World Health Organization

SIXTY-NINTH WORLD HEALTH ASSEMBLY **A69/22 Add.2**
Provisional agenda item 14.2 **20 May 2016**

Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

Report by the Director-General

The Director-General has the honour to transmit to the Sixty-ninth World Health Assembly the following reports:

- Summary report of the Pandemic Influenza Preparedness Framework Advisory Group, reflecting the Group's deliberations during its meeting of 19−22 April 2016 (see Annex 1)

- Summary report on the work undertaken by the Pandemic Influenza Preparedness Review Group to advance the 2016 review of the Framework (see Annex 2).

ANNEX 1

SUMMARY REPORT OF THE MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP, 19−22 APRIL 2016

1. The Advisory Group met at WHO headquarters in Geneva from 19 to 22 April 2016.

2. Seventeen of the 18 members were present. The Advisory Group selected Dr Jarbas Barbosa da Silva (Brazil) and Professor John Watson (United Kingdom of Great Britain and Northern Ireland) as the new Chair and Vice-Chair, respectively.

3. The Advisory Group observed a minute's silence in memory of Dr Oleg Kiselev, a former Advisory Group member.

4. Industry and other stakeholders joined the Advisory Group for the morning of 21 April for discussions and to receive updates from the Secretariat on the work that has taken place since the last meeting in October 2015.

5. The Advisory Group Meeting was followed on 22 April by two information sessions to inform Permanent Missions other stakeholder groups of the outcomes of the Advisory Group meeting. These sessions were chaired by the Chair.

Update on the WHO Global Action Plan for Influenza Vaccines (GAP)

6. The Secretariat provided an update on preparations for the GAP III consultation in November 2016 and summarized the initial results of a survey to assess stakeholder views on progress made with the Global Action Plan during its 10-year existence.

Update on Standard Material Transfer Agreements 2 (SMTA2s)

7. The Secretariat provided an update on signed SMTA2s. It reviewed its strategy for concluding agreements with manufacturers that have a prequalified vaccine. Additionally, the Secretariat informed the Advisory Group of the status of current negotiations with vaccine manufacturers, diagnostics manufacturers and with research or academic institutions. The Secretariat described the ongoing challenges with several manufacturers that have received PIP biological materials but whose engagement with SMTA2 negotiations has been slow and unconstructive.

8. The Secretariat informed the Advisory Group that 37 SMTA2s have been signed with academic and research institutions and that 12 of these institutions have offered to contribute a benefit. The Secretariat will publish details about the types of offers received from these institutions.

Update on the Review Group process

9. The Advisory Group received a briefing on the initial work of the Pandemic Influenza Preparedness (PIP) Framework 2016 Review Group. It also received a description of the work that will be undertaken by the Secretariat to respond to the request from Member States at the Executive Board in January 2016 for an analysis of how implementation of the Nagoya Protocol might affect the

sharing of pathogens and the potential public health implications.[1] Given that the PIP Review Group is separately tasked with reviewing the linkages between the PIP Framework and the Nagoya Protocol, it was decided that, in the interest of coherence, the study would also address the implications of Nagoya Protocol implementation for the PIP Framework, and for the WHO Global Influenza Surveillance and Response System.

Update on collection of the Partnership Contribution

10. The Secretariat updated the Advisory Group on the process to collect the Partnership Contribution, including the number of entities contacted, the number of contributors and the funds received in the period 2013−2016. Some significant contributions remain outstanding for 2015 and the Advisory Group noted the importance of the industry-agreed formula being faithfully honoured, especially by industry leaders.

11. The Secretariat also provided a comprehensive presentation on the implementation of projects funded with Partnership Contribution funds in 2015, indicating that the focus was in the process of shifting away from financial metrics towards measuring progress towards achieving strategic objectives. The Advisory Group was informed of performance across the five areas of work under Pandemic Preparedness and of the indicators used to measure performance.

12. The Advisory Group underscored the importance of ensuring that efforts in priority countries are synergistic, and do not compete with the efforts to respond to public health emergencies. The Advisory Group observed that capacity building is continuing in three related contexts: the PIP Framework, the International Health Regulations (2005) and the Global Health Security Agenda. The Advisory Group underlined the importance of collaboration among these three processes.

Update on progress to implement recommendations on handling of genetic sequence data

13. The Advisory Group received a detailed presentation on initiatives undertaken to date, including: the work of the Technical Expert Working Group on genetic sequence data; the survey on data sharing; the work of the Technical Working Group on the sharing of influenza genetic sequence data; the paper on options to monitor the use of genetic sequence data from influenza viruses with human pandemic potential in end-products; and the collaboration with the World Data Center for Microorganisms.

14. The Advisory Group welcomed the Technical Working Group's revised draft document entitled "Optimal Characteristics of an influenza genetic sequence data sharing system under the PIP Framework" and thanked the Working Group for its work. The Advisory Group encouraged the Working Group to finalize the document, taking into consideration the result of the consultations with industry and other stakeholders, and discussion within the Advisory Group.

[1] See summary record of the Executive Board at its 138th session, seventh meeting, section 2 (document EB138/2016/REC/2).

15. The Advisory Group reiterated the importance of maintaining the principle of equal footing when considering the handling of genetic sequence data under the Framework.[1]

Update on virus sharing

16. Using data from the Influenza Virus Traceability Mechanism, the Secretariat presented an overview of virus sharing in recent years. While the sharing of relevant biological materials initially increased after adoption of the PIP Framework, recent data point to a decreasing trend virus sharing through the Traceability Mechanism. Detailed figures for H5N1, H7N9, H10N8 and H9N2 illustrated how in some specific countries the number of viruses shared was considerably lower than the number of confirmed human cases during the period 2011−2016.

17. The Secretariat provided possible reasons for this trend. These included: (1) a lack of understanding among National Influenza Centres that sharing the genetic sequence data of influenza viruses with human pandemic potential does not replace the sharing of biological material; (2) different interpretations of the phrasing of the PIP Framework that all influenza viruses with human pandemic potential should be shared "as feasible"; (3) export procedures that can be lengthy and involve ministries in other areas in addition to health; and (4) the fact that laboratories with dual roles as both National Influenza Centres and WHO Collaborating Centres lacked clarity regarding their international sharing responsibilities.

18. The Advisory Group questioned whether these reasons fully accounted for the recent decline in sharing and urged that WHO investigate the matter in order better to understand its causes. The Advisory Group further indicated that this decline be brought to the attention of the Review Group, noting with concern that a decrease in virus sharing is a challenge to the PIP Framework.

[1] See section 1 of Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits (http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf, accessed 5 May 2016).

ANNEX 2

THE REVIEW OF THE PIP FRAMEWORK IN 2016

1. In accordance with subparagraph 4(2) of resolution WHA64.5 (2011) and Section 7.4.2 of the PIP Framework, the Framework and its annexes are to be reviewed by 2016 "with a view to proposing revisions reflecting developments as appropriate …".

2. The Advisory Group of the PIP Framework met in a Special Session on 13 and 14 October 2015, to seek the views of Member States, industry and other stakeholders on the review. The Advisory Group recommended that a small, independent group of experts be established to review implementation of the PIP Framework using a transparent and inclusive approach.[1]

3. To this end, the Director-General has established an independent Review Group, consisting of eight experts covering all the WHO regions, with wide-ranging expertise, and with a good gender balance.

4. The list of Review Group Members and their biographies may be found at the following link: http://www.who.int/influenza/pip/2016-review/members/en/.

5. The Review Group will present its final report to the Health Assembly in 2017, through the Executive Board.

6. The Advisory Group recommended that the review should be guided by three overarching questions:

(a) What are the achievements since the PIP Framework was adopted?

(b) Has implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond?

(c) What are the challenges, and possible ways of addressing them?

7. The Review Group subsequently agreed to the Advisory Group's recommendation.

Method of work

8. As part of its deliberative process, the Review Group will review background documents prepared by key experts and the Secretariat; it will consult widely and transparently with Member States and other stakeholders, and will conduct interviews with a variety of stakeholders.

9. The Review Group has planned both to hold physical meetings and to organize teleconferences. By 23 May 2016, the Review Group will have convened four times in 2016: the first two meetings were conducted via teleconferences held on 7 January and 19 February, the third and fourth meetings were held in Geneva from 30 March to 1 April, and from 9 May to 11 May, respectively. The 19 February teleconference was followed by a webcast debriefing on 23 February, and the Review

[1] See document A69/22 Add.1 for details of the Advisory Group's discussions on the review.

Group had a one-day open consultation with Member States and other stakeholders on 30 March. The meeting from 9 to 11 May was planned as a closed, deliberative session.

10. The Review Group plans to meet from 27 June to 1 July, concluding with a webcast debriefing. The Review Group's final face-to-face meeting is planned for 29 August–2 September, and will include an open consultation with Member States and other stakeholders, to provide information on key findings.

11. In addition to these meetings, the Chair of the Review Group will attend the discussion under agenda item 14.2 at the Sixty-ninth World Health Assembly. At this occasion, the Chair will present the main elements of the Review Group's deliberations so far; will discuss the key questions that the Review will seek to address; will outline the Review Group's work ahead; and will seek the views of Member States on all points.

Key issues in the review

12. At its first meeting, the Review Group agreed to divide into three working groups: (1) virus sharing, including sharing of genetic sequence data; (2) benefit sharing; and (3) governance of the PIP Framework and linkages with other instruments, including the Nagoya Protocol, the International Health Regulations (2005), and the WHO Global Action Plan for Influenza Vaccines.

13. Under these overarching topic headings, the deliberations of the Review Group, consultations with Member States and other stakeholders on 30 March, and interviews with key informants have raised several questions and issues for the Review Group to consider, including, but not limited to:

(a) how genetic sequence data should be handled under the PIP Framework;

(b) whether the principles of the PIP Framework can be applied to other pathogens, and to what extent the PIP Framework can act as a model or template for new agreements;

(c) the potential expansion of the Framework to include seasonal influenza viruses;

(d) the importance of developing a decision mechanism for recommending the start of pandemic vaccine production that may entail critical steps including switching from seasonal to pandemic vaccine production in the event of a pandemic;

(e) the importance of building capacity within the WHO Global Influenza Surveillance and Response System to ensure that the System network could handle a surge of viruses in case of a pandemic;

(f) how to improve the understanding of the way in which Partnership Contribution funds are utilized;

(g) whether the 2010 costing of running costs of the WHO Global Influenza Surveillance and Response System, which is the basis for calculating the Partnership Contribution, needs to be updated, and whether the Partnership Contribution could be delinked from these running costs and linked to an economic indicator such as GDP;

(h) the collateral benefits that may have arisen from capacity building of the PIP Framework, such as whether it has improved core capacities under the International Health Regulations (2005) in surveillance and detection.

14. The Review Group has been especially interested in understanding the relevance of the Nagoya Protocol on the PIP Framework's principles of virus sharing and benefit sharing. In its meeting from 30 March to 1 April, the Review Group noted that the Secretariat was in the process of implementing a request to WHO by Member States at the 2016 Executive Board to undertake a study on the public health implications of implementation of the Nagoya Protocol. In the interest of coherence, the Review Group requested the Secretariat to ensure that the report mandated by the Executive Board also address the possible implications of the Nagoya Protocol on the PIP Framework.[1]

Further engagement with Member States and other stakeholders

15. Key stakeholders, including Member States, industry, and civil society organizations, will have further opportunities to engage with the Review Group, through face-to-face meetings, webcast debriefings by the Chair, and through written submissions to the following email address: PIPreviewcomments@workspace.who.int, with a deadline for responses by 15 July 2016. Member States are also encouraged to provide statements and raise questions during the Chair's presentation at the Health Assembly.

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[1] See summary records of the Executive Board at its 138th session, second meeting, section 1 and seventh meeting, section 2 (document EB138/2016/REC/2).