
Open-ended working group: report on progress to date

1. Expressing a sense of urgency the open-ended working group (OEWG) of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits, met in Geneva on 3–4 April 2008. The working group was convened in accordance with the decision of the Intergovernmental Meeting when it met in November 2007, as expressed in the Interim Statement.¹ Ms Jane Halton (Australia), the Chair of the Intergovernmental Meeting, chaired the open-ended working group. Participants included delegates from about 75 Member States, regional economic integration organizations, and a representative of the United Nations (Annex 1).
2. The Director-General delivered opening remarks.
3. After discussion, the open-ended working group adopted the agenda (Annex 2).
4. The Secretariat gave a report on progress with the virus traceability mechanism since the November 2007 IGM. A rapidly convened technical working group developed a web-based electronic interim system, launched on 21 January 2008. The Secretariat outlined plans to develop a Phase II system.
5. Member States welcomed the establishment of the virus traceability mechanism. The United States of America announced a pledge of US\$ 500 000 towards the development of Phase II. The Secretariat was requested to ensure more balanced geographical representation, including developing countries and affected countries, as well as end-users of the system and collaborating centres, in the development of Phase II. Concerns were raised about the cost and the two-year proposed timeframe for development, as well as the capacity of the system to generate useful summary information understandable and meaningful to all users. It was noted that the design of the system must not prejudge the outcome of the IGM.
6. The Secretariat presented an initial proposal on the Advisory Mechanism. The Director-General sought guidance from Member States on the proposal and equitable representation of WHO regions and affected countries. The proposed functions are to monitor and provide guidance to strengthen the

¹ Document EB122/5, page 29.

functioning of the trust-based system needed to protect public health and to undertake necessary assessments of the trust based system. Textual guidance was discussed.

7. The Secretariat reported also on progress on the development of stockpiles of antivirals and vaccines. The WHO Strategic Advisory Group of Experts (SAGE) on Immunization recommendation on the establishment of a 150 million dose H5N1 vaccine stockpile was discussed, and it was requested that at the resumed meeting of the IGM, SAGE be invited to brief the IGM on the stockpile recommendations. Member States encouraged the Secretariat to accelerate work on the stockpile, including on ensuring that logistical aspects of the distribution of the vaccine to affected persons are taken into account.

8. The Secretariat reported on virus sharing activity since the last IGM in November 2007. Member States expressed concern about the suboptimal number of viruses and clinical samples that had been provided.

9. The OEWG decided to further the work on sharing influenza viruses and access to vaccines and other benefits by discussing, in an issue-based manner, aspects on which it was likely for the meeting to reach consensus. Document EB122/5, containing a compilation of the work of the Intergovernmental Meeting to date, was used as the basis for the discussion. The group focused its deliberations on the following issues:

- research and publication: authorship, acknowledgement and attribution;
- safe handling of materials;
- transparency/traceability;
- advisory mechanism; and
- identification of parties (commenced).

10. Consolidated text was prepared to a large extent on each of the items (Annex 3) and will contribute to the preparation of the Chair's text. It was recognized that benefit sharing is crucial and the issue will be discussed in November 2008.

11. The OEWG agreed to the timetable for the way forward. A Chair's text will be prepared in close consultation with Member States, through the Bureau, for discussion at the resumption of the open-ended working group which will be convened just before the resumed Intergovernmental Meeting. Both meetings will take place in the week 9–15 November 2008. The timetable is as follows:

- Mid-May First draft of Chair's text to Bureau Members;
- 19 May Bureau meeting, during the World Health Assembly to discuss draft text;
- 31 May First draft sent to translation;
- 29 June First draft sent to Member States, through the Bureau, in all official languages;
- 27 July Deadline for contributions from Member States;

- 24 August Final version Chair's text sent to translation;
- 28 September Chair's text in six languages dispatched to Member States;
- 9 November Resumed open-ended working group, followed by resumed IGM.

12. The OEWG suspended its work and will resume in November 2008.

ANNEX 1



**INTERGOVERNMENTAL MEETING ON
PANDEMIC INFLUENZA PREPAREDNESS:
SHARING OF INFLUENZA VIRUSES AND
ACCESS TO VACCINES AND OTHER
BENEFITS: OPEN-ENDED WORKING GROUP**

**A/PIP/IGM/WG/DIV/1 Rev.1
3 April 2008**

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ANNEX 2



**INTERGOVERNMENTAL MEETING ON PANDEMIC
INFLUENZA PREPAREDNESS: SHARING OF
INFLUENZA VIRUSES AND ACCESS TO VACCINES
AND OTHER BENEFITS
OPEN-ENDED WORKING GROUP
Geneva, 3–4 April 2008**

**A/PIP/IGM/WG/1 Rev.1
3 April 2008**

Agenda

- 1. Opening of the session, adoption of the agenda and method of work**
- 2. Progress reports by the Secretariat on immediate measures referred to in the Interim Statement¹**
 - **Traceability mechanism**
 - **Advisory mechanism**
 - **Update on virus sample sharing**
- 3. Sharing of influenza viruses and access to vaccines and other benefits**

Document EB122/5
- 4. Report on outcome of the open-ended working group to the Intergovernmental Meeting**
- 5. Closure of session**

¹ Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits (document EB122/5, Annex 5).

ANNEX 3

Consolidated Text**RESEARCH AND PUBLICATION: AUTHORSHIP, ACKNOWLEDGEMENT AND ATTRIBUTION****Originating Countries (Member States)**

The originating country providing access to virus: (4) has the right to [collaborate in] [participate in] the execution of research and participate actively in publications ; and (5) has the right to be adequately acknowledged. (IGM 5 Fundamental Elements 6)

Participation in research including skills transfer and capacity development

The [scope of the parties to be defined] [should/shall] include scientists from the country or institution of origin in research on relevant biological materials [and/or data] to the fullest extent feasible with a view to facilitating meaningful participation, skills transfer and capacity development.

Acknowledgement, attribution and authorship

The [scope of the parties to be defined] [should/shall] appropriately acknowledge and properly attribute contributions by scientists and/or researchers from the country or institution of origin in any medical or scientific journal publication in a manner that is consistent with the guidelines for authorship and acknowledgement as stipulated by the International Committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Similarly proper acknowledgement, attribution and authorship [should/shall] be provided for other formal scientific presentations.

Consent and notification

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SAFE HANDLING OF MATERIALS**BIOSAFETY AND BIOSECURITY****Rights and obligations of all parties**

All parties shall ensure that transfer of materials [under the STC] shall at all times be in compliance with all relevant national and international laws, rules and regulations, including those relating to biosafety and biosecurity, to the full extent that such laws, rules and regulations are applicable to each party concerned.

All parties shall ensure that handling, storage and use of materials [under the STC] shall at all times be in compliance with all relevant national and international laws, rules and regulations, including those

relating to biosafety and biosecurity, to the full extent that such laws, rules and regulations are applicable to each party concerned.

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TRACEABILITY MECHANISM

The Director-General shall establish, maintain and operate a transparent traceability mechanism using an electronic system in order to track in real time the movement of [biological materials] into, within and out of the [[WHO System] - scope of the parties to be defined]. Pending the functioning of such a traceability mechanism, the interim system providing full disclosure of information on transfer and movement of [biological materials] will continue to be operated and maintained.

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ADVISORY MECHANISM

The Director-General [will] establish[ed] a transparent advisory mechanism to monitor, provide guidance to strengthen the functioning of the [WHO system] and undertake necessary assessment of the trust-based system needed to protect public health. An 18 member advisory group [will be] [was] appointed by the Director-General in consultation with Member States, based on equitable representation comprising three members per WHO region and being mindful of [affected countries].

The Director-General will present a report on the work carried out by the advisory group [through the Executive Board] to the World Health Assembly in 2011 for a decision on any future mandate.

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IDENTIFICATION OF PARTIES

Dictionary of Terms

WHO Member States. The 193 States party to the WHO constitution.

Originating States. States submitting novel [new] subtypes of human [and/or animal] influenza A viruses of human pandemic potential or samples thought to contain them.

[OR

States, where influenza A viruses of human pandemic potential or samples thought to contain them were collected from either humans or animals.]

Affected States. States which have confirmed infection in humans and/or animals of novel [new] subtypes of influenza A viruses with human pandemic potential.

WHO Secretariat. Includes the Director-General and the technical and administrative staff of the Organization in accordance with Article 30 of the Constitution.

WHO System.

Scope – H5N1 and/or other influenza viruses of pandemic potential.

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