

ANNEX 3

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

DRAFT TECHNICAL PROVISIONS OF THE STANDARD MATERIAL TRANSFER AGREEMENT

BACKGROUND

General considerations

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 aspects 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 (the “Framework”) is an international mechanism to implement a fairer, more transparent, equitable and efficient system. In developing countries, support to implement national integrated human and animal influenza action plans and build national minimum core capacity for detection, risk assessment, laboratory confirmation and rapid containment are critical success factors. (*IGM Text Principles – Introductory paragraph*)¹

Drafting considerations

The following draft standard material transfer agreement has been prepared in response to the request by the Intergovernmental Meeting to the Director-General to prepare “a revised version of the technical part of the Standard Material Transfer Agreement, following the agreed principles of the Intergovernmental Meeting text”.²

The specific part of the request to revise “the technical part” of the Agreement raised a question of interpretation. Many, if not all, of the provisions of the Agreement are technical in some sense, that is to say they are either scientifically or legally technical. Accordingly, and in the interest of completeness, the Secretariat has provided as comprehensive a draft Agreement as possible. The text follows as closely as possible the agreed principles of the Intergovernmental Meeting’s text. Where agreed principles were absent or unclear, placeholder language has been inserted indicating that relevant provisions of the Framework would be added as they become agreed in the course of the intergovernmental process, or an option for consideration has been provided, in all cases clearly indicated as such. Such options are not intended to suggest agreed outcomes but rather to facilitate discussion on the relevant topic.

In preparing this draft, the Secretariat examined several models of format and technical provisions, including, in particular, the standard material transfer agreement connected with the International

¹ Document EB124/4 Add.1, Annex 2.

² Document EB124/4 Add.1, Annex 1.

Treaty on Plant Genetic Resources for Food and Agriculture adopted by the Food and Agriculture Organization of the United Nations in 2001 (“the FAO treaty”). Eight other material transfer agreements regularly used or proposed for transfer of biological materials were also reviewed as useful examples of format and technical provisions generally familiar to the community of providers and recipients of biological materials.

Regarding compliance with the standard material transfer agreement, Articles 7 and 8 address applicable law and dispute settlement. They are modelled on the relevant provisions of the agreement in the FAO treaty. As in the case of the latter’s standard material transfer agreement a range of dispute settlement options are provided, including negotiation, mediation and, ultimately, binding arbitration. By its terms, the applicable law, under Article 7, would be the general principles of international commercial law, as opposed to particular domestic law. Enforcement of any arbitral decisions would be in accordance with the aforementioned principles.

Draft Standard Material Transfer Agreement

Preamble

Whereas WHO coordinates a network of influenza laboratories (hereinafter, the “WHO network”) that conduct pandemic influenza risk assessment and risk response activities under agreed terms of reference;

Whereas enabling the global public health community to prevent, protect against, control and provide a public health response to the threat of pandemic influenza through the Framework is a global public good for health;

Whereas the Framework recognizes 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; (*IGM Text preambular paragraph 3, consensus*)

Whereas the Parties to the Framework 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; (*IGM Text preambular paragraph 15, consensus*)

Whereas the Framework is to be implemented in a manner consistent with relevant national and international laws, regulations, ethical norms, and obligations;

Whereas the objective of the Framework is to improve pandemic influenza preparedness and strengthen the protection against the spread of pandemic influenza by 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.];(*IGM Text preambular paragraph 2.1*)

Whereas Parties to the Framework have adopted this Standard Material Transfer Agreement, referred to in Section 5.3 of the Framework, for use by all entities that use, transfer or receive influenza viruses through or from the [WHO Network];

ARTICLE 1 – PARTIES TO THE AGREEMENT

1.2 This Agreement is:

BETWEEN: *(name and address of the provider or providing institution,¹ name of authorized official, contact information for authorized official)* (hereinafter referred to as “the Provider”),

AND: *(name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official)* (hereinafter referred to as “the Recipient”²).

1.3 The parties to this Agreement hereby agree as follows:

ARTICLE 2 – DEFINITIONS

In this Agreement, the definitions and use of terms referred to in Section 4 of the Framework are incorporated herein by reference.

ARTICLE 3 – SUBJECT MATTER OF THE STANDARD MATERIAL TRANSFER AGREEMENT

Pandemic Influenza Preparedness (PIP) Biological Materials are hereby transferred from the Provider to the Recipient subject to the terms and conditions set out in this Agreement.

ARTICLE 4 – GENERAL PROVISIONS

4.1 This Agreement is entered into under the Framework and shall be implemented and interpreted in accordance with the objectives and provisions of said Framework.

[ARTICLE 5 – RIGHTS AND OBLIGATIONS OF THE PROVIDER]

The Provider undertakes that the PIP Biological Materials specified in Appendix 1 are transferred in accordance with the following provisions:

5.1 The Provider will make the transfer of such PIP Biological Materials in accordance with its applicable WHO Terms of Reference and record the transfer in the WHO Influenza Virus Traceability Mechanism.

¹ This identifies the entity that sends the PIP Biological Materials – it could be, for example, a National Influenza Centre, or a WHO Collaborating Centre or any other institution that transfers PIP Biological Materials to another entity.

² This is the recipient of the PIP Biological Materials in this transaction.

5.2 The Provider will ensure that such PIP Biological Materials contain materials treated as optimally as possible to retain the viability of the materials.

[Insert other provisions as agreed ...]

ARTICLE 6 – RIGHTS AND OBLIGATIONS OF THE RECIPIENT

The Recipient undertakes that the PIP Biological Materials specified in Appendix 1 shall be used or conserved in accordance with the following provisions:

6.1 The Recipient shall record receipt of such Material in the WHO Influenza Virus Traceability Mechanism. In the event that the Recipient further transfers the PIP Biological Materials, such transfer will be subject to this SMTA and such transfer shall be recorded in the WHO Influenza Virus Traceability Mechanism.

6.2 Any Recipient that receives PIP Biological Materials in its capacity as a [WHO Network] entity shall handle PIP Biological Materials in accordance with its WHO Terms of Reference.

6.3 *The Recipient shall not seek to obtain any intellectual property rights in connection with such PIP Biological Materials, unless the Recipient agrees to grant to WHO a royalty-free, non-exclusive, transferable licence with respect to such rights. WHO may then transfer this licence to developing countries, with appropriate terms and conditions, as determined by the Director-General in accordance with sound public health principles, with transparent rules and procedures, informed by expert guidance and evidence. (Option for consideration)*

6.4 *For a recipient who produces or is capable of producing influenza vaccines: In the event of an influenza pandemic, such a recipient agrees to reserve at least [10]% of doses of pandemic influenza vaccine it produces, after the start of pandemic vaccine production, for purchase, at cost, by organizations in the United Nations system for use first in developing countries. (Option for consideration)*

[Insert other provisions as agreed, such as those concerning publication information and acknowledgement ...]

ARTICLE 7 – APPLICABLE LAW

The applicable law shall be the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT), as well as the objectives, principles and other relevant provisions of the Framework.

ARTICLE 8 – DISPUTE SETTLEMENT

- 8.1 Dispute settlement may be initiated by the Provider or the Recipient.
- 8.4 Any dispute arising from this Agreement shall be resolved in the following manner:
- (a) amicable dispute settlement: the Parties shall attempt in good faith to resolve the dispute by negotiation;
 - (b) mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed;
 - (c) arbitration: If the dispute has not been settled by negotiation or mediation, any Party 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 dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. Either party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the [Advisory Group] may establish for this purpose; both parties, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.
- 8.5 Any costs associated with dispute settlement shall be shared equally between the Parties.

ARTICLE 9 – ADDITIONAL ITEMS

Warranty

9.1 Notwithstanding provision 5.2, the Provider makes no warranties as to the safety of the PIP Biological Materials, nor as to the accuracy or correctness of any data provided with them. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the PIP Biological Materials being furnished. The Provider and the Recipient assume full responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials, on the understanding that such regulations and rules shall, at a minimum, meet the relevant WHO standards that are current at the time of acceptance of this Agreement.

Duration of Agreement

9.2 This Agreement shall remain in force so long as the Framework remains in effect.

ARTICLE 10 – SIGNATURE/ACCEPTANCE

The Provider and the Recipient may choose one of the three following methods of acceptance, it being understood that all three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and that only one method is required to establish acceptance.¹

Method 1 – Acceptance by signature of printed document

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Provider** and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement, both by letter and in principle, in order to promote the sustainable sharing of PIP Biological Materials and benefits under the Framework.

Signature Date.....

Name of the Provider

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Recipient** and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement, both by letter and in principle, in order to promote sustainable sharing of PIP biological materials and benefits under the Framework.

Signature Date.....

Name of the Recipient.....

Method 2 – Acceptance of Agreement by acceptance of PIP Biological Materials (Shrink-wrap Standard Material Transfer Agreements)²

The PIP Biological Materials are provided conditional on acceptance of the terms of this Agreement. The provision of the PIP Biological Materials by the Provider and the Recipient’s acceptance of the PIP Biological Materials (i.e., the retention of the materials expressed by the signature of the courier’s delivery documentation) constitutes acceptance of the terms of this Agreement.

¹ Where the Provider chooses signature of printed document, only the wording for Method 1 will appear in the Standard Material Transfer Agreement. Similarly where the Provider chooses either Method 2 or 3 (shrink-wrap or click-wrap), only the wording for that Method will appear in the Standard Material Transfer Agreement. Where the “click-wrap” form is chosen, the PIP Biological Materials should also be accompanied by a printed copy of the Standard Material Transfer Agreement.

² A “shrink-wrap” Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the PIP Biological Materials, and the Recipient’s acceptance of the PIP Biological Materials constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.

Method 3 – Acceptance of Agreement electronically (Click-wrap Standard Material Transfer Agreement)¹

The PIP Biological Materials are provided upon acceptance of this Agreement concluded through electronic means, such as the Internet. For example, “digital signature” may be used instead of physical signatures to establish acceptance of the terms of this Agreement.

¹ A “click-wrap” Standard Material Transfer Agreement is where the agreement is concluded on the Internet and the Recipient accepts the terms and conditions of the Standard Material Transfer Agreement by clicking on the appropriate icon on the web site or in the electronic version of the Standard Material Transfer Agreement, as appropriate.

APPENDIX 1

LIST OF MATERIALS PROVIDED

This *Appendix* contains a list of the PIP Biological Materials provided under this Agreement:
[List to be completed by Provider]

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