

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

### **Resumed Intergovernmental Meeting**

#### **Report by the Director-General**

1. In May 2007, the Health Assembly in resolution WHA60.28 requested the Director-General to report on progress in implementing the resolution, including the work of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits. In May 2008, the Health Assembly noted the work of the Intergovernmental Meeting before its suspension in November 2007 and that of the open-ended working group that had met in April 2008.<sup>1</sup>
2. Both the open-ended working group and the Intergovernmental Meeting resumed their work in Geneva in December 2008 under the chairmanship of Ms Jane Halton (Australia). The open-ended working group agreed that the Chair's revised text<sup>2</sup> should be forwarded to the resumed Intergovernmental Meeting as the basis for its work (see Annex 1 for the report of the resumed Intergovernmental Meeting).
3. At its resumed session, the Intergovernmental Meeting made considerable progress and reached consensus on many items in the text (see Annex 2) before suspending its meeting. It agreed to reconvene in Geneva in connection with the Sixty-second World Health Assembly (19–24 May 2009) in order to resume its discussions.
4. The Director-General herewith submits the report on progress of the Intergovernmental Meeting.

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

5. The Board is invited to note this report and the progress made by the Intergovernmental Meeting.

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<sup>1</sup> Document WHA61/2008/REC/3, summary record of the second meeting of Committee A.

<sup>2</sup> Document A/PIP/IGM/WG/6.



ANNEX 1

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

**Report on progress to date**

1. The resumed session of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits was held in Geneva, from 8 to 13 December 2008. Ms Jane Halton (Australia), Chair of the Intergovernmental Meeting, presided over the resumed session. Participants included delegates from over 100 Member States, one regional economic integration organization, two invited observers and representatives from United Nations specialized agencies and nongovernmental organizations in official relations with WHO.
2. The Intergovernmental Meeting elected Dr J.L. Valdespino (Mexico) as Vice-Chair.
3. The Director-General delivered opening remarks.
4. The Chair provided an update of the process to date, and the Intergovernmental Meeting agreed, upon the recommendation of the Open-Ended Working Group, to use the Chair's text as the basis for its work.<sup>1</sup>
5. The Intergovernmental Meeting expressed appreciation for the work undertaken with respect to the Chair's text by the Chair and the five Vice-Chairs: Mr A. Dick (Timor-Leste), Dr J.L. Valdespino (Mexico) taking the seat vacated by Dr E. Palacios (Mexico), Mr K. Ahmadi (Islamic Republic of Iran), Dr A. Nasidi (Nigeria) and Mrs S. Hodne-Steen (Norway).
6. The Intergovernmental Meeting decided to establish two working groups and agreed that Working Group A, with Mrs Hodne-Steen as Chair, would consider sections 5, 6 and Annex 1 of the Chair's text, and that Working Group B, with Dr A. Nasidi as Chair, would consider section 7 and Annexes 2 and 3 of the Chair's text.
7. The Secretariat provided presentations on progress to date regarding:
  - (a) the Advisory Mechanism
  - (b) the Influenza Virus Traceability Mechanism
  - (c) progress on implementing strategies identified under the global action plan to increase supply of pandemic vaccine<sup>2</sup>

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<sup>1</sup> Document A/PIP/IGM/WG/6.

<sup>2</sup> Document WHO/IVB/06.13 – WHO/CDS/EPR/GIP/2006.1.

- (d) establishment of the international stockpile of H5N1 vaccines
- (e) antiviral stockpiles.

8. The Secretariat presented recommendations regarding the H5N1 vaccine stockpile and reported on the work being undertaken by the Strategic Advisory Group of Experts on Immunization on behalf of its H5N1 Working Group Chair, Dr Supamit Chunsuttiwat (Thailand).

9. Professor Bruno Lina, Chairman of the Advisory Group – established by the Director-General in accordance with the Interim Statement of the Intergovernmental Meeting – provided an oral report of the meeting of the Advisory Group held on 21 October 2008.<sup>1</sup>

10. The Intergovernmental Meeting opened discussions of sections 1–4 of the Chair’s text and made progress in further developing the text. The working groups then convened their meetings.

11. Working Group A made progress on sections 5 and 6 of the Chair’s text.

12. Working Group B reviewed and reached general agreement on section 7 and prepared for consideration by the Intergovernmental Meeting in plenary session the following two documents,<sup>2</sup> which were subsequently agreed by the plenary as indicated:

- (a) Terms of reference for the Advisory Mechanism/Group (consensus)
- (b) Guiding principles for the development of terms of reference for [WHO Network] laboratories for H5N1 and other influenza viruses with human pandemic potential (consensus on guiding principles 1–8).

13. The Intergovernmental Meeting agreed that Member States are committed to share, on an equal footing, H5N1 and other influenza viruses with human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health.

14. The Intergovernmental Meeting decided to:

- (a) suspend the Intergovernmental Meeting and reconvene in connection with the Sixty-second World Health Assembly;
- (b) acknowledge the need to have informal consultations among interested Member States and relevant regional economic integration organizations in the intersessional period, using all possible forums, in order to find ways of resolving the remaining issues;
- (c) request the Chair and the Bureau to facilitate such consultations; and
- (d) request the Director-General to undertake, taking into account the Intergovernmental Meeting’s revised text, and if necessary with the advice of the Advisory Group, the following preparatory work:

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<sup>1</sup> The report of the meeting is contained in document A/PIP/IGM/8, Annex 2.

<sup>2</sup> Attached to this Annex as Appendices 1 and 2.

- (i) further development of the traceability mechanism;
- (ii) preparation of the detailed terms of reference of WHO Collaborating Centres on Influenza, the WHO H5 Reference Laboratories, essential regulatory laboratories, and the National Influenza Centres, following the guiding principles included in the Intergovernmental Meeting text;
- (iii) preparation of a revised version of the technical part of the Standard Material Transfer Agreement, following the agreed principles of the Intergovernmental Meeting text;
- (iv) preparation of a report identifying the needs and priorities for each of the benefits listed in section 6 of the Intergovernmental Meeting text, in particular concerning the vaccine stockpile, as well as options for their financing.

15. The text as developed by the Intergovernmental Meeting, is attached as Annex 2.

## APPENDIX 1

**ADVISORY GROUP  
TERMS OF REFERENCE****1. Background and mandate of Advisory Group**

The Interim Statement adopted by WHO Member States attending the 20–23 November 2007 Intergovernmental Meeting on Pandemic Influenza Preparedness urged action to develop fair, transparent, and equitable international mechanisms on virus sharing and benefit sharing. Member States called on the Director-General to establish an Advisory Mechanism to monitor, provide guidance to strengthen the functioning of the trust-based system needed to protect public health and undertake necessary assessment of that system. To carry this out, Member States specified that an Advisory Group will be appointed by the Director-General in consultation with Member States, based on equitable representation of the WHO regions and of affected countries.

The trust-based system is now referred to as the “Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits” (hereinafter “the Framework”). The scope of the Advisory Group is to monitor, assess and report on the system for sharing H5N1 influenza viruses and other influenza viruses with human pandemic potential as well as access to vaccines and other benefits of the Framework. The institutional components of the Framework to be monitored by the Advisory Group are National Influenza Centres, Other authorized laboratories, WHO Collaborating Centres, H5 Reference Laboratories, and essential regulatory laboratories, as defined in Section [4] of the Framework. [The pharmaceutical industry is not included although they can be consulted (but not monitored) by the Advisory Group.]

**2. Functions of the Advisory Group**

2.1 To monitor, assess and report on how the different functions of the Framework are implemented by its components. The information to conduct these tasks should be provided by the WHO Secretariat and other independent sources, if available. Monitoring by the Advisory Group will enable ongoing assessment of the functioning of the Framework and should include at least:

- (a) the rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with the [WHO Network];
- (b) the Influenza Virus Traceability Mechanism;
- (c) the global improvement of laboratory capacity, particularly in developing countries, to enhance pandemic influenza preparedness;
- (d) the fair and equitable sharing of benefits.

2.2 To carry out the necessary assessment of the Framework according to quantitative and qualitative indicators developed from information provided by the WHO Secretariat and other independent sources, if necessary.

- 2.3 To provide guidance to strengthen the functioning of the Framework to the Director-General.
- 2.4 Recommendations and reports of the Advisory Group shall be evidence based.
- 2.5 To report annually, through the Director-General to the Executive Board and the World Health Assembly on its activities.

### **3. Nomination of members**

3.1 The Advisory Group will comprise 18 members drawn from three Member States in each WHO region, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza. In the exercise of their functions the Members shall act as international experts serving WHO exclusively.

3.2 Each member will serve for three years. The duration of appointment of each member will be three years with a renewal of one third of the members every year; replacements must maintain the equitable representation of the six WHO regions and affected countries; all members will be eligible for two appointments. In the event of resignation or incapacity of a member for any reason, the Director-General will appoint a replacement member with a view to maintaining the equitable representation of the six WHO regions and affected countries. The replacement will complete the term of the previous member. The Group will select from among its members, a Chairperson and a Vice-Chairperson. The Chairperson and Vice-Chairperson will serve for two years after which another Chairperson and Vice-Chairperson will be selected by the Group members.

3.3 The Director-General will regularly accept nominations of representatives and will draw from this list to replace outgoing members with a view to maintaining the equitable representation of the six WHO regions and affected countries.

### **4. Working procedures**

The Director-General will apply to this Advisory Group working procedures consistent with WHO practices and procedures.

The regulations applying to the procedures of expert committees will apply to the Advisory Group, including with respect to the private nature of meetings. Furthermore, members of the Advisory Group will not make public statements, individually or on behalf of the group, on the work of the Advisory Group, except as authorized in connection with reporting requirements or by the Director-General.

### **5. Resources for implementation**

The Director-General will make available the necessary human and financial resources to support the work of the Advisory Group.

## APPENDIX 2

**GUIDING PRINCIPLES FOR THE DEVELOPMENT OF TERMS OF REFERENCE FOR CURRENT AND POTENTIAL FUTURE [WHO NETWORK] LABORATORIES FOR H5N1 AND OTHER HUMAN PANDEMIC INFLUENZA VIRUSES**

The specific roles, responsibilities and activities conducted by the different [WHO Network] laboratories can differ depending on whether they are a National Influenza Centre, a WHO Collaborating Centre, an H5 Reference Laboratory or an essential regulatory laboratory. However, in the context of pandemic influenza preparedness and their work with H5N1 and other viruses of human pandemic potential, the development of the Terms of Reference for each group of [WHO Network] laboratories shall comply with the following core guiding principles.

1. All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.
2. The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.
3. The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.
4. The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States where necessary.
5. The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.
6. If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or Other authorized laboratory, especially those from developing countries, including through the publication process.
7. The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.
8. The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.
9. The [WHO Network] laboratories will share [publicly] genetic sequence data consistent with the Standard Material Transfer Agreement.]
10. The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or Other authorized laboratory.]

## ANNEX 2

**PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK<sup>1</sup>  
FOR THE SHARING OF INFLUENZA VIRUSES AND  
ACCESS TO VACCINES AND OTHER BENEFITS**

	<b>Page</b>
1. PRINCIPLES .....	11
2. OBJECTIVE .....	14
3. SCOPE .....	15
4. DEFINITIONS AND USE OF TERMS	
4.1 Scientific terms.....	16
4.2 Institutions, organizations and entities.....	17
4.3 Other terms.....	18
5. PANDEMIC INFLUENZA PREPAREDNESS SYSTEM FOR SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES WITH HUMAN PANDEMIC POTENTIAL	
5.1 General.....	20
5.2 Traceability and reporting mechanisms.....	21
5.3 Standard Material Transfer Agreement .....	22
General.....	22
Execution of the Standard Material Transfer Agreement.....	22
6. PANDEMIC INFLUENZA PREPAREDNESS BENEFIT SHARING SYSTEM	
6.1 General.....	23
6.2 Pandemic risk assessment and risk response .....	23
6.3 Provision of PIP Candidate Vaccine Viruses .....	24
6.4 Provision of diagnostic reagents and test kits.....	24
6.5 Provision of reference reagents for potency determination of vaccines .....	24
6.6 Laboratory and influenza surveillance capacity building .....	24
6.7 Regulatory capacity building.....	25
6.8 [WHO and [other] multilateral] antivirals stockpiles .....	25
6.9 [WHO] pandemic influenza preparedness vaccine stockpile .....	25

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<sup>1</sup> A proposal has been made for the use of the term “Guidelines” in place of “Framework” throughout this text. Proposals have also been made for the use of the terms “Multilateral Framework” or “International Framework” and/or “Global sharing”.

6.10	Access to vaccines [for developing and least developed country use] .....	26
6.11	[Production of] Pandemic influenza vaccines.....	27
6.12	[Tiered][Affordable] Pricing OR [concessional and/or preferential rates] OR [differential pricing policies].....	27
6.13	Technology transfer.....	27
6.14	Sustainable financing mechanism.....	28
6.15	Innovative financing mechanisms for national vaccine requirements.....	29
7.	GOVERNANCE AND REVIEW	
7.1	General.....	31
7.2	Advisory Group .....	32
[7.3	Dispute resolution .....	33]
7.4	Governance and Review of Terms of Reference for [WHO Network] Laboratories .	34
7.5	Review of Framework.....	34
	APPENDICES <sup>1</sup>	
	Appendix 1 Standard Material Transfer Agreement .....	35
	Appendix 2 Terms of Reference of the Advisory Mechanism.....	43
	Appendix 3 Terms of Reference of the WHO Collaborating Centres on Influenza, the WHO H5 Reference Laboratories and the National Influenza Centres.....	45

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<sup>1</sup> In the interests of clarity in the present document, the title “Annex” in the original text has been changed to “Appendix”.

Proposed preambular paragraphs

[Noting there has been a breakdown of trust in a global influenza surveillance network and the network does not deliver the desired level of transparency fairness and equity]

## 1. PRINCIPLES

[That the threat of pandemic influenza persists. Timely sharing of surveillance information and highly pathogenic avian influenza viruses, as well as ensuring equitable access to effective vaccinations, medicines and related technology are important ingredients of global readiness to respond to the pandemic. The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits is an international mechanism to implement a fairer, more transparent, equitable and efficient system. In developing countries, support to implementation of national integrated human and animal influenza action plans and building national minimum core capacity for detection, risk assessment, laboratory confirmation and rapid containment are critical success factors.]

[1.1 In relation to Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, WHO Member States:

(PP1) Recall World Health Assembly resolution WHA60.28 on Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits; *consensus*

(PP2) Note the continuing risk of an influenza pandemic with potentially devastating health, economic and social impacts, particularly for developing countries which suffer a higher disease burden and are more vulnerable; *consensus*

(PP3) Recognize that Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health; *consensus*

(PP4) This Framework will be guided by the goal of its universal application for the protection of all people of the world from the international spread of disease; *consensus*

(PP5) Recall the need for rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as a contribution to assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines; *consensus*

(PP6) Reaffirm obligations of States Parties under the International Health Regulations (2005);<sup>1</sup> *consensus*

(PP7) Recognize this Framework is to be implemented in a manner consistent with relevant national and international laws, regulations [, rights] and obligations;

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<sup>1</sup> <http://www.who.int/csr/ihr/en/>.

(PP8) Recognize that the benefits arising from the sharing of H5N1 and other influenza viruses with human pandemic potential should be shared with all Member States based on public health risk and need; *consensus*

[(PP9) Recognize the need for a fair, transparent, equitable and efficient framework for the sharing of H5N1 and other influenza viruses with human pandemic potential [and [for the] sharing [of benefits] [of pandemic influenza preparedness benefits] [needed to face the threat of the pandemics]/[arising from broad collective action.]/[including but not limited to those] [arising from their use.]] [many of them resulting from the use of shared viruses.];

(PP10) Recognize also the WHO leadership and oversight functions over these issues and the need for collaboration with UNSIC and other relevant intergovernmental organizations; *consensus*

(PP11) Recognize the [sovereign right of States over their biological resources and the] importance of collective action to mitigate public health risks;

[(PP12) Recognize that this Framework and the Convention on Biological Diversity will be mutually supportive and nothing in this Framework will be interpreted as implying in any way a change in the rights and obligations of the contracting parties under the Convention on Biological Diversity;]

[(PP13) [Recognize]/[Recall] the Doha Declaration on the TRIPS Agreement and Public Health as well as the Global strategy on public health, innovation and intellectual property, adopted in resolution WHA61.21.];

[(PP14) Recall that resolutions WHA60.28 and WHA61.21 recognize that “intellectual property rights do not and should not prevent Member States from taking measures to protect public health” [and that intellectual property rights are an important incentive in the development of new health care products]];

(PP15) Recognize that the commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits enables WHO Member States and the Director-General to assess the global risk of an influenza pandemic and allows WHO Member States and the Director-General to take actions to reduce the risk of the emergence of a pandemic and to facilitate the development and production of vaccines, diagnostic materials and other pharmaceuticals that can assist in rapidly responding to and containing an emerging pandemic; *consensus*

(PP16) Acknowledge with serious concern that current global influenza vaccine production capacity remains insufficient to meet anticipated need in a pandemic; *consensus*

(PP17) Acknowledge with serious concern that the distribution of influenza vaccine manufacturing facilities is inadequate particularly in developing countries and that some Member States can neither develop, produce, afford nor access the vaccines and other benefits; *consensus*

(PP18) Note the WHO Global pandemic influenza action plan to increase vaccine supply (GAP)<sup>1</sup> and its goal of reducing the gap between potential vaccine demand and supply during an influenza

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<sup>1</sup> Document WHO/CDS/EPR/GIP/2006.1;  
[http://www.who.int/csr/resources/publications/influenza/CDS\\_EPR\\_GIP\\_2006\\_1.pdf](http://www.who.int/csr/resources/publications/influenza/CDS_EPR_GIP_2006_1.pdf).

pandemic, by expanding the global capacity to produce influenza vaccine, including in developing countries; *consensus*

(PP19) Recognize the importance of Member States, pharmaceutical manufacturers and other entities with access to relevant technologies in respect of influenza vaccine, diagnostics, and pharmaceuticals making specific efforts to transfer these technologies, skills, knowledge and know-how to countries, particularly developing countries, that do not currently have access to these technologies, skills, knowledge and know-how; *consensus*

(PP 20) Recognize the need for financing mechanisms that would promote affordability and equitable access to quality influenza vaccines, medicines and technologies by developing countries. *consensus*

## 2. OBJECTIVE

2.1 The objective of this Pandemic Influenza Preparedness Framework is to improve pandemic influenza preparedness and strengthen the protection against the spread of pandemic influenza by [establishing a WHO pandemic influenza network] [reforming the Global Influenza Surveillance Network as the [WHO Network<sup>1</sup>]]/[improving and strengthening the Global Influenza Surveillance Network [and implementation of the IHR (2005)]] and implementing a fair[er, and more] transparent, equitable, efficient and effective system for:

- (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
- (ii) the sharing of the benefits arising from the use of H5N1 and other influenza viruses with human pandemic potential including the generation of information, diagnostics, medicines, vaccines and other technologies.]

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<sup>1</sup> The term [WHO Network] has been used throughout this draft chair's text as neutral terminology. Proposals have been made to retain the use of the term "Global Influenza Surveillance Network" or to use the term "WHO Influenza Network" in its place.

### 3. SCOPE

3.1 This Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits covers [the sharing of] H5N1 and other influenza viruses with human pandemic potential [and the sharing of benefits].

OR

[This Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits resulting from their use.]

OR

[This Framework covers H5N1 and other influenza viruses with human pandemic potential and benefits resulting from their use.]

3.2 This Framework does not apply to seasonal influenza viruses or the benefits arising from their use. [The current system for] the sharing of seasonal influenza viruses and [benefits resulting from their use should continue in accordance with relevant national laws and regulations and WHO guidance.]/[the production of seasonal influenza vaccines should continue in accordance with the relevant WHO guidance.]

3.3 This Framework does not [apply to]/[cover] the non-influenza pathogens or biological materials that may be contained in clinical specimens shared under this Framework. [The sharing and use of these pathogens or materials should be done in accordance with relevant national laws and regulations.]

#### 4. DEFINITIONS AND USE OF TERMS

*(On the good faith understanding that all uses of the term “influenza virus” are understood to refer to “H5N1 and other influenza viruses with human pandemic potential”.)*

For the purpose of this Framework, the following terms have the meanings assigned to them below.  
*consensus*

##### 4.1 Scientific terms

**["Pandemic Influenza Preparedness biological materials" or "PIP biological materials"** under this Framework designates [any [original] clinical specimen of H5N1 or other wild type influenza virus with human pandemic potential provided for the purposes of risk assessment and influenza testing for the H5N1 sub-type or other sub-type of influenza virus with human pandemic potential; any virus isolate of the H5N1 sub-type or other sub-type of influenza virus with human pandemic potential; high growth reassortant viruses; and candidate vaccine viruses generated therefrom.] [any original clinical specimen believed to contain H5N1 or other influenza virus with human pandemic potential provided for the purposes of influenza testing and any material generated from that specimen by a [WHO Network] laboratory, including virus isolates or related hybrid viruses created through laboratory techniques or resulting from laboratory techniques used on the clinical specimen, virus nucleic acid, virus protein and other parts of the virus, genes, gene sequence information, peptides, cells and cell parts and derivatives, functional subunits of the materials, expression products of the materials, purified or fractionated subsets of the materials, clones and sub clones derived from the materials, and antibodies, proteins and other biological materials derived, synthesized or otherwise obtained from the materials.]]

OR

**["Pandemic Influenza Preparedness biological materials" or "PIP biological materials"** under this Framework designates “clinical specimens”, “wild-type H5N1 and other influenza viruses with human pandemic potential”, “influenza reference viruses and related strains”, [viral RNA and cDNA copies of viral genes,] “WHO-recommended influenza viruses for vaccine use”, and “pandemic influenza preparedness vaccine virus” originating from H5N1 or other influenza virus with human pandemic potential.]<sup>1</sup>

The terms “Pandemic Influenza Preparedness biological materials” and “PIP biological materials” specifically do not include [products and technologies generated] [influenza vaccines, diagnostics or pharmaceutical products generated] from the use of the PIP biological materials.

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<sup>1</sup> These two definitions are provided as alternatives for discussion. Both would carry the caveat of the following paragraph: that they specifically do not include influenza vaccines, diagnostics or pharmaceutical products generated from the use of the PIP biological materials.

**“Influenza virus with human pandemic potential”** designates any [wild-type] influenza virus that has been found to infect a human [and animal] and that has a haemagglutinin antigen that is distinct from those in seasonal influenza viruses so as to indicate that the virus has potential to be associated with pandemic spread within human populations.

OR

[**“Influenza virus with human pandemic potential”** are viruses that are designated by NICs, H5 reference laboratory, WHO CCs, and covers any influenza virus that has been found to infect human or animal and that has haemagglutinin antigen that is known or suspected to be distinct from those in contemporary seasonal influenza viruses so as to indicate that the virus has potential to be associated with pandemic spread within human populations.]

**“Pandemic Influenza Preparedness vaccine virus”** or **“PIP vaccine virus”** designates any high-growth reassortant virus or any influenza reference virus, WHO-recommended influenza virus for vaccine use or other influenza virus material generated, including by new and emerging technologies, from H5N1 or other **influenza virus with human pandemic potential [as designated by WHO]** that is provided to influenza vaccine manufacturers for the purposes of developing a prototype pandemic, pre-pandemic, pandemic or other influenza vaccine against H5N1 or other influenza virus with human pandemic potential.

**“Clinical specimens”** means materials collected from humans, generally for examination, diagnostic confirmation, study or analysis. For influenza, most commonly, clinical specimens are taken from the respiratory tract (for example, swabs and aspirated fluid) but they can be from other locations.

[**“High-growth reassortant influenza viruses”** [means influenza viruses that have been genetically modified to grow better in eggs for optimal influenza vaccine production] / [means hybrid influenza viruses that have been generated from two different influenza viruses and selected to grow better in eggs for optimal influenza vaccine production].]

**“Influenza reference viruses”** means wild-type influenza viruses of human or animal origin that WHO has selected as representative of important groups of influenza viruses on the basis of extensive antigenic and genetic studies and comparisons with influenza viruses from many countries. As the influenza viruses evolve in nature, new influenza reference viruses are selected.

**“WHO-recommended influenza viruses for vaccine use”** means wild-type influenza viruses that are recommended by WHO as the basis for an influenza vaccine.

**“Wild-type influenza viruses or influenza virus isolates”** means influenza viruses that have been cultured either in eggs or cells (i.e. isolated) directly from clinical specimens or subsequent culture passages and have not been purposefully modified.

#### 4.2 Institutions, organizations and entities

**“Essential regulatory laboratories”** means influenza laboratories, located in national regulatory agencies, and which have a critical role at the global level for developing, regulating and standardizing influenza vaccines. In this capacity they work closely with WHO and industry.

**“Influenza vaccine manufacturers”** means public or private entities, [including [academic researchers,] government owned or government subsidized entities, nonprofit organizations or commercial entities,] that [develop and] produce human influenza vaccines.]

**“Influenza vaccine, diagnostic and pharmaceutical manufacturers”** means public or private entities [including [academic researchers,] government owned or government subsidized entities, nonprofit organizations or commercial entities] that [develop and] produce human influenza vaccines and other biological products [derived from H5N1 or other influenza viruses of human pandemic potential].

**“National Influenza Centres”** or **“NICs”** means influenza laboratories designated by a Member State and authorized by the Member State to provide PIP biological materials to the [WHO Network]. NICs are recognized by WHO and, participate in the [WHO Network] in accordance with Terms of Reference.

**“Other authorized laboratory”** means influenza laboratories authorized by a Member State to provide PIP biological materials to the [WHO Network], [and is intended to cover those Member States which do not have a National Influenza Centre].

**“Public health researchers”** means researchers at universities and other academic institutions whose primary research focus is public health.]

**“WHO Collaborating Centres on Influenza”** or **“WHO CCs”** means animal or human influenza laboratories designated by WHO and fully supported by national authorities to perform certain roles within the [WHO Network], and which have accepted formal Terms of Reference from WHO. In general, they differ from National Influenza Centres and WHO H5 Reference Laboratories in having global responsibilities and more extensive technical capacities. As of May 2008, WHO CCs included the WHO Collaborating Centres for Reference and Research on Influenza in London, Melbourne and Tokyo, the WHO Collaborating Centre for the Surveillance, Epidemiology and Control of Influenza in Atlanta and the WHO Collaborating Centre for Studies on the Ecology of Influenza in Animals in Memphis.

**“WHO H5 Reference Laboratories”** means influenza laboratories that have been designated by WHO in order to strengthen national and regional capacity for reliably diagnosing H5 virus infection until this capacity is more widespread.

**“WHO Network”**] means the international network of influenza laboratories, coordinated by WHO, that conduct year-round surveillance of influenza, assessing the risk of pandemic influenza and assisting in preparedness measures. The [WHO Network] comprises National Influenza Centres, WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and essential regulatory laboratories.

### 4.3 Other terms

**“Advisory Group”** means the Group referred to in paragraph 7.2 of this Framework.

**“Affected country”** means countries with laboratory confirmed cases of H5N1, or other influenza viruses with human pandemic potential, in humans or in animals.

**“Director-General”** means the Director-General of the World Health Organization.

**“Least developed country”** means those countries that represent the poorest and weakest segment of the international community, as defined by the UN Committee for Development Policy.]

**“Originating laboratory”** means the laboratory where the [PIP biological materials] / [clinical specimens] were first collected[, obtained and/or developed].

**“Originating Member State”** means the Member State where the [PIP biological materials] / [clinical specimens] were first collected[, obtained and/or developed].

**“Pandemic Influenza Preparedness Framework”** means this Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits.

**“Pandemic Influenza Preparedness Traceability Mechanism”** or **“PIP Traceability Mechanism”** means the traceability mechanism referred to in paragraphs 5.2 and 7.2.4 and in paragraphs 1.1 and 1.2 in Annex 1<sup>1</sup> to this Framework.

**“[WHO] antivirals stockpile”** is the stockpile of antiviral medicines referred to in paragraph 6.6 of this Framework.

**“WHO Member States”** means the States party to the WHO Constitution.

**“[WHO] pandemic influenza preparedness vaccine stockpile”** or **“PIP vaccine stockpile”** is the stockpile of vaccines for H5N1 or other influenza viruses with human pandemic potential referred to in paragraph 6.7 of this Framework.

**“WHO Secretariat”** has the meaning assigned to it in the WHO Constitution.

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<sup>1</sup> See Appendix 1.

## 5. PANDEMIC INFLUENZA PREPAREDNESS SYSTEM FOR SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES WITH HUMAN PANDEMIC POTENTIAL

### 5.1 General

5.1.1 Member States, through their National Influenza Centres and Other authorized laboratories, should in a rapid, systematic and timely manner provide PIP biological materials from all cases of H5N1 and other influenza viruses with human pandemic potential, as feasible [to the WHO Network]: *consensus*

(i) to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State's choice, and (*consensus*)

[(ii) through those laboratories to other WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, Essential Regulatory Laboratories, National Influenza Centres and Other authorized laboratories, influenza vaccine, diagnostic and pharmaceutical manufacturers and public health researchers, for the purposes of: full virus characterization, pandemic risk assessment, the development and validation of diagnostics and pharmaceuticals, the development of pandemic influenza preparedness vaccine viruses and the development and production of vaccines.]

OR

[(ii) WHO Collaborating Centres on Influenza or WHO H5 Reference Laboratories receiving the PIP biological materials may transfer PIP biological materials only to:

- (a) ERLs, [and] NIC [of originating country], solely for the purpose of fulfilling their respective terms of reference;
- (b) Influenza vaccine, diagnostic and pharmaceutical manufacturers solely for the development and/or production of vaccines, diagnostics, pharmaceuticals and Other biological products;
- (c) Other researchers solely for influenza related research other than developing and/or producing vaccines, diagnostics and pharmaceutical products and Other biological products.]

(iii) Essential Regulatory Laboratories, on receiving PIP biological materials from WHO Collaborating Centres on Influenza or WHO H5 Reference Laboratories may transfer PIP biological materials only to respective to WHO Collaborating Centres on Influenza and NICs of the originating country.

(iv) Influenza vaccine, diagnostic and pharmaceutical manufacturers and Other researchers that receive PIP biological materials from WHO Collaborating Centres on Influenza or ERLs will not further transfer those materials to any other person or entity, including institutions, organizations or entities.

(v) The transfer of PIP biological materials mentioned in 5.1.1(i) and 5.1.1(ii) and 5.1.1(iii) will be done using the standard material transfer agreement in Annex 1<sup>1</sup> and only on due completion and execution of the SMTA of relevant entities.]

5.1.2 By providing PIP biological materials from National Influenza Centres and Other authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as set out in paragraph 5.1.1(i) above, Member States provide their [prior informed consent] / [consent] for the onward transfer and use of PIP biological materials to the institutions, organizations and entities [as set out in 5.1.1(ii)].

5.1.3 National Influenza Centres and Other authorized laboratories will make, as feasible, efforts to ensure that PIP biological materials, from cases of H5N1 and other influenza viruses with human pandemic potential, that they provide to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories: (*consensus*)

- (i) contain viable material; (*consensus*) and
- (ii) are accompanied by information as agreed in the traceability mechanism and other clinical and epidemiological information needed for risk assessment. (*consensus*)

5.1.4 Member States may also provide PIP biological materials directly to any other party or body on a bilateral basis provided that the same materials are provided on a priority basis to the WHO Collaborating Centres on Influenza and/or H5 Reference Laboratories under this Framework. (*consensus*)

## 5.2 Traceability and reporting mechanisms

5.2.1 The Director-General, in consultation with the [Advisory<sup>2</sup> Group], will put in place in a timely manner a transparent traceability mechanism that uses an electronic system in order to track in real time the movement of PIP biological materials in, to, within, and out of the WHO Network.

5.2.2 To ensure that rapid, systematic and timely feedback is provided to Originating laboratories and Member States, the Director-General will also include in the traceability mechanism and associated electronic reporting systems a request that WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories provide a summary report of laboratory analyses and on request any other available information required by the originating laboratory regarding PIP biological materials. *consensus*

5.2.3 Pending the further development and functioning of subsequent versions of the transparent traceability mechanism, the WHO Secretariat will operate and maintain the current interim system, providing full disclosure of information on the transfer and movement of PIP biological materials into, within and out of the [WHO Network]. *consensus*

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<sup>1</sup> See Appendix 1.

<sup>2</sup> At the November 2007 session of the IGM, the term “advisory mechanism” was substituted for the term “oversight mechanism” used in resolution WHA60.28.

### 5.3 Standard Material Transfer Agreement<sup>1</sup>

#### General

5.3.1 Member States and the Director-General should [require/urge] that [WHO Network] laboratories use the Standard Material Transfer Agreement consistent with Annex 1<sup>2</sup> to this Framework to cover all transfers [and use] of PIP biological materials as a [mandatory condition].

5.3.2 The Standard Material Transfer Agreement [, [preferably in] [including] electronic form,] will be standardized, universal and globally applicable to all transfers [in, to, within, and out of the [WHO Network] [and use] / [and uses] of PIP biological materials [their uses] and not be subject to further negotiation [, additional permissions].

#### Execution of the Standard Materials Transfer Agreement

[5.3.4A [The Standard Materials Transfer Agreement will be self-executed in relation to transfers of PIP biological materials [in, to, within, and out of the [WHO Network]] the [WHO Network]] [from National Influenza Centres and authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories and in relation to transfers of PIP biological materials within the WHO Network.]]

[[WHO Network] laboratories transferring PIP biological materials to influenza vaccine, diagnostic and pharmaceutical manufacturers or public health researchers will ensure that those institutions, organizations and entities agree in writing to comply with the Standard Material Transfer Agreement.]]

OR

[[5.3.4B The SMTA will be executed, preferably in electronic form, [including fax] and will be duly completed and signed by the institutions, organizations, and entities providing and receiving PIP biological materials.] or (DELETE 5.3.4B)

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<sup>1</sup> Standard Material Transfer Agreement is being used in place of the term “standard terms and conditions” used in resolution WHA60.28.

<sup>2</sup> See Appendix 1.

## 6. PANDEMIC INFLUENZA PREPAREDNESS BENEFIT SHARING SYSTEM

### 6.1 General

6.1.1 Member States, [institutions, organizations and entities] / [influenza vaccine, diagnostic and pharmaceutical manufacturers and public health researchers] should, [work] working with the WHO Secretariat, [to concretely and effectively operationalize the], [contribute [voluntarily] to a] Pandemic Influenza Preparedness Benefit Sharing System[.] [for the sharing of benefits[.][ arising from the use of H5N1 and other influenza viruses with human pandemic potential.]] (or DELETE 6.1.1)

6.1.2 The PIP Benefit Sharing System will operate to:

- (i) provide pandemic surveillance and risk assessment and early warning information and services to all countries; *consensus*
- (ii) provide benefits, including, where appropriate, capacity building in pandemic surveillance, risk assessment, and early warning information and services to Member States. *consensus*
- (iii) prioritize important benefits, such as and including antiviral medicines and vaccines against H5N1 and other influenza viruses with human pandemic potential as high priorities, to developing countries, particularly affected countries, according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. Prioritization will be based on assessment of public health risk and need, by experts with transparent guidelines; *consensus*
- (iv) build capacity in receiving countries over time for and through technical assistance and transfer of technology, skills and know-how and expanded influenza vaccine production, tailored to their public health risk and needs. *consensus*

6.1.3 The Pandemic Influenza Preparedness Benefit Sharing System will include the elements set out in the remainder of this part. *consensus*

### 6.2 Pandemic risk assessment and risk response

6.2.1 [WHO Network] laboratories will make available to the WHO Secretariat and the originating Member State, in a rapid, systematic and timely manner, a summary report of laboratory analyses and on request any other available information required regarding PIP biological materials to enable the affected countries and in particular, developing countries, an effective and meaningful risk response. *consensus*

6.2.2 WHO will provide information on risk response including, but not limited to, information on development of vaccines, candidate virus and effective antivirals to all affected countries and in particular, to developing countries, to enable an effective and meaningful risk response. *consensus*

6.2.3 [The WHO Secretariat] will make available to all Member States, in a rapid, systematic and timely way, pandemic risk assessments [and risk response] with all necessary supporting information.

6.2.4 WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories and the Director-General will actively continue to provide technical assistance to Member States to enhance research and surveillance capacity, including staff training, with the objective of improving national pandemic risk assessment and pandemic risk response. *consensus*

### **[6.3 Provision of PIP Candidate Vaccine Viruses**

6.3. Any entity receiving PIP candidate vaccine viruses will meet appropriate biosafety guidelines (WHO Laboratory Biosafety Manual, 3rd edition) [and employ laboratory protection best practices.] The Director-General will ensure that WHO CC/H5 Reference Labs and ERLs, provide [at no cost] PIP candidate vaccine viruses upon request

- (i) to influenza vaccine manufacturers on a no preference basis *consensus*
- (ii) at the same time to the laboratories of originating and other Member States *consensus*
- [ (iii) to any other laboratory, as agreed in the Terms of Reference. ]

### **6.4 Provision of diagnostic reagents and test kits**

6.4.1 WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and Essential Regulatory Laboratories, working with the WHO Secretariat, will continue to make available to National Influenza Centres and Other authorized laboratories, without charge, supplies of noncommercial diagnostic reagents and test kits for the identification and characterization of clinical specimens of influenza. (*consensus*)

6.4.2 Influenza diagnostic manufacturers receiving PIP biological materials are urged to make available to [WHO Network] laboratories, without charge or at concessional and/or preferential rates, supplies of diagnostic reagents and test kits for the identification and characterization of clinical specimens of influenza, if circumstances warrant. (*consensus*)

### **6.5 Provision of reference reagents for potency determination of vaccines**

6.5.1 Essential regulatory laboratories will continue to provide, upon request, reference reagents for potency determination of vaccines against H5N1 and other viruses of human pandemic potential to national regulatory laboratories and influenza vaccine manufacturers of all Member States. *consensus*

6.5.2 ERLs will continue to provide upon request, training in quality control of vaccines against H5N1 and other viruses of human pandemic potential to national regulatory laboratories of all Member States. *consensus*

### **6.6 Laboratory and influenza surveillance capacity building**

6.6.1 Upon request, Member States with advanced laboratory and influenza surveillance capacity are urged to continue to work with WHO and other Member States, particularly developing countries to develop national laboratory and influenza surveillance capacity, including: (*consensus*)

- (i) to conduct early detection, isolation and characterization of viruses; (*consensus*)
- (ii) to participate in pandemic risk assessment and response; (*consensus*)
- (iii) to develop research capacity related to influenza; (*consensus*)
- (iv) to achieve technical qualifications for consideration of laboratories as National Influenza Centres, WHO H5 Reference Laboratories and WHO Collaborating Centres on Influenza. (*consensus*)

## **6.7 Regulatory capacity building**

6.7.1 Upon request, Member States with advanced regulatory capacity should improve and strengthen the work that has been undertaken by Member States with WHO, particularly developing countries to strengthen the capacity of regulatory authorities to carry out the necessary measures for the rapid approval of safe and effective human influenza vaccines, diagnostics and pharmaceutical products, including products developed from the use of PIP biological materials, especially those derived from new sub-types of influenza viruses. (*consensus*)

[6.7.2 [[Member States should make available through the WHO Secretariat in a timely manner] / [ WHO Secretariat should examine the feasibility of creating a database] publicly available information related to health regulatory approval of H5N1 and other influenza viruses with human pandemic potential vaccines, diagnostics and pharmaceutical products including those developed from the use of PIP biological materials.] WHO Secretariat should examine the feasibility of creating a database of such information.]

## **6.8 [WHO and [other] multilateral] antivirals stockpiles**

6.8.1 The Director-General will continue to work with other multilateral agencies, donors, international philanthropic organizations/entities, private foundations, and other potential partners, including institutions, organizations and entities and in particular influenza vaccine, diagnostic and pharmaceutical manufacturers, to seek commitments for contributions, maintain and further develop a stockpile of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human pandemic potential. *consensus*

6.8.2 The Director-General will continue to coordinate with Member States, institutions, organizations and other entities and encourage them to maintain and further develop stockpiles of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human pandemic potential. *consensus*

6.8.3 The Director-General will continue to seek the guidance of expert advice in determining the size, composition, replenishment, operational use and deployment procedures for use of the WHO antivirals stockpile. *consensus*

## **6.9 [WHO] pandemic influenza preparedness vaccine stockpile**

6.9.1 The Director-General will establish and maintain a stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential and associated equipment, including syringes, needles and applicators, consistent with expert guidance. The WHO stockpile will initially include

150 million doses of H5N1 vaccine for use in accordance with expert guidance including SAGE. Indicatively: *consensus*

(i) 50 million doses will be for use in Affected countries, according to public health risk and need, to assist in containing the first outbreak or outbreaks of an emerging pandemic; and *consensus*

(ii) 100 million doses will be for distribution, once a pandemic begins, to developing countries that have no or inadequate access to H5N1 influenza vaccines, on a per capita basis, with use to be determined by those countries. *consensus*

6.9.2 The Director-General will [continue to] seek the guidance of experts in determining the size, composition, replenishment and operational use of the vaccines in the [WHO] PIP vaccine stockpile.

6.9.3 Member States should urge influenza vaccine manufacturers to [provide] / [donate] sufficient doses of H5N1 vaccine for the [WHO] PIP vaccine stockpile. If insufficient doses are [provided] / [donated], the Director-General will work with Member States to explore use of [sustainable financing mechanisms] (in Section 6.12 below) to meet the requirements of the [WHO] PIP vaccine stockpile.

[6.9.4A Member States should urge influenza vaccine manufacturers to prioritize and immediately respond to the needs of the WHO PIP vaccine stockpile.]

AND/OR/ OR DELETE BOTH

[6.9.4B Member States should urge influenza vaccine manufacturers to set aside  $x\%$  of [production][future production unallocated as of November 2008] for provision to the WHO PIP vaccine stockpile.]

6.9.5 The Director-General will, with the guidance of experts, keep under review the potential for the pre-pandemic use of the [WHO] PIP vaccine stockpile in Affected countries, including by supporting trials as appropriate.

6.9.6 The Director-General will work with relevant experts and Member States to develop and exercise operational plans for the deployment of the vaccines in the [WHO] PIP vaccine stockpile.

## **6.10 Access to vaccines [for developing and least developed country use]**

[6.10.1 Separately from the [WHO] PIP vaccine stockpile, Member States should continue to work with each other, with the Director-General and with influenza vaccine manufacturers with the aim of ensuring that adequate quantities of vaccines for H5N1 and other influenza viruses with human pandemic potential, and pandemic influenza vaccines, are made available [to developing and least developed countries at the same time as to developed countries,] on the basis of public health risk and needs and at affordable prices.]

OR

[6.10.1B Separately from the [WHO] PIP vaccine stockpile, Member States should urge vaccine manufacturers to set aside [x%]<sup>1</sup> of each production cycle of vaccines for H5N1 and other influenza viruses of human pandemic potential for provision to developing and least developed countries.] (or DELETE 6.10.1B).

## **6.11 [Production of] Pandemic influenza vaccines**

6.11.1 Noting that pandemic influenza vaccines can only be produced after a pandemic begins; *consensus*

[6.11.2A Member States should urge vaccine manufacturers to set aside [x%] of each production cycle of pandemic influenza vaccine for use by developing and least developed countries.] (or DELETE 6.11.2A)

AND/OR

[6.11.2B The Director-General, consulting Member States and the Advisory Group, will convene an expert group to develop [or continue to develop] international mechanisms [including existing ones] on the production and distribution of influenza vaccines during a pandemic for consideration by the World Health Assembly in 2010.]

## **6.12 [Tiered][Affordable] Pricing OR [concessional and/or preferential rates] OR [differential pricing policies]**

6.12.1 Member States should urge influenza vaccine manufacturers to implement [tiered pricing][affordable pricing] OR [concessional and/or preferential rates] OR [differential pricing policies] for vaccines for H5N1 and other influenza viruses with human pandemic potential and for pandemic influenza vaccines.

[6.12.2 “Tiered pricing” involves different countries paying different prices for the same product, usually according to their income level.] (or DELETE 6.12.2)

[6.12.3 “Affordable pricing” could be defined to mean:

- (i) for developing countries, a price no higher than marginal cost per unit plus 5%;
- (ii) for least developed countries, at ‘no profit no loss’ to the manufacturer.] (or DELETE 6.12.3)

## **6.13 Technology transfer**

6.13.1 The Director-General will continue to work closely with Member States and influenza vaccine manufacturers to implement the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, notably Strategy 4.2 to increase [human] influenza vaccine production capacity by building

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<sup>1</sup> A proposal is yet to be made for a minimum percentage.

new production facilities in, and transferring technology [, skills] and know-how as appropriate to, developing and/or industrialized countries.

[6.13.2 Member States should urge [institutions,] organizations [and entities] with access to vaccine manufacturing and other technologies for the control of influenza to make specific efforts to transfer these technologies [as appropriate] to other Member States, particularly developing countries.] (or DELETE 6.13.2)

6.13.3 Technology transfer should be conducted in a manner consistent with national laws and international laws and obligations, facilitated progressively over time, on mutually agreed terms, and be [appropriate] / [suitable] to the capacity of recipient Member States, to empower developing countries to study and manufacture influenza vaccines, diagnostics and pharmaceuticals.

[6.13.4A Member States should urge influenza vaccine manufacturers who receive PIP biological materials to grant, on request, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from the Member State where the relevant clinical specimen was collected from which the relevant PIP biological materials were derived, to use its intellectual property and other protected substances, products, technology, [skills,] know-how, information and knowledge used in the process of influenza vaccine development and production in particular for pre-pandemic and pandemic vaccines.] (or DELETE 6.13.4A)

OR

[6.13.4B Influenza vaccine manufacturers who receive PIP biological materials may grant [as appropriate and subject to any existing licensing restrictions] [on a voluntary basis], [and mutually agreed terms] a [non-exclusive, royalty-free] licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines [for use in that developing country.]

#### **6.14 Sustainable financing mechanism**

[6.14.1 Member States should work with the Director-General to [establish a sustainable financing mechanism] / [seek sustainable financing] to support the PIP Benefit Sharing System.]

[6.14.2 The sustainable financing mechanism should have a particular priority on meeting the needs of affected developing and least developed countries for access to vaccines for H5N1 and other influenza viruses with human pandemic potential, including through the [WHO] PIP vaccine stockpile[, but may also be used to support the provision of other benefits including technology transfer and capacity building.]]

[6.14.3 The Director-General, with the support of Member States and the Advisory Group, will explore the use of existing fund-holding institutions and organizations to hold and administer funds for the sustainable financing mechanism, before any new arrangement within the WHO or elsewhere is considered.]

[6.14.4 The Director-General will report to the World Health Assembly [in 2009] on whether a suitable existing fund-holding institution or organization is willing to hold and administer funds for the sustainable financing mechanism. If such an arrangement cannot be agreed, the Director-General, in

consultation with the Advisory Group and Member States, will propose a new arrangement to the World Health Assembly [in 2009].]

[6.14.5 The sustainable financing mechanism will receive funding from:]

[A. voluntary contributions from influenza vaccine, diagnostic and pharmaceutical manufacturers, Member States, nongovernmental organizations and any other individuals or entities;]

AND/OR

[B. mandatory contributions from influenza vaccine, diagnostic and pharmaceutical manufacturers based on [x%]<sup>1</sup> of the sales of products developed using PIP biological materials;] (or DELETE 6.14.5B)

AND/OR

[C. annual assessed contributions from Member States [according to the UN scale of assessment], ranging from US\$ 0.006 per capita from Member States in the lowest decile of per capita gross domestic product to US\$ 0.015 per capita for Member States in the highest decile of per capita gross domestic product;] (or DELETE 6.14.5C)

AND/OR

[D. annual assessed contributions from influenza vaccine manufacturers, at US\$ 0.20 per influenza vaccine dose manufactured by them in that year]. (or DELETE 6.14.5D)

## **6.15 Innovative financing mechanisms for national vaccine requirements**

[6.15.1 Interested Member States may work together, with the Director-General and with nongovernmental and international organizations as appropriate, to establish urgently a fund for the procurement of national stocks of vaccines for H5N1 and other influenza viruses of human pandemic potential, using a revolving fund for immunization, potentially modelled after the Pan American Health Organization (PAHO) Revolving Fund for Immunization, or other similar types of funds, as a reference point.] (or DELETE 6.15.1)

[6.15.2 The fund may be used for, but not limited to:

- (i) procure supplies of vaccine for H5N1 and other viruses with human pandemic potential, and associated equipment, that meet WHO standards, on behalf of participating countries;
- (ii) seek to provide such vaccines and associated equipment for developing countries at concessional or preferential rates;
- (iii) provide affordable financing arrangements to developing [and least-developed] countries to support procurement of vaccines and associated equipment.] (or DELETE 6.15.2)

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<sup>1</sup> Member States are still to propose a specific percentage.

[6.15.3 The mechanism for capitalization and governance arrangements for the fund should be agreed by participating Member States and organizations, but may include voluntary contributions from Member States and nongovernmental organizations.] (or DELETE 6.15.3)

[6.15.4 Neither the existence of, nor participation in, the sustainable financing mechanism or the innovative financing mechanism will prevent Member States from making other unilateral or multilateral arrangements to procure vaccines [for H5N1 and other viruses with human pandemic potential].] (or DELETE 6.15.4)

## 7. GOVERNANCE AND REVIEW

**Text of section 7 reflects the outcome of discussions of Working Group B.  
This text was not considered in Plenary.**

### 7.1 General

7.1.1 The implementation of this Framework will be overseen by the World Health Assembly with advice from the Director-General. *consensus*

OR

### 7.1 General (*proposal based on IGM/PIP/Group B – WhitePaper 1 Rev.1*)

7.1.1 Noting that World Health Assembly resolution WHA60.28, in addressing sharing of influenza viruses and access to vaccines and other benefits, requested the Director-General, inter alia, “to convene an interdisciplinary working group to ... devise oversight mechanisms”;

7.1.2 Further noting that any such oversight mechanism needs to be established in accordance with the WHO Constitution, and appropriate roles need to be identified for the various components of any such mechanism;

7.1.3 An oversight mechanism is hereby established, which includes the World Health Assembly, the Director-General and the independent “Advisory Group”, established in connection with the Interim Statement of November 2007, and composed of international experts serving the Organization exclusively. Respectively, their function will be as follows:

(a) The WHA, consistent with the Organization’s Constitutional function to act as the “directing and co-ordinating” authority on international health work, as set forth in Article 2(a) of the WHO Constitution, will oversee implementation of the Framework.

(b) The Director-General, consistent with her role and responsibilities, particularly in connection with Collaborating Institutions and Other Mechanisms of Collaboration, inter alia, will promote implementation of the Framework within WHO and among relevant WHO-related entities.

(c) In order that the Health Assembly and Director-General have appropriate expert monitoring and evaluation processes to support these functions, the Advisory Group, as provided for in this section, will provide evidence-based reporting, assessment and recommendations regarding the functioning of the Framework. The Advisory Group, consistent with WHO practice regarding such independent expert bodies, will advise the Director-General but will not itself engage in administrative functions, such as the recognition, or withdrawal of recognition, of technical institutions, nor will it have a public role, except as authorized.

## 7.2 Advisory Group

7.2.1 The Director-General will maintain the Advisory Group, referenced in section 7.1.3 above, to monitor and provide guidance to strengthen the functioning of the [WHO Network] and undertake necessary assessment of the trust-based system needed to protect public health and to help ensure implementation of this Framework. (*Secretariat proposal for consistency with revised 7.1*)

OR

7.2.1 The Director-General will establish a transparent Advisory Group to monitor and provide guidance to strengthen the functioning of the [WHO Network] and undertake necessary assessment of the trust-based system needed to protect public health and to help ensure implementation of this Framework.

7.2.2 The Director-General, in consultation with Member States, will continue to ensure that the Advisory Group is based on equitable representation of the WHO regions and of Affected countries, taking into account balanced representation between developed and developing countries.

7.2.3 The Advisory Group will comprise 18 members drawn from three Member States in each WHO region, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza. *consensus*

7.2.4A The Advisory Group will function to assist the Director-General in monitoring the implementation of this Framework, in accordance with the terms of reference for the Advisory Group at Annex 2<sup>1</sup> to this Framework.

OR

[7.2.4B The Advisory Group will function to:

- (i) advise on necessary technical capacity of GISN, WHO Collaborating Centres (CC), H5 Reference Laboratories, National Influenza Centres (NICs) and Essential Regulatory Laboratories (ERLs)
- (ii) advise on operational functioning of GISN
- (iii) advise on global GISN influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)
- (iv) advise on increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential
- (v) advise on the traceability mechanism]

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<sup>1</sup> See Appendix 2.

7.2.5 The WHO Secretariat will provide secretariat services to the Advisory Group. *consensus*

7.2.6 The terms of reference for the Advisory Group are at Annex 2<sup>1</sup> to this Framework. *consensus*

7.2.7A [The Advisory Group will present an annual report to the [WHA through the] Director-General on its evaluation of the implementation of this Framework.]

OR

[7.2.7B The Advisory Group will present an annual report to the Director-General on its evaluation of:

- (i) necessary technical capacities of GISN WHO Collaborating Centres (CC), H5 Reference Laboratories, National Influenza Centres (NICs) and Essential Regulatory Laboratories (ERLs)
- (ii) operational functioning of GISN
- (iii) global GISN influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)
- (iv) increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential
- (v) the traceability mechanism.]

7.2.8 The Director-General will present a report on the work carried out by the Advisory Group through the Executive Board to the World Health Assembly in [2011] / [2010] for its consideration including a decision on the Advisory Group's future mandate.

### **[7.3 Dispute resolution**

7.3.1 In the event of a dispute between two or more Member States concerning the interpretation or application of this Framework, the Member States concerned should seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to settle the dispute will not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

7.3.2 In the event that the dispute is not settled by the means described under paragraph 7.3.1 above, the Member States concerned may agree to refer the dispute to the Director-General,<sup>1</sup> who will make every effort to settle it.

7.3.3 In the event of a dispute between the Director-General and one or more Member States concerning the interpretation or application of this Framework, the matter should be submitted through the Advisory Group and Executive Board to the World Health Assembly.]

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<sup>1</sup> The Advisory Group was suggested as an alternative.

## **7.4 Governance and Review of Terms of Reference for [WHO Network] Laboratories**

7.4.1 The Terms of Reference of the WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, National Influenza Centres [and Essential Regulatory Laboratories] are at Annex 3<sup>1</sup> to this Framework.

7.4.2 The Director-General will regularly review the Terms of Reference of the WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, National Influenza Centres [and Essential Regulatory Laboratories], in consultation with said entities and the Advisory Group, and amend these Terms of Reference, when needed, to promote the principles provided by this Framework, and report thereon to the World Health Assembly.

7.4.3 In the event of any alleged breaches of the Terms of Reference or the [Standard Material Transfer Agreement] by a WHO Collaborating Centre on Influenza, WHO H5 Reference Laboratories or National Influenza Centre [, and Essential Regulatory Laboratories], [the Director-General will review the circumstances and [may] / [as well as] discuss with the Advisory Group any appropriate] action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant laboratory.

## **7.5 Review of Framework**

[7.5.1 The Director-General, in consultation with Member States and the Advisory Group, will report every two years beginning in 2010 on the operation of this Framework and all of its components for consideration by the World Health Assembly, through the Executive Board. The Director-General will submit through the Executive Board a full evaluation on this Framework and all of its components for consideration by the World Health Assembly in 2014. [Under this review, Member States should give special consideration to explore the possibility of a binding instrument regarding the sharing of PIP biological material and the sharing of benefits arising from their use.]]

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<sup>1</sup> See Appendix 3.

APPENDIX 1<sup>1</sup>**STANDARD MATERIAL TRANSFER AGREEMENT**

The institution, organization or entity accepting PIP biological materials under cover of an attached e-mail or on a signed hard copy of this Annex,<sup>2</sup> agrees to accept, upon receipt of the PIP biological materials, the following standard terms and conditions.

**Execution of the Standard Material Transfer Agreement**

[(same as text of 5.3.4A) [The Standard Material Transfer Agreement will be self-executed in relation to transfers of PIP biological materials [into within [and out of] the [WHO Network]] [from National Influenza Centres and authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories and in relation to transfers of PIP biological materials within the WHO Network.]]

[[WHO Network] laboratories transferring PIP biological materials to influenza vaccine, diagnostic and pharmaceutical manufacturers or public health researchers will ensure that those institutions, organizations and entities agree in writing to comply with the Standard Material Transfer Agreement.]]

OR

[(same as text of 5.3.4B) The SMTA will be executed, preferably in electronic form, [including fax] and shall be duly completed and signed by the institutions, organizations, and entities providing and receiving PIP biological materials.]

[(similar to text of 5.1.1) National Influenza Centres or Other authorized laboratories party to this agreement that have PIP biological materials in their possession will send these materials to the WHO Network consistent with the terms and conditions of this agreement.]

**1. Traceability**

1.1 National Influenza Centres and Other authorized laboratories providing clinical specimens from human [and animal] cases of H5N1 and other influenza viruses of human pandemic potential shall register those specimens in the PIP traceability mechanism as PIP biological materials.

1.2 As a condition of receiving PIP biological materials, all National Influenza Centres, [Other] authorized laboratories, WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, influenza vaccine, diagnostic and pharmaceutical manufacturers and public health researchers [essential regulatory laboratories] shall register receipt of the PIP biological materials through the traceability mechanism [and shall comply with any other data provision requirements of the traceability and associated reporting mechanisms.]

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<sup>1</sup> In the interests of clarity in the present document, the title “Annex” in the original text has been changed to “Appendix”.

<sup>2</sup> See footnote 1 above.

## 2. No further transfer outside [WHO Network] OR [conditions of transfer]

[2.1 Influenza vaccine, diagnostic and pharmaceutical manufacturers and [public health] researchers outside the [WHO Network] receiving PIP biological materials from the [WHO Network] shall [not further transfer those materials without [the prior informed consent] / [informing] [of]] [notifying] the originating Member State and the [WHO Network] laboratory that provided the materials.] (or DELETE 2.1)

[*text from 5.1.2:* By providing PIP biological materials from National Influenza Centres and Other authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as set out in paragraph 5.1.1(i) above, Member States provide their [prior informed consent] / [consent] for the onward transfer and use of PIP biological materials to the institutions, organizations and entities [as set out in 5.1.1(ii)].

## 3. Biosafety [and biosecurity<sup>1</sup>] / [and laboratory protection]

3.1 [All institutions, organizations and entities shall ensure that transfer of PIP biological materials shall at all times be in compliance with all relevant national and international laws, rules and regulations, including those relating to biosafety and biosecurity, to the full extent that such laws, rules and regulations are applicable to each party concerned.]

OR

[All institutions, organizations and entities agree to act in accordance with applicable laws, rules, and regulations and agree to follow international biosafety and shipping guidelines (WHO Laboratory Biosafety Manual, 3rd edition) as well as laboratory protection best practices.]

3.2 [All institutions, organizations and entities shall ensure that handling, storage and use of PIP biological materials shall at all times be in compliance with all relevant national and international laws, rules and regulations, including those relating to biosafety and biosecurity, to the full extent that such laws, rules and regulations are applicable to each party concerned.]

OR

[All institutions, organizations and entities agree [for handling, storage, and use of PIP biological materials] to act in accordance with applicable laws, rules, and regulations and agree to follow international biosafety guidelines (WHO Laboratory Biosafety Manual, 3rd edition) as well as laboratory protection best practices.]

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<sup>1</sup> This section was debated in the April 2008 session of the IGM Working Group. The term “institutions, organizations and entities” has been substituted for “parties” for consistency with the rest of the Framework. Suggestions have been made to combine these two paragraphs. In addition, some concern has been expressed about the term “biosecurity”. Alternative suggestions are “biosafety and security of biological materials” or “biosafety, shipping and laboratory protection” be used in place of “biosafety and biosecurity.”

#### 4. Fees and charges

4.1 [WHO Network] laboratories shall not impose charges for the provision of PIP biological materials. However:

4.1.1 National Influenza Centres and Other authorized laboratories in developing and least developed countries may charge a nominal administrative fee to recover the costs of shipping, handling, storage or other direct administrative overheads associated with transferring the PIP biological materials to WHO Collaborating Centres on Influenza and/or H5 Reference Laboratories. Where such a fee is sought, the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory receiving the PIP biological materials shall pay the fee. [query: location]

4.1.2 WHO Collaborating Centres, H5 Reference Laboratories and essential regulatory laboratories may charge a nominal administrative fee to recover the costs of shipping, handling, storage or other direct administrative overheads associated with transferring the PIP biological materials to influenza vaccine, diagnostic and pharmaceutical manufacturers and public health researchers. Where such a fee is sought, the influenza vaccine, diagnostic or pharmaceutical manufacturer or public health researcher shall pay the fee. [query: location]

#### 5. Feedback

[5.1 WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories shall provide in a routine and timely way to National Influenza Centres and Other authorized laboratories providing clinical specimens and/or viruses, all relevant information about the clinical specimens and/or viruses received, including the results of virus sequencing, characterization and pandemic influenza risk assessment, and respond in a timely way to requests from those laboratories for further information about the specimens or viruses provided.]

OR

[5.1 (original 5.2.2, edited) To ensure that timely feedback is provided to Originating laboratories and Member States, the Director-General will request that WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories provide [[all] [relevant] [available] information]] / [a summary report of laboratory analyses [and other appropriate information regarding] PIP biological materials to the Originating laboratories [and WHO Member States] [in a timely manner].]

5.2 Upon request, WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories, and essential regulatory laboratories shall provide, in a timely way, aliquots of isolated virus strains to the originating National Influenza Centre or Other authorized laboratory, which meet biosafety guidelines and employ laboratory [protection] best practices.

5.3 Upon request, WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and essential regulatory laboratories shall provide PIP vaccine viruses to the originating National Influenza Centre or Other authorized laboratory, where those laboratories which meet biosafety guidelines and employ laboratory [protection] best practices, at the same time as the PIP vaccine viruses are provided to influenza vaccine manufacturers.

## 6. Research

6.1 [WHO Collaborating Centres and H5 Reference Laboratories] / [All institutions, organizations and entities receiving PIP biological materials] [shall] / [should], to the fullest extent feasible, include scientists from the originating Member State or originating National Influenza Centre or Other authorized laboratory in research on those biological materials, with a view to facilitating meaningful participation, skills transfer and capacity development.

## 7. Publication of research

7.1 Institutions, organizations and entities<sup>1</sup> receiving PIP biological materials may publish or otherwise disseminate scientific results generated from the PIP biological materials [with the [[informed] / [written]] consent of the originating National Influenza Centre or Other authorized laboratory] / [with [28<sup>2</sup> days] written notice to the originating National Influenza Centre or Other authorized laboratory, prior to submission for publication].<sup>3</sup>

## 8. Acknowledgment, attribution and authorship

8.1 Institutions, organizations and entities<sup>4</sup> publishing research arising from the use of PIP biological materials [[shall] / [should]] [disclose the origin of the biological source and] appropriately acknowledge and properly attribute contributions by scientists and/or researchers from the originating Member State or originating National Influenza Centre or Other authorized laboratory in any medical or scientific journal [or] publication in a manner that is consistent with the guidelines for authorship and acknowledgment as stipulated by the International Committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals [including [recognition], by way of authorship or partnership in patenting, to the scientists from the originating Member State laboratory]. Similarly, proper acknowledgment, attribution and authorship shall be provided for other formal scientific presentations.

## 9. Sharing of risk assessment information

9.1 [WHO Network] laboratories [shall] [may, with the written consent of the originating Member State,] make available in a timely manner pandemic influenza risk assessment information relating to PIP biological materials, including viral genetic sequence data and complete antigenic characterization, to other institutions, organizations and entities in accordance with the other terms and conditions of this Standard Material Transfer Agreement.]

OR

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<sup>1</sup> This text was debated extensively by the open-ended working group at its session in April 2008. For consistency with the rest of the Framework, the terms “institutions, organizations and entities” have been substituted here for “WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and other parties”.

<sup>2</sup> Notice periods of 14, 28 and 30 days have been suggested.

<sup>3</sup> These two phrases suggested as alternatives for discussion.

<sup>4</sup> This paragraph was debated extensively by the open-ended working group at its session in April 2008. Terms have been adjusted for consistency with the rest of the Framework. The suggestion has since been made to delete the word “or” between “journal” and “publication” in the fourth line.

[9.1. (original 6.2.1) [WHO Network] laboratories will make available to the Director-General and the originating Member State, in a rapid, systematic and timely manner, [[all] [relevant] [available] [information] / [a summary report of laboratory analyses] [and other appropriate information regarding]] derived from their examination of the PIP biological materials [conducted in accordance with their respective terms of reference].]

#### **10. [Permitted use and limitations] / [Limitation of use] by [WHO Collaborating Centres on Influenza and WHO H5] Reference Laboratories**

[10.1 WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories shall seek the [prior written] consent of the originating National Influenza Centre or Other authorized laboratory for any use of the PIP biological materials outside the terms of reference of that WHO Collaborating Centre or H5 Reference Laboratory, and any such use will be subject to mutually agreed terms.]

OR

[10.1 National Influenza Centres or Other authorized laboratories providing PIP biological materials may request that WHO Network Laboratories seek written permission to use materials outside the terms of reference for those laboratories and any such use will be subject to mutually agreed terms.]

OR

[[10.1 WHO Network Laboratories shall use the PIP biological materials solely for purposes listed in their respective TORs in Annex 3<sup>1</sup> as applicable and shall not seek to derive any financial gain from use in any way from the PIP biological materials and related information, including any product or process derived from or developed using PIP biological materials.]

10.2. Influenza vaccines, diagnostics and pharmaceutical manufacturers shall use the PIP biological materials solely for the purpose of developing and/or producing vaccines, diagnostics, pharmaceutical products and other biological products. [Other uses of these materials can be done only with the informed consent of the originating laboratory.]

10.3 In addition to 10.1 and 10.2, all institutions, organizations, and entities shall use the PIP biological materials in accordance with the terms and conditions contained herein.]

#### **11. Ownership**

[11.1A By providing PIP biological materials, the originating Member States do not transfer ownership rights over those materials to the receiving institution, organization, entity or Member State.] (or DELETE 11.1A)

OR

[11.1B Institutions, organizations, entities or Member States providing or receiving PIP biological materials shall not assert ownership rights over the PIP biological materials.]

OR

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<sup>1</sup> See Appendix 3.

[11.1B WHO Member States participating in the [WHO Network] will not claim sovereignty or ownership rights over viruses as found in nature.] (or DELETE 11.1B)

## 12. Intellectual property

[12.1 Institutions, organizations and entities providing or receiving PIP biological materials shall not assert intellectual property rights over viral gene sequence data directly based on those materials.] (or DELETE 12.1)

OR

[12.1 Institutions, organizations and entities providing or receiving PIP biological materials shall not [assert intellectual property rights over those materials] / [seek or claim intellectual property rights over those materials in any form.]

OR

[12.1 At all times to grant royalty-free licences to developing countries to use products and processes developed from PIP biological materials.]

OR

[12.1 Use of an MTA shall have no effect on obligations or restrictions that arise from intellectual property rights. Any intellectual property rights associated with the materials or its use will not be disturbed by the conveyance and subsequent distribution of the materials.]

OR

[12.1 Member States shall exclude from patentability any invention developed from using PIP biological materials in accordance with Article 27 para 2 of the TRIPS agreement.]

[12.2 Institutions, organizations, entities or Member States inventing patentable processes or products using PIP biological materials shall:

(i) at all times, grant royalty-free licences upon request to any institution, organization, entity or Member State seeking to use those processes or products for non-commercial public health research; and

(ii) during a pandemic declared by the World Health Organization, grant royalty-free licences to any institution, organization, entity or Member State to use those processes or products for the production of influenza vaccines, diagnostics and pharmaceuticals.]<sup>1</sup>

OR

[12.2 Institutions, organizations and entities receiving PIP biological materials shall not seek intellectual property rights over any method of use, application, or specific uses of PIP biological

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<sup>1</sup> Chair's suggestion.

materials; or over any products, processes or other inventions including vaccines, diagnostics, or pharmaceuticals derived from, or developed by, using PIP biological materials.]

[12.3 Any institution, organization, entity or Member State receiving PIP biological materials that seeks patent protection or other intellectual property rights over inventions directly based on PIP biological materials shall disclose in the patent application the country in which the PIP biological materials were first collected, obtained and/or developed.]

### **13. Benefits**

[13.1A PIP biological materials are provided to receiving institutions, organizations and entities with the objective of improving pandemic influenza preparedness and strengthening public health. In consideration of this, and recalling resolution WHA60.28, the PIP benefit sharing system set out in the “Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits” aims to improve access for developing and least developed countries, especially Affected countries, to vaccines and other benefits from the sharing of H5N1 and other influenza viruses of human pandemic potential. The priorities of the Framework are fairness, transparency, equity and efficiency.] (or DELETE 13.1A)

OR

[13.1B Institutions, organizations and entities receiving PIP biological materials shall contribute to the PIP Benefit Sharing System.]

[13.1B *bis* Institutions, organizations and entities receiving PIP biological materials [shall / should comply with] / [are encouraged to participate in] the PIP Benefit Sharing System, and shall / should be in the following tangible forms, but not limited to: pandemic risk assessment; provision of diagnostic tests and materials; laboratory capacity building; regulatory capacity building; WHO antiviral stockpiles; WHO PIP Influenza vaccine stockpiles; access to vaccines for developing country use; pandemic influenza vaccines; tiered pricing; transfer of technology, skills and know-how; sustainable financing mechanisms; and innovative financing mechanisms for national vaccine requirements.]

13.1B *ter* The provision and receipt of vaccines and other benefits and the sharing of [influenza viruses] [PIP biological materials] are part of the collective action to prepare for pandemic influenza. This STMA is an integral element of this broad collective action. Benefits should be prioritized based on an assessment of public health risks and needs. [The sharing of a sample is not related to the receipt of a benefit.]

OR

[13.1C Institutions, organizations and entities receiving PIP biological materials shall comply with the PIP Benefit Sharing System. The PIP Benefit Sharing is an integral part of this Standard Material Transfer Agreement.]

### **14. Warranties and indemnities**

14.1 Under this Standard Material Transfer Agreement, PIP biological materials are provided without any warranty whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose.

14.2 Under this Standard Material Transfer Agreement, institutions, organizations and entities receiving PIP biological materials shall assume all responsibility for any claims, costs, damages or expenses resulting from or otherwise related to their possession and use of the materials.

## **15. Dispute settlement**

[15.1 In the event of a dispute relating to the operation of this Standard Materials Transfer Agreement, institutions, organizations and entities providing or receiving PIP biological materials may initiate Dispute Settlement procedures as follows:

15.1.1 Amicable dispute settlement. The parties to the dispute shall attempt in good faith to resolve the dispute by negotiation.

15.1.2 Mediation. If the dispute is not resolved by negotiation, the parties to the dispute may choose mediation through a neutral third party mediator, to be mutually agreed.

15.1.3 Arbitration. If the dispute has not been settled by negotiation or mediation, any party to the dispute may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the party that wishes a dispute to be referred to an arbitration tribunal shall give notice to the other party in writing specifying the person it has appointed as an arbitrator on its part. The other party shall appoint one arbitrator on its part within 60 days from receipt of such notice. The two arbitrators nominated by the parties shall appoint the third arbitrator who shall preside over the arbitration tribunal. Should the two arbitrators fail to appoint a third arbitrator, the Director-General of WHO shall appoint the third arbitrator. All parties shall facilitate the work of the Tribunal and, in particular, using all means at their disposal, shall provide it with all relevant documents, information and facilities; and enable it, when necessary, to call witnesses or experts and receive their evidence. The decision of the arbitration tribunal shall be final and binding on the parties without appeal.]

## **16. Termination**

[16.1 If an institution, organization or entity providing or receiving PIP biological materials violates any of the terms of the Standard Materials Transfer Agreement, and dispute settlement procedures have been unsuccessful, the aggrieved party to the dispute may give the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate the Standard Material Transfer Agreement.

16.2 Upon termination, the party subject to the termination of the Standard Material Transfer Agreement shall immediately discontinue use of the PIP biological materials in any manner including either derivation or development of substances, processes or products from the materials, and shall arrange the return or the destruction of any remaining materials.

16.3 Termination of the Standard Material Transfer Agreement shall not affect the accrued rights and obligations that were due prior to the effective date of termination.]

## **[17. Applicable law**

17.1 The applicable law shall be the UNIDROIT Principles of International Commercial Contracts, 2004.]]

## APPENDIX 2

**THE FOLLOWING TERMS OF REFERENCE OF THE ADVISORY GROUP  
WERE DISCUSSED AND AGREED IN PLENARY****Advisory Group  
Terms of Reference****1. Background and mandate of Advisory Group**

The Interim Statement adopted by WHO Member States attending the 20–23 November 2007 Intergovernmental Meeting on Pandemic Influenza Preparedness urged action to develop fair, transparent, and equitable international mechanisms on virus sharing and benefit sharing. Member States called on the Director-General to establish an Advisory Mechanism to monitor, provide guidance to strengthen the functioning of the trust-based system needed to protect public health and undertake necessary assessment of that system. To carry this out, Member States specified that an Advisory Group will be appointed by the Director-General in consultation with Member States, based on equitable representation of the WHO regions and of affected countries.

The trust-based system is now referred to as the “Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits” (hereinafter “the Framework”). The scope of the Advisory Group is to monitor, assess and report on the system for sharing H5N1 influenza viruses and other influenza viruses with human pandemic potential as well as access to vaccines and other benefits of the Framework. The institutional components of the Framework to be monitored by the Advisory Group are National Influenza Centres, Other authorized laboratories, WHO Collaborating Centres, H5 Reference Laboratories, and essential regulatory laboratories, as defined in Section [4] of the Framework. [The pharmaceutical industry is not included although they can be consulted (but not monitored) by the Advisory Group.]

**2. Functions of the Advisory Group**

2.1 To monitor, assess and report on how the different functions of the Framework are implemented by its components. The information to conduct these tasks should be provided by the WHO Secretariat and other independent sources, if available. Monitoring by the Advisory Group will enable ongoing assessment of the functioning of the Framework and should include at least:

- (a) the rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with the [WHO Network];
- (b) the Influenza Virus Traceability Mechanism;
- (c) the global improvement of laboratory capacity, particularly in developing countries, to enhance pandemic influenza preparedness;
- (d) the fair and equitable sharing of benefits.

2.2 To carry out the necessary assessment of the Framework according to quantitative and qualitative indicators developed from information provided by the WHO Secretariat and other independent sources, if necessary.

2.3 To provide guidance to strengthen the functioning of the Framework to the Director-General.

2.4 Recommendations and reports of the Advisory Group will be evidence based.

2.5 To report annually, through the Director-General to the Executive Board and the World Health Assembly on its activities.

### **3. Nomination of members**

3.1 The Advisory Group will comprise 18 members drawn from three Member States in each WHO region, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza. In the exercise of their functions the Members will act as international experts serving WHO exclusively.

3.2 Each member will serve for three years. The duration of appointment of each member will be three years with a renewal of one third of the members every year; replacements must maintain the equitable representation of the six WHO regions and affected countries; all members will be eligible for two appointments. In the event of resignation or incapacity of a member for any reason, the Director-General will appoint a replacement member with a view to maintaining the equitable representation of the six WHO regions and affected countries. The alternate will complete the term of the previous member. The Group will select from among its members, a Chairperson and a Vice-Chairperson. The Chairperson and Vice-Chairperson will serve for two years after which another Chairperson and Vice-Chairperson will be selected by the Group members.

3.3 The Director-General will regularly accept nominations of representatives and will draw from this list to replace outgoing members with a view to maintaining the equitable representation of the six WHO regions and affected countries.

### **4. Working procedures**

The Director-General will apply to this Advisory Group working procedures consistent with WHO practices and procedures.

The regulations applying to the procedures of expert committees will apply to the Advisory Group, including with respect to the private nature of meetings. Furthermore, members of the Advisory Group will not make public statements, individually or on behalf of the group, on the work of the Advisory Group, except as authorized in connection with reporting requirements or by the Director-General.

### **5. Resources for implementation**

The Director-General will make available the necessary human and financial resources to support the work of the Advisory Group.

## APPENDIX 3

**GUIDING PRINCIPLES FOR THE DEVELOPMENT OF TERMS OF REFERENCE FOR CURRENT AND POTENTIAL FUTURE [WHO NETWORK] LABORATORIES FOR H5N1 AND OTHER HUMAN PANDEMIC INFLUENZA VIRUSES**

The specific roles, responsibilities and activities conducted by the different [WHO Network] laboratories can differ depending on whether they are a National Influenza Centre, a WHO Collaborating Centre, an H5 Reference Laboratory or an essential regulatory laboratory. However, in the context of pandemic influenza preparedness and their work with H5N1 and other viruses of human pandemic potential, the development of the Terms of Reference for each group of [WHO Network] laboratories will comply with the following core guiding principles.

1. All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.
2. The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.
3. The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.
4. The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States where necessary.
5. The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.
6. If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or Other authorized laboratory, especially those from developing countries, including through the publication process.
7. The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.
8. The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.
- [9. The [WHO Network] laboratories will share [publicly] genetic sequence data consistent with the Standard Material Transfer Agreement.]
- [10. The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or Other authorized laboratory.]

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