EXECUTIVE BOARD 124th Session Provisional agenda item 4.1 EB124/4 27 November 2008

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

Report by the Secretariat

- 1. In May 2007, the Sixtieth World Health Assembly adopted resolution WHA60.28 on Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits which, inter alia, requested the Director-General to report to the Sixty-first World Health Assembly, through the Executive Board, on progress made in implementing the resolution, including the work of the Intergovernmental Meeting. In May 2008, the Health Assembly noted the report submitted by the Secretariat.¹
- 2. In the period since the Intergovernmental Meeting held in November 2007, several activities have been undertaken to implement resolution WHA60.28.

INTERGOVERNMENTAL PROCESS

3. At the Intergovernmental Meeting session, Member States adopted an Interim Statement² calling for urgent implementation of two measures and requesting the Chair to convene an open-ended working group to carry work forward. The working group met in Geneva in April 2008 and focused on five issues, calling on the Chair to prepare a text, through the Bureau and in close consultation with Member States, for discussion at the resumption of the group's meeting and the Intergovernmental Meeting scheduled for 9–15 November 2008 (subsequently rescheduled for 8–13 December 2008). The outcome of those meetings will be submitted to the Board as an addendum to this document.

TRACEABILITY MECHANISIM

4. In the Interim Statement the Intergovernmental Meeting invited the Director-General to establish "a technical and feasible system as soon as possible within WHO to track all shared H5N1 and other potentially pandemic human viruses and the parts thereof". During the two months between the suspension of the Intergovernmental Meeting in November 2007 and the opening of the

¹ Document WHA61/2008/REC/3, summary records of the first and second meetings of Committee A.

² Document EB122/5, Annex 5.

122nd session of the Executive Board (21–26 January 2008), the Secretariat devised and launched an interim influenza virus traceability system. The system was well received by the technical influenza community; in its first nine months of operation there were 24 532 visits to the virus tracking system web site with an average of 10 000 page views per month.

- 5. The interim influenza virus traceability mechanism provides many of the features and information requested by Member States, notably information on all influenza A (H5N1) viruses and clinical specimens shared by Member States with WHO's Global Influenza Surveillance Network since 24 November 2007, and tracking of all influenza A (H5N1) viruses that have been selected and developed under WHO's aegis into candidate vaccine viruses using reverse genetics. The system also provides information on analysis results and progeny materials, if any, that have been generated. However, given the rapidity with which the interim system was developed, it suffers from certain deficiencies such as lack of linkages with other databases and redundant or cumbersome data-entry requirements.
- 6. In order to define the scope and identify critical technical parameters of an improved system, WHO convened a technical consultation (Ottawa, 24–26 September 2008), which brought together participants, with diverse backgrounds, from more than 21 countries, to discuss the technical parameters and required features of the improved system with due reference to the mandate of the Intergovernmental Meeting. Two members of the Advisory Mechanism attended the meeting as observers and submitted a report of the proceedings directly to the Advisory Mechanism.
- 7. On the recommendation of the technical consultation participants, a small technical working group of experts was convened to finalize the technical specifications of the system. WHO will use the combined work of these groups in order to proceed with appropriate procurement actions for the improvement of the system.

ADVISORY MECHANISM

- 8. The Director-General, in close consultation with Member States, appointed an Advisory Mechanism of 18 members comprising internationally recognized policy makers, public health experts and technical experts in the field of influenza, and based on equitable representation of WHO regions and affected countries.
- 9. This Advisory Mechanism will advise the Director-General on strengthening the trust-based system needed to protect public health and undertake necessary monitoring and assessment of the system. At the first meeting of the Advisory Mechanism (Geneva, 21 October 2008) members drafted provisional terms of reference and considered progress made on the development of the Influenza Virus Traceability Mechanism, notably through the report of the two members of the Advisory Mechanism who attended the technical consultation (see paragraph 6).

INTERNATIONAL STOCKPILE OF VACCINES

10. Pursuant to resolution WHA60.28, the Secretariat has undertaken work towards establishing an international stockpile of vaccines for H5N1 or other influenza viruses of pandemic potential. In collaboration with a consulting group funded by the Bill & Melinda Gates Foundation, WHO has developed several options for the stockpile, including the associated costs and possible financing mechanisms.

- 11. The Secretariat continues to seek guidance from Member States on appropriate and sustainable mechanisms for operating the stockpile, including rules and procedures for deployment, management, oversight, and financing. Two options for the H5N1 vaccine stockpile are being considered:
 - **Option 1.** Manufacturers pledge to reserve specified amounts of antigen and adjuvant in bulk form (analogous to current arrangements for WHO stockpiles of yellow fever and meningitis vaccines), with fill and finish operations being undertaken when WHO announces that the need for vaccine is identified. Industry would ensure that all products released from the stockpile have at least six months' remaining shelf life.
 - **Option 2**. Manufacturers hold a stockpile of filled and finished vaccine. Industry would ensure that all products released from the stockpile have at least six months' remaining shelf life.
- 12. WHO will look to the guidance of the WHO Strategic Advisory Group of Experts on immunization and the specialized working group on H5N1 vaccines in order to consider and provide further recommendations on the use of H5N1 influenza vaccines in high-risk and priority groups (as defined in country plans) and the use of H5N1 vaccine that has been stockpiled but is reaching the end of its shelf life. Meetings of the Strategic Advisory Group of Experts on immunization and its working group are scheduled for November 2008 and April 2009.
- 13. As requested by the open-ended working group, the Strategic Advisory Group of Experts on immunization will be invited to brief the Intergovernmental Meeting on its stockpile recommendations.

STRENGTHENING SURVEILLANCE AT THE ANIMAL-HUMAN INTERFACE

Collaboration between FAO, WHO, UNICEF and OIE is continuing, as exemplified by the Global Early Warning System for Major Animal Diseases, the Global Framework for Transboundary Animal Diseases, the Mediterranean Zoonosis Control Programme, a recent jointly sponsored scientific meeting that brought together animal and human influenza scientists, and the Canadian International Development Agency-funded tripartite programmes on avian influenza. This collaboration has been strengthened as a result of joint responses to H5N1 disease in poultry and humans. There is now an acceptance that, in order to maintain the momentum in the response to H5N1 infection and increased preparedness for a pandemic of influenza, there should be a framework to enable a response to diseases at the human-animal interface, which includes human public health, and domestic and wildlife animal health using the concept of "One World, One Health" from the Wildlife Conservation Society 2004. A strategic framework for "One World, One Health" will be presented to the next Ministerial Meeting on Avian and Pandemic Influenza (Sharm-el-Sheikh, Egypt, 25-26 October 2008) by FAO, WHO, UNICEF, OIE, the World Bank and the United Nations System Influenza Coordinator. The success of the current response to avian influenza will help to promote a sustained response to avian influenza and other diseases which have a profound effect on human and animal health and the health of communities and economies.

ACTION BY THE EXECUTIVE BOARD

15. The Executive Board is invited to note this report.