Non-Paper

~~10/05/2010~~ 11/05/2010 Revision Drafting Group

Draft Standard Material Transfer Agreement 2

PREAMBLE

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In furtherance of the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (the "Framework"), this Standard Material Transfer Agreement ("Agreement" or "SMTA") has been developed.

THE PARTIES TO THIS AGREEMENT HEREBY AGREE AS FOLLOWS:

ARTICLE 1 – PARTIES TO THE AGREEMENT

1.1 Parties to this SMTA 2 include influenza laboratories that have been designated or recognized by WHO that have accepted to work under agreed WHO Terms of Reference and entities outside WHO Network. In this Agreement:

- The Provider is a WHO Network laboratory or an entity outside the WHO Network sending Materials, as herein defined,

and

- The Recipient is the entity outside the WHO Network receiving Materials, as herein defined.

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT

2.1 PIP Biological Materials, genetic sequences, reference reagents, reference reagents for potency determination of vaccines/vaccine potency reagents, influenza reference viruses, WHO recommended influenza viruses for vaccine use, as defined in Section 4.1 of the Framework (hereinafter "Materials") transferred from the Provider to the Recipient are subject to the provisions of this Agreement.

ARTICLE 3 – RIGHTS AND OBLIGATIONS OF THE PROVIDER

3.1 The Provider undertakes the following with respect to the Materials:

3.1.1 To comply with their respective WHO Network Terms of Reference and the Framework where applicable

3.1.2 To ensure that the Materials are handled in accordance with applicable WHO guidelines and existing national bio-safety standards.[1]

3.3 The Provider agrees to the onward transfer and use of the Materials, to any on the same terms and conditions as those provided in this SMTA.

[1] "WHO Guidelines on Regulations for the Transport of Infectious Substances" and "WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection."

3.4 The Provider consents to the onward transfer of the Materials to entities outside the WHO Network **on the condition that any such transfer shall be accompanied by a copy of the attached "SMTA - 2".**

3.5. Provider will inform WHO of shipments of Materials to entities inside and outside the WHO Net work for recording in the Influenza Virus Traceability Mechanism.

ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENTS

4.1Recipients shall:

- record receipt of such material in the WHO IVTM

- in the event of further transfers, execute SMTA 2 with respect to each such further transfer

- grant to WHO royalty free, non-exclusive, transferable license with respect to such rights. WHO may then transfer this license to developing countries, with appropriate terms and conditions, as determined by the Director-General in accordance with sound public health principles, and transparent rules and procedures, informed by expert guidance and evidence..

- pay, in accordance with charge structure (Swiss proposal)

- provide donations of 10% of production to WHO stockpile

- provide under tiered pricing vaccines, antivirals, and diagnostics;

- transfer technology, skills, know how and processes to developing countries on an ongoing basis enabling them to conduct research, development and produce vaccines, reagents and antiviral medicines in a timely manner;

- promote capacity-building;

- support the strengthening of the laboratory and influenza surveillance capacity

4.2. Actively seek the participation of scientists from originating laboratories/countries in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.

4.3. Appropriately acknowledge in presentation and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

ARTICLE 5 – 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 6 – DISPUTE SETTLEMENT

6.1 Dispute settlement may be initiated by the Provider or the Recipient.
6.2 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.
6.3 Any costs associated with dispute settlement shall be shared equally between the Parties.

ARTICLE 7 – ADDITIONAL ITEMS

Warranty
7.1 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
6.2 This Agreement shall remain in force so long as the Framework remains in effect.

ARTICLE 7 - SIGNATURE/ACCEPTANCE

This SMTA shall be a "click-wrap" arrangement if executed by electronic means, or a "shrink-wrap" agreement otherwise, unless either party requires this Agreement to be executed by signature of a

printed document. All three methods are equally valid, biding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.