EXECUTIVE BOARD **EB138/21**
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Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

Report by the Director-General

1. The Pandemic Influenza Preparedness Framework ("PIP Framework") was adopted by the Sixty-fourth World Health Assembly in resolution WHA64.5 (2011).

2. Section 7.4.1 of the PIP Framework states that the Director-General shall on a biennial basis inform the World Health Assembly, through the Executive Board, on the status of, and progress on:

(i) Laboratory and surveillance capacity (see Framework section 6.6);

(ii) Global influenza vaccine production capacity (see Framework sections 6.13.1 and 6.13.2);

(iii) The status of agreements entered into with industry, including information on access to vaccines, antivirals and other pandemic material (see Framework sections 6.14.3 and 6.14.4);

(iv) The financial report on the use of the partnership contribution (see Framework section 6.14.5);

(v) The experience arising from the use of the definition of PIP biological materials (see Framework section 4.1).

3. This report summarizes information on the status and progress of these topics. Much of the information for this report is derived from the Pandemic Influenza Preparedness Framework Advisory Group's Annual Reports to the Director-General for 2014[1] and 2015.[2] The Director-General has accepted these reports and the findings contained therein.

[1] See the report of the Advisory Group's meeting held in Geneva from 21 to 24 October 2014, Annex 6 (http://www.who.int/influenza/pip/pip_ag_oct2014_meetingreport_final_7nov2014.pdf?ua=1, accessed 16 November 2015).

[2] See http://www.who.int/influenza/pip/ag_annual_report_2015.pdf?ua=1, accessed 30 November 2015.

LABORATORY AND SURVEILLANCE CAPACITY

4. In May 2012, the Executive Board at its 131st session decided, inter alia, that for the period 2012–2016, 70% of the partnership contribution resources should be used for pandemic preparedness measures for building laboratory and surveillance capacity.[1] This decision, which was in line with the advice of the Advisory Group, reflects both the foundational importance of influenza surveillance to pandemic preparedness and response, as well as the critical gaps that exist in this capacity at global and national levels.[2]

5. Development work, undertaken by means of consultations involving the Advisory Group, industry and stakeholders, enabled a high-level implementation plan to be published in January 2014.[3] Workplans and implementation systems across the three levels of WHO were also elaborated during 2014.

6. Partnership contribution resources are currently supporting 43 target countries to develop, through their national and subnational influenza laboratories, capacity for detecting and monitoring novel influenza and other respiratory viruses. Countries are working to put functioning event-based epidemiological surveillance in place as well. Key achievements to date for the 43 target countries include the following: 9 (21%) with functioning event-based surveillance; 28 (65%) reporting virological data and 9 (21%) reporting epidemiological data to WHO and 24 (56%) sharing virus samples with the WHO Global Influenza Surveillance and Response System.

7. The System continues to expand. In October 2014 the Institute Pasteur in Cambodia was designated as the 13th laboratory in the WHO H5 Reference Laboratory Network. This is a well-placed asset as avian influenza A(H5N1) viruses continue to circulate in Cambodia. Two new national influenza centres were designated in Africa, namely: in the United Republic of Tanzania (November 2014) and Zambia (in September 2015). The network of national influenza centres has grown from 136 laboratories in 106 countries in 2011 to its current size of 143 laboratories in 113 countries.

8. In February 2012, the Advisory Group recommended that laboratories in the WHO Global Influenza Surveillance and Response System undertake a self-assessment focusing on the role, function and capacities of the System in relation to the Framework. The assessment was completed in September 2014. Among the key findings was the observation that significant geographical gaps in the System remain in Africa, the Middle East and eastern Europe, despite the System's general solidity and the strong technical foundations and expertise from which it benefits. Also, due to the economic situation and so-called "flu fatigue" many national influenza centres face challenges posed by insufficient funding and government commitment.

[1] The remaining 30% of preparedness resources support the following areas of work: burden of disease; regulatory capacity building; planning for deployment; and risk communications.

[2] See Pandemic Influenza Preparedness Partnership Contribution, 2013–2016: Gap Analyses (http://www.who.int/influenza/pip/pip_pc_ga.pdf, accessed 16 November 2015).

[3] See Partnership Contribution Implementation Plan 2013 – 2016 (http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1, accessed 16 November 2015).

GLOBAL INFLUENZA VACCINE PRODUCTION CAPACITY

9. The WHO Global Action Plan for Influenza Vaccines[1] has catalysed an increase in global vaccine production capacity of seasonal vaccine – from 500 million doses in 2006 to 1503 million doses a year in 2013. It is anticipated that capacity will grow to at least 1700 million doses a year by 2016. This seasonal capacity translates to a potential pandemic vaccine capacity of at least 4509 million doses annually (assuming that 15 micrograms of antigen would be needed per dose). The number of developing countries with approved pandemic influenza vaccines has grown from zero in 2006 to seven in 2015.

10. The projected global vaccine production capacity would still fall short of needs during a pandemic, based on currently available vaccines. Dose-sparing technologies are becoming increasingly available and may increase this number significantly. The emphasis is on accelerating research into more broadly protective vaccines.

11. The Global Action Plan for Influenza Vaccines will be sunset in 2016. It is anticipated that the 2016 review of the PIP Framework will include consideration of implications stemming from the sunsetting of the Global Action Plan, in particular with respect to activities that could continue under the PIP Framework.

STATUS OF AGREEMENTS ENTERED INTO WITH INDUSTRY, INCLUDING INFORMATION ON ACCESS TO VACCINES, ANTIVIRALS AND OTHER PANDEMIC MATERIAL

12. An agreement with the with vaccine manufacturer Sanofi Pasteur was signed in 2014, increasing the amount of vaccine WHO would have access to during a pandemic. Based on agreements entered into to date, it can be estimated that WHO has already secured 7.8% of the potential global pandemic vaccine production:[2] GlaxoSmithKline and the Serum Institute of India have each made a commitment to provide WHO with 10% of pandemic influenza vaccines as they come off the production line; Sanofi Pasteur will provide 15% of its pandemic vaccine production.[3] GlaxoSmithKline also committed to providing access to 10 million treatment courses of antiviral medicine.

13. Since 2014, the secretariat of the PIP Framework has been actively conducting negotiations with over 20 influenza vaccine manufacturers and diagnostics companies from around the world to conclude additional agreements, and these negotiations are progressing.

[1] See http://www.who.int/influenza_vaccines_plan/en/ (accessed 23 November 2015).

[2] This figure is based on 2013 global production capacity figures and assumes 15 micrograms of antigen/dose.

[3] See http://www.who.int/influenza/pip/benefit_sharing/smta2/en/ (accessed 23 November 2015).

14. A total of 29 agreements with research or academic institutions have been signed; several of these entities have offered to provide benefits such as laboratory and surveillance capacity building. Work is under way to determine how to operationalize these offers.

15. Certain challenges have affected the pace of negotiations, including a lack of knowledge about the PIP Framework among smaller companies. Communications and outreach efforts have been undertaken to increase such knowledge, as well as company briefings about the WHO prequalification process requirement. Uncertainty about the ability to provide real-time donations because of advance purchase agreements, and instances of companies not offering reasonable benefit sharing commitments have also hampered progress.

FINANCIAL REPORT ON THE USE OF THE PARTNERSHIP CONTRIBUTION

16. A methodology and formula for calculating how much each contributor should pay,[1] as well as standard operating procedures for the Partnership Contribution,[2] have both been established. WHO is to receive a total annual amount of US$ 28 million based on the estimated cost of running the WHO Global Influenza Surveillance and Response System. As of September 2015, 30 of the 32 contributors identified in 2013, and 36 of the 43 identified in 2014, contributed US$ 27 538 586 and US$ 26 933 271, respectively.

17. For the period 2012–2016, approximately 70% of Partnership Contribution resources have so far been used for pandemic preparedness activities, and 30% for pandemic response activities.[3] In addition, a portion of Partnership Contribution Funds not exceeding 10%, as averaged during 2013–2016, is available to the PIP secretariat to support implementation of the Framework.[4]

18. As of 30 September 2015, funds (in US$ million) have been distributed across five areas of work as follows:[5] laboratory and surveillance capacity building, US$ 22.37 million; burden of disease, US$ 0.83 million; regulatory capacity building, US$ 1.99 million; risk communication, US$ 3.96 million; and planning for deployment, US$ 1.54 million. Funds were distributed across 43 countries for laboratory and surveillance capacity building. National capacity building began in mid-2014 and is being steadily scaled up. In some instances, competing public health priorities, notably the ongoing Ebola virus disease outbreak in west Africa, have hampered the impact of Partnership Contribution support for national capacity building.

[1] See Pandemic Influenza Preparedness Framework: Distribution of Partnership Contribution among companies (http://www.who.int/influenza/pip/pc_distribution.pdf?ua=1, accessed 27 November 2015).

[2] See Partnership Contribution Standard Operating Procedures June 2015. (http://www.who.int/influenza/pip/benefit_sharing/pc_collection_sop.pdf?ua=1, accessed 27 November 2015).

[3] See decision EB131(2) (2012).

[4] See document A66/17 Add.1.

[5] Pandemic Influenza Preparedness Framework Partnership Contribution Implementation Plan 2013–2016. Geneva: World Health Organization; 2010 (http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1) (accessed 27 November 2015).

19. In October 2014, the Advisory Group, with input from industry and other stakeholders, developed a set of guiding principles for use of PIP Partnership Contribution Response Funds.[1] The guidance is designed to assist the Director-General in deciding on the use of the Partnership Contribution for response purposes without requiring further advice from the Advisory Group or interaction with industry and other stakeholders. The guidance was accepted by the Director-General and endorsed by the Executive Board at its 131st session. As at 30 September 2015, US$ 18.3 million have been set aside for pandemic response activities, including, purchase and shipment of vaccines, antivirals, diagnostics and other pandemic-related products.

20. As part of the commitment to transparency, a web portal[2] was established and is being updated quarterly with financial and technical data on progress in the use of Partnership Contribution funds. The first annual report on the partnership contribution was issued in April 2015.[3]

EXPERIENCE ARISING FROM THE USE OF THE DEFINITION OF PIP BIOLOGICAL MATERIALS

21. Genetic sequence data are being used to manufacture some vaccines and other influenza-related products, a trend that is anticipated to increase. Although genetic sequence data fall within the PIP Framework,[4] there are different views about whether they are included in the definition of PIP biological materials. In considering the handling of genetic sequence data for influenza viruses with pandemic potential, the Advisory Group noted that the spirit of the Framework, as well as the need to maintain a level playing field in the sharing of viruses and in benefiting from doing so, must be kept in mind.[5]

22. To assist the Advisory Group in preparing guidance for the Director-General on a process for resolving the issues related to the handling of genetic sequence data, a Technical Expert Working Group was established in 2013. Its report addressed, inter alia, the use of genetic sequence data, regulatory and intellectual property issues, monitoring and tracing methods, and biosecurity and biosafety issues.[6]

23. The Advisory Group subsequently recommended carrying out work to identify the optimal characteristics of a system for handling genetic sequence data for influenza viruses with pandemic potential, which included data sharing systems and systems for monitoring the use of genetic sequence

[1] See (http://www.who.int/influenza/pip/guiding_principles_pc_response_funds.pdf?ua=1, accessed 27 November 2015).

[2] See https://extranet.who.int/pip-pc-implementation/ (accessed 27 November 2015).

[3] See *Pandemic influenza preparedness framework partnership contribution 2013–2016: annual report 2014*. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/161369/1/WHO_HSE_PED_GIP_PIP_2015.2_eng.pdf?ua=1&ua=1, accessed 27 November 2015).

[4] See PIP Framework, Section 5.2; Annex 4, Point 9; Annex 5 "Guiding Principles".

[5] See report of the April 2014 meeting of the PIP Advisory Group, document A67/36.

[6] See Technical Expert Working Group (TEWG) on Genetic Sequence Data Final Report to the PIP Advisory Group http://www.who.int/influenza/pip/advisory_group/PIP_AG_Rev_Final_TEWG_Report_10_Oct_2014.pdf?ua=1, accessed 30 November 2015.

data in end products.[1] Activities undertaken to date include: the development of a prototype search engine that could be used to monitor the use of genetic sequence data in end products; a questionnaire survey to gain a better understanding of how genetic sequence data are generated, shared and used; and the preparation of a paper on options for monitoring the use of genetic sequence data. A Technical Working Group was established in April 2015 to draft a document defining the optimal characteristics of a system for sharing genetic sequence data that is best suited for meeting the objectives of the Framework. Following a public consultation, the draft document will be revised and the results will be made available to the Secretariat for integration in the 2016 review of the Framework.

ACTION BY THE EXECUTIVE BOARD

24. The Board is invited to note the report.

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[1] See report of the October 2014 meeting of the PIP Advisory Group (http://www.who.int/influenza/pip/combined_pipagmroct2014corr.pdf?ua=1, accessed 1 December 2015).