



**World Health
Organization**

**INTERGOVERNMENTAL MEETING ON PANDEMIC
INFLUENZA PREPAREDNESS: SHARING OF
INFLUENZA VIRUSES AND ACCESS TO VACCINES
AND OTHER BENEFITS
Provisional agenda item 3**

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Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness

At the request of the Permanent Mission of Thailand to the United Nations and other International Organizations at Geneva, the Director-General has the honour to transmit the attached proposal to the Intergovernmental Meeting.

ANNEX

A PROPOSAL FROM THAILAND FOR THE IGM–PIP, 20–23 NOVEMBER 2007**Standard Terms and Conditions (STCs) for the Transfer and Use of Influenza Biological Materials and Fair and Equitable Benefits Sharing
(Between Member States [MS] and WHO Secretariat [WS])****1. Preamble**

(a) The Member States have the sovereign rights over their biological resources (*Remark: This means that Member States (MS) should not transfer the rights to the WHO Secretariat (WS) but should permit WS to use the influenza biological materials for certain purposes.*)

(b) It is important to have collective action to mitigate public health risks. (*Remark: This means that, since influenza pandemic is a global health risk, sharing of influenza viruses and resultant vaccines that are produced with use of the virus should be done in the way that it mitigates the global risk as a collective action.*)

(c) It is important to have timely international sharing of influenza viruses as a contribution to risk assessment and risk response, and the need for concrete, effective, operational and transparent international mechanisms for fair and equitable sharing of benefits. Sharing of influenza viruses and sharing of benefits including access to influenza vaccines, therefore, need to be considered together and managed under the same mechanism by the same entity. (*Remark: This clause reiterates and expands clause 2.*)

(d) It is agreed that intellectual property rights do not and should not prevent Member States from taking measures to protect public health.

(e) It is recognized that developing and least developed countries are at the highest risk of being the epicenter of the next influenza pandemic and are likely to be less or least prepared to cope with the pandemic because of their limited capacities and economic, technical, financial and administrative constraints. Therefore, fair and equitable benefits sharing of influenza vaccines as a result of timely international sharing of influenza virus needs to provide a more favorable condition to developing and least developed countries. (*Remark: This preamble is important when we detail benefits sharing.*)

2. Identification of Parties

(a) This is the STCs between Member States (MS) and the WHO Secretariat (WS) only.

(b) The Member States include only members of the WHO and shall be represented by an agency or unit or organization, as to be designated and notified to the WS in writing by the MS.

(c) The WHO Secretariat is represented by the Director General (DG) and/or his/her designate(s). The DG of the WHO could designate, and publicly announce, one of his/her deputies or assistants or departments or units to act on his/her own behalf.

(Remark: Please note that this identification of parties is markedly different from previously-proposed STC because it limits the number of parties to only two. In addition, these STCs do not use the term “GISN”, nor does it mention NICs, WHOCCs, WHOH5RLs, etc. The omission of

these terms does not mean to undermine or diminish the importance of GISN and its members. The omission is done for the sake of simplicity and clarity. As a matter of fact, the NICs, WHOCCs, WHOH5RLs have well-defined TORs that could be easily agreed by MS. If the NICs, WHOCCs, and WHOH5RLs play their roles and do the functions as set forth in the TORs, the GISN as a whole will be strengthened automatically, without the need to include the term GISN and the TORs of these GISN-associated entities in these STCs.)

3. Definition and Scope

(a) The MS agrees to provide to the WS certain materials (e.g. throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including data and information on genetic and biological characteristics, and derivatives including clones, plasmids, and recombinants) obtained from their citizens (regardless of where they live) and also agrees to allow the WS to use the materials for the purpose of research, development, and production of an influenza vaccine (whether it be seasonal, inter-pandemic, potential pandemic, pre-pandemic and/or pandemic vaccines) only.

(b) The materials to be provided from the MS to the WS under these STCs cannot be used for other purposes, e.g. laboratory diagnosis, laboratory confirmation, development of new diagnostic methods, development of new test kits, development of new antivirals, unless there is a separate written agreement between the sending entity and the receiving entity.

(c) In addition, these STCs do not provide coverage for use of other agents or pathogens that may be contained in the materials, e.g. respiratory bacteria, non-influenza respiratory viruses. Use of these agents or pathogens need separate written arrangements.

(d) Materials provided from the MS to the WS for other purposes (e.g. for laboratory diagnosis and confirmation) but are later used for the purpose of influenza vaccine research, development, and production are automatically covered by these STCs and all conditions of these STCs shall apply.

(e) These STCs are legally binding on all parties involved. (*Remark: As some MS may have governing law requiring that a material transfer agreement (MTA) be signed before materials could be transferred outside the country, it is necessary, under this provision, that the MS seek authorization from appropriate bodies, e.g. the cabinet, the parliament, before the MS endorse these STCs in the World Health Assembly. Along the same line, some receiving MS may have governing law indicating that genetically-modified organisms derived from the viruses (e.g. reverse-genetics viruses) become "select agents" which cannot be transferred back to sending MS. In that case, the receiving MS shall arrange for waiver of such requirements before they endorse these STCs in the World Health Assembly.*)

(f) All annexes form an integral part of these STCs. (*Remark: This clause reiterates the sovereign rights of the MS over the biological resources. Therefore, we need to clearly mention that all specimens and their derivatives obtained from a citizen of a Member State belong to the Member State and will be covered by these STCs. Please note that these STCs do not mention that the specimens have to be sent from an NIC [As a matter of fact, NIC are existing in only 92 Member States]. Specimens sent from a Member State, whether it is from a public or private laboratory or entity or any individual, belong to the Member State and shall be covered by these STCs.*)

4. General Provisions

- (a) *Safety*: All parties shall ensure that all transfers under these STCs will at all times be in compliance with all relevant national and international laws, rules, and regulations governing the handling, safe transfer and use of infectious substances and living microorganisms.
- (b) *Warranty*: All materials delivered pursuant to these STCs are understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representation and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other propriety right.
- (c) *Indemnity*: Recipients of materials shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the materials. The MS will not be liable for any loss, claim or demand made to or arising from the use, storage or disposal of the materials.
- (d) *Applicable Law*: The applicable law shall be _____.
- (e) *Dispute Settlement*: Dispute settlement may be initiated by the MS or the WS in relation to their respective relationships in the context of these STCs. Any dispute arising from these STCs shall be resolved through the Oversight Mechanism to be established by the WS and agreed by the MS in a World Health Assembly.

5. Termination

- (a) When one of the parties fails to fulfill its obligations or violates any of these STCs and the aggrieved party has given 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 these STCs.
- (b) Upon termination, the WS shall immediately arrange discontinuation of any use of the materials in any manner including either derivation or development of substances, processes, products from the materials, and shall arrange the return or the destruction of any remaining materials.
- (c) Termination of these STCs shall not affect the accrued rights and obligations that were due prior to the effective date of termination of these STCs.
- (d) With regard to termination of these STCs, each Member State constitutes one party to the STCs.

6. Notices

- (a) Any notices or requests to be made under these STCs shall be in writing and shall, except where it is otherwise stated, be delivered by courier, or by facsimile, or by electronic mail, to the address of the entity to be designated by each party, and shall be deemed to have been received on the date of delivery, if delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile or electronic mail, if sent by facsimile or electronic mail.

7. Duration of Agreement

(a) These STCs shall remain in force until otherwise determined by a World Health Assembly.

8. Non-compliance

(a) If a subsequent recipient of materials from the WS does not comply with these STCs, the MS, individually or collectively, and/or the WS have the right to deny the recipient with new materials as appropriate.

9. Traceability

(a) The WS shall establish a tracking system and database for transfer and movement of materials and their derivatives (including but not limited to throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including genetic characteristics, biological characteristics, clones, plasmids, and recombinants) on a real-time basis.

10. Miscellany

(a) Upon request by the MS, the WS shall arrange return or destruction of the materials provided to the WS by the MS without delay.

11. Rights and Obligations of the MS

(a) The MS shall provide to the WS or other WS-designated entity the materials that may contain influenza virus or part thereof or antibody to the virus as soon as possible without request from the WS. The provision may be accompanied by a cover letter indicating that such provision is automatically covered by these STCs.

(b) If there is a good reason to believe that the WS or any of entities that receive the influenza virus or part thereof or antibody to the virus does not comply with these STCs, the concerned MS(s) has the right to deny the WS or the entity/-ties with the new materials. In addition, the MS(s) may request the Oversight Mechanism to investigate the incident(s) that may be associated with such non-compliance.

(c) The MS has the right to access, at no cost, to information related to influenza virus or part thereof or antibody to the virus, as generated by the WS or any of the entities that subsequently receive the virus or the antibody.

(d) The MS has the right to receive, at no cost, all outputs of activities undertaken in relation to the materials provided to the WS or any WS-designated entity including influenza viruses isolated from the materials and sequence data of the influenza viruses.

(e) The MS has the right to provide the materials under these STCs to any other non-WS-associated entity/-ties on a bilateral or multilateral basis provided that such provision does not deprive the WS of the right to receive the same under these STCs.

(f) The MS has the obligations to strengthen its surveillance and risk assessment system to be able to early and accurate detection of influenza outbreaks.

(g) The MS has the obligations to contribute to the Global Influenza Vaccine Fund (GIVF – pronounced “give”).

12. Rights and Obligations of the WS

(a) The WS has the right to designate any entity within or outside its organization to receive the materials under these STCs, provided that

(i) such designation is made in writing

(ii) the use of the materials is consistent with these STCs

(iii) there is a written agreement for each transaction of transfer of the materials or products made out of the materials

(iv) the transaction of transfer of materials is recorded in the real-time tracking system of the WS that is publicly accessible

(v) the recipient of the materials agrees in writing not to subsequently transfer of the materials to any other entity

(vi) the recipient of the materials agrees in writing to contribute to the Global Influenza Vaccine Fund (GIVF)

(vii) the recipient of the materials agrees in writing to participate fully in the Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS – pronounced “give bes(t)”)

(viii) the recipient of the materials agrees in writing not to seek or assert intellectual rights or other rights over substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the materials, developed through the use or that contain and/or incorporate the materials.

(b) The WS shall ensure that, if the recipients of the materials from the WS wish to transfer the materials subsequently to another recipient or recipients, these STCs shall apply and the subsequent transfer of the materials needs prior approval from the WS and is considered “executed by the WS”.

(c) The WS and the recipient of the materials through the WS has the right to publish sequence data of the viruses obtained from the MS under these WS in a public-domain database provided that

(i) the WS clearly indicates in the intended publication that such publication is covered by these STCs and use of the publicized data shall be consistent with these STCs

(ii) the MS is properly acknowledged in such intended publication

(iii) the MS is notified in writing of such intended publication

- (iv) the MS does/do not object to such intended publication within 14 days of receipt of such written notification.
- (d) The WS and the recipient of the materials through the WS has the right to present, publish or otherwise disseminate scientific results generated from the materials provided that
 - (i) the WS clearly indicates in the presentation, publication or dissemination that such presentation, publication, and dissemination are covered by these STCs
 - (ii) the MS and its scientists and/or researchers are properly acknowledged or included as co-authors in the manner that is consistent with the guidelines for authorship and acknowledgement stipulated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals
 - (iii) the MS is notified in writing of such intended presentation, publication, or dissemination
 - (iv) the MS does/do not object to such intended presentation, publication, and dissemination within 14 days of receipt of such written notification.
- (e) If the materials provided to the WS by the MS have led to a product or products (e.g. candidate vaccine virus, vaccine seed) that may be used to production of an influenza vaccine, the WS has the obligations to obtain a written agreement from the recipient of the materials that manufacturers of the vaccine or product agree in writing to contribute to the GIVF and the GIVBeSS.
- (f) The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, a real-time tracking system for the materials provided under these STCs and derivatives and products made out of the materials.
- (g) The WS has the obligations to develop, together with MS the GIVF and the GIVBeSS.
- (h) The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, an electronic system that renders material transfer agreements between the WS and the recipients of the materials publicly available and accessible within 3 days of execution of the agreements.
- (i) The WS has the obligations to respond to the inquiry and request from the MS as stipulated in these STCs.

13. Oversight Mechanism

- (a) The WS shall, with adequate participation of the MS, propose an Oversight Mechanism to be considered and approved by the World Health Assembly.
- (b) The WS shall facilitate the works of the Oversight Mechanism.

Annex I: Global Influenza Vaccine Fund (GIVF)

Annex II: Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS)

Annex III: Oversight Mechanism

Annex I: Global Influenza Vaccine Fund (GIVF)

GIVF is a global fund created specifically to ensure that there are sufficient financial resources to implement these STCs to ensure that influenza virus and part thereof, and antibody to the virus are shared in a timely manner so that influenza vaccines are produced and distributed in a fair and equitable manner as a collective global action to mitigate the risk of an influenza pandemic.

The Fund is made of

- annual assessed contributions from Member States
- annual assessed contributions from influenza vaccine manufacturers
- voluntary contributions from any individual or entity (excluding tobacco-related entity)

Annual assessed contributions from Member States

Each Member State shall pay annual contribution based on its level of economic advancement and number of population. The Member States are divided into 10 deciles based on their level of Gross Domestic Product per capita. The amount of contribution to the Fund for the Member States is calculated as follows:

1st decile = lowest decile	Contribution = 0.6 US cent x number of population
2nd decile	Contribution = 0.7 US cent x number of population
3rd decile	Contribution = 0.8 US cent x number of population
4th decile	Contribution = 0.9 US cent x number of population
5th decile	Contribution = 1.0 US cent x number of population
6th decile	Contribution = 1.1 US cents x number of population
7th decile	Contribution = 1.2 US cents x number of population
8th decile	Contribution = 1.3 US cents x number of population
9th decile	Contribution = 1.4 US cents x number of population
10th decile = highest decile	Contribution = 1.5 US cents x number of population.

Annual assessed contributions from influenza vaccine manufacturers

Influenza vaccine manufacturers who have agreed to contribute to the Fund will be assessed at the level of 20 US cents x number of influenza vaccine doses manufactured by them in each year.

Management of the Fund

The Fund is managed by a board composed of 11 members. Six members are selected by the Executive Board of the WHO from nominations by Member States. The six selected members from Member States shall represent the six regions of the WHO. The other five members are selected from nominations from influenza vaccine manufactures by the nominees themselves. The 11 members select a chairperson and a secretary. The chairperson of the board shall be one of the six members representing the Member States. The term of the board is 2-year. The board members can be re-selected. The WHO Secretariat shall facilitate the works of the board.

Annex II: Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS)

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

- (1) Use of Fund to secure 20% of global production capacity of influenza vaccines for use during a pandemic through advance purchase agreement with the vaccine manufacturers and the governments which have reserved the vaccine production capacity with the vaccine manufacturers
- (2) Use of Fund to improve and facilitate transfer of technology of influenza vaccine production among developing countries
- (3) Use of Fund to pay for license fee for transfer of technology of influenza vaccine manufacturing to developing countries at a pre-negotiated rate

Calculation of the pre-negotiated rate for license fee for transfer of technology**For egg-based technology**

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

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

For cell-based technology

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

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

Annex III: Oversight Mechanism

An Oversight Board is to be established by the World Health Assembly. The Board is composed of 24 members (4 from each WHO region with balanced representation of countries affected and not affected by the current avian influenza outbreaks and of countries with high and low economic advancements). The chairperson, the vice chairperson, and the secretary are selected by and among the Board members themselves. At the beginning, one-third of the members shall have a one-year term, another one-third two-year term, and the other one-third three-year term. Determination of the duration of term of the Board at this initial stage is done by lottery system. WHO regions of which the Board members have finished their terms have the right to nominate new members for approval at the World Health Assembly. Newly designated members shall have three-year term.

The Board has the following responsibilities:

1. Establish a mechanism whereby MS can use to petition inconsistency of practice under these STCs
2. Establish a monitoring system and an internal audit mechanism for implementation of these STCs with the frequently of audits of not less frequently than biannually
3. Request a report from the WS on the status of specific implementation of these STCs as well as obstacles, as needed
4. Arrange an investigation of complaints or irregularities in implementation of these STCs
5. Provide recommendations as to improve collective actions to share influenza virus and resultant benefits
6. Report to the World Health Assembly on execution of its functions on a yearly basis
7. Perform other duties as assigned by the World Health Assembly

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