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

Report of the meeting of the Pandemic Influenza Preparedness Framework Advisory Group

Report by the Director-General

1. The Director-General has the honour to transmit to the Sixty-sixth World Health Assembly the report of the Pandemic Influenza Preparedness Framework Advisory Group. The Advisory Group met in Geneva from 20 to 22 March 2013 to review progress on implementation of the Framework, notably: progress by the Secretariat in negotiating and concluding Standard Material Transfer Agreements-2 and in developing the Partnership Contribution. The Advisory Group also held consultations with industry and other stakeholders to discuss the use of Partnership Contribution resources. The deliberations and recommendations of the Advisory Group are contained in the attached report (see Annex).
ANNEX

MEETING OF THE PANDEMIC INFLUENZA PREPAREDNESS (PIP) FRAMEWORK
ADVISORY GROUP

20-22 MARCH 2013, GENEVA, SWITZERLAND

Report to the Director-General

ORGANIZATION AND PROCESS OF THE MEETING

1. The Advisory Group met at WHO headquarters in Geneva, 20-22 March 2013, with the following agenda:

   1. Registration
   2. Welcome remarks from the Chair
   3. Declarations of Interest
   4. Adoption of agenda
   5. SMTA-2
      - Update on-going negotiations
      - Review of GSK agreement
   6. Review of PIP Framework-related tasks/activities table and recommendations concerning the continuity of the activities
   7. Partnership Contribution (PC)
      - Review of 2012 results
      - Update on process to identify contributors for 2013
   8. Partnership Contribution
      - Review of draft implementation plan
   10. Preparations for meetings with industry and other stakeholders
11. Meeting with industry on Partnership Contribution
   • Update on Partnership Contribution
   • Use of the Partnership Contribution

12. Meeting with other stakeholders on Partnership Contribution
   • Update on Partnership Contribution
   • Use of the Partnership Contribution

13. Joint session with industry and other stakeholders: Use of Partnership Contribution

14. Review outcomes of meetings

15. Technical matters:
   • Update on the Global Influenza Surveillance and Response System (GISRS) self-assessment
   • Overview of GISRS Terms of Reference (TORs)
   • Brief update on GISRS surveillance
   • Update on experience arising from the use of the definition of PIP Biological Materials, 7.4.1 (v)

16. Update on SAGE discussions of influenza vaccine

17. Update on novel coronavirus

18. Review and approve Meeting Report

19. Next steps
   • Next meeting of the Advisory Group
   • Election of the new Chair and Vice-Chair
   • Any other business

20. 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 Chair made a number of introductory remarks.

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

5. The Chair asked Dr William Ampofo to provide a brief summary of the GAP Advisory Group meeting discussions held on 19 March 2013, in Dubai, United Arab Emirates. The Advisory Group adopted the agenda with this addition.
SMTA-2: Update on on-going negotiations

6. The PIP Secretariat updated the Advisory Group on the status of Standard Material Transfer Agreement 2 (SMTA-2) negotiations. One SMTA-2 has been concluded with Glaxo Group Limited (GSK). Negotiations are underway with three other manufacturers: Baxter, China National Biotec Group (CNBG) and the Serum Institute of India (SII) and pre-negotiation discussions are on-going with two large manufacturers (Sanofi and Novartis). The complex and time-consuming work to negotiate and conclude SMTA-2s as well as the lack of resources – both human and financial – to scale up the pace of negotiations was noted.

7. The Secretariat brought to the attention of the Advisory Group several of the issues raised during negotiations with vaccine manufacturers:

1. Concern over delivery of vaccines during pandemic times
   - Vaccine manufacturers expressed concern about their ability to export vaccines from the country of production in pandemic times.

2. Minimum percentage commitments under A1 and A2¹
   - Vaccine and antiviral manufacturers must commit to two of six options. In discussions with two developing country influenza vaccine manufacturers (in China and in India), both have indicated that they are ready to commit to a donation under A1 and a reserve under A2 for a total commitment of 10% of their real-time pandemic vaccine production.

   • This raises the issue of how to apportion the amounts allocated to A1 and A2.

   • Given that under A2, WHO will need to pay for any doses of vaccine that are accepted, the Secretariat has sought to reduce the amount of commitments under A2 and increase the amount of donation under A1.

   • This would mean, however, that the 5% minimum indicated in footnote 1 of the model SMTA-2 found in Annex 2 of the PIP Framework would not be respected.

2. Prequalification
   a. During the discussions with the two developing country influenza vaccine manufacturers, the issue of pre-qualification was raised.

   b. Manufacturers are interested in gaining pre-qualification and wish to have a better understanding of the process.

8. The Advisory Group expressed its deep appreciation for the work of the PIP Secretariat in concluding an SMTA-2 agreement as well as ongoing work in negotiating additional SMTA-2s.

¹ See PIP Framework, Annex 2 Article 4.1.1 for a description of options A1-A6 under SMTA-2 for manufacturers of vaccines and/or antivirals.
Advice to the Director-General on the SMTA-2

9. The Advisory Group recalled that one of the principal objectives of the PIP Framework is to provide Member States in need access to pandemic vaccines and other benefits. In view of this, the Advisory Group recommended that the Director-General:

- Seek assurances, in an appropriate manner, from Member States, to ensure that pandemic products (i.e. vaccines, antivirals, diagnostics) produced in their territory during a pandemic, which companies agreed to provide to WHO through SMTA-2 agreements, are delivered to WHO so the products can be made available to countries in need.

- Facilitate, including in consultation with Member States, and in ways consistent with the spirit of the PIP Framework, maximization of donations of pandemic influenza vaccine (A1) through concomitant reduction of reservations of vaccine (A2) which will need to be purchased by WHO.

  - This could be accomplished as part of SMTA-2 negotiations by permitting some manufacturers to commit to reserve less than 5% under A2 on the condition that there is a concomitant increase in their donation under A1 so that their total commitment (A1 and A2) is at least 10%.

  - The flexibility to reduce a commitment below 5% would apply only to A2 (vaccine reserve), not A1 (vaccine donation).

- Strongly encourage manufacturers to consider options A5 and A6, the Advisory Group having noted that to date, these two options were not proposed by them.

- Accelerate the conclusion of SMTA-2s to ensure access to pandemic influenza vaccines.

SMTA-2: Review of the GSK agreement

10. The Advisory Group reviewed the GSK agreement. Because the GSK agreement included certain proprietary information, each member of the Advisory Group signed a Supplementary Confidentiality Undertaking prior to reviewing the WHO-GSK SMTA-2 agreement.

11. The Advisory Group noted the document.

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1 These provisions are, respectively, as follows:

  A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.

  A6. Grant royalty-free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on granted licenses and the status of implementation of the licensing agreement. WHO shall provide such information to the Advisory Group.

Review of PIP Framework-related tasks/activities table and recommendations concerning the continuity of the activities

12. The Advisory Group proposed a number of suggestions for the tasks/activities table. The table should provide more details such as:

- Quantitative indicators
- Progress on implementation, including delays

13. It was agreed that the table was a useful internal document for the Advisory Group and WHO to track implementation of PIP Framework. It can also help to inform the development of the Advisory Group’s Annual Report and preparations for the review of the PIP Framework in 2016. The Advisory Group noted that additional tools will need to be developed to monitor and assess the effectiveness of implemented activities.

Partnership Contribution: Review of 2012 results

14. The PIP Secretariat reported on its work to develop, in collaboration with industry, the Pandemic Influenza Preparedness Framework: Proposal for distribution of Partnership Contribution among companies. Although this proposal was not finalized in 2012, through the voluntary contributions of 7 manufacturers in 2012, US $18.121 million was received under the Partnership Contribution.

Partnership Contribution: Update on the process to identify contributors for 2013

15. The PIP Secretariat posted the 2013 Questionnaire to identify influenza vaccine, diagnostic and pharmaceutical manufacturers using WHO Global Influenza Surveillance and Response System (GISRS) under Section 6.14.3 of the PIP Framework on the PIP website on 18 March 2013; it will close on 18 April 2013.

16. Following discussions with industry on 13 February 2013, the Secretariat has revised the Pandemic Influenza Preparedness Framework: Proposal for distribution of Partnership Contribution among companies and shared it with industry. The PIP Secretariat will apply the formula to secure 2013 PC funds.

17. The PIP Secretariat also provided the Advisory Group a copy of the draft Partnership Contribution Standard Operating Procedures which include procedures for identification of manufacturers using GISRS, application of the PC formula, and securing of PC funds.

Partnership Contribution: Review of draft implementation plan

18. The Assistant Director-General (ADG), Health Security and Environment, provided an overview of PIP Framework Partnership Contribution: Implementation Plan 2013-2016. The document is a proposed general approach to use the PC in the four pandemic preparedness areas of focus: strengthening laboratory and surveillance; conduct of burden of disease studies; regulatory enhancement and risk communications. He emphasized the need for robust monitoring, evaluation and accountability. The plan does not include activities related to pandemic response, which the Secretariat will need to address in the future.

19. The ADG asked the Advisory Group for its guidance on the general direction, scope and focus of the implementation plan for preparedness activities.
20. The Advisory Group, in its extensive discussion of the proposed approach, raised a number of points for inclusion in a subsequent more detailed version of the implementation plan, including:

- Quantitative indicators, or defined measures of success, to monitor results, evaluate outputs, measure impacts
- A detailed, multi-year plan that includes roles and responsibilities, estimated budgets, and a notional implementation calendar
- Clear and transparent accounting mechanism(s) for PC resources
- A gap analysis
- A risk analysis

21. The Advisory Group also noted that due to the complexity of implementing projects in all four focus areas at once, the Secretariat should consider sequential rather than simultaneous implementation of activities. The Advisory Group also underscored the merit in identifying one or more projects that could produce demonstrable results over a short period of time (i.e. “quick wins”) as many of the projects are envisioned to run over several years; finally, the Group suggested that projects should be modular and scalable to offer more flexibility.

22. The Group highlighted the importance of considering the sustainability of capacities strengthened or built with PC funds when deciding where projects will be implemented. The Secretariat concurred with these points and will work to balance the number of projects and the timing of their implementation.

23. The Advisory Group raised concerns about the human and financial resource implications for the PIP Secretariat and regional offices with regard to implementing complex PC projects.

Summary of GAP meeting

24. Dr William Ampofo provided an overview of discussions at the recent GAP Advisory Group meeting on linkages between the PIP Framework and GAP related to vaccine production, including regulatory capacity issues.

Meetings with industry and other stakeholders on the PC

25. The Advisory Group met with representatives of industry associations, manufacturers, and stakeholders (see Appendix 3 for the list of participants). The Secretariat provided a review of the voluntary donations received in 2012; the process to identify PC contributors for 2013; and the draft of the *PIP Framework Partnership Contribution: Implementation Plan 2013-2016*. The following views were expressed, *inter alia*:

- The Advisory Group expressed its sincere gratitude to industry for their voluntary contributions in 2012.

- Industry reaffirmed its commitment to provide fair and equitable annual contributions to the PC.

- Industry noted the general consensus on the goals presented by the ADG in his presentation on the PC implementation plan.

- Both industry and other stakeholders noted the importance of having PC-funded activities build on existing initiatives such as the International Health Regulations (IHR) and the Global Action Plan for Influenza Vaccines (GAP) where appropriate to avoid overlap or duplication of work.
Both industry and stakeholders supported the development of a comprehensive plan of work for use of the PC funds and requested the opportunity to have input into the plan.

Industry proposed that a “supply chain-like gap analysis” from identification of virus to development and supply of pandemic vaccine be done prior to implementation of PC activities.

Industry and civil society emphasized that any entity using GISRS needs to be identified as a contributor to the annual PC.

Industry and stakeholders stressed that PC funds should be used to supplement, and not replace, usual funding sources for pandemic preparedness activities.

Both industry and civil society supported the idea that some of the PC funds be used to support the Secretariat.

Advice to the Director-General on the Partnership Contribution

26. The Advisory Group expressed its gratitude and appreciation for the very significant voluntary donations received in 2012 under PIP Framework section 6.14.3.1. It welcomes the efforts made by the Secretariat to secure contributions in 2013 from all contributors identified. The Advisory Group recommended to the Director-General to:

- Continue efforts to identify all entities who should be contributing PC
- Send the Questionnaire and follow-up with companies identified to obtain responses
- Apply the formula and send invoices to receive payments in 2013

Use of Partnership Contribution

27. The Advisory Group supported the overall general approach presented by the PIP Secretariat in PIP Framework Partnership Contribution: Implementation Plan 2013-2016 and requested that the Secretariat conduct the analytic and other preparatory work needed to develop the detailed work plans, in 2013, while noting the need for:

- Coherence with other WHO programs such as IHR and GAP;
- Time-phased project design, budget, and management plans. (These should be scalable, and should incorporate identification and mitigation of potential risks, and include indicators to monitor progress and outcomes);
- Strategies that promote achievement of tangible results as rapidly as possible;
- Sustainability of outcomes.

28. The Advisory Group noted with extreme concern that the current staffing capacity of the PIP Secretariat is inadequate to continue and efficiently complete implementation of Framework components, notably to:

- Negotiate SMTA-2s with recipients of PIP Biological Materials;
- Coordinate and communicate with WHO programs, Regional offices, Member States, industry and other stakeholders;
- Secure annual PC funds;
- Develop detailed PC implementation plans
- Supervise and monitor activities underway both at headquarters and in the regions.
29. The Advisory Group is aware that WHO has been unable so far to mobilize sufficient resources to undertake this work in a timely and predictable fashion, and unanimously agreed that it is necessary to strengthen the PIP Secretariat with additional resources for both headquarters and in the regional offices, including use of PC. This was further discussed during the consultations with industry and other stakeholders, and supported by them. These additional resources, resulting from donations or contributions, should allow for scalability of the work of the PIP Secretariat. This will enable work, either ongoing but at risk, or not yet undertaken because of lack of funds, to be made possible and required to meet the objectives of the PIP Framework. The Advisory Group further noted that use of the PC funds for this effort should not replace the need for Member States and other donors to continue to support the work of the Secretariat in implementing the PIP Framework. In view of this the Advisory Group recommended that the Director-General:

- Direct a portion of PC funds, not exceeding 10%, averaged over the next 4 years (2013-2016), to the PIP Secretariat for this purpose;
- Use the PC funds in a manner that is faithful to the principles of good governance and accountability at all levels;
- Continue to work with Member States to encourage their support of the wide implementation of the PIP Framework, including through the provision of additional resources.

Technical matters

30. GISRS self-assessment: An informal virtual working group has been established comprised of headquarters, regional offices and GISRS representatives. A simplified approach, necessitated by reduced financial resources, is planned: 1) a questionnaire survey will be sent to all WHO GISRS laboratories and 2) all GISRS Collaborating Centres (CCs), Essential Regulatory Laboratories (ERLs), and a subset of National Influenza Centres (NICs) will be interviewed; a subset of external partners will be interviewed if resources permit. A report is planned for October 2013 that will be shared with the Advisory Group. The Advisory Group requested that they be given the opportunity to provide input into the questionnaire and interview documents under development.

31. Overview of GISRS TORS: The current TORs for WHO GISRS laboratories have not changed and are working well. The Secretariat provided the Advisory Group draft TORs for a new category of WHO CCs under GISRS: WHO Collaborating Centres for Influenza at the Human-Animal Interface (CCHAI). The Advisory Group suggested that: 1) more information be included in the Background section about the need for this category of laboratories; and 2) veterinary laboratories be added to Core TOR A.9. The Advisory Group noted the difficulty likely to be faced by countries that have an interest in applying to become a CCHAI. The Group encouraged the Secretariat to find ways to support capacity building in countries that are engaged in human-animal interface work and are committed to achieving the TORs for the CCHAI. The Advisory Group indicated that it wished to revisit the subject of the CCHAI and the draft TORs at a future meeting.

32. Brief update on GISRS surveillance: As part of the update, the Secretariat reported that reductions in financial support for the Shipping Fund Project have resulted in fewer shipments of viruses in the WHO GISRS. This in turn reduces the number of viruses available to GISRS to conduct risk assessment.
33. **Update on the experience arising from the use of the definition of PIP Biological Materials, 7.4.1 (v):** The Secretariat reported that WHO CCs and ERLs have found the advice provided by the Advisory Group in October 2012 on the definition of PIP Biological Materials to be very helpful; the definition of PIP Biological Materials in their view is appropriate and has resulted in improved efficiency.

34. The Advisory Group noted that mapping of current gaps in the WHO GISRS such as countries’ access to CCs, NICs or reference labs may help target laboratory strengthening activities under the PC.

**Update on SAGE discussions of influenza vaccine stockpile**

35. Framework Section 6.9.2 requires the Director-General to establish a stockpile of 150 million doses of H5N1 vaccine for use in accordance with expert guidance including that provided by Strategic Advisory Group of Experts on Immunization (SAGE). Prior to the 2009 H1N1 pandemic, two vaccine manufacturers had pledged a voluntary donation of a total of 110 million doses of H5N1 vaccine to WHO to rapidly contain an emerging H5N1 pandemic. One of these manufacturers recently concluded an SMTA-2 with WHO and cancelled its voluntary pledge of H5N1 vaccine for the stockpile given its commitment to provide pandemic vaccine under the SMTA-2. It is expected that the second manufacturer will do the same.

36. SAGE is expected to consider issues related to the WHO stockpile, including appropriate size, composition, and operational use, in late 2013 or early 2014.

**Update on novel coronavirus**

37. The Secretariat provided an update on the novel coronavirus. WHO continues to work with countries in gathering additional virological, clinical and epidemiological information about the virus.

**Review and approval of meeting report**

38. The Meeting Report was adopted unanimously by the Advisory Group after review of an electronic copy subsequent to the meeting.

**Next steps**

**Future meetings**

39. The Advisory Group will convene by audio-conference in early May 2013; agenda items include an update on the PC implementation plan and the GISRS self-assessment questionnaire.

40. The Advisory Group will meet in Geneva on 7-9 October 2013. Agenda items include:
   - Overview of issues related to the Human-Animal Interface within the context of the PIP Framework
   - Discussion on diagnostic tools
   - Annual Report
   - Gap analysis for PC
   - Election of a new Chair and Vice-Chair
Appendix 1

Pandemic Influenza Preparedness Framework Advisory Group Meeting

20–22 March 2013

List of Advisory Group participants

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, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada, 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 Mark Jacobs, Director of Public Health, Ministry of 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

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

Dr Adrian J Puren, Deputy Director, 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

Dr Yu Wang, Director General, Chinese Center for Disease Control and Prevention, China
Appendix 2

Pandemic Influenza Preparedness Advisory Group Meeting

20-22 March 2013

Summary of Declarations of Interest by members

In accordance with WHO policy, in advance of the meeting, all PIP Framework Advisory Group members were asked to provide a duly completed Declaration of Interests to inform WHO about real, potential or actual conflicts of interests that they might have in relation to the subject matter of the meeting. Over the course of the meeting, the Advisory Group discussed, reviewed, or provided updates on the following matters:

• SMTA 2s
• Partnership Contribution
• Technical matters related to virus sharing, GISRS Terms of Reference and the SAGE review of matters related to the H5N1 vaccine stockpile.

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 Engelhardt (Canada)
• Mr David E Hohman (United States of America)

Eastern Mediterranean:

• Dr Rajae El Aouad (Morocco)
• Dr Amr Mohamed Kandeel (Egypt)

Europe:

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

1 Dr Ziad A Memish (Saudi Arabia), Professor Tjandra Y Aditama (Indonesia) and Dr Nobuhiko Okabe (Japan) were unable to attend.
South-East Asia: ¹
- Dr P V Venugopal (India)
- Professor Prasert Thongcharoen (Thailand)

Western Pacific: ¹
- Dr Mark Jacobs (New Zealand)
- Dr Yu Wang (China)

The following interests and/or affiliations were disclosed to the Secretariat and are relevant to the subject of the Advisory Group’s work:

<table>
<thead>
<tr>
<th>Name</th>
<th>Interest declared</th>
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<tbody>
<tr>
<td>Dr William Kwabena Ampofo</td>
<td>Affiliated with a GISRS laboratory</td>
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<tr>
<td>Dr Rajae El Aouad</td>
<td>Civil Servant</td>
</tr>
<tr>
<td>Dr Hama Issa Moussa</td>
<td>Civil Servant</td>
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<tr>
<td>Dr Adrian J Puren</td>
<td>Civil Servant</td>
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<tr>
<td>Dr Jarbas Barbosa da Silva, Jr</td>
<td>Civil Servant</td>
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<tr>
<td>Dr Rainer Engelhardt</td>
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<tr>
<td>Dr Amr Mohamed Kandeel</td>
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<td>Civil Servant</td>
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<tr>
<td>Dr Yu Wang</td>
<td>Civil Servant</td>
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<tr>
<td>Professor Prasert Thongcharoen</td>
<td>Professor Prasert Thongcharoen received a consultancy honorarium and round trip ticket to attend a meeting from a vaccine manufacturer. In addition, the institution with which Professor Thongcharoen is affiliated received funding from a vaccine manufacturer to conduct research on H5N1 vaccine development. Neither the consultancy honorarium nor the research work were deemed to be directly related to the work of the PIP Advisory Group meeting because the Advisory Group is not discussing or making recommendations on vaccine development.</td>
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The interests declared by Professor Prasert Thongcharoen were reviewed by WHO and determined not to present a conflict of interest with the objectives of the meeting. No other interests declared by members of the Advisory Group were deemed relevant to the work of the group.

¹ Dr Ziad A Memish (Saudi Arabia), Professor Tjandra Y Aditama (Indonesia) and Dr Nobuhiko Okabe (Japan) were unable to attend.
Appendix 3

Pandemic Influenza Preparedness Framework Advisory Group Meeting

20-22 March 2013

Civil society organizations and other stakeholders:

Participants

• Berne Declaration
• Third World Network

Manufacturers and industry associations:

Participants

• AdvaMedDx
• Denka Seiken Co., Ltd.
• International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
• Kaketsuken
• Kitasato Daiichi Sankyo Co., Ltd.
• Research Foundation for Microbial Diseases of Osaka University

1 Adimmune, Baxter, Biotechnology Industry Organization (Bio), China National Biotec Group Company Limited (CNBG), and PT Bio Farma (Persero) followed the meeting via audio-conferencing. An additional three listeners linked into the meeting with manufacturers and industry associations via audio-conferencing, however it was not possible to determine their identity.

2 One listener linked into the joint meeting with manufacturers/industry associations and civil society organizations/other stakeholders via audio-conferencing, however it was not possible to determine their identity.