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

Standard Material Transfer Agreement 2 (SMTA 2)

Article 1. Parties to the Agreement

Zydus Lifesciences Limited (hereinafter the "Company") Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej – Gandhinagar Highway Ahmedabad – 382481, Gujarat, India

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 Company 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) "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).
- (c) For the purposes of this Agreement, the Company shall be construed to refer not only to Zydus Lifesciences Limited, but also to any other company within the Zydus Lifesciences Limited group of companies or affiliates thereof.

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 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:
 - Donate 8% (eight per cent) of real time pandemic vaccine production to WHO (see Annex 1).
 - 2. Reserve 2% (two per cent) 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 2 with WHO. The Company 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 Company may exchange the Materials with any other holder of an SMTA concluded with WHO.
- In the event that the Company 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 vaccines, diagnostics, or pharmaceuticals, the Company 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

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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 emergency, and at the latest upon the determination by the WHO Director-General of a public health emergency of international concern for influenza pursuant to the International Health Regulations (2005) ("PHEIC"), 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. The Parties will also conduct an after action review of the Term Sheets following the end of an influenza pandemic emergency.

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

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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 earry 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 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 influenza pandemic emergency.
- 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 Term Sheets).

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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 Company:

Zvdus Lifesciences Limited.

Zydus Corporate Park, Scheme No. 63, Survey No. 536,

Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej - Gandhinagar Highway,

Ahmedabad – 382481, Gujarat,

India.

Attention:

Mr. Keyar Parekh

Email: keyuttatekh @eydatlife.com

With copy to Legal Department: Mukund.Thakkar@zyduslife.com

- 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.

[SIGNATURE PAGE FOLLOWS]

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Article 16. Signature and Acceptance

In WITNESS whereof, this Agreement has been duly executed by the Parties.

This Agreement may be executed in one or more counterparts, each of which shall be an original, and all of which together shall constitute a single instrument. Further, the Parties agree that this Agreement may be signed and/or transmitted by electronic mail of .PDF document and thereafter maintained in electronic form, and that such electronic record shall be valid and effective to bind the Party so signing as a paper copy bearing such Party's hand-written signature.

SIGNED for and on behalf of WHO

SIGNED for and on behalf of Zydus Lifesciences Limited

Signature

Name: Dr Chikwe Ihekweazu

Title: Executive Director

WHO Health Emergency Preparedness

and Response Programme

Date:

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Signature:

Name: Mukund Thakkar

M. A Kouras

Title: SVP-Legal

Date:

Signature:

Name: Dhaval Soni

Title: Company Secretary

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Date: