World Health Organization

INTERGOVERNMENTAL MEETING ON PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS
OPEN-ENDED WORKING GROUP
Provisional agenda item 3

A/PIP/IGM/WG/4
3 April 2008

Extracts from EB122/5

BENEFIT SHARING

This document contains extracts from document EB122/5. The passages may be found in the consolidated outcome text (Annex 6), at the pages indicated.

Key to document references:

IGM/2 Rev.1 refers to document A/PIP/IGM/2 Rev.1, Reports by the Director-General: Summary progress reports. (The document summarizes actions undertaken and planned in order to implement the following paragraphs of resolution WHA60.28: 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.)

IGM/4 refers to document A/PIP/IGM/4, Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness (resolution WHA60.28 (paragraph 2(5)) (Singapore, 31 July – 4 August 2007).

IGM/5 refers to document A/PIP/IGM/5: 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. (This text was proposed by Indonesia to be considered as a working document for the discussion in the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007.)

IGM/6 refers to document A/PIP/IGM/6, Annex: A proposal from Thailand for the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007: Standard Terms and Conditions (STCs) for the transfer and use of influenza biological materials and fair and equitable benefits sharing (between Member States [MS] and WHO Secretariat [WS]).

AFRO refers to document A/PIP/IGM/7, Annex: Standard Terms and Conditions for the transfer and use of influenza biological materials and fair and equitable benefit sharing; A proposal from the African Region for the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007.

In all cases, the **bold number** immediately following the document number refers to the paragraph in the document.

The following section is extracted from White Paper 3 (21 November 2007); document EB122/5, Annex 6, pages 45–50.

NOTES for this section ONLY

(1) Text **agreed** by consensus at the IGM is marked in ***bold, italics,*** followed by the word ***"agreed"*** in parenthesis. Only text marked in this manner was agreed by consensus at the IGM.

(2) Submission of revised text from delegations to the IGM is marked in *italics* with country/region attribution in parenthesis, in ***bold, italics.***

BENEFIT SHARING

DEFINITION OF BENEFITS

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 beneficiary country; and WHO's oversight of the process of establishing, securing and delivering a benefit. (IGM/2 Rev.1)

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 related to influenza preparedness and response (USA); 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). (IGM/2 Rev.1) (agreed)***
- *[benefits must be concrete, specific and provided to developing countries, especially affected countries and their geographic vicinities* ***(Indonesia)****] (to be discussed in the plenary session on principles)*

SCOPE

Global public health security

[One of the important benefits derived from virus sharing is WHO's continued ability to assess the global risk of the emergence of a strain with pandemic potential. This global public health benefit and other benefits are within the context of an equal relationship among countries at the global level. The delivery of such benefits requires among others:

(1) risk assessment

(2) access to broadest range of circulating influenza viruses

(3) up-to-date influenza labs and specialists

(4) information systems to provide timely feedback to countries for response

(5) access to and transfer of technology

(6) strengthened national capacity

(7) aim at ensuring fair and equitable access to vaccines and medicines

(8) access to supplies needed for response]

Access to and transfer of technology

In resolution WHA60.28 the Health Assembly noted the global pandemic influenza action plan to increase vaccine supply, 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. (IGM/2 Rev.1)

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. (IGM/2 Rev.1)

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. (IGM/2 Rev.1)(agreed)

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. (IGM/2 Rev.1) (agreed)

[Bilateral discussions therefore continue *between* interested companies *affiliated to IFPMA, DCMN, or other influenza vaccine manufacturers.* Issues that could be addressed between interested parties include *exploitation and use of existing technologies*, *and, as appropriate, to consider development of innovative mechanisms* ***(~~IFPMA~~)/USA*** **]** .

Strengthened national capacity

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: (IGM/2 Rev.1)

(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 newly reformed and improved (France) 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. (IGM/2 Rev.1)

(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. (IGM/2 Rev.1)

(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. (IGM/2 Rev.1)

(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. (IGM/2 Rev.1) (agreed)

[(c) Research capacity: involvement of developing countries' scientists in research and publication in scientific journals through a participatory process where developing countries' scientists are involved in the conception and execution of the research and drafting as well as finalization of publications (Indonesia)]

or:

[The WHO Collaborating Centres and other institutions are to include scientists from country or institution of origin in research work on relevant samples to the fullest extent feasible; and are to appropriately acknowledge, according to standards of international medical journals, and properly attribute to scientists from the country or institution of origin in any medical or scientific journal or publication of work on relevant samples ***(USA electronic submission).****] (to be agreed)*

Access to Vaccines

H5N1

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. (IGM/2 Rev.1)

Pandemic vaccine

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. (IGM/2 Rev.1)

In the event of a pandemic next year, it would take time to produce the first ~~1000 million~~ 9 billion 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. (IGM/2 Rev.1)

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. (IGM/2 Rev.1)

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. (IGM/2 Rev.1) (agreed)

Seasonal vaccines

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. (IGM/2 Rev.1) (agreed)

[Sequence data from virus samples in the GISN are to be uploaded to a public available database ***(USA electronic submission)****/regulated database, with the permission of the originating country* ***(Indonesia)****]*

Vaccine manufacturers should support benefit sharing (such as preferential pricing policies for relevant products in developing countries, donations to WHO-managed stockpiles, and transfer of technology to developing countries to expand safe and effective influenza vaccine production capacity), and should join in related capacity-building activities for developing country health professionals and laboratories (USA electronic submission) (*to be placed elsewhere under Benefit sharing****) (agreed)***

Access to Supplies Needed for Response

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

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. (IGM/2 Rev.1)

Non-commercial diagnostic materials

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. (IGM/2 Rev.1) (agreed)

MECHANISM FOR OPERATION

[The World Health Organization is to establish and manage a global stockpile of vaccine against novel influenza viruses being perceived as a significant pandemic threat. The purposes of the stockpile are to mount containment operations and to assist in pandemic preparedness efforts in countries affected by novel influenza viruses being perceived as a significant pandemic threat, according to public health needs ***(EU)****. The WHO Secretariat is to devise a clear and transparent concept of operations for the use of the stockpile, including clear parameters and procedures for its deployment and an algorithm for prioritization.]* ***(USA)***

Furthermore, the World Health Organization is to actively explore options that will maximize equitable access to pandemic vaccine according to public health needs in the event of a pandemic. (Norway) (agreed)

[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. **(IGM/5 Fundamental Element 9)**]

[Distribution of global stockpile of pre-pandemic and pandemic vaccines must be prioritized to developing countries, especially affected countries and their geographic vicinities. **(IGM/5 Fundamental Element 10)**]

[*Also should be considered as a benefit sharing the technological transfer of vaccine and reagents production as well as the strengthening of the production capacity of manufacturers in developing countries. WHO will promote and address the above mentioned capacities, making sure that the third party that receives the virus dor vaccine production will be committed with this obligation. WHO and MS will promote the scientific and technological information and dissemination seeking the development of capacity building on influenza research, epidemiological investigation and laboratory and diagnostic techniques.*] ***(Brazil)***

ROLE OF WHO *(described under the STCs)*

ROLE OF MS *(described under the STCs)*

ROLE OF OTHER PARTIES *(described under the STCs)*

The following section is extracted from White Paper 3 (21 November 2007); document EB122/5 Annex 6, pages 52–53.

[Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS) (the following is Annex II of IGM/6)

The Global Influenza Vaccine Fund shall be used in the Global Influenza Vaccine Benefits Sharing Scheme for the following activities:

(1) Use of Fund to secure ~~20%~~ *sufficient* global production capacity of influenza vaccines for use during a pandemic through advance purchase agreement with the vaccine manufacturers and the governments which have reserved the vaccine production capacity with the vaccine manufacturers

(2) Use of Fund to improve and facilitate transfer of technology of influenza vaccine production among developing countries

(3) Use of Fund to pay for license fee for transfer of technology of influenza vaccine manufacturing to developing countries at a pre-negotiated rate

Calculation of the pre-negotiated rate for license fee for transfer of technology

For egg-based technology

The total amount of X (payable for a period of 3-5 years, depending on the duration of influenza vaccine plants design, construction and validation) for license fee for technology transfer is determined by finding the value of X that satisfies the following condition:

"X + investment cost for a new influenza vaccine plant (with a production capacity of 10 million doses per year) is completely offset within 10 years by the margins (profits) generated by the vaccines produced at full capacity and sold at the price half of the average market prices of 5 leading brands of similar vaccines in that country".

For cell-based technology

The total amount of X (payable for a period of 3-5 years, depending on the duration of influenza vaccine plants design, construction and validation) for license fee for technology transfer is determined by finding the value of X that satisfies the following condition:

"X + investment cost for a new influenza vaccine plant (with a production capacity of 10 million doses per year) is completely offset within 30 years by the margins (profits) generated by the vaccines produced at full capacity and sold at the price half of the average market prices of 3 leading brands of similar vaccines in that country".]

The following section is extracted from White Paper 3 (21 November 2007); document EB122/5 Annex 6, pages 77–78.

IGM/4 Annex 2

Contribution Agreement to

WHO's Coordinated International Sharing of Influenza Viruses & Benefits

By and between WHO and [COMPANY NAME]

In consideration for the use of GISN Biological Specimens, as defined herein, [COMPANY NAME] agrees to contribute to the following components of the WHO's Coordinated International Sharing of Influenza Viruses & Benefits.

Examples of possible contributions by Manufacturers

1. Cash: as a % of sales or other defined formula contributed to a WHO managed trust fund.

AND/OR

2. Access to technology:

a. Royalty Free Licences

The Company agrees to grant on request, a non-exclusive, royalty-free license to any domestic influenza vaccine manufacturer from developing and least developed countries to use its intellectual property and other protected substances, products (including technology), know-how, information used in the process of influenza vaccine development and production. A copy of the request should also be sent to WHO.

AND/OR

b. Transfer of Technology & Know-How

The Company agrees on request to allow access to and transfer of, its technology and related know-how particularly to domestic influenza vaccine manufacturers from developing and least developed countries especially to the Providing Country and other countries in need. A copy of the request should also be sent to WHO.

AND/OR

c. Pandemic & Pre-pandemic Vaccines

The Company agrees to set aside X% of vaccines for developing and least developed countries especially to those in need and particularly during the pandemic period. These vaccines will be made available at an affordable price for developing countries and least developed countries. The Company, in pricing its products should consider "Affordable price" for developing countries as a price no higher than cost per unit + X% (e.g. 5%), while for least developed countries as "no profit no loss", particularly during the pandemic period.

AND/OR

3. Access to diagnostics, antivirals and vaccines

a. Contribute to stockpile of H5N1 vaccines and ancillary supplies, support downstream management of this stockpile, equitable distribution,

b. Provide antivirals

c. Provide funds for advance procurement arrangements for pandemic vaccines

d. Donate funds to constitute a supply of safe and effective H5N1 and pandemic vaccines

e. Donate or earmark part of the Advanced Market Purchasing (AMP) by some Member States and manufacturers of pandemic vaccines, for access by affected countries during pandemic.

f. In the event of a pandemic, the Company agrees to transfer at least 60% of every production batch of vaccines developed to an international stockpile prior to commercialization.

g. In pre-pandemic period the Company agrees to transfer at least 40% of every production batch of vaccines developed to an international stockpile prior to commercialisation.

AND/OR

4. Vaccine development [for some MS having potential vaccine production capacity but spill-over to all MS]

a. Provide access to technologies

   i. Royalty free license to intellectual property protected technologies

   ii. Access to and use of regulatory approval data [clinical trial data for registration]

b. Transfer technology [clarify which specific technologies, e.g. platform technologies or vaccine production]

c. Contribute to fund national investments to increase vaccine production capacity in developing countries.

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