earlier version of this report that contained a draft decision.[1] During the discussions,[2] consensus could not be reached on the text of the draft decision. Certain paragraphs of the text remained pending, and the Board therefore adopted a decision containing a bracketed draft decision.[3] The Board then agreed that the discussion of the outstanding paragraphs would be continued during the intersessional period. A separate report will be submitted to provide details of the outcome of the consultations.[4]

BACKGROUND

2. In May 2018, the Seventy-first World Health Assembly adopted decision WHA71(11) approving the recommendations contained in the Director-General's report on progress in implementing decision WHA70(10) (2017) on the review of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits[5] and requested that the final text of the analysis, requested under paragraph 8(b) of decision WHA70(10), be submitted to the Seventy-second World Health Assembly in 2019, through the Executive Board at its 144th session. In accordance therewith, the Director-General submits this report on implementation of the recommendations contained in decision WHA71(11).

[1] Document EB144/23.

[2] See the summary records of the Executive Board at its 144th session, twelfth and fourteenth meetings, section 2.

[3] Decision EB144(6).

[4] See document A72/21 Add.1.

[5] See document A71/24, paragraph 19.

Progress in implementing decision WHA71(11)

Annex, paragraph (a):[1] implementing the recommendations in the report of the 2016 PIP Framework Review Group[2]

3. The Secretariat has taken measures to implement all the recommendations in the report of the 2016 PIP Framework Review Group that are within its mandate. A tracking tool is available that provides information on the actions taken to implement these recommendations.[3]

Annex, paragraph (c):[4] strengthening critical pandemic preparedness

4. Implementation of the high-level Partnership Contribution Implementation Plan 2018–2023 began in January 2018, focusing on six areas of work: laboratory and surveillance capacity-building; burden-of-disease studies; regulatory capacity-building; risk communication and community engagement; planning for pandemic product deployment; and influenza pandemic preparedness planning. In the biennium 2018–2019, the US$ 31 million budget for Partnership Contribution pandemic preparedness activities is being used to strengthen capacities in 72 countries, as well as to support regional and global preparedness and response capacity-building. Progress reports link financial and technical implementation, and include the progress made against the 31 milestones and 19 indicators established in the implementation plan. The January to June 2018 progress report describes the work carried out and achievements made in strengthening regulatory capacity and carrying out burden-of-disease studies.[5]

5. Progress in concluding Standard Material Transfer Agreements 2 and in the collection of annual PIP Partnership Contributions is described in the January to June 2018 progress report (pages 6–7). In addition, reporting on the PIP Framework is now included on the WHO Programme Budget Portal, where further details of financial implementation can be found.[6]

6. Engagement with the secretariats of the Convention on Biological Diversity and other relevant international organizations that are involved in implementation of access and benefit-sharing mechanisms has continued and is ongoing. In June 2018, a workshop on facilitating access and benefit sharing for pathogens to support public health was organized by WHO in collaboration with the Secretariat of the Convention on Biological Diversity. The objectives of the workshop were: to promote awareness and coordination on access to pathogens and sharing of benefits arising from their use; to learn from countries' experience in implementing the Nagoya Protocol and its public health provisions; and to develop preliminary considerations regarding access and benefit-sharing practices for sharing of

[1] See decision WHA70(10), paragraph 8(a).

[2] Document WHA70/2017/REC/1, Annex 8.

[3] 2016 PIP Framework Review Group Recommendations – Draft Implementation Tracking Tool, as of 1 October 2018. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/pip/2016RGRecTracking_Oct2018.pdf, accessed 8 April 2019).

[4] See decision WHA70(10), paragraphs 8(c), (d) and (f).

[5] Pandemic Influenza Preparedness Framework. Progress report, 1 January–30 June 2018. Geneva: World Health Organization; 2018:12–13 (http://www.who.int/influenza/pip/pip_progressreport_30jun2018.PDF, accessed 8 April 2019).

[6] Pandemic Influenza Preparedness (PIP) Framework (Category). Geneva: World Health Organization (http://open.who.int/2018-19/our-work/category/20/about/about, accessed 8 April 2019).

pathogens that could support public health surveillance, preparedness and response, as well as the equity objectives of the Nagoya Protocol. The workshop brought together participants from a cross-section of technical areas, such as health and environment, as well as from a broad variety of sectors, including: public, private, nongovernmental, academic and laboratory.[1]

Annex, paragraph (d):[2] implementing the recommendations of the External Auditor

7. The External Auditor performed an audit of PIP Partnership Contributions funds in order to provide: assurances that WHO's Financial Regulations were appropriately applied in the use of funds and that the financial information reported was accurate and reliable; and recommendations to further increase the transparency of reporting on the linkages between expenditure and technical impact. The auditors concluded that, overall, revenues, receipts and expenditures incurred were properly accounted for and generally conformed to WHO's Financial Regulations and Financial Rules. The audit report[3] also contained five recommendations that were accepted and have been fully implemented by WHO.

Annex, paragraph (b):[4] carrying out an analysis of issues related to the sharing of seasonal influenza viruses and genetic sequence data

8. In decision WHA70(10), paragraph 8(b), the Seventieth World Health Assembly requested the Director-General to conduct a thorough and deliberative analysis of the issues raised by the 2016 PIP Framework Review Group's recommendations concerning seasonal influenza and genetic sequence data , including the implications of pursuing or not pursuing possible approaches.

9. The Secretariat collaborated with the PIP Advisory Group and representatives of the WHO Collaborating Centres for Influenza and Essential Regulatory Laboratories that are part of the Global Influenza Surveillance and Response System to develop the analysis in an iterative and consultative manner. The process began with development of an annotated outline, or scoping paper, of the analysis,[5] which was discussed during a consultation in November 2017 to collect the views of Member States, representatives of the Global Influenza Surveillance and Response System, members of the PIP Advisory Group and relevant stakeholders.

10. In April 2018, the Secretariat held an information session for Member States, representatives of the Global Influenza Surveillance and Response System, members of the PIP Advisory Group, and relevant stakeholders to provide, inter alia, information about the role and work of the Global Influenza Surveillance and Response System and to preview the Director-General's draft report on progress to implement decision WHA70(10).

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[1] For more information, see the meeting report and presentations (http://www.who.int/influenza/ABSworkshop_June2018/en/, accessed 8 April 2019).

[2] See decision WHA70(10), paragraph 8(e).

[3] Commission on Audit, Republic of the Philippines. Report of the External Auditor on the Implementation of the Pandemic Influenza Preparedness Framework – Partnership Contribution (PIP-PC). Geneva: World Health Organization; 2017 (http://www.who.int/influenza/pip/pip_audit_report.pdf?ua=1, accessed 8 April 2019).

[4] See decision WHA70(10), paragraph 8(b).

[5] Implementation of decision WHA70(10) 8(b). Scoping Paper on approaches to seasonal influenza and genetic sequence data under the PIP Framework ("Scoping paper"). Geneva: World Health Organization; 2017 (http://www.who.int/influenza/pip/scopingpaper.pdf, accessed 8 April 2019).

11. With a view to increasing Member States' and stakeholders' understanding, several fact sheets and a timeline of all events relevant to the completion of the analysis were developed and shared before the information session.

12. In September 2018, the Secretariat published the draft analysis in all six official languages. The draft was developed using the following sources: evidence on seasonal influenza and genetic sequence data collected by the 2016 PIP Framework Review Group; the PIP Advisory Group's work to provide guidance to the Director-General on the handling of genetic sequence data of influenza viruses with pandemic potential under the PIP Framework; and the findings contained in the Secretariat's study on the public health implications of the implementation of the Nagoya Protocol.[1]

13. In addition, considerable input was obtained from the PIP Advisory Group and WHO Collaborating Centres for Influenza that are part of the Global Influenza Surveillance and Response System. They provided quantitative and qualitative data and evidence on virus and sharing of genetic sequence data as well as on the functions of the Global Influenza Surveillance and Response System in the handling of both seasonal influenza viruses and influenza viruses with pandemic potential.

14. The Secretariat also gathered evidence and views from Member States and relevant stakeholders through two in-person consultations (November 2017 and October 2018) and an online consultation (from October 2017 to October 2018).

15. The draft analysis contained three substantive parts: (i) matters with overarching implications to the analysis; (ii) seasonal influenza viruses in the context of the PIP Framework; and (iii) genetic sequence data in the context of the PIP Framework. Parts (ii) and (iii) presented the issues at stake and contained different approaches that could be considered to address them. Each approach presented potential opportunities and challenges.

16. On 15 and 16 October 2018, the Secretariat held a consultation to receive views on the draft analysis; to identify potential points of convergence or divergence; and to identify potential next steps.

17. The consultation brought together Member States, representatives of the Global Influenza Surveillance and Response System, members of the PIP Advisory Group and relevant stakeholders. About 115 participants participated in person or via videoconference, including 37 Member States, from all six WHO regions. The stakeholders present included representatives of intergovernmental organizations, industry, nongovernmental or civil society organizations, academic institutions, and databases and initiatives.

High-level outcomes of the consultation – sharing of seasonal influenza viruses

18. Participants discussed some overarching views, as outlined below.

(a) The PIP Framework is a successful instrument governing access and benefit sharing for pandemic influenza preparedness. The Global Influenza Surveillance and Response System, one of the oldest laboratory networks, functions well and laboratories within it share seasonal influenza viruses in a timely manner. It is therefore important to ensure that the outcome of discussions on the scope of the PIP Framework should not negatively affect the work of the Global

[1] See document EB140/15.

Influenza Surveillance and Response System and should not reduce the value of the PIP Framework as an access and benefit-sharing instrument.

(b) Implementation of the Nagoya Protocol presents both opportunities and potential challenges for public health. In two recent cases, difficulties arising from compliance with domestic access and benefit-sharing requirements have had an impact on the processes of the Global Influenza Surveillance and Response System. These issues should be addressed urgently.

19. Participants discussed the four approaches to and potential implications of expanding or not expanding the PIP Framework to include seasonal influenza viruses described in the draft analysis.

(a) Participants underscored that discussions within the Nagoya Protocol on the criteria and process for recognizing specialized international access and benefit-sharing instruments were unlikely to be resolved quickly. Until the outcomes of this process are known, it may be difficult to identify or develop the best approach to the sharing of seasonal influenza viruses.

(b) Participants agreed on the importance of timely sharing of seasonal influenza viruses, and benefits arising from such sharing. However, there was also general agreement that the PIP Framework should not be expanded at this time.

High-level outcomes of the consultation – genetic sequence data

20. Participants offered different views on whether new technologies using genetic sequence data put at risk the principle of access and benefit-sharing on an equal footing for influenza viruses with pandemic potential , the severity of such a risk and whether the risk would be short or long term.

21. Participants agreed on the importance of maintaining trust in the PIP Framework and ensuring that its principles remain relevant in the face of technological change.

High-level conclusions of the consultation and next steps

22. Participants encouraged the Director-General to identify actionable items that could help to address seasonal influenza viruses and genetic sequence data in the context of the PIP Framework.

23. Following the consultations, the PIP Advisory Group met on 17–19 October 2018 to discuss the implementation of the PIP Framework, including the outcomes of the consultation. The Advisory Group noted that there appeared to be a convergence of views at the consultation that the current scope of the PIP Framework should be maintained at this time.

24. In its report to the Director-General, the Advisory Group provided several specific, short-term recommendations on seasonal influenza and genetic sequence data under the PIP Framework.[1] The Advisory Group further recommended that the Director-General take forward, through the necessary steps, a proposed amendment to the language of footnote 1 of Annex 2 to the PIP Framework. The proposed amendment is set out in the Annex to this report and aims at addressing a loophole that has arisen in connection with indirect use 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.

[1] 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 8 April 2019).

The Director-General accepted all the Advisory Group recommendations, finding them to be reasonable and feasible, and included them in the draft decision that was submitted to the Executive Board.

25. The final text of the analysis has been prepared,[1] taking into account the feedback received as part of the consultation and relevant decisions from the November 2018 meetings of the fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity and the third meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol.[2]

ACTION BY THE HEALTH ASSEMBLY

26. The Health Assembly is invited to note the report and consider the draft decision recommended by the Executive Board in decision EB144(6) taking into account, as appropriate, the outcome of the consultations set out in document A72/21 Add.1.

[1] Approaches to seasonal influenza and genetic sequence data under the PIP Framework. Analysis. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/pip/WHA70108b_Analysis.pdf, accessed 8 April 2019).

[2] United Nations Biodiversity Conference, Sharm El-Sheikh, Egypt, 13–29 November 2018. Montreal: Secretariat of the Convention on Biological Diversity; 2018 (https://www.cbd.int/conferences/2018,accessed 8 April 2019).

ANNEX

PROPOSED AMENDMENT TO FOOTNOTE 1 OF ANNEX 2 OF THE PIP FRAMEWORK[1]

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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[1] Proposed new text is shown in bold.