World Health Organization

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

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Reports by the Director-General

Summary progress reports

1. Resolution WHA60.28 "Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits" requested the Director-General, inter alia, to identify and propose, in close consultation with Member States, frameworks and mechanisms that aimed to ensure fair and equitable sharing of benefits. This report summarizes actions undertaken and planned in order to implement the following paragraphs of the resolution: 2(1) on frameworks and mechanisms, 2(2) on establishing an international stockpile of vaccines, and 2(3) on mechanisms and guidelines for distributing vaccines fairly and equitably.

IDENTIFICATION OF FRAMEWORKS AND MECHANISMS FOR SHARING BENEFITS (RESOLUTION WHA60.28, PARAGRAPH 2(1))

Principles of sharing of and access to benefits

2. Guiding principles for the sharing of, and access to, benefits that result from the sharing of influenza viruses have been agreed through close consultation with Member States. These principles are distributed across several documents, including resolution WHA60.28 paragraph 2(5)(a)–(h) and the Best practices for the sharing of influenza viruses and sequence data[1] (which were endorsed by WHO's Influenza Pandemic Task Force in September 2006[2]). These principles have shaped the formulation and attainment of the objectives of virus sharing, as reflected in this report.

Definition of benefits

3. In the context of pandemic influenza preparedness, the issue of access to benefits arose from the identification of influenza viruses of pandemic potential. In discussion of the benefits provided or leveraged by WHO, the following criteria have been applied: a clear, established link to influenza surveillance, risk assessment or containment/response; a demonstrated need for the benefit by the

[1] Document EB120/INF.DOC./3.

[2] Document WHO/CDS/ESR/GIP/2006.5.

beneficiary country; and WHO's oversight of the process of establishing, securing and delivering a benefit.

4. On the basis of these criteria, benefits may be:

- increased global public health security, resulting from risk assessment;
- access to and transfer of technology for influenza vaccine development and production;
- strengthened national capacity; and
- improved risk management through establishment of stockpiles and/or provision of: pharmaceuticals, personal protective equipment and other supplies necessary during the response to an outbreak; non-commercial diagnostic tests and materials; influenza vaccines and ancillary supplies (e.g. syringes).

Global public health security

5. One of the most important benefits derived from virus sharing is WHO's continued ability to assess the global risk of the emergence of a strain of influenza virus with pandemic potential, as required under the International Health Regulations (2005). This global public health benefit requires at a minimum: access to the broadest range of circulating influenza viruses; up-to-date influenza laboratories and specialists; and information systems to provide timely feedback to countries for response. The information derived from risk assessment enables the updating of vaccines, pharmaceuticals and diagnostic materials, all of which contribute to effective global responses to influenza outbreaks. WHO will continue to coordinate provision of this global public health benefit.

The time frame for this objective is ongoing.

Access to and transfer of technology

6. In resolution WHA60.28 the Health Assembly noted the global pandemic influenza action plan to increase vaccine supply,[1] which had been elaborated through a broad consultative process with Member States and vaccine experts. Following receipt of funds from several donors, implementation has begun, with requests for proposals and award of development grants of US$ 2.0–2.6 million to six companies from developing countries for them to plan, build or strengthen manufacturing capacity for influenza vaccine. On 19 October 2007, WHO convened a meeting of the steering committee of the action plan in order to review activities since May 2006, prioritize the action plan's strategies, revise and update the plan in light of progress in science, technology and preparedness, and facilitate identification of sources of funding for the plan's implementation. The report of the meeting would be considered by WHO's Strategic Advisory Group of Experts.

7. The type of technology to be transferred depends on the level of development of vaccine manufacturing in the host country: as a first step, "fill and finish" manufacturing facilities; at a later stage, full vaccine-manufacturing capacity may be developed if funding and support of vaccine manufacturers are secured.

[1] Document WHO/IVB/06.13–WHO/CDS/EPR/GIP/2006.1.

8. Full-scale implementation of the action plan hinges on the availability of funds from Member States and other donors. The Secretariat continues to work with industry in order to explore further areas for transfer of, or broader access to, technology. In that respect, the Organization will pursue its work with public-sector vaccine manufacturers in order to establish a base for the transfer of technology for manufacturing influenza vaccine that includes procurement of equipment and training.

9. Bilateral discussions therefore continue with interested companies and the International Federation of Pharmaceutical Manufacturers and Associations in order to explore collaboration or partnership between the Federation and its counterpart, the Developing Country Vaccine Manufacturers Network. Issues that could be addressed through these entities include development of innovative mechanisms to licence existing or future intellectual property rights and of platforms to promote further access to technology by developing countries.

The time frame for realizing this objective is 3–10 years.

Strengthened national capacity

10. WHO has several programmes for developing and strengthening the capacity of Member States to conduct risk assessment, thereby contributing to global risk assessment. These programmes focus on strengthening (a) national laboratory and regulatory agency capacity and (b) Member States' core capacity for surveillance and response as required under the International Health Regulations (2005), and include the following:

(a) National laboratory and regulatory agency capacity

(i) to strengthen national capacity for risk assessment: activities include monitoring the evolution of influenza viruses, risk information analysis, updating and development of diagnostic protocols and reagents, monitoring susceptibility to antiviral medicines, expanding the network of laboratories working with the Global Influenza Surveillance Network, and strengthening the capacity of existing laboratories through targeted training (with, depending on demand from Member States and availability of funding, increased participation, for instance, in Field Epidemiology Training Programmes). Such training could enhance Member States' ability to make preventive public health interventions.

(ii) to strengthen national influenza pandemic preparedness and response, including stronger surveillance and risk assessment systems, greater capacity to detect rapidly and contain potentially pandemic outbreaks, better communication of information about risk, and improved health systems infrastructure: work is also directed towards strengthening national regulatory agencies' ability to assess and approve vaccines.

(iii) to broaden influenza surveillance and build research capacity: activities include participation in vaccine strain selection, clinical trials, involvement of scientists from developing countries in research and publications, and technical training on international regulations for shipping infectious substances.

The time frame for these objectives is ongoing.

(b) Member States' core capacity for surveillance and response

To detect, assess, notify and report public health events through implementation of the International Health Regulations (2005), Member States will need better laboratories, expanded laboratory capacity and improved surveillance. The Secretariat will continue to work with Member States to upgrade information systems so that they provide full, reliable and timely access to information on the use and flow of specimens and viruses contributed to the Global Influenza Surveillance Network.

The time frame for this objective is ongoing.

Improved risk management

Pharmaceuticals, personal protective equipment and other supplies needed for response to outbreaks

11. In order to develop capacity for the rapid control of a potential influenza pandemic and as a first line of defence against outbreaks due to the H5N1 virus, WHO has created a stockpile of oseltamivir sufficient to treat five million adults. Guidelines are being implemented for the placement of some of the pharmaceutical stockpile at locations in WHO regions and the release of required quantities to Member States to contain outbreaks due to H5N1 virus. The Organization has also put together an outbreak-response kit containing guidance on actions and investigations, personal protective equipment and sampling kits. The kits are stored at locations in all WHO regions and high-risk countries. The Secretariat will work closely with Member States in order to ensure that these stockpiles are replenished as needed.

The time frame for implementation is ongoing.

Non-commercial diagnostic materials

12. As members of the Global Influenza Surveillance Network, national influenza centres receive annual supplies, without charge, of non-commercial diagnostic test materials and reagents for the identification and characterization of influenza-related biological specimens collected in their country.

The time frame for this activity is ongoing.

H5N1 influenza vaccines

13. An international H5N1 vaccine stockpile is being established, and, in June 2007, WHO was offered the first donation of 50 million doses of vaccine. In addition, the Secretariat is drawing up with experts transparent rules and procedures for the geographical placement, operation (including prioritization of release of vaccine), management and oversight of such a stockpile. The Secretariat will be consulting with Member States, industry and other partners before the present Intergovernmental Meeting. Scheduled meetings include: a global consultation on the use of human H5N1 vaccines (1–3 October 2007) with the aim of developing consensus on policy options for the use of H5 vaccines, including those in an international stockpile. The report of this meeting will be submitted to WHO's Strategic Advisory Group of Experts for consideration. An informal consultation on technical specifications for an international H5N1 vaccine stockpile (17–18 October 2007) was organized in order to try to resolve technical issues such as regulatory and operational questions relevant to stockpiled H5 vaccines. Expected outcomes include: proposals to guide the regulatory oversight and operational management of the H5N1 vaccine stockpile; criteria for acceptance of

donations; resources needed for upkeep of the stockpile; and criteria and processes for equitable access to the stockpile. Further studies needed on stockpiled H5 vaccines may be identified. A meeting of the Strategic Advisory Group of Experts (6–9 November 2007) will draw up policy options for the Director-General's consideration.

The time frame for implementing this work is 6–12 months.

Mechanism to ensure broader access to pandemic vaccine

14. Global capacity to produce influenza vaccine is limited. Extreme time constraints will be faced in developing an influenza vaccine following isolation of the pandemic strain. Best estimates for current vaccine production are less than 500 million doses of trivalent seasonal influenza vaccine (containing 15 µg of each antigen or 45 µg total per dose) in one year. This capacity could produce about 1500 million monovalent pandemic vaccine doses (15 µg antigen per dose). The potency level for an effective pandemic vaccine dose has not, however, been established.

15. In the event of a pandemic next year, it would take time to produce the first 1000 million doses of a suitable vaccine. Furthermore, pre-arranged supply contracts between vaccine manufacturers and clients mean that many countries without vaccine production would have no access to a pandemic vaccine from existing manufacturers.

16. The Secretariat therefore proposes to pursue, with Member States and influenza vaccine manufacturers, an advance commitment mechanism. One possibility would be for Member States in which there are producers of vaccine to agree in advance to release a pre-defined quantity of pandemic influenza vaccine drawn from existing purchase contracts. The vaccine so released would then be available, through purchase or donation, to countries without access to pandemic vaccine. In such a manner, developing countries and countries without manufacturing capacity for influenza vaccine would have some guaranteed access to pandemic influenza vaccine. Possible ways of gaining this type of advance commitment include: pledges made by Member States to release manufacturers within their countries from national legislation and/or supply contracts up to a predefined quantity, thereby making such predefined quantity of pandemic influenza vaccine available for purchase as and when manufacturers produce the actual pandemic vaccine; and funding arrangements such as advance purchase agreements, insurance policies, or bilateral aid commitments by agencies, international lending institutions and other donors.

17. Many details remain to be worked out, for instance when would the vaccine be available, in what quantity, at what price, and with what financial commitments by donors and countries to pay or fund vaccine purchases. The Secretariat will continue to work with Member States and all potential partners, including the vaccine manufacturing industry, on refining this mechanism.

The time frame for development of mechanism is 12 months.

Increased use of seasonal influenza vaccine

18. Increasing the use of the seasonal vaccine will raise demand and trigger an expansion of manufacturing capacity. The prerequisites of such changes may include: studies of the burden of disease due to influenza, assessment of the capacity of Member States to deliver influenza vaccines, and work with industry in order to reduce the price of seasonal vaccine to a level that is affordable for developing countries. The Secretariat will continue to work with Member States, donors and industry on this matter.

NEXT STEPS

19. Through existing consultative mechanisms, the Secretariat will continue to explore with partners: the sustainability of benefit sharing and mechanisms to stimulate the discovery, development, and production of, and access to, pandemic and other influenza vaccines; and innovative but sustainable financing mechanisms for the timely and affordable procurement of all types of influenza vaccines (H5N1, pandemic and seasonal). Tiered pricing, preferential pricing, bulk purchasing and other procurement mechanisms that take advantage of economies of scale will be discussed and closely reviewed with interested Member States, donors and industry in order to put rapidly in place necessary contractual agreements.

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