INTERGOVERNMENTAL MEETING ON PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS
Agenda item 2.1

A/PIP/IGM/8
27 November 2008

Reports of the Director–General

Establishment of the Advisory Mechanism

1. Member States participating in the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (Geneva, 20–23 November 2007), in its Interim Statement[1] requested the Director-General to establish an advisory mechanism that would provide guidance for strengthening the trust-based system needed to protect public health, and to undertake necessary monitoring and assessment of that system. Members of the advisory mechanism were to be selected in consultation with Member States, based on equitable representation of WHO regions and affected countries.

2. During the meeting of the open-ended working group of the Intergovernmental Meeting (Geneva, 3–4 April 2008), further guidance was sought from Member States on the appropriate size and composition of the advisory mechanism. Member States agreed that it should have 18 Members and comprise internationally-recognized policy makers, public-health experts and technical experts in the field of influenza.

3. As a result, the Director-General consulted with the Chair and Vice-Chairs of the Intergovernmental Meeting and subsequently received nominations of candidates from all six WHO regions. Following careful review, 18 persons were invited to serve on the Advisory Mechanism. All have accepted, and are listed in Annex 1.

4. Before the resumption of the open-ended working group and the Intergovernmental Meeting, the Director-General convened a one-day meeting of the Advisory Mechanism (Geneva, 21 October 2008). The purpose of the meeting, inter alia, was to enable the Advisory Mechanism to discuss provisional terms of reference, review the report by two of its members who attended the WHO Technical Consultation on the Development of a WHO Influenza Virus Traceability Mechanism (Ottawa, 24–26 September 2008), also requested by the Intergovernmental Meeting, and discuss other matters as necessary.

5. The report of the meeting of the Advisory Mechanism is attached as Annex 2, and the summary report of the technical consultation as Annex 3.

[1] http://www.who.int/gb/pip/e/E_pip1.html.

ANNEX 1

LIST OF MEMBERS OF THE ADVISORY MECHANISM

African Region		
Dr Abdul Nasidi	Director, Special Projects, Federal Ministry of Health	Nigeria
Dr Barry Schoub	Executive Director, National Institute for Communicable Disease	South Africa
Dr Ambrose Talisuna	Former Head of Epidemiology and Surveillance, Ministry of Health	Uganda
Region of the Americas		
Dr Arlene King	Director-General, Centre for Immunization and Respiratory Infectious Diseases, Public Health Agency of Canada	Canada
Dr Claudia Gonzalez	Chief of Epidemiology, Ministry of Health	Chile
Dr Bruce Gellin	Director, National Vaccine Program Office, US Department of Health and Human Services	United States of America
South-East Asia Region		
Dr Biswajit Dhar	Professor and Head, Centre for WTO Studies, India Institute of Foreign Trade	India
Dr Widjaja Lukito	Adviser to the Minister on Health Public Policy, Ministry of Health	Indonesia
Professor Prasert Thongcharoen	Professor Emeritus, Department of Microbiology, Faculty of Medicine, Siriraj Hospital, Mahidol University	Thailand
European Region		
Professor Bruno Lina	Professor of Virology, Director, National Influenza Centre for South France, Director, CNRS FRE3011, Lyon University Laboratory	France
Dr Olav Hungnes	Director, WHO National Influenza Centre, Department of Virology, Division of Infectious Disease Control, Norwegian Institute of Public Health	Norway
Professor Patricia Troop	Former Chief Executive, Health Protection Agency	United Kingdom of Great Britain and Northern Ireland

Eastern Mediterranean Region		
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Dr Mahmoud Fikri	Executive Manager for Health Policies Affairs, Ministry of Health	United Arab Emirates
Western Pacific Region		
Dr Liu Xia	Deputy Division Director, Bureau of Disease Prevention and Control, Ministry of Health	China
Dr Takeshi Kurata	Director, Toyama Institute of Health	Japan
Professor Suok Kai Chew	Deputy Director of Medical Services, Ministry of Health	Singapore

ANNEX 2

Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits
Meeting of the Advisory Mechanism
WHO headquarters
21 October 2008

Report of the meeting

Participants

1. The Advisory Mechanism held its first meeting at WHO headquarters on 21 October 2008, with 15 of its 18 members attending. The list of participants is attached as Appendix A to this annex and the list of members of the Advisory Mechanism is in Annex 1.

Election of Chair and Vice-Chair

2. The participants elected Professor Bruno Lina (France) as Chair and Professor Prasert Thongcharoen (Thailand) as Vice-Chair.

Mandate and terms of reference of the Advisory Mechanism

3. There were rich discussions on the scope and mandate of the Advisory Mechanism and the draft provisional terms of reference are attached as Appendix B to this annex. The Advisory Mechanism reached consensus on the following:

- The broad scope of the draft provisional terms of reference is derived directly from the Interim Statement, which is a text agreed by Member States and which forms the basis for the establishment of the Advisory Mechanism.

- The Advisory Mechanism is of the view that: the duration of appointments of its members should be three years with a renewal of one third of the members every year; replacements must maintain the equitable representation of the six WHO regions and affected countries; and that all members should be eligible for two appointments.

Issues for further clarification

4. Questions and issues on which further guidance is sought from the Intergovernmental Meeting are set out below.

- Greater clarity is required on the expectations of the Intergovernmental Meeting regarding the role of the Advisory Mechanism in monitoring the functioning of the trust-based system.

- Regarding the provisional terms of reference taken directly from the Interim Statement, there is a need for clarity from the Intergovernmental Meeting on: the specifics of the mandate, such as definitions of certain terms – “monitor”, “trust-based system” and “necessary

assessment"; and indicators that will permit the Advisory Mechanism to carry out these functions.

- The need was also expressed for more clarity from the Intergovernmental Meeting on the definitions of the terms "fair", "equitable", "timely sharing" and "transparent" which are used in the text of the Interim Statement, although not in the section mandating establishment of an Advisory Mechanism.

- There is a need to define the institutional components of the trust-based system (such as National Influenza Centres, WHO Collaborating Centres, H5 Reference Laboratories, and essential regulatory laboratories) that will be monitored, strengthened and assessed by the Advisory Mechanism.

- The Intergovernmental Meeting should clarify whether monitoring the availability of benefits and access to them are a responsibility of the Advisory Mechanism.

- There is a need for clarity on the expected duration of the Advisory Mechanism.

- There is a need for clarity on how the trust-based system will interact with the International Health Regulations (2005).

Traceability and reporting system

5. For the information of participants, the Secretariat gave a detailed presentation of the existing interim Influenza Virus Traceability Mechanism and reported on the WHO technical consultation (Ottawa, 24–26 September 2008) in order to define the scope and technical parameters of an improved Influenza Virus Traceability Mechanism.

6. The two members of the Advisory Mechanism who attended the Ottawa technical consultation as observers presented their written report, which was discussed. In this connection there was consensus that:

- Section 3 of their report contains necessary elements for the improved Influenza Virus Traceability Mechanism.

- Viruses tracked by the Influenza Virus Traceability Mechanism within the trust-based system should be limited to H5N1 and other potentially pandemic human influenza viruses and the parts thereof.

- To ensure continuing confidence in the Influenza Virus Traceability Mechanism, its operational arrangements need to be clear, including the roles and responsibilities of the various contributors to the Influenza Virus Traceability Mechanism (National Influenza Centres, WHO Collaborating Centres, H5 Reference Laboratories and others that would input data to the Influenza Virus Traceability Mechanism).

- The Intergovernmental Meeting must provide greater clarity regarding the duration of tracking of H5N1 and other potentially pandemic human influenza viruses and the parts thereof.

General observations and conclusions

7. The participants made general observations and reached conclusions, as follows:

- Progress to date on the development of an Influenza Virus Traceability Mechanism and on the establishment of the Advisory Mechanism is supporting the development of a trust-based system, but further work is needed.

- The improved Influenza Virus Traceability Mechanism is expected to be an interactive web-based system that will track H5N1 and other potentially pandemic human influenza viruses, and the parts thereof, submitted to WHO and within the trust-based system and with other bodies, and is a part of the overall framework being developed through the Intergovernmental Meeting.

- WHO is facilitating access to benefits, including: vaccine and antiviral stockpiles; transfer of influenza vaccine manufacturing technology; development and distribution of influenza diagnostic tests at no cost to National Influenza Centres; laboratory capacity strengthening; and other goods and services needed for pandemic preparedness.

- Risk assessment and risk management for pandemic influenza are also benefits that are included in WHO's event management system that is linked to the International Health Regulations (2005).

- Clarification is needed from the Intergovernmental Meeting on the proposed mandate and terms of reference of the Advisory Mechanism, as in paragraphs 3 and 4 above.

- There was also agreement that other issues, such as improvement in surveillance and tools for risk assessment, should be brought to the attention of the Intergovernmental Meeting.

APPENDIX A

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APPENDIX B

FOR CONSIDERATION

Provisional Terms of Reference

1. Background

The Interim Statement adopted by WHO Member States attending the 20–23 November 2007 Intergovernmental Meeting on Pandemic Influenza Preparedness called on the Director-General to establish an Advisory Mechanism to monitor, provide guidance to strengthen the functioning of the trust-based system needed to protect public health and undertake necessary assessment of that system. To carry out these duties, Member States specified that an advisory group will be appointed by the Director-General in consultation with Member States, based on equitable representation of the WHO regions and of affected countries.

2. Terms of reference

Monitor, provide guidance to strengthen the functioning of the trust-based system needed to protect public health and undertake the necessary assessment of that trust-based system.

3. Nomination of members

3.1 The Members are appointed by the Director-General in consultation with Member States, based on equitable representation of the six WHO regions and of affected countries.

3.2 Each representative will serve for two years. To allow for continuity, half of the Members appointed in the first year will serve only one year. The other half will serve for two years. In the event of resignation or incapacity of a representative for any reason, the Director-General will appoint a replacement member with a view to maintaining the equitable representation of the six WHO regions and affected countries. The alternate will complete the term of the previous representative. The Group will select from among its members, a Chairperson and a Vice-Chairperson. The Chairperson and Vice-Chairperson will serve for two years after which another Chairperson and Vice-Chairperson will be selected by the Group members.

3.3 The Director-General will regularly accept nominations of representatives and will draw from this list to replace outgoing Members with a view to maintaining the equitable representation of the six WHO regions and affected countries.

4. Working procedures

The Director-General will apply to this Advisory Mechanism working procedures consistent with WHO practices and procedures.

ANNEX 3

WHO Technical Consultation on the Development of a WHO Influenza Virus Traceability Mechanism

A summary report from the Advisory Mechanism member observers

1. Purpose

A WHO Technical Consultation meeting to define the scope and parameters of an Influenza Virus Traceability Mechanism (IVTM) was held on 24–26 September 2008.

The purpose of this paper is to provide a summary report of that meeting for the Advisory Mechanism meeting of 21 October 2008.

2. Background

The meeting was arranged as a result of the World Health Assembly resolution WHA60.28 "Pandemic preparedness: sharing of influenza viruses and access to vaccines and other benefits" and the Interim Statement of the Intergovernmental Meeting of November 2007. Two measures were identified at that meeting to delivery transparency and increase trust:

- a Traceability Mechanism
- an Advisory Mechanism.

The objectives of the consultation meeting were to:

- define the scope and purpose of the WHO influenza virus traceability mechanism
- identify real-world considerations, practical limitations and potential risks to be addressed
- consider existing models and identify opportunities for synergies
- develop implementation assumptions and a roadmap for the overall process.

Two members of the Advisory Mechanism were invited to the Technical Consultation to report back to the meeting of 21 October 2008.

The meeting was chaired by Dr John Spika of Canada and Dr Pathom Sawanpanyalert of Thailand and attended by participants from 21 countries, representing the range of laboratories in the Global Influenza Surveillance Network, industry associations, other potential users and representatives of other comparable systems.

Prior to the meeting a Survey of the Global Influenza Surveillance Network (GISN) laboratories on the development of a future IVTM had been carried out and the results were presented to the meeting. The meeting received presentations setting out perspectives from a range of potential users; experience from the Interim Influenza Virus Traceability Mechanism and other traceability mechanisms; technical considerations; and the timetable and process for commissioning the new system. The representatives considered and agreed the principles and a number of technical details of the IVTM to enable WHO to prepare a Project Initiation Document, which would be used to commission the IVTM. They also identified a number of wider issues they wished to be brought to the attention of the Advisory Mechanism and the Intergovernmental Meeting.

3. Commentary

There was acknowledgement that the traceability mechanism was part of a wider picture, which also included the Material Transfer Agreement (MTA) and benefits to be shared. Therefore, certain issues were not for discussion at the Technical Consultation meeting, but some of the recommendations from the meeting might have a bearing on them.

During the discussion, there were inevitably different viewpoints from a diverse group. However, a broad consensus was achieved on the future principles of the IVTM, which should achieve transparency and help rebuild trust. It was recognized that not all laboratories enjoyed the same level of resources, whether in equipment, trained personnel or fast internet access. Whilst these issues might be addressed as part of implementation, this needed to be taken into account when designing the mechanism.

The following principles were broadly agreed:

1. The IVTM should be limited to influenza viruses of pandemic potential.
2. It should be web-based, simple and "user friendly", in terms of entering and use of data, and access.
3. Duplicate entering of data for different purposes should be avoided.
4. It should be comprehensive, with all movements into and out of the mechanism recorded.
5. It should be an "inclusive" mechanism, with involvement of National Influenza Centres, WHO Collaborating Centres, Essential Regulatory Laboratories and outside receivers of material, although it was recognized that this last group would be considered more under the MTA.
6. There should be "open access" as much as possible, with the principle that data should be considered to be accessible, unless there were reasons of patient identification or other sensitivities; this might lead to differential levels of access.
7. There should be clear ownership of data, with clarity as to who had the right of entry and editing.
8. No other databases should be duplicated, such as genetic sequencing; but there should be notification that the data had been entered onto these and where possible, direct links.

To ensure continuing confidence in the IVTM, the governance arrangements need to be clear, including the roles and responsibilities of all participants. Whilst it was recognized that this will be a mechanism within WHO, the Member States should feel a sense of ownership, with the accompanying rights and responsibilities. These might include issues such as involvement in the commissioning of the IVTM, the process for making decisions to modify the mechanism, and the length of time that material should be retained.

A range of the technical issues were also agreed, such as the data to be entered and the number of licences per laboratories. These are not set out here, but will be part of the WHO Project Initiation Document. However, whilst those might vary, the principles set out above should remain. It was agreed at the meeting that a small working group from the Technical Consultation meeting should work with WHO to finalize these technical details.

Two particular concerns were raised: utility and costs. Whilst the mechanism is aimed at contributing to a global benefit, the direct users need to consider that the mechanism will be of direct benefit to them. There was strong agreement with the following quote from one of the presenters, "users use systems if they are useful to them (even if they are rubbish) and do not if they are not (even if they are

brilliant)". Therefore the mechanism should be used to streamline procedures and avoid any duplication. One suggestion was that data entry could be used to produce the shipping document needed to go with material being transferred. The IVTM might also be used as a means of improving the resources of laboratories, for example in staff training. Without these benefits, there was concern that, with all other pressures on staff time, the standard of participation may be variable.

The second concern was that there had already been expenditure allocated to the Interim Mechanism, and some questioned the need for further spending. Therefore the Interim Mechanism should be tested against the specification of the future IVTM. However, the meeting also received advice that modifications to the Interim Mechanism could be as costly as designing a new one.

4. Wider issues

Flexibility and scalability

There was broad agreement that whilst the Mechanism would be for influenza viruses of pandemic potential, a situation might arise when the WHO and Member States might wish to include different viruses, for example, an equivalent to the emergence of severe acute respiratory syndrome (SARS). Therefore the mechanism should be flexible enough to accommodate this.

There was considerable discussion on the inclusion of Seasonal Influenza. There were different views on the value of this, and whilst it was supported by some representatives, others were concerned that it would overwhelm the system. It was also acknowledged that such use would require a further mandate. Nevertheless, it was considered that the system should be designed to be able to be scaled up should the need arise.

Wider uses of the Mechanism

This was linked to value for money, but also potential wider uses of the Mechanism for other purposes. There were some suggestions that more detailed clinical or epidemiological data might be included, in order to assist surveillance and risk assessment. Whilst some thought there might be some future potential for this, caution would be needed in taking this forward. First, systems designed for one purpose (in this situation a "traceability mechanism"), often do not adapt well to another such as an information database. Representatives recognized that "simple" and "sophisticated" did not sit well together.

The second concern was that the request for more detailed entry of data suggested a current deficiency in surveillance and tools for risk assessment. If this is the case, this needs addressing now, rather than through some future potential of the traceability mechanism, and the representatives wished this to be considered by the Intergovernmental Meeting.

5. Conclusions

There was a broad consensus on the principles of the IVTM, as set out in paragraph 3, and the Advisory Mechanism are asked to note and comment on these principles.

More detailed technical issues were also agreed and further work was planned to complete these, which will be included in the Project Initiation Document.

The roles and responsibilities of the various contributors to the IVTM and the governance arrangements need clarifying.

There were some wider issues raised, such as improvement in surveillance and tools for risk assessment that the representatives wish to bring to the attention of the Intergovernmental Meeting.

Professor P. Troop

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Advisory Mechanism Observers

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