

Appendix 8

Confidential disclosure agreement

This Agreement, effective as from the last date of signature, is between: _____
_____, of the one part,

and

WORLD HEALTH ORGANIZATION (“WHO”), 20 Avenue Appia, 1211 Geneva 27, Switzerland, of the other part.

WHEREAS, _____ has developed certain information and data relating to _____ which it considers to be confidential and its proprietary property (such confidential information and data being hereinafter collectively referred to as the “Information”).

WHEREAS, _____ is willing to release the Information to WHO, to enable WHO to assess such Information and conduct activities relating to the Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities, including but not limited to collaboration with _____ (the “Purpose”), provided that WHO undertakes to regard the Information as confidential and the property of _____, and release it only to persons who are bound by like obligations of confidentiality and non-use, as are contained in this Agreement.

NOW IT IS HEREBY AGREED as follows:

1. The Parties hereto agree that any disclosure of Information by _____ to WHO will be subject to the following terms and conditions.
2. Any Information which is supplied directly by _____ in written or other tangible form shall be marked by _____ as “confidential”. Any Information which is supplied indirectly by _____, such as from a Stringent Regulatory Authority with _____’s consent, need not be marked “confidential”. Any Information which is disclosed by _____ in oral form shall be confirmed by it in written summary form within 30 days from the date of oral disclosure.

3. In accepting the Information, WHO agrees with _____ as follows:
- a) WHO shall regard the Information disclosed by _____ as confidential and the property of _____. In this regard, WHO agrees to use such Information only for the Purpose (as defined above) and to make no other use thereof, unless and until a further agreement is executed with _____ governing the use thereof;
 - b) nothing in this Agreement shall prevent _____ from disclosing the Information to any third party; and
 - c) WHO has no right in or to the Information of _____.
4. WHO undertakes to maintain the Information received from _____ in confidence. In connection with the foregoing, WHO shall take all reasonable measures to ensure that the Information received from _____ shall not be used for any purpose other than the Purpose (as defined above) and shall not be disclosed to any person who does not have a need to know for the aforesaid Purpose and is not bound by similar obligations of confidentiality and restrictions on use as contained in this Agreement.

For the avoidance of doubt, WHO shall be entitled to disclose the Information to third parties collaborating with WHO in connection with the Purpose (including, without limitation, with the relevant regulatory and other authorities of WHO Member States), provided that such third parties are bound by similar obligations of confidentiality and restrictions on use as contained herein.

The obligations of confidentiality and restrictions on use contained in this Agreement shall continue for a period of five (5) years from the date of disclosure by _____ to WHO.

5. The obligations of confidentiality and restrictions on use contained in this Agreement shall not apply to any part of the Information which WHO is clearly able to demonstrate:
- a) was lawfully in its possession and known to it prior to disclosure by _____ hereunder, as evidenced by documents antedating the date of disclosure; or
 - b) was in the public domain or the subject of public knowledge at the time of disclosure by _____ hereunder; or
 - c) becomes part of the public domain or the subject of public knowledge through no fault of WHO; or
 - d) becomes available to WHO from a third party not in breach of a legal obligation of confidentiality to _____ in respect thereof; or

- e) was subsequently and independently developed by or on behalf of WHO, as shown by written records, by persons who had no knowledge of such Information; or
 - f) is required to be disclosed by law, provided that WHO shall in such case immediately notify _____ in writing of such obligation and shall provide adequate opportunity to _____ to object to such disclosure or request confidential treatment thereof (provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or to submit WHO to any national court jurisdiction).
6. WHO undertakes that it will disclose the Information only to those persons who need to receive the Information of _____ for the Purpose (as defined above).
 7. WHO undertakes to ensure that all persons who receive the Information disclosed to WHO hereunder shall be bound by similar obligations of confidentiality and restrictions on use as contained in this Agreement.
 8. Nothing contained in this Agreement shall be construed, by implication or otherwise, as an obligation to enter into any further agreement relating to any of the Information or as the grant of a licence to WHO to use the Information other than for the Purpose (as defined above).
 9. Upon completion of the aforesaid Purpose and in the absence of any further written agreement between the Parties, WHO shall cease all use, shall make no further use of the Information disclosed to it hereunder, and shall, upon written request from _____, promptly return to _____ all of the Information received which is in tangible form, except that WHO may retain one copy of the Information in its files to determine any continuing obligations hereunder.
 10. This Agreement constitutes the entire understanding of the Parties hereto with respect to the subject matter hereof and shall not be modified except by mutual agreement in writing.
 11. Without the prior written consent of the other Party, 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 to the relationship of the other Party to the Information and/or the Purpose.
 12. Any matter relating to the interpretation or the execution of this Agreement which is not covered by its terms shall be resolved by reference to the laws of Switzerland. Any dispute relating to the interpretation or application of this

Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties or, in absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final. It is agreed furthermore that nothing contained in this Agreement shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Made in two (2) original copies,

World Health Organization

By: _____ By: _____

Title: _____ Title: _____

Date: _____ Date: _____