

**Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and  
access to vaccines and other benefits (PIP Framework)**

**Standard Material Transfer Agreement 2**

**Article 1. Parties to the Agreement**

Serum Institute of India, Ltd. (hereinafter "the Company" or "SII")  
212/2 Off Soli Poonawalla Road, Hadapsar,  
Pune - 411001, India

and

The World Health Organization (hereinafter "WHO")  
20 avenue Appia  
1211 Geneva 27  
Switzerland

hereinafter together the "Parties" and each a "Party"

**Article 2. Subject matter of the Agreement**

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

**Article 3. Definitions**

- (a) Terms defined in Section 4 of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits shall have the same meaning when used in the context of this Agreement.
- (b) Other terms as may be agreed by the parties in writing.
- (c) "Term Sheets" shall mean the terms and conditions describing the rights and obligations of each Party with regard to each of the Commitments (as defined below).

#### **Article 4. Obligations of WHO**

WHO will report to the Advisory Group any exceptional transfers of Materials authorized by the Director-General under Article 5.4 below.

#### **Article 5. Obligations of the Company**

**5.1** The Company agrees to comply with the commitments below ('the Commitments'), in accordance with the terms set out hereunder and in the Term Sheets Annexed to this Agreement and forming an integral part thereof, including with respect to timetables established thereunder.

**5.1.1** The Company, as a manufacturer of vaccines, commits to the following, subject to and in accordance with the respective Term Sheet with regard to each influenza pandemic during the term of this Agreement:

1. Donate eight per cent (8%) of real time pandemic vaccine production to WHO (see Annex 1).
2. Reserve two per cent (2%) of real time pandemic vaccine production at affordable prices to WHO (see Annex 2).

**5.2** The Company shall ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

**5.3** If applicable, the Company shall appropriately acknowledge in presentations and publications, the contributions of WHO laboratories providing the Materials, using existing scientific guidelines.

**5.4** The Company shall only further transfer the Materials if the prospective recipient has concluded an SMTA with the World Health Organization. The Company shall report any such further transfers to the World Health Organization. The Director-General may, under exceptional circumstances, allow the Materials to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an SMTA. For the avoidance of doubt, such transfers are understood not to include provision by the Company of Materials for utilization on its behalf to entities under contract to the Company, provided that (a) the Materials are returned to the Company or destroyed, in accordance with appropriate bio-safety standards, at the end of utilization; and, (b) the Materials shall not be utilized by such entities for research, development or production other than as directed by the Company; and, (c) the Company shall, in such cases, remain fully responsible for the compliance by such entities of the obligations for handling the Materials in accordance with this Agreement.

**5.5** The Company may exchange the Materials with any other holder of an SMTA concluded with the World Health Organization.

## **Article 6. Term Sheets**

**6.1** The Term Sheets specify the terms for each of the Commitments in Article 5 above, and shall form Annexes 1 and 2 of the Agreement. The Annexes shall be an integral part of this Agreement.

**6.2** At the request of either Party at any time, but at a minimum every four (4) years from the signature of this Agreement, the Parties will review the provisions contained in the Term Sheets to evaluate if modification is necessary and the Term Sheets may be adapted by mutual agreement of the Parties as a result of such review. Any modification requested by either Party shall be discussed by the Parties in good faith and the Parties shall use best reasonable efforts to agree on such modifications within three months of starting such discussions.

**6.3** In case of an imminent risk of a pandemic, at the latest upon declaration by WHO of a Phase 5 (as defined by the WHO definition of pandemic phases in place at the effective date of this Agreement), the Parties will review (and if necessary adapt) the Term Sheets with the objective of ensuring that all mechanisms are in place to enable the speedy implementation of the Commitments once a pandemic is declared. The Parties will also conduct an after action review of the Term Sheets after the end of a pandemic event.

## **Article 7. Dispute resolution**

**7.1** If a dispute cannot be resolved after three-months from its beginning, through negotiations or other amicable, non-binding means of the Parties' choice, including conciliation, disputes shall be subject to, and finally settled under, binding arbitration on conditions that are mutually agreed by the Parties. The parties agree that such conditions include use of the Rules of Arbitration of the International Chamber of Commerce by a panel of three arbitrators appointed in accordance with the said Rules. The seat of the arbitration shall be in Geneva. The arbitral proceedings shall be conducted in English.

**7.2** Any matter relating to the interpretation or application of this Agreement which is not covered by its terms will be resolved by reference to the laws of Switzerland.

## **Article 8. Liability and indemnity**

Provisions on liability and indemnity are contained in the relevant Term Sheets.

## **Article 9. 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 10. Name and Emblem and Provision of Information**

**10.1** Except as otherwise explicitly provided in this Agreement, neither Party shall, in any statement or material of an advertising or promotional nature, refer to the relationship of the Parties under this Agreement, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of that other Party.

**10.2** When information provided in the context of this Agreement is described by the Party providing it as confidential, the receiving Party will treat the information as strictly confidential and will only use the information for the purpose for which it was provided. The receiving Party undertakes to disclose any such confidential information only to persons who have a need to know and who are bound by like obligations of confidentiality and restrictions on use as contained herein

**10.3** However, there will be no obligation of confidentiality or restriction on use where:

- a) the information is publicly available, or becomes publicly available, otherwise than by action of the receiving Party; or
- b) the information was already known to the receiving Party (as evidenced by its written records) prior to its receipt; or
- c) the information was received from a third Party not in breach of an obligation of confidentiality; or
- d) the receiving Party is required by law to disclose the information, provided that the receiving Party will immediately notify the disclosing Party in writing of such obligation and provide adequate opportunity to the disclosing Party to object to such disclosure or request confidential treatment thereof.

## **Article 11. Warranties**

Each Party warrants to the other Party that it has the full power to enter into this Agreement, to carry out its obligations under this Agreement and to grant the rights and benefits granted by it to the other Party under this Agreement.

## **Article 12. Duration of Agreement**

This Agreement will become effective upon the signing by both Parties and shall remain in effect until 31 December 2031, unless terminated by either Party in accordance with Article 13 below.

## **Article 13. Termination**

**13.1** Either Party shall have the right to terminate this Agreement at any time with one hundred and eighty (180) days written notice to the other Party. If a pandemic occurs during such notice period, all obligations under this Agreement will survive and termination will take effect only

after both fulfilment of the obligations by the Parties under the respective Term Sheet and the announcement of the end of the pandemic

**13.2** In case of a termination of this Agreement by the Company, the Company shall, when such termination takes effect, immediately cease any and all use of any Materials and shall return to the provider or destroy (as advised by the provider) any such Materials

#### **Article 14. Force Majeure**

No Party shall be liable for any delay in the performance of or failure to perform its obligations under this Agreement, where such delay or failure is caused by Force Majeure ("Force Majeure" is defined in the relevant Term Sheets).

#### **Article 15. Miscellaneous**

**15.1** Any notice to be given between the Parties shall be effectively given if sent by letter, fax or similar means of communication, postage prepaid or charged to the sender and addressed to the other Party at the address shown below:

(a) If to WHO:

World Health Organization,  
20 Avenue Appia  
1211 Geneva 27  
Switzerland

Attention: PIP Framework Secretariat, with copy to [pipframework@who.int](mailto:pipframework@who.int)

(b) If to the Company:

Serum Institute of India, Ltd.  
212/2 Off Soli Poonawalla Road, Hadapsar, Pune 411028, INDIA

Attention: Dr S S Jadhav, Executive Director

With copies to:

Attention: Mr Makarand Karkare, Company Secretary  
Serum Institute Of India Limited  
"Sarosh" Bhavan" 16/B-1, Dr Ambedkar Road  
Pune - 411001, India

**15.2** This Agreement, including any current or future Annexes, contains all the rights, obligations and terms made by the Parties in connection with the subject matter detailed herein.

Any amendment of the Agreement, including any amendment of this section 15.2, is only valid if made in writing as an amendment to this Agreement and signed by authorized signatories of the Parties.

**15.3** Should any part of this Agreement, including its Annexes, be or become void, ineffective or unenforceable for any reason, the validity of the remaining sections of this Agreement shall not be affected. In such a case, the ineffective section or sub-section shall be deemed as replaced by provisions achieving the purpose of this Agreement as far as possible.

#### **Article 16. 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 Serum  
Institute of India, Ltd.

Signature: 

Signature: 

Name: Keiji Fukuda

Name: S. S. Jadhav

Title: Assistant Director-General for  
Health Security and Environment

Title: Executive Director

Date: 26 Sept 2013

Date: 01 OCT 2013