World Health Organization

SEVENTY-FIRST WORLD HEALTH ASSEMBLY **A71/24**
Provisional agenda item 12.7 **5 April 2018**

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

Progress in implementing decision WHA70(10) (2017) on Review of the Pandemic Influenza Preparedness Framework

Report by the Director-General

1. In May 2017, the Seventieth World Health Assembly adopted decision WHA70(10) on Review of the Pandemic Influenza Preparedness Framework. In accordance with the request in paragraph 8(g) thereof, the Director-General submits this report on progress in implementing the decision and on recommendations for further action.

Background

2. Influenza pandemics are unpredictable but recurring events that can cause severe social, economic and political stress. This year marks the centenary of the 1918 pandemic, which killed tens of millions of people across the world and infected hundreds of millions more. It provides an opportunity to recall the importance of continuing to prepare for the next pandemic.

3. Pandemic preparedness requires a whole-of-society approach to ensure that all countries are able to respond rapidly and effectively in order to reduce morbidity and mortality. A pandemic starts with the emergence of a virus to which people have no pre-existing immunity and which can sustainably spread from person to person. Early detection and characterization of such a virus is the necessary and crucial first step in developing a robust response. Such a response includes: development and/or deployment of diagnostic materials, vaccines and antiviral medicines; effective regulatory processes to authorize emergency use of medical countermeasures; and targeted and effective risk communications. All the many different elements should be reflected in comprehensive national pandemic preparedness plans that have been tested through regular exercises.

4. The effectiveness of a pandemic response will be measured by its ability to provide all countries with timely and equitable access to critical life-saving measures such as antiviral medicines, vaccines and other essential response products. For this reason, fairness and equity must continue to drive all global work to prepare for a pandemic response.

Progress in implementing decision WHA70(10)

5. In **paragraph 8(a)**, the Health Assembly requested the Director-General to take forward expeditiously the recommendations in the report of the 2016 PIP Framework Review Group.

6. The Secretariat has reviewed and developed specific actions to implement each recommendation. Several have been completed and the implementation of others is under way. The Secretariat has developed an instrument to track implementation of the recommendations.

7. In **paragraph 8(b)**, the Health Assembly requested the Director-General to conduct a thorough and deliberative analysis of issues raised by the PIP Framework Review Group in relation to genetic sequence data and seasonal influenza, including the implications of pursuing or not pursuing possible approaches.

8. In 2017, the Director-General developed a process to respond to the request in paragraph 8(b) of decision WHA70(10).[1] The process included collaboration with the Global Influenza Surveillance and Response System Collaborating Centres and the PIP Advisory Group in order to develop an annotated outline, or scoping paper, of the analysis. In November 2017, a consultation to gather views on the scoping paper was held with Member States, representatives of the Global Influenza Surveillance and Response System, members of the PIP Advisory Group and relevant stakeholders.

9. In April 2018, an information session is scheduled to be held for Member States, representatives of the Global Influenza Surveillance and Response System and members of the PIP Advisory Group, and relevant stakeholders at WHO headquarters. The purpose of the session will be to provide information about the present role and work of the Global Influenza Surveillance and Response System and to preview the draft report on progress to implement decision WHA70(10). With a view to increasing Member States' and stakeholders' understanding, several fact sheets are being developed and will be shared before the information session. These include a timeline of all events relevant to the completion of the analysis.

10. In **paragraph 8(c)** the Health Assembly requested the Director-General to continue supporting the strengthening of regulatory capacities and the carrying out of burden-of-disease studies.

11. The high-level partnership contribution implementation plan (2018–2023) will focus on six areas including strengthening of regulatory capacities and undertaking burden-of-disease studies. The work will build on the successes achieved in 2013–2017, including an increase in the number of countries with influenza burden estimates and the publication of a new estimate of the global burden of influenza mortality in 2017. For strengthening regulatory capacities, all 48 targeted countries have defined a regulatory pathway to facilitate the timely approval of pandemic influenza response products. The publication of WHO's regulatory preparedness guidelines in 2016[2] will facilitate further regulatory preparations for the timely and legal regulatory marketing authorization in an emergency.

[1] See Implementation of decision WHA70(10) 8(b), Terms of Reference (http://www.who.int/influenza/pip/8bTORs.pdf, accessed 21 February 2018).

[2] Guidelines on regulatory preparedness for the provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries, 2016 (http://www.who.int/biologicals/expert_committee/PIP_Non-producer_guide_BS_final-working_version-19102016-clean.pdf, accessed 22 February 2018); also included as Annex 7 in the WHO Technical Report Series No. 1004, 2017.

12. In **paragraph 8(d)** the Health Assembly requested the Director-General to continue encouraging manufacturers and other relevant stakeholders to engage in PIP Framework efforts, including conclusion of Standard Material Transfer Agreements 2 and timely payment of PIP Partnership Contributions.

13. To date, the Secretariat has concluded 12 Standard Material Transfer Agreements 2 with industry: 11 of these are with manufacturers of vaccines and antiviral medicines, and one is with a manufacturer of diagnostic test kits. Through its strategic approach to secure rapidly the largest quantity of prequalified vaccine, WHO has now concluded Standard Material Transfer Agreements 2 with all multinational influenza vaccine manufacturers and six of the seven companies with a prequalified influenza vaccine. Through the companies' commitments in the Standard Material Transfer Agreements 2, WHO has secured access to about 400 million doses of pandemic influenza vaccine and 10 million treatment courses of antiviral medicines, for use by countries in need during the next pandemic. The number of doses of vaccine represents four times the amount that WHO had access to during the 2009 pandemic. Moreover, whereas WHO did not have access to any commercial, point-of-care diagnostic products during the last pandemic, 250 000 rapid diagnostic test kits will be available to WHO during the next pandemic at affordable prices. Several agreements are in the pipeline and WHO continues to work toward conclusion of agreements with all recipients of PIP Biological Materials. The Secretariat has continued to encourage the full and timely payment of PIP Partnership Contributions. More detailed information in this regard will be made available shortly on the WHO website.

14. In **paragraph 8(e)** the Health Assembly requested the Director-General to request the External Auditor to perform an audit of PIP Partnership Contribution funds.

15. The External Auditor performed an audit of PIP Partnership Contribution funds in order to provide: (1) assurances that WHO's Financial Regulations have been appropriately applied in the use of funds and that the financial information reported is accurate and reliable; and (2) recommendations to further increase the transparency of reporting on the linkages between expenditure and technical impact. The scope of the audit covered accounts and balances as at 31 December 2015 (covering the biennium 2014–2015) and 31 December 2016. The audit was conducted in accordance with International Standards on Auditing issued by the International Auditing and Assurance Standards Board. Overall, based on their findings, the auditors concluded that revenues, receipts and expenditures incurred were properly accounted for and generally conformed with WHO's Financial Regulations and Financial Rules. The auditors also made several recommendations to WHO, mainly relating to: improving consistency in the reporting of accounts in annual statement and reports; maximizing timeliness of collection of Partnership Contributions; and improving and enhancing monitoring of implementation and reporting. WHO accepted all the recommendations and is taking measures to fully address and implement them.[1]

16. In **paragraph 8(f)** the Health Assembly requested the Director-General to continue consultations with the secretariat of the Convention on Biological Diversity and other relevant international organizations, as appropriate.

[1] For the full audit report and WHO's response see, respectively, http://www.who.int/influenza/pip/pip_audit_report.pdf?ua=1 and http://www.who.int/influenza/pip/mgt_letter.pdf?ua=1 (accessed 21 February 2018).

17. Since May 2017, the Secretariat has collaborated closely with the secretariats of the Convention on Biological Diversity, the Food and Agriculture Organization and the World Organisation for Animal Health to advance work relating to access to pathogens and the fair and equitable sharing of benefits in the interest of public health.[1] The four secretariats have jointly developed a text with questions and answers in order to provide information on the implementation of the Nagoya Protocol in the context of human and animal health and to raise awareness of the importance of rapid and comprehensive sharing of pathogens for public health.[2] The document has been shared broadly, having been sent to national focal points on access and benefit sharing; environment, agriculture and health ministries; relevant laboratories; and other stakeholders.

18. The four secretariats are planning to hold a joint workshop in June 2018 in order to discuss and develop tools that could facilitate access to pathogens and sharing of benefits during public health emergencies. Participants to be invited to the workshop will include relevant experts, government agencies, international organizations and other relevant stakeholders. The secretariats continue to hold regular teleconferences to share information on activities they are undertaking in relevant areas of work. These teleconferences involve staff members across departments and areas of work from the four organizations.

Recommendations on further action

19. As requested in paragraph 8(g) of the decision, the Director-General makes the following recommendations for further action:

(a) **Paragraph 8(a)**

Subject to completion of the analysis as specified in paragraph 8(b) below, the Secretariat aims to implement measures to complete all actions within its mandate before the Seventy-second World Health Assembly.

(b) **Paragraph 8(b)**

The Secretariat intends to complete the analysis in order to submit a comprehensive draft to the Seventy-second World Health Assembly through the Executive Board at its 144th session. The draft will reflect broad input from Member States and relevant stakeholders, notably the PIP Advisory Group and representatives of the Global Influenza Surveillance and Response System. Pursuant to the decisions of the Seventy-second World Health Assembly and any further work so entailed, a final text of the analysis will be submitted to the Seventy-third World Health Assembly through the Executive Board at its 146th session.

[1] For a report on collaboration in the first part of 2017, see document A70/57.

[2] See http://www.who.int/influenza/pip/QAs.pdf?ua=1 (accessed 22 February 2018).

(c) **Paragraphs 8(c), (d) and (f)**

The Secretariat will continue to strengthen critical pandemic preparedness through, inter alia:

(i) implementation of the high-level Partnership Contribution Implementation Plan 2018–2023, which will support strengthening of laboratory, surveillance and regulatory capacities as well as burden-of-disease studies;

(ii) conclusion of more Standard Material Transfer Agreements 2;

(iii) regular 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;

(iv) reporting on the foregoing by the Director-General to Seventy-second World Health Assembly through the Executive Board at its 144th session.

(d) **Paragraph 8(e)**

The Secretariat will take measures to implement the recommendations of the External Auditor and report thereon to the Seventy-second World Health Assembly through the Executive Board at its 144th session.

ACTION BY THE HEALTH ASSEMBLY

20. The Health Assembly is invited to note the report and approve the recommendations contained therein (see paragraph 19) through the adoption of the following draft decision:

> The Seventy-first World Health Assembly, having considered the report by the Director-General on progress to implement decision WHA70(10),[1] approved the recommendations contained therein at paragraph 19. (The recommendations at paragraph 19 will be annexed to the decision, if approved.)

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[1] Document A71/24.