

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

**Outcome of the Open-Ended Working Group of Member States  
on Pandemic Influenza Preparedness: sharing of influenza  
viruses and access to vaccines and other benefits**

**Report by the Director-General**

The Director-General has the honour to submit to the Health Assembly the report of the Open-Ended Working Group (at Annex) on the outcome of its deliberations.



## ANNEX

**REPORT OF THE OPEN-ENDED WORKING GROUP OF MEMBER STATES ON  
PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES  
AND ACCESS TO VACCINES AND OTHER BENEFITS**

1. In January 2010, the Executive Board at its 126th session agreed to establish an open-ended working group of Member States the aim of which was to reach agreement on remaining elements under the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccine and other benefits. The Director-General was requested to facilitate this process. It was agreed that the basis for discussion would be document A62/5 Add.1 and the Director-General's proposals for finalizing remaining elements (document HSE/GIP/PIP/2009.1) would be used as a further reference document.
2. The Open-Ended Working Group was held from 10 to 12 May 2010 at WHO headquarters and was attended by 79 Member States as well as relevant regional economic integration organizations.
3. The following officers were elected: co-chairs: Ambassador J. Gomez Camacho (Mexico), Ambassador B. Angell-Hansen (Norway); vice-chairs: Dr Inés Gabriela Fastame (Argentina), Mr Faiyaz Kazi (Bangladesh), Dr Nasr El Sayed (Egypt), Dr Masato Mugitani (Japan), Ms Jo Newstead (United Kingdom of Great Britain and Northern Ireland), Mrs Petronellar Nyagura (Zimbabwe).
4. The Working Group discussed the strengths and weaknesses of the current global system for sharing influenza viruses and benefits. Although important and productive cooperation is ongoing, significant remaining challenges were identified, and most Member States stressed the need for multiple tools, approaches and sectors to meet these challenges in a sustainable way.
5. The Working Group drafted and negotiated textual proposals for a Standard Material Transfer Agreement (SMTA) for entities inside the WHO network. The Working Group received textual proposals for, and had a preliminary exchange of comments on, a draft SMTA or other type of agreement for entities outside the WHO network.<sup>1</sup>
6. In this regard, Appendix 2 to this report reproduces four proposed texts submitted and discussed during the Working Group: SMTA Proposal from the Co-Chairs (document EB/PIP/OEWG/White Paper 1); SMTA 1 and SMTA 2, joint proposals from Brazil, India and Indonesia (documents EB/PIP/OEWG/White Paper 2 and 3, respectively); and the European Region proposal (document EB/PIP/OEWG/White Paper 4). It was the view of the Working Group that these documents be regarded as the bases for further negotiation, in place of the SMTA text contained in document A62/5 Add.1, Attachment 1, Annex 1.
7. It was recognized that areas requiring further technical consideration and study, drawing on lessons learned from the pandemic (H1N1) 2009 and the ongoing outbreaks of influenza H5N1, included:

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<sup>1</sup> Appendix 2, White Papers 1, 2, 3 and 4.

- (a) current activity, financing and unmet financial and other needs in relation to:
    - 1. laboratory and surveillance capacity building, including that required under the International Health Regulations (2005)
    - 2. expanding global influenza vaccine production capacity including under the Global Action Plan to Increase Supply of Pandemic Influenza Vaccines<sup>1</sup>
    - 3. increasing access, affordability and effective deployment of vaccines, antiviral agents, diagnostics and other materials for pandemic preparedness and response;
  - (b) possible sustainable financing and solidarity mechanisms and other approaches to address the needs identified at subparagraph (a) above.
- 8. General agreement was reached on the importance of sustainable financing.
  - 9. Preliminary views were exchanged on solidarity mechanisms.<sup>2</sup>
  - 10. The Working Group concluded its meeting on 12 May 2010.
  - 11. The Working Group hereby submits its outcome report through the Director-General to the Sixty-third World Health Assembly.

#### **ACTION BY THE HEALTH ASSEMBLY**

- 12. The Health Assembly may wish to consider this report and the draft resolution recommended by the Open-Ended Working Group (as contained in Appendix 1).

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<sup>1</sup> Document WHO/IVB/08.10.

<sup>2</sup> Appendix 2, White Paper 4.

## APPENDIX 1

**Draft resolution proposed by the Open-Ended Working Group  
Pandemic Influenza Preparedness: sharing of influenza viruses and  
access to vaccines and other benefits**

The Sixty-third World Health Assembly,

PP1 Having considered the report of the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits that met in Geneva on 10–12 May, 2010;<sup>1</sup>

PP2 Recalling resolutions WHA60.28 and WHA62.10, which relate to the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits,<sup>2</sup> as well as resolutions WHA56.19 and WHA59.2 on pandemic influenza preparedness;

PP3 Taking note of all experiences and lessons from the pandemic (H1N1) 2009, the ongoing work of the IHR Review Committee, and lessons learnt from the ongoing outbreaks of influenza H5N1;

PP4 Recognizing the continued challenge of improving pandemic influenza preparedness, notably to increase: national and global preparedness and response capacities; improved laboratory and surveillance capacity; global influenza vaccine, antivirals and diagnostics production capacity, and access to vaccines, antivirals and diagnostics, particularly in affected and developing countries, and with special attention to least developed countries;

PP5 Recognizing the need to implement a fair and transparent, equitable, efficient and effective system for the sharing of viruses and access to vaccines and other benefits on an equal footing;

PP6 Recognizing that the solutions to address these challenges involve the implementation of multiple tools, interlinked as necessary, which may include: separate, but complementary Standard Material Transfer Agreements for relevant materials, one within the WHO Network, and one for transfers outside the WHO Network; strengthening support for WHO's Global Pandemic Influenza Action Plan to Increase Vaccine Supply;<sup>3</sup> surveillance capacity building under the International Health Regulations (2005); and ensuring sustainable financing and solidarity mechanisms;

PP7 Recognizing the role of industry as an important contributor to addressing the above challenges in a sustainable and predictable manner;

PP8 Considering that some of the remaining elements require further consideration, and studies, as necessary, in order to reach final agreement,

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<sup>1</sup> Document A63/48.

<sup>2</sup> See document A62/5 Add.1.

<sup>3</sup> Document WHO/IVB/06.13 – WHO/CDS/EPR/GIP/2006.1.

1. REQUESTS the Director-General:

(1) to continue to work with Member States and relevant regional economic integration organizations, on the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits<sup>1</sup> as decided in resolution WHA62.10 and to convene the Open-Ended Working Group before the 128th session of the Executive Board;

(2) to undertake technical consultations and studies as necessary in order to support the work of the Open-Ended Working Group in reaching a final agreement;

2. DECIDES that the Open-Ended Working Group shall report through the Executive Board at its 128th session to the Sixty-fourth World Health Assembly.

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<sup>1</sup> As contained in document A62/5 Add. 1.

## White Paper 1

## APPENDIX 2

**SMTA Proposal from the Co-Chairs<sup>1</sup>**

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. *Consensus*

**THE PARTIES TO THIS AGREEMENT HEREBY AGREE AS FOLLOWS:****ARTICLE 1 – PARTIES TO THE AGREEMENT**

1.1 Parties to this SMTA are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO Terms of Reference.<sup>2</sup> In this Agreement: (*Consensus*)

- The Provider is the laboratory sending Materials, as herein defined,

and

- The Recipient is the laboratory receiving Materials, as herein defined. (*Consensus*)

1.2 Provider and Recipient are hereafter collectively referred to as “Parties”. (*Consensus*)

**ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT**

2.1 PIP Biological Materials,[[genetic sequences,] [genetic materials,] 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 will undertake the following with respect to the Materials:

- 3.1.1 To comply with its respective WHO Network Terms of Reference. (*Consensus*)

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<sup>1</sup> Draft reflects discussions as at 12 May 2010.

<sup>2</sup> Other entities may be included as “Parties”

3.1.2 To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.<sup>1</sup> *Consensus*

3.1.3 To comply with the following provision concerning intellectual property rights:

[If intellectual property rights are obtained on inventions derived from the use of Materials, the holder/[provider] of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and anti-virals, for pandemic influenza preparedness purposes.]

Or

[The provider shall not seek to obtain any intellectual property rights in connection with such materials.]

Or

[If the provider is a national government laboratory, it shall not seek to obtain a patent on PIP biological materials transferred pursuant to this SMTA.]

The provider and the recipient acknowledge that any intellectual property rights associated with the materials or their use will not be disturbed by this SMTA.]

Or

[Delete]

3.2 The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO Network, on the same terms and conditions as those provided in this SMTA. (*Consensus*)

3.3 The Provider consents to the onward transfer [and use] of the Materials to entities outside the WHO Network [on the condition that any such transfer shall be in accordance with SMTA<sup>2</sup>] [**that any such transfer shall be accompanied by a copy of the attached "Standards terms and conditions for the transfer of Materials".**] [Provider will regularly inform WHO of shipments of Materials to entities outside the WHO Network as recorded in the Influenza Virus Traceability Mechanism.]

And

[Provider will inform WHO of shipments of Materials to entities [inside and] outside the WHO Network as recorded in the Influenza Virus Traceability Mechanism.]

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<sup>1</sup> “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.” N.B. As requested, the Secretariat provides the following reference to the current relevant Guidelines: 1) Laboratory biorisk management for laboratories handling pandemic influenza A (H1N1) 2009 virus; 2) Safe transport of pandemic influenza A (H1N1) 2009 virus cultures, isolates and patient specimens as Biological Substance, Category B; 3) Guidance to Influenza Laboratories Diagnosing Swine Influenza A/H1N1 Infections of current concern.

<sup>2</sup> White Paper 3

## **ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENT**

4.1 The Recipient will undertake the following with respect to the Materials:

4.1.1 To comply with its respective WHO Network Terms of Reference [and the Framework], including the sharing of viruses and information.

4.1.2 To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.<sup>1</sup> (*Consensus*)

[4.1.3 The recipient shall record receipt of such material in the WHO IVTM.]

4.1.4 The recipient will consider to support the strengthening of the laboratory and surveillance capacity of the networks of developing countries. (*Consensus*)

4.1.3 To comply with the following provision concerning intellectual property rights:

If intellectual property rights are obtained on inventions derived from the use of Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and anti-virals, for pandemic influenza preparedness purposes.

4.2 [As a member of the WHO Network, Recipient recognizes that Materials are provided to facilitate implementation of Recipient's agreed WHO Terms of Reference. Recipient further agrees that the **Materials will be used solely for the purposes stated in said Terms of Reference**. Recipient agrees that any use of the Materials beyond those purposes will require specific authorization from the Provider.]

4.3 [The recipient shall not seek to obtain any Intellectual property rights in connection with such materials or over any products, processes, other inventions developed using the material.

4.4 In the event of further transfers within the WHO network, the recipient shall do so in accordance with this SMTA.

4.5 In the event of further transfers outside the WHO network, the recipient shall do so in accordance with SMTA2.<sup>2</sup>]

4.6 [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.

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<sup>1</sup> "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." N.B. As requested, the Secretariat provides the following reference to the current relevant Guidelines: 1) Laboratory biorisk management for laboratories handling pandemic influenza A (H1N1) 2009 virus; 2) Safe transport of pandemic influenza A (H1N1) 2009 virus cultures, isolates and patient specimens as Biological Substance, Category B; 3) Guidance to Influenza Laboratories Diagnosing Swine Influenza A/H1N1 Infections of current concern.

<sup>2</sup> White Paper 3

4.7 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 – DISPUTE RESOLUTION/[SETTLEMENT]**

[In the event of a dispute under this SMTA, Parties shall first seek an amicable settlement. Should this fail, [the only other method for seeking dispute resolution shall be that] the dispute may be submitted to the Director-General who will review the circumstances and may consider appropriate action in response to the dispute which may include the suspension or revocation of the WHO designation of the relevant laboratory.<sup>1</sup>]

Or

[In the event of a dispute under this SMTA, Parties shall first seek an amicable settlement. Should this fail, the dispute may be submitted to the Director-General who will review the circumstances and may discuss with the advisory group any appropriate action in response to the dispute. The Director-General may consider suspending or revoking the WHO designation of the relevant laboratory.]

Or

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.]

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<sup>1</sup> As provided in Section 7.3.4 of the Framework.

## **ARTICLE 6 – ACCEPTANCE AND APPLICABILITY**

[Acceptance by laboratories of the WHO Terms of Reference, as contained in the Framework, constitutes their acceptance of this SMTA.] / [With respect to laboratories in the WHO Network at the time of the adoption of the Framework by the World Health Assembly, acceptance by such laboratories of their WHO Terms of Reference, as contained in the Framework, constitutes acceptance of this SMTA.] Following the adoption of the Framework, designation or recognition by WHO of other laboratories as laboratories in the WHO Network will constitute acceptance of this SMTA by such laboratories. This SMTA shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO Network [or upon mutual agreement of the WHO and the laboratory]. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under this SMTA.

Or

## **ARTICLE 8 – 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, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.] *End 12 May 2010 13.00 (GVA, GMT+1)*

## White Paper 1

Annex

**World Health Organization ("WHO")  
Standard Terms and Conditions for Transfers of WHO Pandemic Influenza  
Preparedness Materials**

*This document must accompany all shipments of WHO PIP Materials as defined below*

The biological materials contained herein shall be referred to as "WHO Pandemic Influenza Preparedness materials" or "WHO PIP Materials".

These WHO PIP Materials have been produced through the collaboration of public health laboratories working within the Global Influenza Surveillance Network coordinated by the World Health Organization. These WHO PIP Materials are essential for public health purposes.

The WHO PIP Materials may be used by Recipient subject to the following Standard Terms and Conditions:

1. The WHO PIP Materials contained in this shipment are provided on behalf of the World Health Organization (WHO) as the coordinator of the Global Influenza Surveillance Network.
2. Recipients of the WHO PIP Materials shall:
  - Comply with the established charge schedule attached hereto.<sup>1</sup>
  - Apply tiered pricing in pandemic times
  - If intellectual property rights are obtained on inventions derived from the use of WHO PIP Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on non-profit basis, such as vaccines and anti-virals for pandemic influenza preparedness purposes.
  - Consider providing in-kind contributions to global preparedness stockpiles.
  - Provide information to WHO about further transfers of these WHO PIP Materials, including all relevant information regarding the identity of such recipients.
  - Encourage the publication of the results of any research in scientific publications and in the event of publication, to coordinate with WHO to ensure acknowledgment of the contribution of the appropriate WHO Network institutions.
  - Consider providing further benefit sharing on an *ad hoc* basis

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<sup>1</sup> Such charge schedule to be developed through appropriate studies and consideration

3. Neither WHO nor the laboratory shipping the WHO PIP Materials contained herein make any warranties as to the safety of the WHO PIP Materials contained, or as to the accuracy or correctness of any data provided with them. Neither do they make any warranties as to the quality, viability, or purity (genetic or mechanical) of the WHO PIP Materials being furnished. The Recipient assumes full responsibility for complying with its national bio-security and bio-safety 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 the acceptance of the WHO PIP Materials.
4. Any and all further transfers of WHO PIP Materials shall be subject to these Standard Terms and Conditions. The sending laboratory shall clearly mark the materials as "WHO PIP Materials" and include a copy of these Standard Terms and Conditions with any such shipments.
5. Acceptance by Recipient of the WHO PIP Materials contained herein constitutes acceptance of these Standard Terms and Conditions. If a Recipient does not agree to these Standard Terms and Conditions, it shall immediately notify the providing laboratory to arrange their return.
6. Any questions or disputes relating to the interpretation or implementation of these Standard Terms and Conditions shall be brought to the attention of WHO. No public health laboratories working within the Global Influenza Surveillance Network coordinated by the World Health Organization will be subject to dispute settlement actions relating to interpretation or implementation of these Standard Terms and Conditions.
7. Dispute settlement may be initiated by WHO or the Recipient. Any matter relating to the interpretation or application of these Standard Terms and Conditions which is not covered by its terms will be resolved by reference to the laws of Switzerland. Any dispute relating to the interpretation or application of these Standard Terms and Conditions will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the parties, or in the absence of agreement, with the rules of the International Chamber of Commerce. The parties will accept the arbitral decision as final. Any costs associated with dispute settlement shall be shared as assessed by the arbitral panel.
8. This Agreement shall remain in force as long as the Framework remains in effect.

## White Paper 2

**SMTA 1 Proposal from Brazil, India and Indonesia****Draft Standard Material Transfer Agreement**

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 are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO Terms of Reference. In this Agreement:

- The Provider is the laboratory sending Materials, as herein defined,
- and
- The Recipient is the laboratory 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

3.1.2 To ensure that the Materials are handled in accordance with applicable WHO guidelines and existing national bio-safety standards.<sup>1</sup>

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

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<sup>1</sup> “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 SMTA – 2.**

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

#### **ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENTS**

4. As a member of the WHO Network, Recipient recognizes that Materials are provided to facilitate implementation of Recipient's agreed WHO Terms of Reference. Recipient further agrees that the **Materials will be used solely for the purposes stated in said Terms of Reference.** Recipient agrees that any use of the Materials beyond those purposes will require specific authorization from the Provider.

4.1 The Recipient shall record receipt of such Material in the WHO IVTM.

4.2. In the event of further transfers within the WHO Network, an SMTA will be executed with respect to each such further transfer.

4.3. The Recipient shall not seek to obtain any intellectual property rights in connection with such Materials.

4.4. 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.Y. 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.

5.3 Any costs associated with dispute settlement shall be shared equally between the Parties.

## **ARTICLE 7 – 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 8 – 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, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.

## White Paper 3

**SMTA 2 Proposal from Brazil, India and Indonesia****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.<sup>1</sup>

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.

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**

4.1 Recipients 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
- 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.

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<sup>1</sup> “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.”

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, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.

## White Paper 4

**WHO EURO Region Proposal of an alternative Article 2<sup>1</sup> and an Annex to the Standards Terms and Conditions for Transfers of WHO PIP Materials:**

(Version as of 12.5.2010; 10am)

2. Recipient of the WHO PIP Materials [shall]/ [are urged to]:
  - Participate in the solidarity mechanism as described in the annex
  - Provide information to WHO about further transfers of these WHO PIP Materials, including all relevant information regarding the identity of such recipients
  - Encourage the publication of the results of any research in scientific publications and in the event of publication, to coordinate with WHO to ensure acknowledgment of the contribution of the appropriate WHO Network institutions.
  - Continue to offer tiered pricing.

**Annex:**

The solidarity mechanism will be managed by WHO and consists of:

- a) a contribution of 0.X % of revenues from the sale of seasonal vaccine and X % of revenues from the sales of pre- and/or pandemic vaccine, or
- b) a combination of one or several of the following on the basis of a mutual arrangement between the recipient and WHO such as:
  - donation of pandemic vaccines
  - donation of pre-pandemic vaccines
  - transfer of technology
  - capacity building
  - granting of sublicenses to WHO
  - financial contribution to WHO pandemic preparedness and response activities
  - donation of antiviral and / or medical devices
  - logistics
  - support of surveillance systems

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<sup>1</sup> Refers to article 2 of the Standard Terms and Conditions annexed to the SMTA proposal of the Co-chairs, as contained in White Paper 1, and would also correspond to Article 4 of SMTA2.

In the “Pandemic Influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits” a description of the following elements should be added:

- guiding principles to be applied by WHO in the negotiations with industry (what combination of technology transfer, donations and other elements should be aimed at)
- modalities of the management of the received finances within WHO under its rules
- how these activities are interacting / integrated with existing activities such as the GAP
- the role of voluntary contributions from Member States and other sources
- guiding principles of a mechanism for solidarity and equity of early access to pandemic vaccine<sup>1</sup>

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<sup>1</sup> This mechanism would enable, in time of a pandemic, to vaccinate essential healthcare workers (more or less 2 per cent of each country’s population), as soon as vaccines are available. First, WHO and manufacturers would assess global production capacity and the extent to which each manufacturer could contribute to the mechanism. Then, options should be explored in order to ensure equitable and timely access to vaccines from the start of a pandemic.

WHO would distribute these doses according to its assessment on the public health risks and needs.