
Annex 2

Standard Material Transfer Agreement 2 (SMTA 2)

Standard Material Transfer Agreement outside the WHO global influenza surveillance and response system (GISRS)

Article 1. Parties to the Agreement

WHO and Recipient.¹

Article 2. Subject matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter “Materials”) transferred to the Recipient are subject to the provisions of this Agreement.

Article 2. bis Definitions

- (a) As provided for in Section 4 of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits.
- (b) Other terms as agreed by the parties.

Article 3. Obligations of the Provider

To be agreed by the parties.

Article 4. Obligations of the Recipient

4.1 The recipient agrees to comply with the commitments selected below, in accordance with the terms set out in the Annex to this agreement.

4.1.1 The recipient shall comply with the commitments selected on a timetable determined by the WHO in consultation with the Advisory Group established by the PIP Framework and in coordination with the recipient.

¹ Recipients are receivers of “PIP Biological Materials” from the WHO global influenza surveillance and response system (GISRS), such as manufacturers of influenza vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic preparedness and response, as well as biotechnology firms, research institutions and academic institutions. Recipients shall select from among the commitments identified in SMTA2 Article 4.1.1(a) to (c) based on their nature and capacities; those that are not manufacturers shall only have to consider contributing to the measures set out in SMTA2 Article 4.1.1(c).

Any manufacturer that enters into any contracts or formal agreements with recipients or GISRS laboratories for the purpose of using PIP Biological Materials on the manufacturer’s behalf for commercialization, public use or regulatory approval of that manufacturer’s vaccines, diagnostics or pharmaceuticals shall also enter into an SMTA2 and select from among the commitments identified in Article 4.1.1(a) to (c) based on their nature and capacities.

ent, based on optimal pandemic preparedness and response considerations.

- A. For manufacturers of vaccines and/or antivirals, the recipient shall commit to at least two of the following options:
- A1. Donate at least 10%¹ of real time pandemic vaccine production to WHO.
 - A2. Reserve at least 10%¹ of real time pandemic vaccine production at affordable prices to WHO.
 - A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO.
 - A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices.
 - A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics.
 - A6. Grant royalty-free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on granted licenses and the status of implementation of the licensing agreement. WHO shall provide such information to the Advisory Group.

- B. Manufacturers of products relevant to pandemic influenza preparedness and response, that are not manufacturing vaccines or antivirals, shall commit to one of the following options: A5, A6, B1, B2, B3, B4.
- B1. Donate to WHO at least X² diagnostic kits needed for pandemics.
 - B2. Reserve for WHO at least X² diagnostic kits needed for pandemics, at affordable prices.
 - B3. Support, in coordination with WHO, the strengthening of influenza specific laboratory and surveillance capacity in developing countries.

¹ Recognizing that flexibility is important in negotiating with all manufacturers, in a range of 5–20%.

² Recognizing that flexibility is important in negotiating with all manufacturers.

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- B4. Support, in coordination with WHO, transfer of technology, know-how and/or processes for pandemic influenza preparedness and response in developing countries.
- C. The recipient shall, in addition to the commitments selected under A or B above, consider contributing to the measures listed below, as appropriate:
- Donations of vaccines;
 - Donations of pre-pandemic vaccines;
 - Donations of antivirals;
 - Donations of medical devices;
 - Donations of diagnostic kits;
 - Affordable pricing;
 - Transfer of technology and processes;
 - Granting of sublicenses to WHO;
 - Laboratory and surveillance capacity building.
- 4.2 The Recipient shall ensure that the PIP biological materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.
- 4.3 If applicable, the Recipient shall appropriately acknowledge in presentations and publications, the contributions of WHO laboratories providing the materials identified in Article 2, using existing scientific guidelines.
- 4.4 The recipient shall only further transfer the PIP biological materials if the prospective recipient has concluded an SMTA with the World Health Organization. Any such further transfer shall be reported to the World Health Organization. The Director-General may, under exceptional circumstances, allow the PIP biological materials to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an SMTA, and report to the “Advisory Group” accordingly.
- 4.5 The recipient may exchange PIP biological materials with any other holder of an SMTA concluded with the World Health Organization.

Article 5. Dispute resolution

If a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, disputes shall be subject to binding arbitration on conditions that are mutually agreed by the parties.

Article 6. Liability and indemnity

To be agreed by the parties.

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Article 7. Privileges and immunity

Nothing in or relating to these clauses shall imply the obligation of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

Article 8. Name and Emblem

To be agreed by the parties.

Article 9. Warranties

To be agreed by the parties.

Article 10. Duration of Agreement

To be agreed by the parties.

Article 11. Termination

To be agreed by the parties.

Article 12. Force Majeure

To be agreed by the parties.

Article 13. Governing law

To be agreed by the parties.

Article 14. Signature and Acceptance

In WITNESS Whereof, this Agreement has been duly executed by the parties.

SIGNED for and on behalf of WHO SIGNED for and on behalf of Recipient

Signature..... Signature.....

Name..... Name.....

Title..... Title.....

Annex*
To be agreed by the parties.

* Editor's note: the annex is to be developed, as necessary, by the parties.