

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

Pandemic Influenza Preparedness Framework

Report by the Director-General

1. An earlier version of document EB134/33 was considered and noted by the Executive Board at its 134th session.¹ Paragraphs 8 and 9 of Annex 1 below have been updated.

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is requested to note the report.

¹ See the summary records of the Executive Board at its 134th session, tenth meeting, section 1.



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

Pandemic Influenza Preparedness Framework

Report by the Director-General

1. The Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits established an annual partnership contribution to be paid to WHO by manufacturers of influenza vaccines, diagnostics and pharmaceuticals using the WHO Global Influenza Surveillance and Response System.¹ The distribution of Partnership Contribution resources among companies was to be based on transparency and equity, according to their nature and capacities. The PIP Framework specifies that the Director-General in consultation with the PIP Advisory Group will further define the specific amounts to be contributed by each company and, in so doing, will collaborate with industry. The Framework further specifies that the Director-General will report annually on the outcome to the Executive Board.

2. Between October 2012 and March 2013, the WHO Secretariat collaborated with industry to develop a methodology and formula to distribute the partnership contribution among companies identified as contributors. The methodology and formula are contained in the document entitled "Distribution of Partnership Contribution among companies" posted on the WHO website on 8 May 2013.²

3. For 2013, the Secretariat identified 37 companies that were to contribute the total annual Partnership Contribution of US\$ 28 million. The amount to be paid by each company has been determined by using the approved methodology and formula.

4. As annexes to this report, the Director-General has the honour to transmit to the Executive Board, for its information, a summary of key points discussed by the PIP Advisory Group at its last meeting (Geneva, 7–9 October 2013) (Annex 1) and a synopsis of its second annual report (Annex 2), the annual

¹ Document WHA64/2011/REC/1, Annex 2, section 6.14.3.

² http://www.who.int/influenza/pip/benefit_sharing/pc_distribution_may_2013.pdf (accessed 30 October 2013).

report being produced in accordance with section 7.2.5 of the PIP Framework. The Director-General has accepted the reports and the recommendations and findings contained therein.

ACTION BY THE EXECUTIVE BOARD

5. The Board is invited to note this report.

ANNEX 1

**PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP
MEETING (GENEVA, 7–9 OCTOBER 2013)
SUMMARY OF KEY POINTS OF DISCUSSION**

Standard Material Transfer Agreement 2: Update on current negotiations

1. The PIP secretariat provided an update on the status of Standard Material Transfer Agreement 2 (SMTA 2) negotiations. An SMTA 2 was concluded on 1 October 2013 with the Serum Institute of India (SII), a developing country vaccine manufacturer and also a grantee under the WHO Global pandemic influenza action plan to increase vaccine supply. An SMTA 2 had previously been concluded with Glaxo Group Limited (GSK). Negotiations are under way with Sanofi, Baxter and China National Biotec Group, and pre-negotiation discussions are being held with MedImmune and Novartis. A SMTA 2 concluded in October 2012 with the University of Florida was also discussed and noted.
2. Discussions and negotiations are proving to be time consuming, and reaching agreement with vaccine manufacturers on the terms of benefit sharing is often a lengthy process. The Secretariat plans to initiate discussions with additional manufacturers with legal support from a consultant lawyer who will begin shortly.
3. The Advisory Group provided the following advice to the Director-General on SMTA 2 negotiations:

The Advisory Group welcomed the second SMTA 2 that has been concluded with a vaccine manufacturer.

The Advisory Group recognized, however, that there have been difficulties in concluding additional agreements:

- *The Advisory Group recommended that WHO showcase the successful conclusion of the SMTA 2s with GSK and SII as an incentive to conclude agreements with other vaccine manufacturers as quickly as is feasible.*
- *In situations where discussions with manufacturers would benefit from high level exchanges between the Organization and the manufacturer, the Advisory Group strongly recommended that such exchanges be made.*

Handling genetic sequence data in the context of the PIP Framework

4. The Secretariat provided an overview of synthetic biology with a view to initiating the Group's discussion on the best process to handle the use of influenza virus genetic sequence data under the Framework.
5. The Advisory Group agreed that developments in synthetic biology raise complex issues with legal, technical, public health and biosecurity implications that require careful review and consideration.

6. To assist the Advisory Group in developing guidance for the Director-General on this matter, technical support from a technical expert working group would be beneficial. The Advisory Group developed Terms of Reference for such an expert group.

Partnership Contribution: review of 2013 results

7. The Secretariat provided an update on the process to collect the partnership contributions due for 2013. The Secretariat, through the “PIP PC 2013 Questionnaire”, identified 37 companies as contributors. Following an extensive process to receive Band Selection and Certification Forms from all 37 companies, four Band Selection and Certification Forms were outstanding as at 7 October 2013.

8. Using publically available financial and other information, the Secretariat has placed the outstanding companies into bands. Invoices were sent to the 37 companies in mid-October to allow time for processing before the end of 2013.

9. The Advisory Group concurred with the Secretariat’s approach to generating invoices so that partnership contribution payments for 2013 would be received in a timely fashion. If the estimation of bands for the four companies subsequently needs revision, adjustments could be made in 2014.

Partnership Contributions: gap analysis and implementation plans

10. The Secretariat presented the draft Partnership Contribution implementation plan: 2013–2016, including the process for identifying and analysing gaps and needs. The Advisory Group discussed the plan as well as a document on the Regional Office Recommended Country Recipients.

11. The Advisory Group met representatives of industry associations, manufacturers and other stakeholders to discuss the draft plan.

12. The Advisory Group discussed the views and comments of industry and other stakeholders. The Secretariat will revise the implementation plan to take into account these discussions. The revised implementation plan and the results of the gap analyses will be shared with the Advisory Group, industry and other stakeholders.

13. The Advisory Group provided the following advice to the Director-General on implementation of activities under the Partnership Contribution.

To avoid the risk of perceived conflict of interest in selection of countries, the Advisory Group wished to clearly articulate the process to develop the draft Regional Office Recommended Country Recipients document. The following was noted:

- *The role of the Advisory Group was limited to providing criteria for country selection:*
 - *Country development status;*
 - *IHR core capacities;*
 - *Country needs for influenza epidemiological and laboratory surveillance; and*
 - *H5N1 vulnerability.*

- *These factors were compiled into a database by the PIP Secretariat and shared with Regional Offices for their use in identifying priority countries for strengthening laboratory and surveillance capacities.*
- *Regions further refined their gap analyses with additional elements including:*
 - *Political situation in countries, notably whether a country is in a complex emergency;*
 - *Ongoing donor funding and investments in a country;*
 - *Absorptive capacity of the country;*
 - *Country population size;*
 - *Geographical location of the country in the region/subregion (notably for island states);*
 - *Interest of the country/Ministry of Health to work in influenza; and*
 - *Ability of countries to build on existing capacities to produce influenza surveillance data which could be shared with neighbouring countries.*
- *Using all the factors above, Regional Offices recommended countries in priority order.*

In their review of the list, the Advisory Group:

- *Noted the work of selection which has been made among the numerous possible recipients by the WHO Regional Offices for this first phase of the implementation plan and acknowledged the need for supporting rationales.*
- *Noted the importance of providing PC resources to countries that need basic capacities as well as to countries that have existing capacities but where additional support can serve as a regional resource to other countries.*

The Advisory Group recommended that implementation of activities under the PC begin in January 2014. They noted that the PIP implementation plan should be considered a “living document” that can be revised over time.

Annual report

14. The Advisory Group adopted its annual report to the Director-General (see Annex 2). It was agreed that future reports will cover the period beginning 1 October and ending 30 September of each year.

Election of the new Chair and Vice-Chair of the Advisory Group

15. After an informal consultation, the Advisory Group reached consensus that Dr William Kwabena Ampofo (Ghana) and Professor Rajae El Aouad (Morocco) would be its new Chair and Vice-Chair, respectively.

Next meeting of the Advisory Group

16. The next meeting of the Advisory Group will take place in Geneva on 9–11 April 2014.

ANNEX 2

**PANDEMIC INFLUENZA PREPAREDNESS (PIP) FRAMEWORK
SECOND ANNUAL REPORT OF THE ADVISORY GROUP
TO THE DIRECTOR-GENERAL
SYNOPSIS OF KEY DEVELOPMENTS**

1. INTRODUCTION

This document provides a synopsis of the second Annual Report of the Advisory Group to the Director-General on its evaluation of the implementation of the Framework.¹ It focuses on the main developments during the 17-month period beginning 1 May 2012 to 30 September 2013² and covers the seven areas specified in the Framework.³

2. VIRUS SHARING**2.1 Sharing of influenza viruses with pandemic potential**

Human cases of disease due to avian influenza A(H7N9) virus were detected in China beginning in early 2013. Rapid sharing of viruses and information was essential to the development of candidate vaccine viruses and reference reagents, diagnostic tests, guidance and dissemination of information on risk assessment and pandemic preparedness actions.⁴

Genetic sequence data for influenza A(H7N9) and other influenza viruses with human pandemic potential (i.e. influenza A(H5N1), A(H3N2)v, A(H1N1)v, A(H1N2)v and A(H6N1)) were shared through public-access databases, as required by the Terms of Reference of laboratories of the WHO's Global Influenza Surveillance and Response System (GISRS).

2.2 Influenza Virus Traceability Mechanism

The transparency of the activities of the Global Influenza Surveillance and Response System was enhanced through use of the Influenza Virus Traceability Mechanism to track the movement of PIP biological materials. Between May 2012 and July 2013, 499 shipments of such materials were recorded in the Traceability Mechanism; 342 (69%) of these were sent to 113 laboratories not belonging to the Global Influenza Surveillance and Response System.⁵ During this same period, six

¹ In accordance with section 7.2.5 of the PIP Framework section.

² In some instances data were truncated before October 2013 to allow time for tabulation and analysis.

³ The seven areas specified in the PIP Framework, section 7.2.5 and Annex 3, section 2 are: necessary technical capacities of the WHO GISRS; operational functioning of WHO GISRS; WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity-building); increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential; the Influenza Virus Traceability Mechanism; the sharing of influenza viruses and access to vaccines and other benefits; and the use of financial and non-financial contributions.

⁴ Available at: http://www.who.int/influenza/human_animal_interface/influenza_h7n9/WHO_H7N9_review_31May13.pdf (accessed 30 October 2013).

⁵ Some shipments included more than one PIP biological material.

countries recorded 164 human viruses with pandemic potential (i.e. A(H5N1), A(H7N9), A(H7N7), A(H7N2) and A(H7N3) viruses) in the Traceability Mechanism.

2.3 Definition of PIP biological materials

The directors of WHO Collaborating Centres and Essential Regulatory Laboratories informed the Advisory Group during its meeting in October 2012 of concerns related to the application of the definition of PIP biological materials,¹ based on their discussions with representatives of the animal health sector. A less strict application of the definition could mean that all wild type viruses obtained from infected animals are also covered under the definition of PIP biological materials. The Advisory Group expressed a view that a strict application of the definition met the intent of Member States during the PIP Framework negotiations and would be least likely to dampen collaboration between human and animal sector laboratories.

3. BENEFIT SHARING

3.1 Standard Material Transfer Agreement 2

During SMTA 2 negotiations two developing-country vaccine manufacturers indicated that they were ready to commit to both a donation and a reserve² of pandemic vaccine for a total of 10% of their real-time pandemic vaccine production. Given that WHO is required to pay for the reserve, the Secretariat has sought to keep that portion of the overall 10% as low as possible and to increase the donation amount. This would mean, however, that the 5% minimum indicated in the model SMTA 2 in Annex 2 of the PIP Framework would not be respected. The Advisory Group recommended that manufacturers be permitted to commit to reserve less than 5% if there was a concomitant increase in their donation so that their total commitment under the SMTA 2 would be at least 10%.

3.2 Contributors to the Partnership Contribution

Through the voluntary contributions of six manufacturers, WHO received US\$ 18.121 million in 2012 for the Partnership Contribution. In May 2013, the PIP Secretariat published a methodology for the distribution of the Partnership Contribution among vaccine, diagnostic and pharmaceutical manufacturers that use the Global Influenza Surveillance and Response System.³ Standard operating procedures for the Partnership Contribution were also published.⁴

In 2013, a questionnaire was sent to 193 companies identified as potential contributors; 89 companies responded, of which 37 were determined to be contributors.

¹ See PIP Framework, section 4.1 for the definition of PIP biological materials.

² See PIP Framework, Annex 2 Article 4.1.1 for a list of the options available under SMTA 2 for manufacturers of vaccines and/or antiviral medicines.

³ Pandemic Influenza Preparedness Framework Distribution of Partnership Contribution among companies is available at: http://www.who.int/influenza/pip/benefit_sharing/pc_distribution_may_2013.pdf (accessed 30 October 2013).

⁴ Partnership Contribution Standard Operating Procedures is available at: http://www.who.int/influenza/pip/benefit_sharing/pc_sop_may_2013.pdf (accessed 30 October 2013).

3.3 Use of Partnership Contribution resources

Based on the Advisory Group's recommendations, 70% of the Partnership Contribution is to be used for pandemic preparedness and 30% as a reserve for pandemic response activities. The Director-General accepted the Advisory Group's subsequent recommendation that 70% of preparedness resources be used for surveillance and laboratory capacity-building and that disease burden studies, regulatory capacity-building and risk communications each be allocated 10%.

In March 2013, the Advisory Group, industry and other stakeholders reviewed a high-level, draft implementation plan for pandemic preparedness. The Advisory Group supported the overall approach and requested that the Secretariat develop a more detailed plan including a time-phased project design, budget, risk analysis and indicators.

The Director-General accepted the Advisory Group's recommendation in March 2013 that a portion of the Partnership Contribution funds, not exceeding 10% averaged over the period 2013–2016, be directed to the PIP secretariat to enable it to make progress in its work to implement the PIP Framework.

3.4 Identification of countries for receipt of Partnership Contribution resources for laboratory and surveillance capacity-building

At its meeting in October 2012, the Advisory Group concurred with the Secretariat's gap analysis-based methodology to identify countries for receipt of Partnership Contribution resources to strengthen influenza laboratory and surveillance capacities. The Advisory Group also noted the desirability of having at least one country from each WHO region receive Partnership Contribution funds for this purpose, while retaining a primary focus on countries with the greatest need. The Secretariat conducted a regional-based gap assessment. WHO regional offices further refined the gap analyses and recommended countries eligible for receipt of Partnership Contribution funds; this draft document was shared with the Advisory Group in August 2013.

4. GOVERNANCE

The Advisory Group met twice in Geneva (3–5 October 2012¹ and 20–22 March 2013²) and held one meeting by teleconference (12 June 2013).

Regular collaboration and interaction with industry and other stakeholders have benefited the advancement of plans for the implementation of the PIP Framework. Information sessions in Geneva for representatives of the Permanent Missions to the United Nations in Geneva were held on 18 October 2012 and 15 April 2013, led by the Chair of the Advisory Group, with a telephone briefing for members of civil society on 22 October 2012.

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¹ For meeting see document EB132/16, Annex 2.

² For meeting report see document A66/17 Add.1.