Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report of the Advisory Group

Report by the Director-General

The Director-General has the honour to transmit to the Executive Board, for its consideration, the report of the Pandemic Influenza Preparedness Framework Advisory Group, which reflects its deliberations during its first meeting in November 2011 (see Annex). The Executive Board is invited to consider this report.
BACKGROUND

1. On 24 May 2011, the Sixty-fourth World Health Assembly in resolution WHA64.5 adopted the Pandemic Influenza Preparedness Framework for sharing of influenza viruses and access to vaccines and other benefits (the “PIP Framework”). The PIP Framework was developed for two fundamental purposes: (1) to increase access to pandemic influenza vaccines and other pandemic influenza-related benefits for countries in need in the event of an influenza pandemic; and (2) to ensure the continued sharing of viruses necessary for continuous global monitoring and assessment of risks for an influenza pandemic and for the development of safe and effective influenza vaccines.

2. The implementation of the PIP Framework is overseen by the World Health Assembly and, in accordance with Section 7 of the Framework, promoted by the Director-General. An independent Advisory Group is the third pillar of the PIP Framework’s Governance and Review structure. The Advisory Group monitors and evaluates implementation of the PIP Framework and provides evidence-based reporting, assessment and recommendations regarding its functioning. The Advisory Group provides its guidance and input to the Director-General.

APPOINTMENT OF THE ADVISORY GROUP

3. The Director-General appointed 18 members of the PIP Advisory Group upon receipt of nominees from Regional Directors who consulted with Member States. In accordance with Sections 7.2.2 and 7.2.3 and Annex 3 of the PIP Framework, there are three members from each of WHO’s six regions, representing developed and developing countries, affected countries\(^1\), and a skill mix of policy-makers, public health experts and influenza experts. A list of members may be found in Appendix 1.

ORGANIZATION AND PROCESS OF THE MEETING

4. The first meeting of the Advisory Group took place at WHO headquarters in Geneva, 21–22 November 2011, with the following provisional agenda:

\(^1\) “Affected country” means countries with laboratory confirmed cases of H5N1 or other influenza viruses with human pandemic potential. See Framework section 4.4.
1. Registration
2. Opening
3. Election of Officers
4. Adoption of agenda
5. PIP Framework and its elements, including an update on implementation
6. Role of PIP Secretariat
7. Advisory Group responsibilities
8. Working procedures and methods of work
10. Report to the Director-General
11. Any other business

5. Of the 18 members of the Advisory Group, 17 were present.

6. The meeting was called to order by the Assistant Director-General, Health Security and Environment, followed by his opening remarks. The Assistant Director-General noted that the Advisory Group has a significant role to play. The Director-General will rely on the Group’s advice as she develops plans to implement the many elements of the Framework.

7. The WHO Principal Legal Officer reviewed the process for Declarations of Interests. He requested that all members confirm the interests they had previously declared and disclose any relevant changes that had intervened subsequently. Declarations of Interest can be found in Appendix 2.

8. The Advisory Group elected Professor Didier Houssin (France) as Chair and Professor Tjandra Y. Aditama (Indonesia) as Vice-Chair. The Chair made a number of introductory remarks. The Advisory Group adopted the agenda and subsequently added the following topics under items 7 and 8: the WHO Global Influenza Surveillance and Response System (GISRS) and the Influenza Virus Traceability Mechanism (IVTM); the Advisory Group’s priorities and key deadlines; the Partnership Contribution; the Advisory Group’s roles and responsibilities related to Standard Material Transfer Agreement 2 (SMTA2); and the outline of the Advisory Group’s annual report to the Director-General.

9. The Assistant Director-General made a background presentation on the elements of the PIP Framework and the status of its implementation. The PIP Framework Secretariat reviewed its role and responsibilities. The WHO Principal Legal Officer then reviewed the Advisory Group’s responsibilities, working procedures and methods of work. He reminded the Advisory Group that all members participate in their personal capacity and are not to take instructions from any government or other authority.

10. In accordance with the provisions of the PIP Framework, all members will serve for three years. A three-year appointment period was deemed particularly important for the Advisory Group in the early stages of its work as this would allow for continuity of discussions and facilitate implementation
of critical and time-sensitive tasks required under the PIP Framework. Subsequently, renewal of one third of the members will be initiated every year per the PIP Framework. The Advisory Group expressed a view that any decision on the future mandate of the Advisory Group (per PIP Framework Section 7.2.6) be deferred until the Group had completed a reasonable amount of work.

11. The Chair led a discussion on the priority areas of work that the Advisory Group will undertake in 2012. First, the Group considered its work related to the Partnership Contribution under the Framework. The Group agreed that its advice to the Director-General would: be based on guiding principles to be articulated; take into account input from industry and stakeholders; and bear in mind the needs of developing and affected countries. Second, the Group indicated that its work related to SMTA2 (i.e. the timetables for delivery of commitments by recipients under SMTA2), would be more productive once the Secretariat had begun individual contacts with industry. Third, the Group outlined the principal components of its annual report to the Director-General: (i) virus sharing (e.g. operational functioning of GISRS; IVTM); (ii) benefit sharing (e.g. the Partnership Contribution; status of SMTA2 agreements); and (iii) governance (e.g. assessment and evaluation of PIP Framework implementation; review of GISRS laboratory terms of reference).

12. The Advisory Group plans to hold four meetings during 2012. The meetings will be convened either in Geneva or via teleconference. The Group agreed to hold the first of these four meetings in Geneva during the first quarter of 2012. The proposed agenda for this meeting will include a review of the GISRS system in more detail; an overview of WHO’s interaction with industry; further discussions on the Partnership Contribution; planning for the second meeting during 2012; and preparation of a meeting report. Manufacturers and other stakeholders will be invited to provide their input on the distribution and use of the Partnership Contribution; manufacturers also will be asked to update the Advisory Group on their proposals to define specific amounts to be contributed to the Partnership Contribution by each company.

13. The Advisory Group requested that the Secretariat prepare several documents in advance of its next meeting:

- a report on GISRS functions and operations, including processes to identify and assess viruses with human pandemic potential;
- a report on WHO interactions with influenza-related manufacturers;
- a report on WHO experience during the pandemic (H1N1) 2009 related to acquisition and distribution of antiviral medicines and pandemic vaccine;
- a briefing paper on the potential uses of the Partnership Contribution for pandemic preparedness and response;
- proposed guiding principles to assist the Advisory Group in formulating its advice to the Director-General regarding the proportional distribution (i.e. pandemic preparedness versus response) and use of the Partnership Contribution resources;
- lists of affected countries; developing countries; and countries-in-need.

14. This meeting report was discussed and approved by the Advisory Group.
Appendix 1

Pandemic Influenza Preparedness Framework Advisory Group

List of members

Professor Tjandra Y. Aditama, Director General of Disease Control and Environmental Health, Ministry of Health, Indonesia

Dr William Kwabena Ampofo, Senior Research Fellow & Head – Virology, Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana

Dr Jarbas Barbosa da Silva Jr, Secretary (Vice Minister) of Health Surveillance, Ministry of Health, Brazil

Dr Silvia Bino, Associate Professor of Infectious Diseases, Head, Control of Infectious Diseases Department, Institute of Public Health, Albania

Professor Rajae El Aouad, Director, National Institute of Hygiene, Morocco

Dr Rainer Engelhardt, Assistant Deputy Minister of the Infectious Disease Prevention and Control Branch, Public Health Agency, Canada

Mr David E. Hohman, Senior Advisor, Office of Global Affairs, Department of Health and Human Services, United States of America

Professor Didier Houssin, President, French Evaluation Agency for Research and Higher Education (AERES), France

Dr Hama Issa Moussa, National Technical Assistant, Ministry of Public Health, Niger

Dr Mark Jacobs, Director of Public Health, New Zealand

Dr Amr Mohamed Kandeel, Chief of Preventative and Endemic Diseases Sector, First Undersecretary, Ministry of Health and Population, Egypt

Professor Oleg Ivanovich Kiselev, Director, Research Institute of Influenza, Ministry of Public Health and Social Development, Russian Federation

Professor Ziad Memish, Assistant Deputy Minister of Health for Preventive Medicine, Saudi Arabia

Dr Nobuhiko Okabe, Director of Infectious Disease Surveillance Center, National Institute of Infectious Diseases, Japan
**Dr Adrian J. Puren**, Divisional Head for Centres of Vaccine and Immunology, Respiratory and Meningeal and Enteric Diseases, National Institute for Communicable Disease, South Africa

**Professor Prasert Thongcharoen**, Professor Emeritus, Department of Microbiology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand

**Dr P.V. Venugopal**, Public Health Specialist, India

**Professor Wang Yu**, Director-General, Chinese Center for Disease Control and Prevention, China
Appendix 2

Pandemic Influenza Preparedness Advisory Group Meeting
21–22 November 2011

Summary of Declarations of Interest by members

In accordance with WHO policy, all PIP Framework Advisory Group members completed the “WHO Declaration of Interests for WHO Experts”. Pursuant to WHO guidelines, their declarations were reviewed and assessed for real, potential or apparent conflicts of interest before being appointed to serve as members of the PIP Framework Advisory Group. At the start of the meeting, all participants were asked to confirm their interests, and to provide any additional information that could be relevant to the subject matter of the meeting. The experts participating in the Advisory Group meeting were, by WHO region:

Africa:
- Dr William Ampofo (Ghana)
- Dr Hama Issa Moussa (Niger)
- Dr Adrian Puren (South Africa)

Americas:
- Dr Jarbas Barbosa da Silva Jr (Brazil)
- Dr Rainer Engelhardt (Canada)
- Mr David E. Hohman (United States of America)

South-East Asia:
- Dr P.V. Venugopal (India)
- Professor Tjandra Aditama (Indonesia)
- Professor Prasert Thongcharoend (Thailand)

Eastern Mediterranean:
- Dr Amr M. Kandeel (Egypt)
- Professor Ziad A. Memish (Saudi Arabia)

Europe:
- Dr Silvia Bino (Albania)
- Professor Didier Houssin (France)
- Professor Oleg Kiselev (Russian Federation)

Western Pacific:
- Professor Wang Yu (China)
- Dr Nobuhiko Okabe (Japan)
- Dr Mark Jacobs (New Zealand)

1 Professor Rajae El Aouad (Morocco) was unable to attend the meeting.
No interests declared by members of the Advisory Group were deemed relevant as a conflict of interest matter to the work of the group in the meeting.