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

15-16 October 2015, GENEVA, SWITZERLAND

Report to the Director-General

Organization and process of the meeting

1. The Advisory Group (AG) met at WHO headquarters in Geneva, 15-16 October 2015. The meeting was preceded by the Special Session of the Advisory Group that took place 13-14 October, addressing the upcoming 2016 Framework review.

2. Of the 18 members of the AG, 14 were present. The list of participants in the meeting is available in Annex 1.

3. Declarations of interest were reviewed by the Secretariat and relevant interests were disclosed. The Statement of Declarations of Interests is available in Annex 2.

4. The agenda of the AG meeting is available in Annex 3.

5. Industry and other stakeholders joined the AG for the morning of 15 October 2015 and received updates from the Secretariat on the work that has taken place since the last meeting in April 2015.

Update and discussion on Standard Material Transfer Agreements 2 (SMTA2s)

6. The Secretariat provided an update on the process to conclude SMTA2s, to the AG, industry and stakeholders. While the number of contracts under Category A remains the same, many negotiations are under way. The Secretariat shared many of the challenges it has encountered and requested guidance from the AG, industry and stakeholders.

7. The Secretariat also presented benefit sharing proposals from one Category A and several Category B manufacturers to the AG only. These proposals were discussed in detail and guidance was provided to the Secretariat on the next steps for advancing these proposals. The AG developed recommendations to the Director-General. In so doing, the AG underlined that manufacturers should be clearly informed that access to PIP Biological Materials (PIP BM) may be suspended if agreement cannot be reached on reasonable benefit sharing commitments.

Recommendations to the Director-General on concluding SMTA2s

8. The AG recommended that where manufacturers engaged in SMTA2 negotiations maintain manifestly unreasonable positions, the Secretariat should use a stepwise approach to remind them that access to WHO GISRS PIP Biological Materials (PIP BM) must, in accordance with SMTA1, be suspended to entities that do not have an SMTA2 with WHO. The stepwise approach would involve, as appropriate:
   - Informal and formal communications, in the first instance, with industry and with manufacturers’ associations.
   - Secretariat dialogue with host governments, and
Direct interventions by WHO senior officials, including the DG, with the manufacturer's senior management.

Recommendations to the Director-General on conclusion of Category B SMTA2s

9. The AG recommended that the Secretariat observe the following principles in its negotiations with manufacturers:
   - Clearly communicate with manufacturers to have them understand the commitments that are required for benefit sharing.
   - Seek a good faith valuation of the contribution of approximately 10% of annual sales, understanding that flexibility in this regard may be appropriate.
   - Convey that WHO retains the right to ask at the time of a pandemic, for either a monetary or in-kind contribution where both options are available.

Update on Partnership Contribution (PC) Collection

10. The Secretariat reviewed progress to collect PC for all years (2012-2015), providing up-to-date collection figures. It was noted that while there are still some funds outstanding from 2013 and 2014, manufacturers on the whole have cooperated in the implementation of this sustainable financing mechanism and should be congratulated.

11. The Secretariat informed that it has increased interactions with industry associations about the PIPF to strengthen knowledge and understanding among manufacturers. The Secretariat summarized a range of challenges relating to PC collection, including, the decreasing response rates to the PC questionnaire and Band Selection Form (BSF).

12. Industry requested that work be undertaken to review the applicable years for the calculation of the sales bands. The Secretariat noted this request and indicated that work will commence in the coming months to address this matter.

Update on PC Implementation

13. The Secretariat provided an overview of 2015 activities that have been undertaken to implement the PC funds. The PIPF Secretariat indicated that USD $30.69M has been distributed to date to six Regional Offices across the five Areas of Work and that of the USD $30.69M distributed, US$ 19.97M has been spent to date. There was a general consensus that PIP activities are beginning to show progress to improve pandemic preparedness, but more needs to be done.

14. The Secretariat informed the AG that it will refine indicators and develop better ways of displaying the achievements of the PIP PC for the 2015 PC Annual Report on implementation. The Secretariat noted that efforts in the next biennium will focus on increasing the number of countries receiving PC funds and technical support, with scale-up of activities across all areas of work.

15. In response to recent questions on the process used to select target countries for PC implementation, the Secretariat reminded stakeholders of the principles that were developed and applied in 2012 to choose target countries, including fairness, equity, and public health need.
16. Industry requested that the Secretariat refine its approach to implementation of elements of the “Critical Path Analysis”. They stressed the need to improve regulatory pathways through targeted regulatory capacity building. Industry appreciated the proactive approach of the Secretariat in this area and reiterated their offers of support to the Secretariat.

**Update and discussion on Virus Sharing**

17. Using data from the Influenza Virus Traceability Mechanism (IVTM), the Secretariat presented to the AG, industry and stakeholders an overview of virus sharing since the adoption of the PIPF. Data indicate that sharing of PIPBM has increased since adoption of the PIPF. However, while the number of viruses shared with WHO Collaborating Centres (WHOCCs) and GISRS laboratories is substantial, the recent trend points to a decrease in the number of viruses being shared. Stakeholders commented that the shipping of viruses is critical and presents a challenge to effective virus sharing.

18. It was noted that an increasing numbers of candidate vaccine viruses have been developed since 2011, and these have been shared broadly with GISRS and non-GISRS laboratories.

19. In its closed meeting, the AG further discussed the matter of virus sharing with the Secretariat. The Secretariat presented further data on the number of confirmed human cases and the number of viruses shared with GISRS. The Secretariat recalled the virus sharing expectations set out in the Framework and explained that there are differing understandings about this matter among Member States. On this basis, the AG agreed on the need to remind Member States of the expectations under the Framework, noting the important role of Regional Offices in this process.

**Recommendations to the Director-General on sharing influenza viruses with pandemic potential**

20. The AG, noting the challenges in the recent sharing of PIP BM, recommended that the WHO make efforts to remind all Member States of their responsibilities under the PIPF to provide PIP BM from all cases of H5N1 and other influenza viruses with human pandemic potential, in a rapid, systematic and timely manner, to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of their choice. Member States should be encouraged to ensure inter-ministerial coordination in this regard.

21. The AG recommended that the Secretariat remind Member States that under the Framework they are expected to share PIP BM, and that sharing genetic sequence data (GSD) alone- while helpful - does not suffice to satisfy this expectation.

**Update on progress to implement recommendations on handling of GSD**

22. The Secretariat presented a summary of AG work on GSD to date, including the work of the Technical Working Group (TWG) on GSD which is focusing on the development of optimal characteristics of a system for sharing GSD of influenza viruses with human pandemic potential (IVPP), as well as options to monitor the use of IVPP GSD in end-products. The Secretariat summarised the deadlines for receipt of written input to the
work under way, encouraging stakeholders to provide feedback to ensure a transparent and interactive process.

**Update on Global Action Plan for Influenza Vaccines (GAP)**

23. An update on the GAP, highlighted synergies between GAP and the PIPF. Overall, global production capacity for influenza vaccines has increased but it still falls short of anticipated need; therefore developing country manufacturers will continue to have a growing role in global influenza vaccine production. Participants discussed the implications of the closure of GAP in 2016, for example, the cessation of technical assistance or financial support to GAP supported manufacturers.

24. The general consensus was that there was need for open discussions on work that needs to continue. The GAP review should address this and findings should be available during the PIP 2016 Review. Stakeholders recommended that caution should be exercised to ensure that if any unfinished GAP work was to be undertaken by PIP, it should fit within the PIP scope.

**Update on Communications and outreach**

25. The Secretariat provided an update on outreach and communications work since the last meeting. A range of products in development were described. These included a communications strategy; revised PIPF Questions & Answers; an SMTA2 fact sheet; the 2015 PC Implementation annual report; and a portal upgrade.

**Review of PIVI proposal**

26. The AG reviewed a concept note submitted by the Partnership for Vaccine Introduction (PIVI) for consideration in light of the sunset of the GAP initiative and on-going work to strengthen pandemic preparedness. The AG agreed that more information should be obtained for a better understanding of how PIVI would align with PIP related activities.

**Review of AG Annual Report to the Director-General**

27. The AG discussed and approved its Annual Report to the Director-General subject to some modifications.

**PIP 2016 Review**

28. The AG recommendations to the DG on the 2016 Review are presented in a separate report.

29. The AG requested the Secretariat to post all Member State statements received from the Special Session on the PIP website in the spirit of full transparency and with a view to sharing these statements with all stakeholders.
Final Comments

30. The AG commended the Secretariat for its work in preparing for the Special Session, noted the considerable level of work being undertaken to negotiate SMTA2s in both categories A and B, and the good response to the enhanced communications and outreach about PIPF, and expressed its appreciation for, and confidence in the Secretariat.

Next steps

31. The AG agreed that its next meeting will take place in the week of 11 April 2016.
Annex 1

Pandemic Influenza Preparedness Framework Advisory Group Meeting
15-16 October 2015

List of Advisory Group participants

Professor William Kwabena Ampofo, Head - Virology, Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana

Professor Chris Baggoley, Chief Medical Officer, Department of Health, Australia

Dr Jarbas Barbosa da Silva, Jr, Director-President of Agencia Nacional de Vigilancia Sanitaria (ANVISA), Ministry of Health, Brazil

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

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

Dr Olav Hungnes, Director, National Influenza Centre, Norwegian Institute of Public Health, Norway

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

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

Dr Cuauhtémoc Mancha Moctezuma, Deputy Director-General of Preventive Programs, National Center for Preventive Programs and Disease Control (CENAPRECE), Ministry of Health, Mexico

Dr Janneth Maridadi Mghamba, Assistant Director – Epidemiology and Program Director of TFELTP, Ministry of Health and Social Welfare, United Republic of Tanzania

Dr Frances McGrath, Chief Advisor, Clinical Leadership, Protection and Regulation, Ministry of Health, New Zealand

Professor Dr Mahmudur Rahman, Director Institute of Epidemiology, Disease Control and Research (IEDCR) & National Influenza Centre, Bangladesh

Dr Huma Qureshi, Executive Director, Pakistan Medical Research Council, Pakistan

Dr P V Venugopal, Former Director of International Operations, Medicines for Malaria Venture, Public Health Specialist, India
Pandemic Influenza Preparedness Advisory Group Meeting
15-16 October 2015
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 form 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 was provided updates on the following matters:

1. 2016 PIP Framework review
2. The Partnership Contribution
   - Inflows of funds
   - Implementation of Preparedness activities
   - Proposals for use of funds
3. Handling genetic sequence data in the context of the PIP Framework
4. SMTA 2s
5. Virus sharing

During the meeting, the Advisory Group also interacted with manufacturers and other stakeholders regarding the implementation of the Framework, including, Partnership Contribution, the 2016 review, and the handling of genetic sequence data.

Members, in the exercise of their functions on the Advisory group, serve in their individual capacity acting as international experts serving WHO exclusively. The experts participating in the Advisory Group meeting were, by WHO region:

Africa:
- Dr William Kwabena Ampofo (Ghana)
- Dr Hama Issa Moussa (Niger)
- Dr Janneth Maridadi Mghamba (United Republic of Tanzania)

Americas:
- Dr Rainer Engelhardt (Canada)
- Dr Jarbas Barbosa da Silva Jr, (Brazil)
- Dr Cuauhtémoc Mancha-Moctezuma (Mexico)

Eastern Mediterranean:
- Dr Huma Qureshi (Pakistan)

Europe:
- Professor Didier Houssin (France)
- Dr Olav Hungnes (Norway)
- Professor Oleg Ivanovich Kiselev (Russian Federation)

South-East Asia:

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1 Dr Amr Mohamed Kandeel (Egypt), Dr Ziad A. Memish (Kingdom of Saudi Arabia), Dr Paba Palihawadana (Sri Lanka), and Professor Yu Wang (China) were unable to attend.
• Professor Dr Mahmudur Rahman (Bangladesh)
• Dr P V Venugopal (India)

Western Pacific:
• Dr Frances McGrath (New Zealand)
• Professor Chris Baggoley (Australia)

Given that discussions in the meeting were on the use or allocation of Partnership Contribution resources, and in the interest of transparency, the following interests and/or affiliations are relevant to the subject of work and are hereby disclosed:

<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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<td>Professor Chris Baggoley</td>
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No comments were received as a result of the Public Notice and Comment period. No other interests declared by members of the Advisory Group were deemed relevant to the work of the group.
Annex 3

Pandemic Influenza Preparedness Framework Advisory Group Meeting
15-16 October 2015

Agenda

1. Consultation with industry, CSOs and databases
   • Implementation Updates
     o SMTAs 2
     o Partnership Contribution Collection
     o Partnership Contribution Implementation
     o Virus Sharing
     o Update on progress to implement recommendations on handling of Genetic Sequence Data (GSD)
     o Communications and outreach
     o Global Action Plan for Influenza Vaccines (GAP)

2. Standard Material Transfer Agreements 2 proposals

3. Update on Virus Sharing

4. Review of PIVI proposal

5. Update on Technical Working Group on the Sharing of Genetic Sequence Data

6. Review Recommendations and Reports

7. Next steps
   • Advisory Group Rotation
   • Next meeting of the Advisory Group
   • Any other business

8. Close of meeting

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