



**Draft  
Chair's text**

**PANDEMIC INFLUENZA PREPAREDNESS:  
MULTILATERAL FRAMEWORK FOR THE SHARING  
OF INFLUENZA VIRUSES AND ACCESS TO  
VACCINES AND OTHER BENEFITS**

|   | <b>Page</b> |
|---|-------------|
| 1. PRINCIPLES .....   | 3           |
| 2. OBJECTIVES .....   | 4           |
| 3. SCOPE .....  | 5           |
| 4. DEFINITIONS AND USE OF TERMS .....   | 6           |
| 5. SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES<br>WITH HUMAN PANDEMIC POTENTIAL |             |
| 5.1 General Provisions .....  | 8           |
| 5.2 Traceability and reporting mechanisms .....                                 | 8           |
| 5.3 Standard Material Transfer Agreement .....                                  | 8           |
| 5.3.1 General .....   | 8           |
| 5.3.2 Traceability .....  | 9           |
| 5.3.3 Biosafety and biosecurity .....   | 9           |
| 5.3.4 Fees and charges .....  | 9           |
| 5.3.5 Feedback .....  | 9           |
| 5.3.6 Involvement in research .....   | 10          |
| 5.3.7 Publication of research .....   | 10          |
| 5.3.8 Acknowledgment, attribution and authorship .....                          | 10          |
| 5.3.9 Sharing of risk assessment information .....                              | 10          |
| 5.3.10 Limitation of use to terms of reference .....                            | 10          |
| 5.3.11 Ownership rights .....   | 10          |
| 5.3.12 Benefits .....   | 11          |
| 5.3.13 Legal .....  | 11          |

|  | <b>Page</b> |
|--|-------------|
| <b>6. MULTILATERAL BENEFIT SHARING SYSTEM</b>  |             |
| 6.1 General .....  | 12          |
| 6.3 Pandemic risk assessment .....   | 12          |
| 6.4 Provision of diagnostic tests and materials .....  | 12          |
| 6.5 WHO stockpile of antiviral medicines and equipment .....   | 12          |
| 6.7 WHO stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential ..... | 12          |
| 6.10 Financing of WHO stockpile of vaccines and other benefits.....                                    | 13          |
| 6.14 Technology transfer.....  | 14          |
| 6.17 Innovative financing mechanisms for national vaccine requirements .....                           | 14          |
| 6.21 Capacity building .....   | 15          |
| <b>7. GOVERNANCE AND REVIEW</b>  |             |
| 7.1 General .....  | 16          |
| 7.2 Advisory mechanism.....  | 16          |
| 7.6 Dispute resolution .....   | 16          |
| 7.9 Terms of Reference .....   | 16          |
| 7.10 Review of Framework.....  | 17          |

## **1. PRINCIPLES**

### **WHO Member States**

Recalling World Health Assembly Resolution WHA60.28 on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccines and other benefits;

Noting the continuing risk of an influenza pandemic with potentially devastating health, economic and social impacts;

Recognizing the need for a fair, transparent and equitable multilateral framework for the sharing of H5N1 and other influenza viruses with human pandemic potential and the benefits resulting from their use;

Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks;

Recognizing that intellectual property rights do not and should not prevent Member States from taking measures to protect public health;

Acknowledging the entry into force of the International Health Regulations (2005) and their continued importance as the key global instrument for protection against the international spread of disease;

Noting that the routine and timely sharing of H5N1 and other influenza viruses with human pandemic potential enables the World Health Organization to ensure that the world's best expertise is brought to bear in assessing the global risk of an influenza pandemic and allows the World Health Organization and Member States to take actions to reduce the risk of the emergence of a pandemic and to facilitate the development and production of the vaccines, diagnostic materials and other pharmaceuticals that can assist in containing and responding to an emerging pandemic;

Recognizing that global influenza vaccine manufacturing capacity is insufficient to meet demand in a pandemic and that in the absence of a multilateral system of benefit sharing, some Member States, particularly developing countries, can neither afford nor access the vaccines and other benefits resulting from the system of virus sharing;

Noting the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP) and its goal of reducing the gap between potential vaccine demand and supply during an influenza pandemic, by expanding the global capacity to produce influenza vaccine;

Recognizing that Member States and organisations with access to vaccine manufacturing and other technologies for the control of influenza should make specific efforts to transfer these technologies to other Member States, particularly developing countries, consistent with international and national laws, including those relating to property rights and access;

**[Have agreed as follows]:**

## **2. OBJECTIVE**

The objective of this Multilateral Framework is to improve pandemic influenza preparedness and strengthen global public health security by reforming the Global Influenza Surveillance Network as the [WHO Network] and implementing a fairer, more transparent and more equitable system for the sharing of H5N1 and other influenza viruses with human pandemic potential and the benefits resulting from their use.

### **3. SCOPE**

This Multilateral Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, to which all Member States commit, applies to H5N1 and other influenza viruses with human pandemic potential. It does not apply to seasonal influenza viruses.

## 4. DEFINITIONS AND USE OF TERMS

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

### Scientific terms

**“Pandemic Influenza Preparedness biological materials”** or **“PIP biological materials”** under this Framework designates any original clinical specimen of H5N1 or other influenza virus with human pandemic potential provided for the purposes of influenza testing and any physical material generated from that specimen, including virus isolates or related hybrid viruses created through laboratory techniques, resulting from laboratory techniques used on the clinical specimen. [The terms “Pandemic Influenza Preparedness biological materials” and “PIP biological materials” do not refer to vaccines, diagnostics or pharmaceutical products generated from use of the clinical specimen or related materials, which are referred to specifically where relevant in this Framework.]

**“Influenza virus with human pandemic potential”** designates any influenza virus that has been found to infect a human 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.

**“Pandemic influenza preparedness vaccine virus”** or **“PIP vaccine virus”** designates any wild-type influenza virus, influenza reference virus, high-growth reassortant virus, WHO-recommended virus for vaccine use or other influenza virus material generated from H5N1 or other **influenza virus with human pandemic potential** provided to vaccine manufacturers for the purposes of developing a prototype pandemic, pre-pandemic or pandemic influenza vaccine.

**“Clinical specimens”** means materials collected from humans, generally in order to confirm a diagnosis. 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. Clinical specimens can be frozen and stored for later use.

**“High-growth reassortant viruses”** means influenza viruses that have been genetically modified to grow better in eggs for optimal influenza vaccine production.

**“Influenza reference viruses”** means wild-type influenza viruses 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 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”** (synonym: virus isolates) means influenza viruses that have been cultured either in eggs or cells (i.e. isolated) directly from clinical specimens and have not been purposefully modified.

## **Institutions and Organizations**

**“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 that develop and produce human influenza vaccines.

**“Vaccine, diagnostic and pharmaceutical manufacturers”** means public or private 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.

**“WHO Collaborating Centres”** specialising in 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.

## **Other Terms**

**“Multilateral Framework”** means the system and mechanisms adopted and agreed by Member States to govern the sharing of H5N1 and other influenza viruses with human pandemic potential and the benefits resulting from their use. Parties and/or entities contributing to and participating in the Multilateral Framework include but are not limited to: WHO Member States, the **[WHO Network]** and **Influenza Vaccine Manufacturers**.

**“WHO MEMBER STATES”**. The 193 States party to the WHO Constitution.

## **5. SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES WITH HUMAN PANDEMIC POTENTIAL**

### **5.1 General Provisions**

5.1.1 With the objective of improving pandemic influenza preparedness and strengthening global public health security and in consideration of the multilateral benefit sharing system being established under this Framework, Member States agree to routinely provide clinical specimens or viruses from all human cases of H5N1 and other influenza viruses of human pandemic potential in a timely fashion:

(a) to the WHO Collaborating Centre for Influenza or H5 Reference Laboratory of their choice, and

(b) through those laboratories to other laboratories in the [WHO Network], 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.

[5.1.2 Member States may also provide clinical specimens from human cases of H5N1 and other influenza viruses of human pandemic potential directly to any other party or body on a bilateral or multilateral basis provided that this does not preclude the same materials being provided to the WHO Collaborating Centres and/or H5 reference laboratories under this Framework.]

### **5.2 Traceability and reporting mechanisms**

5.2.1 The Director-General, in consultation with the Advisory Mechanism, shall ensure a transparent traceability mechanism is put in place that uses an electronic system in order to track in real time the movement of PIP biological materials into, within and out of the [WHO Network].

5.2.2 To ensure timely feedback is provided to originating laboratories and Member States, the traceability mechanism and associated electronic reporting systems should also require that receiving organizations provide as much information as possible to the originating laboratories about the clinical specimens received.

5.2.3 Pending the functioning of the transparent traceability mechanism, the interim system providing full disclosure of information on the transfer and movement of biological materials will continue to be operated and maintained.

### **5.3 Standard Material Transfer Agreement**

#### **5.3.1 General**

The transfer of PIP biological materials into, within and out of the [WHO Network] shall be governed by a Standard Materials Transfer Agreement containing the following elements. The Standard

Materials Transfer Agreement shall be standardized, universal and globally applicable to all transfers of biological materials and not subject to further negotiation.

#### 5.3.2 Traceability

A. National Influenza Centres and other laboratories designated by Member States to provide clinical specimens from human cases of H5N1 and other influenza viruses of human pandemic potential shall register those specimens in the traceability mechanism as PIP biological materials.

B. As a condition of receiving PIP biological materials, all organizations within and outside the [WHO Network] 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.

C. Organizations outside the [WHO Network] receiving PIP biological materials shall not further transfer the materials outside the [WHO Network] without the prior informed consent of the Member State where the clinical specimens were collected and the [WHO Network] laboratory that provided the materials, except insofar as the materials have been transformed to become an indivisible element of a vaccine, diagnostic or pharmaceutical product.

#### 5.3.3 Biosafety and biosecurity

A. All parties 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.

B. All parties 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.

#### 5.3.4 Fees and charges

[WHO Network] laboratories may not impose charges for the provision of PIP biological materials but may seek to recover the costs of shipping, handling, storage or other direct administrative overheads associated with transferring the PIP biological materials.

#### 5.3.5 Feedback

WHO Collaborating Centres and H5 Reference Laboratories shall provide in a routine and timely way to National Influenza Centres, and other laboratories designated by Member States to provide clinical specimens, all relevant information about the clinical specimens received, including the results of virus sequencing, characterization and risk assessment, copies of isolated virus strains and/or PIP vaccine viruses and respond in a timely way to requests from those laboratories for further information about the specimens provided.

#### 5.3.6 Involvement in research

WHO Collaborating Centres and H5 Reference Laboratories [should/shall] include scientists from the Member State or laboratory where the PIP biological materials were collected in research on those biological materials to the fullest extent feasible with a view to facilitating meaningful participation, skills transfer and capacity development.

#### 5.3.7 Publication of research

WHO Collaborating Centres, H5 Reference Laboratories and other parties receiving PIP biological materials may publish or otherwise disseminate scientific results generated from the PIP biological materials with 14 days' written notice to the originating National Influenza Centre or other laboratory designated by the relevant Member State to provide clinical specimens.

#### 5.3.8 Acknowledgment, attribution and authorship

WHO Collaborating Centres, H5 Reference Laboratories and other parties publishing research arising from the use of PIP biological materials shall appropriately acknowledge and properly attribute contributions by scientists and/or researchers from the Member State or laboratory which collected those materials 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. Similarly, proper acknowledgment, attribution and authorship shall be provided for other formal scientific presentations.

#### 5.3.9 Sharing of risk assessment information

[WHO Network] laboratories may make available risk assessment information relating to PIP biological materials, including viral genetic sequence data, to other [WHO Network] laboratories, diagnostic, pharmaceutical and vaccine manufacturers and public health researchers.

#### 5.3.10 Limitation of use to terms of reference

WHO Collaborating Centres and H5 Reference Laboratories shall seek the prior written consent of the originating National Influenza Centre, or other laboratory designated by the relevant Member State to provide clinical specimens, for any use of the 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.

#### 5.3.11 Ownership rights

[A. Organisations providing and/or receiving PIP biological materials shall not claim or assert intellectual property or other ownership rights over the PIP biological materials.]

OR

[B. No party receiving, handling and using PIP biological materials under this framework shall claim exclusive ownership rights over those biological materials.]

and

[C. Any party receiving, handling and using PIP biological materials seeking patent protection or other intellectual property rights in respect of such materials shall disclose in the patent application the country in which the PIP biological materials were collected.]

#### 5.3.12 Benefits

PIP biological materials are provided to the [WHO Network] laboratories, vaccine, diagnostic and pharmaceutical manufacturers and public health researchers with the objective of improving pandemic influenza preparedness and strengthening global public health security. In consideration of this, and recalling Resolution WHA60.28, the multilateral benefit sharing system set out in the WHO 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.

#### 5.3.13 Legal

[Note from Chair: Any “legal” provisions, e.g. relating to indemnities etc, will need to be defined and drafted following further advice from WHO’s Legal Counsel.]

## **6. MULTILATERAL BENEFIT SHARING SYSTEM**

### **General**

6.1 Acknowledging the contribution of countries affected by H5N1 and other influenza viruses with human pandemic potential, particularly developing countries, in collecting clinical specimens and sharing viruses with the [WHO Network] and recognizing the global and indivisible nature of the pandemic threat, Member States agree to establish a multilateral system for the sharing of benefits arising from the use of H5N1 and other influenza viruses with human pandemic potential.

6.2 This system will include the following elements:

### **Pandemic risk assessment**

6.3 [WHO Network] laboratories shall make available to the WHO Secretariat, in a timely way, all information derived from their examination of the PIP biological materials and the WHO Secretariat shall make available to all Member States, in a timely way, pandemic risk assessments based on that information.

### **Provision of diagnostic tests and materials**

6.4 WHO Collaborating Centres [and H5 Reference Laboratories] shall make available to National Influenza Centres and other laboratories designated by Member States to provide clinical specimens, without charge, supplies of noncommercial diagnostic test materials and reagents for the identification and characterization of clinical specimens of influenza.

### **WHO stockpile of antiviral medicines and equipment**

6.5 The WHO Secretariat shall, with contributions from pharmaceutical manufacturers and Member States, maintain a stockpile of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human pandemic potential.

6.6 The WHO Secretariat will seek the guidance of expert advice in determining the size, composition and operational use of this stockpile.

### **WHO stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential**

6.7 The WHO Secretariat shall establish and maintain a stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential and associated equipment for:

- (a) use in response to the first detection of pandemic influenza if considered technically feasible; and
- (b) distribution to developing countries on a per capita basis once a pandemic begins with use to be determined by those countries.

6.8 The WHO Secretariat shall seek the guidance of its Strategic Advisory Group of Experts on Immunization in determining the size, composition and operational use of the vaccines.

6.9 The WHO Secretariat shall work with relevant experts and Member States to develop and exercise operational plans for the deployment of these vaccines.

**Financing of WHO stockpile of vaccines and other benefits**

6.10 The stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential [, and other benefits arising from this Framework,] will be financed through:

A. voluntary in-kind or financial contributions from vaccine manufacturers, Member States and nongovernmental organizations to the WHO;

AND/OR

B.  $x\%$  of the sales by vaccine, diagnostic and pharmaceutical manufacturers of products developed using PIP biological materials, to be paid into a WHO-managed trust fund;

AND/OR

C. a Global Influenza Vaccine Fund financed from:

(i) annual assessed contributions from Member States, 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;

(ii) annual assessed contributions from influenza vaccine manufacturers, at US\$ 0.20 per influenza vaccine dose manufactured by them in that year; and

(iii) voluntary contributions from any individual or entity.

[Access to vaccines for developing and least-developed countries]

[6.11 Vaccine manufacturers shall set aside  $x\%$  of each production cycle of vaccines for H5N1 and other influenza viruses of human pandemic potential for provision to the WHO stockpile free of charge.]

[6.12 Vaccine manufacturers shall also set aside  $x\%$  of each production cycle of pandemic vaccine for provision through the WHO on the basis of public health need.]

[6.13 Member States shall continue to work with each other, with the WHO and with vaccine manufacturers with the aim of ensuring that adequate quantities of vaccines for H5N1 and other influenza viruses of human pandemic potential, and pandemic vaccines, are made available to developing and least developed countries at the same time as to developed countries, on the basis of public health need and at affordable prices.]

### **Technology transfer**

6.14 Member States and organizations with access to vaccine manufacturing and other technologies for the control of influenza should make specific efforts to transfer these technologies to other Member States, particularly developing countries, consistent with international and national laws, including those related to property rights and access.

6.15 The WHO Secretariat shall continue to work closely with Member States to implement the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, notably Strategy 4.2 to increase influenza vaccine production capacity by building new production facilities in developing and/or industrialized countries.

[6.16 Vaccine manufacturers who receive PIP biological materials will 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, know-how, information and knowledge used in the process of influenza vaccine development and production in particular pre-pandemic and pandemic vaccines.]

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

6.17 Interested Member States will work together, with the WHO Secretariat 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 the Pan American Health Organization (PAHO) Revolving Fund for Immunization, or other similar types of funds, as a reference point.

6.18 Working with manufacturers of vaccines and associated equipment, the fund will, at a minimum:

- (a) 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;
- (b) seek to provide such vaccines and associated equipment for low-income and middle-income countries at tiered or subsidized prices;
- (c) provide affordable loans to developing and least-developed countries to support procurement of vaccines and associated equipment.

6.19 The mechanism for capitalization and governance arrangements for the fund will be agreed by participating Member States and organizations, but may include voluntary contributions from Member States and nongovernmental organizations.

6.20 Neither the existence of, nor participation in, the fund will prevent Member States from making other unilateral or multilateral arrangements to procure vaccines for H5N1 and other viruses with human pandemic potential.

### **Capacity building**

6.21 On request, WHO and Member States with advanced laboratory and influenza surveillance capacity will work with developing countries to develop national laboratory and influenza surveillance capacity, including to:

- (a) to conduct isolation and characterization of viruses;
- (b) to participate in pandemic risk assessment;
- (c) to develop research capacity;
- (d) to achieve technical qualifications for consideration of laboratories as National Influenza Centres, H5 Reference Laboratories and WHO Collaborating Centres.

## **7. GOVERNANCE AND REVIEW**

### **General**

7.1 This Framework will be overseen by the Director-General of WHO.

### **Advisory mechanism**

7.2 The Director-General will establish a transparent advisory mechanism 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.

7.3 An 18-member advisory group will be appointed by the Director-General in consultation with Member States, based on equitable representation comprising three members per WHO region and being mindful of affected countries.

7.4 The advisory group will consider progress in the implementation of this Framework, including the sharing of H5N1 and other influenza viruses with human pandemic potential, the multilateral benefit sharing mechanism and the traceability mechanism. Terms of Reference for this function shall be developed.

7.5 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 for a decision on any future mandate.

### **Dispute resolution**

7.6 In the event of a dispute between two or more Member States concerning the interpretation or application of this Framework, the States Parties concerned shall 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 reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

7.7 In the event that the dispute is not settled by the means described under paragraph 7.6 above, the Member States concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it.

7.8 In the event of a dispute between WHO and one or more Member States concerning the interpretation or application of this Framework, the matter shall be submitted to the Health Assembly.

### **Terms of Reference**

7.9 The Terms of Reference of the WHO CCs, H5 Reference Laboratories and NICs will be reviewed through the Advisory Mechanism.

## **Review of Framework**

7.10 The Director-General, consulting Member States and the Advisory Mechanism as appropriate, will conduct a review of this Framework and all of its components for consideration by the World Health Assembly in 2014.

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