SMTA 2

Standard Material Transfer Agreement outside the WHO Network

Article 1. Parties to the Agreement

Article 2. Subject Matter of the Agreement

Article 3. Obligations of the Provider

Article 4. Obligations of the Recipient

4.1 The recipient[1] agrees to comply with the commitments selected below, in accordance with the terms set out in the Annex to this agreement.

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, based on optimal pandemic preparedness and response considerations.

[and making sure that technology essential for production of influenza vaccine, adjuvants, antivirals or diagnostics can be broadly used]

[1] Recipients are all entities that receive "PIP Biological Material" from the WHO Network System, such as influenza vaccine, diagnostic and pharmaceutical manufacturers, as well as biotechnology firms, research institutions and academic institutions. Each recipient shall select options based on its nature and capacities.

The recipient shall commit to at least two of the following options:

1. Donate at least **10%** (5-20 %) of real time pandemic vaccine production to WHO
2. Reserve at least **10%** (5-20 %) of real time pandemic vaccine production at affordable prices to WHO
3. Donate at least **Y treatment courses** of needed antiviral medicine for the pandemic to WHO
4. Reserve at least **Y treatment courses** of needed antiviral medicine for the pandemic at affordable prices

5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, [based on the UNDP Human Development Index,] 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.

Or

5. Within 2 years of signing this SMTA, 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 product, on IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics

6. [Grant royalty-free licenses]/ [Grant to WHO royalty-free non-exclusive, transferrable licenses]/ [Waive royalties under license agreements] for intellectual property rights on technology, products, know-how and processes for which it holds IPR for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. [WHO may transfer these licenses to developing countries on appropriate terms and

conditions and in accordance with sound public health principles.]

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

Or

6. Grant royalty free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive, transferrable licenses on IPR for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic.

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. For recipients that manufacture neither vaccines nor antiviral, one option among the following: **A.** 5 and A.6 and B 1, B2, B3 and B4. listed below.

1) Donate at least x diagnostic kits needed for pandemics

2) Reserve at least x diagnostic kits needed for pandemics

3) Through partnership agreements with developing countries or through WHO, support, at a reasonable level as determined by WHO, strengthening influenza

specific laboratory and surveillance capacity.

4) Through partnership agreements with developing countries or through WHO, transfer technology, know-how and/or processes of a reasonable value for pandemic influenza preparedness and response as determined by WHO.

C. The recipient shall in addition to the commitments selected under A or B above, [contribute to at least one of the options below] consider contributing to the measures listed below, as appropriate:

- Donations of vaccines
- Donations pre-pandemic vaccines
- Donations of antivirals

- Donation of medical devises
- Affordable pricing
- Capacity building
- Transfer of technology and processes
- Granting of sublicences to WHO
- Laboratory and surveillance capacity building

4.2 The Recipient shall ensure that the 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 '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.

4.4. ter The recipient may exchange "Materials" with any other holder of an SMTA concluded with the World Health Organization

4.4 bis Article 4.1-4.3 do not apply to entities that do not (i) manufacture products essential for pandemic preparedness and response and/or (ii) do not hold IPR essential for pandemic preparedness or response

4.5 Bolivia-[the recipient shall not seek or claim Intellectual Property over the material

or its genetic or over other parts in any form]

Article 5. Dispute Resolution

Article 6. Liability and Indemnity

Article 8. Privileges and Immunity

Article 9. Name and Emblem

Article 10. Warranties

Article 11. Duration of Agreement

Article 12. Termination

Article 13. Force Majeure

Article 14. Governing law

Article 15. 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** _____

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Title _____ **Title** _____

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