



**World Health
Organization**

**INTERGOVERNMENTAL MEETING ON PANDEMIC
INFLUENZA PREPAREDNESS: SHARING OF
INFLUENZA VIRUSES AND ACCESS TO VACCINES
AND OTHER BENEFITS
Provisional agenda item 3**

**A/PIP/IGM/5
19 November 2007**

Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness

At the request of the Permanent Mission of the Republic of Indonesia to the United Nations and other International Organizations at Geneva, the Director-General has the honour to transmit the attached proposal to the Intergovernmental Meeting.

ANNEX

**FUNDAMENTAL PRINCIPLES AND ELEMENTS FOR THE DEVELOPMENT OF
A NEW SYSTEM FOR VIRUS ACCESS AND FAIR AND EQUITABLE
BENEFIT SHARING ARISING FROM THE USE OF THE VIRUS
FOR THE PANDEMIC INFLUENZA PREPAREDNESS**

Proposed by Indonesia

**To be considered as a working document for the discussion in the Intergovernmental
Meeting on Pandemic Influenza Preparedness (IGM-PIP), 20–23 November 2007**

It is now recognized by the international community of the need for concrete, effective, operational and transparent international mechanisms for fair and equitable sharing of benefits arising from the use of viruses, which cannot be present within the current system, including GISN, when the states' sovereign rights and their respective governing laws are taken into consideration. Thus there is a need to urgently develop a new system for virus access and fair and equitable sharing of benefits arising from the use of the virus to replace the currently existing system.

The new system must be based on the following fundamental principles:

1. Recognition of the sovereign right and the governing laws of states over their biological resources.
2. Virus can be accessed based on prior informed consent, mutually agreed terms and fair and equitable sharing of benefits.
3. Benefit sharing must be concrete, specific and provided to developing countries, especially affected countries and their geographic vicinities.
4. Authority to determine access to influenza viruses rests within the national government and subject to national laws.
5. Intellectual property rights must not prevent Member States from taking measures to protect public health.
6. The right of a state to provide access to virus on a bilateral arrangement is upheld.
7. Recognition that developing countries have limited capacities and they face economic, financial and administrative constraints thus empowering and capacity building are urgently required.

The new system must be based on the following fundamental elements:

1. Access to virus is provided within the framework of the establishment of a global vaccine stockpile. The global stockpile should be formulated by WHO and endorsed by Member States.
2. Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States.

3. The virus accessed is to be used only for non-commercial risk assessment and response according to the Terms of Reference which is to be agreed.
4. Any use of virus outside the Terms of Reference must get prior informed consent from the originating country.
5. Subsequent transfer of the virus can be done only with the prior informed consent of the originating country.
6. The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged.
7. Sequence data must be placed in a database only with the prior informed consent of the originating country. The database will be governed by rules and regulations to prevent misappropriation.
8. Manufacturers can only obtain seed virus from the system with prior informed consent of the originating country and must commit to benefit sharing.
9. Framework of benefit sharing is to be developed through agreed terms and conditions to ensure global stockpile of pre-pandemic and pandemic vaccines, accessibility of vaccine at an affordable price, access to and transfer of technology and know-how for production of vaccines, and empowerment and capacity building of vaccine manufacturing in developing countries.
10. Distribution of global stockpile of pre-pandemic and pandemic vaccines must be prioritized to developing countries, especially affected countries and their geographic vicinities.
11. No entity can acquire intellectual property rights over the virus, parts thereof and their derivatives.
12. WHO shall develop a database accessible to Member States to track movement of all viruses and seed viruses.

The elements are necessary to ensure a fair and equitable system, taking into account the needs and interests of developing countries.

= = =