

# **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 Sixty-fifth World Health Assembly, for its consideration, the report of the Pandemic Influenza Preparedness Framework Advisory Group, which reflects its deliberations during its second meeting in February 2012 (see Annex).



ANNEX

**MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS  
FRAMEWORK ADVISORY GROUP  
22–24 FEBRUARY 2012, GENEVA, SWITZERLAND**

**Report to the Director-General**

**ORGANIZATION AND PROCESS OF THE MEETING**

1. The second meeting of the Advisory Group took place at WHO headquarters in Geneva, 22–24 February 2012, with the following revised provisional agenda:

1. Registration
2. Declarations of interest
3. Welcome remarks from Chair
4. Adoption of agenda
5. Information on Technical Consultation on H5N1 Research Issues
6. Partnership Contribution background presentations: Pandemic vaccine and antiviral deployment during the 2009 pandemic: Gaps identified and lessons learnt to improve future responses
7. Update on SMTA 2 including “interim” process for transferring PIPBM
8. Discussion of Guiding Principles for the use of Partnership Contribution
9. Country classification lists
10. Discussion of “Proposals for the potential uses of the PIP Partnership Contribution for pandemic preparedness and response”
11. Discussion questions for consultations with industry and other stakeholders
12. Finalize preparations for consultations with stakeholders and industry on the Partnership Contribution
13. Discussion with other stakeholders: Use of the Partnership Contribution
14. Discussion with industry associations (IFPMA, DCVMN and Bio) on Guiding principles for annual contributions to the Partnership Contribution
15. Discussion with manufacturers: Use of the Partnership Contribution

16. Presentation: GISRS functions and operations
17. Discuss and finalize comments on “Proposals for the potential uses of the PIP Partnership Contribution for pandemic preparedness and response”
18. Discussion: Preparations for Annual Report to the Director-General
19. Review and approve Advisory Group Meeting Report
20. Next steps and close of meeting

2. Of the 18 members of the Advisory Group, 15 were present. The list of meeting participants is found in Appendix 1.

3. The WHO Principal Legal Officer reviewed the process for Declarations of Interests. The summary of Declarations of Interest is found in Appendix 2.

4. The Chair made a number of introductory remarks. The Advisory Group adopted the revised provisional agenda.

### **Information on Technical Consultation on H5N1 Research Issues**

5. The Assistant Director-General, Health Security and Environment (HSE) summarized the proceedings and outcomes of the WHO Technical Consultation on H5N1 Research Issues, 16–17 February 2012. The consultation noted the role of the PIP Framework in global preparedness and response.

### **Pandemic vaccine and antiviral deployment during the 2009 pandemic**

6. The Assistant Director-General, Innovation, Information, Evidence and Research (IER), and the Acting Coordinator, Antimicrobial Resistance, Infection Control and Publications, Department of Pandemic and Epidemic Diseases (PED) made presentations on the deployment of pandemic vaccines and antiviral medicines, respectively, during the 2009 pandemic. The presentations focused on gaps identified and lessons learnt to improve future responses.

7. The Advisory Group was informed about several factors that contributed to delays in deploying vaccine to potential recipient countries. The discussions underscored that preparedness to access and distribute pandemic vaccine requires a broad and multi-faceted approach that spans legal, regulatory and logistics measures.

8. Deployment of the WHO global rapid response stockpile of oseltamivir was accomplished quickly due in part to the existence of a WHO stockpile and extensive operational planning and procedures that were in place prior to the pandemic.

### **Update on SMTA 2 including “interim” process for transferring PIPBM**

9. The Assistant Director-General, HSE updated the Advisory Group on two issues related to the Framework Standard Material Transfer Agreement 2 (SMTA 2): (1) the transfer of pandemic influenza preparedness biological materials (PIPBM) to entities outside of the Global Influenza Surveillance and Response System (GISRS); and (2) the status of negotiations to conclude SMTA 2s.

10. The Secretariat explained that SMTA 1, Article 4.3, provides that “the Provider [of PIPBM] consents to the onward transfer and use of PIPBM to entities outside GISRS on the condition that the prospective recipient has concluded an SMTA 2.” The Framework, including its annexes, came into effect when it was adopted by the World Health Assembly in May 2011.

11. The Secretariat informed the Advisory Group that work to begin SMTA 2 negotiations has continued. Draft template agreements that could be used for negotiations have been prepared. WHO is engaged in ongoing discussions with Member States to identify necessary human and financial resources, including legal support, for negotiation of SMTA 2s.

12. The Secretariat reported that since the adoption by the World Health Assembly of the Framework in May 2011, GISRS laboratories have received requests for PIPBM from entities outside GISRS. Direct application of Article 4.3 would result in complete cessation of sharing PIPBM until WHO and recipients have concluded SMTA 2 agreements. In view of this, WHO considered three approaches: (1) cease sharing PIPBM until an SMTA 2 is concluded with each recipient requesting PIPBM; (2) transfer PIPBM with no conditions; or (3) permit, as an interim approach, for a transitional period, transfer of PIPBM under certain conditions. WHO exercised this last approach (i.e. approach (3), for reasons of public health and to meet the spirit of the Framework, and indicated in the Information Note issued to WHO Collaborating Centres (CCs), that if recipients wish to receive PIPBM, they will enter into discussions with WHO on an SMTA 2.

13. The Advisory Group observed that the spirit of the Framework is trust and balance between virus sharing and benefit sharing. The Advisory Group noted that sharing of PIPBM is critical for health security and must continue. However, for the sake of benefit sharing, the incentive to conclude SMTA 2s cannot be lost.

14. *Advice to the Director-General on SMTA 2 including “interim” process for transferring PIPBM*

1. The Secretariat should on a priority basis begin discussions on at least one SMTA 2 as soon as possible, and no later than the Sixty-fifth World Health Assembly.

2. The Secretariat should obtain the necessary human and financial resources, including legal support, to negotiate SMTA 2s and the Director-General should further encourage Member States to provide such support.

3. The Advisory Group understands the reasons that have led to the interim approach contained in subparagraph 12(3) and recommends that the Secretariat should elaborate a practical, balanced and uniform approach for the transitional period to obtain recognition from recipients of PIPBM outside GISRS that they will enter into discussions with WHO on an SMTA 2. If an SMTA 2 is not concluded with the recipient within six months after the beginning of negotiations, no further PIPBM will be transferred to that recipient.

### **Guiding principles for the use of the Partnership Contribution**

15. The Advisory Group reviewed relevant parts of the Framework and considered guiding principles that could inform the development of its advice to the Director-General. The principles are fairness, equity, public health risk and need, and the particular vulnerability of countries affected by H5N1.

## Country classification lists

16. As requested by the Advisory Group, the Coordinator of Influenza and Respiratory Diseases, Hepatitis and the PIP Framework (PED), presented an overview of internationally recognized systems that categorize countries according to economic, health, social and/or development indicators. The Advisory Group discussed how such information may be of potential use in identifying countries that could benefit from Partnership Contribution resources.

## Proportional allocation of Partnership Contribution resources between preparedness and response (Framework Section 6.14.5)

17. The Advisory Group noted one of the conclusions from the review of the functioning of the International Health Regulations (2005) (IHR) and the pandemic response completed in 2011<sup>1</sup> which states that the world is ill-prepared for a severe pandemic. The Group also considered lessons learnt from the H1N1 2009 pandemic, which demonstrated that implementation of response measures, such as access to vaccines, would be enhanced with advance preparation. The Group stressed the need to achieve the greatest impact by building capacity in countries where it is lowest and observed that preparedness requires long-term investment, particularly when capacity building requires training and transfer of knowledge. Finally, the Group noted that the full implementation of the Framework will provide access to quantities of pandemic vaccines and antiviral drugs necessary to establish a response. In view of these considerations the Advisory Group provided the following advice to the Director-General.

### 18. *Advice to the Director-General on proportional allocation of the Partnership Contribution*

1. In the early phases of the Framework's implementation, more of the Partnership Contribution should be used for preparedness than for response.
2. Specifically, over the next five years (2012 through 2016) approximately 70% of contributions should be used for pandemic preparedness measures and approximately 30% should be reserved for response activities, recognizing the need and usefulness of flexibility in allocating funds.
3. In order to ensure that the proportional division does not hinder necessary response measures during pandemic influenza emergencies, the Director-General should be able to temporarily modify the allocation of Partnership Contribution resources as required to respond to said emergencies. The Director-General should report on any such modification to Member States.
4. The proportional division should be reviewed again in 2016.

## Discussions with stakeholders, industry associations and manufacturers

19. The Advisory Group held consultations with stakeholders, representatives of industry associations, and manufacturers on the Partnership Contribution (see Appendix 3 for a list of participants). The Director-General made several interventions. The Chair invited all participants to submit their views in writing. The following views were expressed, inter alia:

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<sup>1</sup> The report is available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA64/A64\\_10-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf).

- Partnership Contribution resources should be directed more to pandemic preparedness than to response.
- A key focus of preparedness should be building influenza surveillance and laboratory capacity in developing countries, including improving the coverage of National Influenza Centres (NICs) and WHO CCs, with a view to optimal strategic geographical balance among regions, transfer of technology, training of staff, and long-term sustainability.
- The importance of national regulatory activities and the WHO prequalification process was underlined with the view of accelerating access to drugs and vaccines.
- The Secretariat should begin SMTA 2 negotiations as soon as possible.
- Implementation of the Framework should be as transparent as possible.
- There was general agreement that such interactions should continue on an annual basis.

### **GISRS functions and operations**

20. The Secretariat provided an overview of GISRS functions and operations. The presentation provided information on the component laboratories in GISRS and their main responsibilities; these include surveillance, risk assessment, the Influenza Virus Traceability Mechanism (IVTM), and influenza vaccine virus selection and development.

21. In preparation for its future role regarding the reinforcement of GISRS, the Advisory Group suggested that a self-assessment of GISRS with respect to its role, function and capacities in connection with the Framework be made. Representatives of GISRS present supported this suggestion. The Secretariat should work with relevant GISRS labs to implement this suggestion in an efficient and practical manner.

### **Proposals on use of the Partnership Contribution**

22. The Advisory Group considered the Secretariat's proposals. Based on their discussions as well as comments received during the consultations, the Advisory Group considered that the allocations should:

- take into account Framework principles including fairness, equity, public health risk and need of all Member States, and the particular vulnerability of countries affected by H5N1;
- be evidence-based and consider indicators adapted to the Framework such as IHR core capacities, income, health and epidemiology;
- consider the critical foundation of epidemiological and laboratory surveillance;
- take into account the modest amount of Partnership Contribution resources.

The Advisory Group further considered that:

- The use of Partnership Contribution resources for pandemic preparedness in the Partnership Contribution paper could be revised as follows: 70% to build and/or strengthen surveillance and laboratory capacity; 10% to conduct disease burden studies (not including sustainability

of new influenza vaccine production); 10% to improve access and effective deployment of pandemic vaccines and antiviral medicines; and 10% to strengthen risk communications.

- Resources be directed to all countries subject to the indicators mentioned above (e.g. IHR core capacities, income, health and epidemiology).
- The Director-General should continue, in connection with Section 6.14.3.1 of the Framework, to encourage Member States and other stakeholders to contribute additional funds and in-kind resources. The Director-General should also continue her efforts to encourage Member States to reinforce and maintain epidemiological and laboratory surveillance.

### **Preparations for Annual Report to the Director-General**

23. The Advisory Group discussed the format of the future annual report and considered that a table of actions to be implemented under the Framework should be established.

#### **Next steps**

24. The Advisory Group discussed next steps and future activities. These include:

- an Information Session for Permanent Missions scheduled for 5 March 2012;
- a meeting by audio teleconference to be held 3 May 2012 to discuss revisions to the document on Partnership Contribution and further the development of advice to the Director-General regarding use of the Partnership Contribution;
- a meeting in September 2012 to be held in Geneva to discuss the Annual Report, progress on SMTA 2s, a presentation on GISRS Terms of Reference and progress on the Partnership Contribution.

## Appendix 1

**Pandemic Influenza Preparedness Framework Advisory Group Meeting  
22–24 February 2012****List of Advisory Group participants**

**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

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

**Mr David E. Hohman**, Former Deputy Director, 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, Institutional Support Unit, Ministry of Public Health, Niger

**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

**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 Diseases, South Africa

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

**Dr P. V. Venugopal**, Former Director of International Operations, Medicines for Malaria Venture, Public Health Specialist, India

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

## Appendix 2

**Pandemic Influenza Preparedness Advisory Group Meeting  
22–24 February 2012****Summary of Declarations of Interest by participants**

In accordance with WHO policy, all PIP Framework Advisory Group members completed the “WHO Declaration of Interests for WHO Experts”. In advance of the meeting, all members were asked to confirm the interests they had previously declared, disclose any relevant changes that had intervened subsequently, and provide any additional information that could be relevant to the subject matter of the meeting. Pursuant to WHO guidelines, their declarations were reviewed and assessed for real, potential or apparent conflicts of interest. The experts participating in the Advisory Group meeting were, by WHO region:

## Africa:

- Dr William Kwabena Ampofo (Ghana)
- Dr Hama Issa Moussa (Niger)
- Dr Adrian J. Puren (South Africa)

## Americas:

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

Eastern Mediterranean:<sup>1</sup>

- Dr Amr Mohamed Kandeel (Egypt)

## Europe:

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

## South-East Asia:

- Dr P.V. Venugopal (India)
- Professor Tjandra Y. Aditama (Indonesia)
- Professor Prasert Thongcharoen (Thailand)

Western Pacific:<sup>1</sup>

- Professor Yu Wang (China)
- Dr Nobuhiko Okabe (Japan)

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<sup>1</sup> Dr Rajae El Ouad (Morocco); Dr Ziad A. Memish (Saudi Arabia); and Dr Mark Jacobs (New Zealand) were unable to attend.

In the interest of transparency, the following interests and/or affiliations were deemed relevant to the subject of work and are hereby disclosed:

<b>Name</b>	<b>Interest declared</b>
Dr William Kwabena Ampofo	Affiliated with a GISRS laboratory
Dr Hama Issa Moussa	Civil Servant
Dr Adrian J Puren	Civil Servant
Dr Jarbas Barbosa da Silva Jr	Civil Servant
Dr Rainer Englehardt	Civil Servant
Dr Amr Mohamed Kandeel	Civil Servant
Dr Silvia Bino	Affiliated with a GISRS laboratory
Professor Oleg Ivanovich Kiselev	Affiliated with a GISRS laboratory
Professor Tjandra Y Aditama	Civil Servant
Professor Yu Wang	Civil Servant
Dr Nobuhiko Okabe	Civil Servant

No other interests declared by members of the Advisory Group were deemed relevant to the work of the group.

## Appendix 3

**Pandemic Influenza Preparedness Framework Advisory Group Meeting  
22–24 February 2012****Consultation with civil society organizations and other stakeholders:  
participants<sup>1</sup>**

- Knowledge Ecology International
- People's Health Movement
- Third World Network
- South Centre (Intergovernmental)

**Consultation with influenza vaccine, diagnostic  
and pharmaceutical manufacturers and industry associations:  
participants<sup>2</sup>**

- Abbott Biologicals
- AdvaMedDx
- Baxter
- Becton Dickinson
- Biken
- Biotechnology Industry Organization (Bio)
- CSL Limited
- Denka Seiken Co., Ltd.
- Developing Countries Vaccine Manufactures Network (DCVMN)
- Green Cross Corporation
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Japan Pharmaceutical Manufacturer Association
- Kitasato Daiichi Sankyo Co., Ltd.
- Novartis International AG
- Protein Science Corporation
- Sanofi Pasteur
- The Chemo-Sero-Therapeutic Research Institute (Kaketsuken)

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<sup>1</sup> An additional three civil society organizations/other stakeholders pre-registered to link into the consultation via video streaming; however, it is not possible to verify if they participated.

<sup>2</sup> An additional nine companies pre-registered to link into the consultation via video; however, it is not possible to verify if they participated.