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

The Government Pharmaceutical Organization (hereinafter the "GPO")
75/1 Rama VI Road, Ratchathewi,
Bangkok 10400
Thailand

and

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

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

In connection with the PIP Framework, adopted by the World Health Assembly on 24 May 2011, the Parties hereby agree as follows:

Article 2. Subject Matter of the Agreement

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

Article 3. Definitions

(a) Terms defined in Section 4 of the PIP Framework 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).

(d) For the purposes of this Agreement, the company shall be construed to refer only to the GPO.

Article 4. Obligations of WHO

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

Article 5. Obligations of the GPO

5.1 The GPO 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 GPO, 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 five percent (5%) of real time pandemic vaccine production to WHO (see Annex 1).

2. Reserve five percent (5%) of real time pandemic vaccine production at affordable prices to WHO (see Annex 2).

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

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

5.4 The GPO shall only further transfer the Materials if the prospective recipient has concluded a Standard Material Transfer Agreement ("**SMTA**") with WHO. The GPO shall report any such further transfers to WHO. 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.

5.5 The GPO may exchange the Materials with any other holder of an SMTA concluded with WHO.

5.6 In the event that the GPO enters into any contract or formal agreement with a manufacturer for the purpose of using PIP biological materials for commercialization, public use or regulatory approval of that manufacturer's vaccine, diagnostics, or pharmaceuticals, the GPO shall:

(a) Inform the manufacturer that it will be contacted by WHO to discuss conclusion of an SMTA 2 (if one is not already concluded); and

(b) Inform WHO of the use of the PIP biological materials on behalf of that manufacturer and provide WHO with the name of said manufacturer by sending an email to pipframework@who.int with the subject line: "SMTA 2 Notice".

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 this 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 an influenza pandemic, and at the latest upon declaration by WHO of an influenza pandemic, 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 an influenza pandemic is declared. The Parties will also conduct an after action review of the Term Sheets after the end of the 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, Switzerland. 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 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 of 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 an influenza 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 GPO, the GPO 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 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

(b) If to the GPO:

The Government Pharmaceutical Organization
75/1 Rama VI Road, Ratchathewi,
Bangkok 10400
Thailand

Attention: Deputy managing director/Senior expert responsible for Biological product development of GPO, with copy to seniexpt2@gpo.or.th and d_biologics@gpo.or.th

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 this 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

Signature

Name: FOR Dr. Jaouad Mahjour

Title: Assistant Director-General,
WHO Emergency Preparedness

Date: June 24, 2020

SIGNED for and on behalf of the Government Pharmaceutical Organization

Signature

Name: Dr. Withoon Danwiboon

Title: Executive Managing Director

Date: June 24, 2020