EXECUTIVE BOARD 117th Session Provisional agenda item 4.2

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# Strengthening pandemic-influenza preparedness and response

## Application of the International Health Regulations (2005): follow up

#### **Report by the Secretariat**

- 1. A meeting on avian influenza and human pandemic influenza, convened jointly by WHO, FAO, the World Bank and OIE (7-9 November 2005) reviewed the status of avian influenza in animals and assessed the related risks to human health, including those that would arise following the emergence of a pandemic virus. Concern about the consequences of such an event steered discussions on human health matters towards consideration of two main sets of actions. These were aimed at preventing the emergence of a pandemic virus or, should this prove impossible, delaying the initial international spread of a pandemic; and preparing all countries to cope with a pandemic in ways that reduce morbidity and mortality and mitigate economic and social disruption. It was agreed that the risk of a pandemic was a shared and significant concern for all countries, and that actions to prevent a pandemic or mitigate its consequences were likewise a responsibility shared by all countries. The closing remarks of the Director-General to the meeting are attached at Annex.
- 2. Participants attached great importance to the early detection, rapid diagnostic confirmation, and thorough investigation of human cases of infection with the highly pathogenic H5N1 strain of *Influenzavirus A*. In this regard, rapid and transparent reporting of cases and information acquired during their investigation was especially critical. Rapid, reliable and complete epidemiological data were needed in order to assess possible changes in the pandemic risk and thus declare an appropriate phase of pandemic alert. Rapid sharing of clinical samples and viruses with WHO-affiliated laboratories was equally important, as molecular study of viruses is another mechanism for detecting early signals that a pandemic may be imminent. The success of early intervention, with WHO's stockpile of antiviral drugs, near the start of a pandemic, aimed at preventing a pandemic or delaying its early spread, would depend, to a large extent, on sensitive surveillance and rapid reporting.
- 3. As noted during the meeting, not all countries affected by outbreaks of highly pathogenic H5N1 avian influenza in poultry have adequate surveillance systems and laboratory capacity for detecting associated human cases of infection. Improvement of capacity to detect human cases was identified as one of the highest priorities for funding to assist affected or at-risk countries. For various reasons, not all information formally requested by WHO is being provided in a timely manner. Such inadequacies hinder risk assessment and reduce the chances for successful preventive intervention near the start of a pandemic.

4. For all these reasons, participants asked that proposals for the immediate voluntary compliance with relevant provisions of the International Health Regulations (2005) before their entry into force should be submitted to the Executive Board for consideration during its 117th session. Doing so would allow the international community to benefit immediately from the Regulations, which were revised and strengthened to make them an effective legal instrument for responding to public health risks and emergencies of international concern in the unique conditions of the twenty-first century.

#### PROPOSALS FOR VOLUNTARY COMPLIANCE

- 5. The Regulations set out requirements and responsibilities, establish mechanisms and procedures for undertaking required activities, and specify time frames for completing activities of particular urgency. They also provide for dialogue with affected countries, and the international community, whereby countries agree to meet certain requirements and time frames and, when unable to do so, can request specific technical support from WHO and seek collaboration and assistance, including the mobilization of financial support, from the international community. The strengthening of surveillance and response capacity to enable countries to respond to the pandemic risk would also strengthen capacity to defend the world against many other emerging and epidemic-prone diseases. In this regard, the general core-capacity requirements for surveillance and response set out in Annex 1 of the Regulations can be used as guidance for countries requesting or providing assistance in the present threat of pandemic influenza. This threat also serves to emphasize the urgent need to continue and enhance WHO's assistance to developing countries in establishing these capacities, as called for in resolution WHA58.3 operative paragraph 6(6).
- 6. Several provisions in the Regulations could be applied immediately to improve information sharing and risk assessment, expedite communications, and harmonize measures implemented by countries, particularly pertaining to international travel. The Regulations include a procedure for determining when an event constitutes a public health emergency of international concern, at which point a set of mechanisms becomes operational. Under the Regulations, a case of human influenza caused by a new virus subtype must be notified to WHO and is an event that may constitute a public health emergency of international concern. For dealing with such emergencies, the Regulations also set out a procedure, led by the Director-General, for communications and decisions concerning recommendations for response measures. These can function to promote uniformity and predictability during the international response to an influenza pandemic.
- 7. Provisions within the Regulations that may be considered most relevant to the risk of avian influenza and pandemic influenza include the following:
  - (a) Annex 2, which makes human influenza caused by a new virus subtype a notifiable disease:
  - (b) Article 4 pertaining to the designation or establishment of National IHR Focal Points, thereby providing a mechanism for reporting urgent events to WHO, which will designate IHR Contact Points;

<sup>&</sup>lt;sup>1</sup> Resolution WHA58.3.

- (c) articles in Part II, which pertain to surveillance, notification, reporting, and information sharing; set out requirements and time frames for collaborative risk assessment through verification of events and the provision of information to WHO; and elaborate functions and responsibilities during the public health response, including offers by WHO to mobilize international assistance;
- (d) articles 23 and 30-32 in Part V pertaining to general provisions for public health measures for travellers on arrival or departure and special provisions for travellers;
- (e) articles 45 and 46 in Part VIII pertaining to the treatment of personal data and the transport and handling of biological substances, reagents and materials for diagnostic purposes.
- 8. To facilitate voluntary compliance with these and possibly other provisions in the Regulations, an influenza pandemic task force is being established to perform, on a temporary basis, a role analogous to that of the Emergency Committee, as provided for in Article 48 of the Regulations. The task force, composed of external experts, will provide support in assessment of the changing pandemic risk and advise the Director-General on the declaration of pandemic alert phases and the corresponding recommended response measures.
- 9. Such voluntary compliance does not render the Regulations legally binding for Member States that comply with them and does not prejudice the position of any Member State when the Regulations come into force on 15 June 2007.

#### **ACTION BY THE EXECUTIVE BOARD**

10. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report on application of the International Health Regulations (2005);<sup>1</sup>

RECOMMENDS to the Fifty-ninth World Health Assembly the adoption of the following resolution:

The Fifty-ninth World Health Assembly,

Having considered the report on application of the International Health Regulations (2005);

Recalling resolutions WHA58.3 on revision of the International Health Regulations and WHA58.5 on strengthening pandemic-influenza preparedness and response;

Reaffirming the serious risk to human health, including the possible emergence of a pandemic virus, arising from ongoing outbreaks in poultry of highly pathogenic avian influenza, caused by the H5N1 strain of *Influenzavirus A*, in parts of Asia and elsewhere;

<sup>&</sup>lt;sup>1</sup> Document EB117/31.

Noting with concern the persistence of outbreaks in poultry, the continuing occurrence of sporadic cases of severe human disease associated with these outbreaks, the endemicity of the virus in several countries, the spread of the virus through the migration of wild waterfowl to new areas, and its predicted further spread;

Aware that these and other developments have increased the probability that a pandemic may occur;

Highlighting the importance of WHO's global influenza preparedness plan<sup>1</sup> and the control measures recommended therein:

Mindful that rapid detection of human cases, supported by adequate national capacity, and rapid and transparent reporting of findings underpin WHO's ability to issue a reliable risk assessment and declare an appropriate phase of pandemic alert, and are further needed to ensure that the earliest epidemiological signals of increased transmissibility of the virus among humans are not missed;

Aware that several provisions in the International Health Regulations (2005) would be useful in ensuring a strengthened and coordinated response on the part of the international community both to the present situation and a possible pandemic;

Further aware that strengthened capacity to respond to human cases of avian influenza and the corresponding pandemic threat will strengthen the capacity to respond to many other emerging and epidemic-prone infectious diseases, and thus increase global public-health security against the threat of infectious diseases;

Noting that the International Health Regulations (2005) will not enter into force until 15 June 2007;

Recalling the main conclusions reached and recommended actions agreed on during a joint meeting convened by WHO, FAO, the *Office International des Epizooties* and the World Bank on avian influenza and human pandemic influenza (Geneva, 7-9 November 2005); and

Responding to the specific request, made during that meeting, to put forward proposals to the Fifty-ninth World Health Assembly through the Executive Board at its 117th meeting for immediate voluntary compliance with relevant provisions of the International Health Regulations (2005),

- 1. CALLS UPON Member States to comply immediately, on a voluntary basis, with provisions of the International Health Regulations (2005) considered relevant to the risk posed by avian influenza and pandemic influenza;
- 2. DECIDES that relevant provisions of the International Health Regulations (2005) shall include the following:

<sup>&</sup>lt;sup>1</sup> Document WHO/CDS/CSR/GIP/2005.5.

- (1) Annex 2, in so far as it requires prompt notification to WHO of human influenza caused by a new virus subtype;
- (2) Article 4 pertaining to the designation or establishment of a National IHR Focal Point within countries and the designation of WHO IHR Contact Points, and the definition of their functions and responsibilities;
- (3) articles in Part II, pertaining to information-sharing, consultation, verification and public health response;
- (4) articles 23 and 30-32 in Part V pertaining to general provisions for public health measures for travellers on arrival or departure and special provisions for travellers:
- (5) articles 45 and 46 in Part VIII pertaining to the treatment of personal data and the transport and handling of biological substances, reagents and materials for diagnostic purposes;
- 3. NOTES that such voluntary compliance is without prejudice to the position of any Member State with regard to the International Health Regulations (2005) after their entry into force:

#### 4. URGES Member States:

- (1) to designate or establish immediately a National IHR Focal Point, as provided for in Article 4 of the Regulations, and inform WHO accordingly within 90 days, the said Focal Point having the authority to communicate official information and participate in collaborative risk assessment with WHO;
- (2) to follow, in matters pertaining to human cases of avian influenza, mechanisms and procedures set out in the Regulations for a disease that may constitute a public health emergency of international concern;
- (3) to provide transparent and urgent notification and subsequent continued communication to WHO of any suspected or confirmed human cases of avian influenza, including exported or imported cases;
- (4) to respect time frames stipulated in the Regulations for undertaking and completing urgent activities and communications, particularly for the reporting of human cases of avian influenza, verification of events, and response to requests for further information from WHO:
- (5) to collaborate, including through the mobilization of financial support, to build, strengthen, and maintain the capacity for influenza surveillance and response in countries affected by avian influenza;
- (6) to follow any recommendations issued by the Director-General, with technical advice from the influenza pandemic task force, considered necessary for the international response to avian influenza or pandemic influenza;

- (7) to inform the Director-General of the measures that they have taken in voluntary compliance with the International Health Regulations (2005);
- 5. REQUESTS the Director-General:
  - (1) to designate immediately WHO IHR Contact Points, as provided for in Article 4 of the Regulations;
  - (2) to implement, in so far as feasible and relevant for the purpose of this resolution, measures in Parts II and III of the Regulations falling under the responsibility of WHO;
  - (3) to further accelerate steps to establish a roster of experts and to invite proposals for its membership, pursuant to Article 47;
  - (4) to use the influenza pandemic task force as a temporary mechanism to advise the Organization on the response to avian influenza, the appropriate phase of pandemic alert and the corresponding recommended response measures, the declaration of an influenza pandemic, and the international response to a pandemic;
  - (5) to collaborate with Member States in implementation of the present resolution, as appropriate, including through:
    - (a) provision or facilitation of technical cooperation and logistical support;
    - (b) mobilization of international assistance, including financial support, in consultation with Member States lacking sufficient operational capacity, especially when control measures against international spread are unlikely to succeed:
    - (c) production of guidelines to support Member States in development of capacities for a public-health response specific to the risk posed by avian influenza and pandemic influenza;
  - (6) to collaborate with Member States to the extent possible in providing support to developing countries in building and strengthening the capacities required under the International Health Regulations (2005);
  - (7) to report to the Sixtieth World Health Assembly through the Executive Board at its 119th session on implementation of this resolution.

#### **ANNEX**

### MEETING ON AVIAN INFLUENZA AND HUMAN PANDEMIC INFLUENZA: CLOSING REMARKS OF THE DIRECTOR-GENERAL

Thank you for making this a remarkable and productive meeting. The world has been watching and listening as, over these three days, the scale of the challenges has emerged. The international solidarity to confront these threats is clear. The urgency of acting now is felt by us all. Precise recommendations for action have emerged. Equally, precise offers of help and support have been put forward, by both developing and industrialized countries.

I will now review the central points that have come out of the meeting. Next I will outline an integrated programme of action which responds to the issues raised.

- 1. Minimizing the threat at source to both animal and human populations through rapid reduction of the viral burden of H5N1 is essential. This entails timely notification of outbreaks in birds, poultry culling and vaccination as indicated, including "backyard" flocks, and provision of appropriate compensation for farmers.
- 2. "Early warning" and surveillance systems for animal and human influenza are critical to effective response. The current window of opportunity to intervene is measured in days. Transparent and immediate reporting is essential.
- 3. The introduction of avian infection with H5N1 to other countries is predicted, following the patterns of migratory birds, and as a result of production systems and market practices. Other strains of avian flu are also an ongoing and emerging threat and must be monitored. Strengthened veterinary services are a crucial aspect of detection and response. Open sharing of virus samples is essential. Quality assured animal vaccines produced to international standards should be used in healthy poultry when appropriate.
- 4. At present many governments are not ready to cope with outbreaks, still less a pandemic. Preparedness is vital in every country, in every Region. Integrated country plans will build on and strengthen existing systems and mechanisms. They will be comprehensive, costed, and evaluated. Response mechanisms should be rehearsed through simulation exercises. These plans will include protection of vulnerable groups such as children, refugees and displaced populations.
- 5. Resources needed to slow down or contain the emergence of a pandemic are insufficient. Supplies of antiviral drugs currently do not meet potential demand. Issues remain of equitable access to medicines and deployment of stockpiles.
- 6. A universal non-specific pandemic vaccine may be the ultimate protective solution for human influenza. "Smart" solutions are being investigated. Issues of technology transfer, resolution of licensing and regulatory obstacles, sustained use of good manufacturing practices and pre-qualification are under discussion. Predictable, increased orders for seasonal flu vaccine will support greater manufacturing capacity, including in developing countries.
- 7. Communications. The recent series of high-level meetings on avian influenza and human pandemic influenza have successfully created a shared agenda. The public needs clear, regular, reliable information. Civil society, nongovernmental organizations and other community groups must be involved.

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8. A rich array of resources is potentially available to support government and institutional efforts. Countries that have successfully controlled outbreaks of avian influenza are prepared to help others.

- 9. Mechanisms for donor support are in place. There is broad commitment to minimize transaction costs of international support through alignment and harmonization. International support to country plans should supplement national resources, as well as existing donor resources, and should target resource-poor countries.
- 10. Investments are urgently needed at national level potentially reaching 1 billion dollars over the next three years. An additional 35 million dollars is needed immediately to support high priority actions by technical agencies at the global level over the next six months.

The 10 points I have outlined need detailed and concrete actions. This meeting has identified a series of integrated actions that will start straight away.

- 1. Support the development of integrated national plans for avian influenza control and human pandemic influenza preparedness and response.
- 2. Assist countries in aggressive control of avian influenza in birds, and deepen the understanding of the role of wild birds in virus transmission.
- 3. Nominate "rapid response" teams of experts to support epidemiological field investigations.
- 4. Strengthen country and regional capacity in surveillance, laboratory diagnosis, and alert and response systems.
- 5. Expand the network of influenza laboratories, with regional collaborative systems for access to reference laboratories.
- 6. Establish and integrate multi-country networks for the control or prevention of animal trans-boundary diseases, and regional support units as established in the Global Framework for the Progressive Control of Trans-boundary Animal Diseases.
- 7. Expand the global antiviral stockpile, and prepare standard operating practices for its rapid deployment to achieve early containment.
- 8. Assess the needs and strengthen veterinary infrastructure in line with OIE standards.
- 9. Map out a global strategy and work plan for coordinating antiviral and influenza vaccine research and development, and for increasing production capacity and equitable access.
- 10. Put forward proposals to the WHO Executive Board at its 117th meeting for immediate voluntary compliance with relevant articles of the International Health Regulations (2005).
- 11. Finalize detailed costing of country plans and the regional and global requirements to support them, in preparation for the January pledging meeting to be hosted by the Government of China.
- 12. Finalize a coordination framework building on existing mechanisms at the country level, and at the global level, building on international best practices.

This is a challenging agenda which will require all our best efforts.