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. It focuses on the main developments during the 17-month period beginning 1 May 2012 to 30 September 2013 and covers the seven areas specified in the Framework.

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.

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. During this same period, six...

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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.
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, 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 reserve 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. Standard operating procedures for the Partnership Contribution were also published.

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

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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.


3.3 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 identity 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 2012\(^1\) and 20–22 March 2013\(^2\)) 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.

\(^1\) For meeting see document EB132/16, Annex 2.
\(^2\) For meeting report see document A66/17 Add.1.