

**CONFIDENTIALITY UNDERTAKING
BY NATIONAL REGULATORY AUTHORITIES
(FOR BDBV PRODUCTS ONLY)**

This Confidentiality Undertaking (this **“Undertaking”**) is made by the following National Regulatory Authority (the **“Undersigned NRA”**), acting through its duly authorized representative whose name, title and signature appears below:

Name of the Undersigned NRA: _____
Name of Country (the **“Country”**):

Full Mailing Address: _____

Email: _____

Telephone (including country code): _____

1. The World Health Organization (**“WHO”**), 20 Avenue Appia, 1211 Geneva 27, Switzerland, have access to certain information, materials and/or data relating to:

- a. WHO’s activities and/or efforts to facilitate appropriate access to vaccines, therapeutics, diagnostics and/or other types of medical products for the prevention, treatment and/or detection of BDBV for affected populations (collectively, **“BDBV Products”**) including, without limitation: (i) the generation—in a timely and scientifically valid manner—of data, information and evidence relating to the efficacy, safety, effectiveness and/or preferred characteristics of BDBV Products; (ii) the Emergency Use Listing (EUL) and/or Prequalification (PQ) assessment of BDBV Products by WHO; and/or (iii) the establishment of regulatory pathways for BDBV Products in countries affected or potentially affected with BDBV; and/or
- b. BDBV Products that have been granted a WHO EUL or PQ recommendation or that are currently undergoing an EUL or PQ assessment by WHO (including without limitation the BDBV products listed in the table below), including but not limited to: (i) non clinical and clinical data and information, including data and information regarding the efficacy, safety and effectiveness of the BDBV Products in humans; (ii) data and information regarding quality control and quality assurance of the BDBV Products; and (iii) regulatory information (including product dossiers and information on any regulatory approvals) regarding the BDBV Products,

which information, materials and data are confidential and/or proprietary to (i) the World Health Organization (WHO), (ii) the manufacturer of the relevant BDBV Product and/or to the applicant submitting a dossier for the relevant BDBV Product to undergo EUL or PQ assessment by WHO (hereinafter collectively referred to as the **“Manufacturer/EUL-PQ Applicant”**), and/or (iii) third parties collaborating with WHO and/or the Manufacturer(s)/EUL-PQ Applicant(s) (all of the aforementioned information, materials and data are hereinafter collectively referred to as the **“Information”**).

	Name of BDBV Product	Name of Manufacturer/EUL-PQ Applicant
1.		
2.		
3.		
4.		
5.		

2. Subject to and in accordance with the provisions of this Undertaking, and subject also to WHO obtaining the prior written approval of the relevant Manufacturer/EUL-PQ Applicant(s) and/or the relevant national regulatory authority(ies) of reference (hereinafter collectively referred to as the “**collaborating third parties**”), WHO is willing to disclose the Information to the Undersigned NRA exclusively for the purpose of allowing the Undersigned NRA to evaluate and assess the BDBV Products (including, but not limited to, their efficacy, safety and effectiveness for the prevention, treatment and/or diagnosis, as applicable, of BDBV in human patients), in the context of:

- a. enabling the Undersigned NRA to assess and/or determine whether any special authorizations, national registrations and/or emergency use authorizations of the BDBV Products can be granted in the Country;
- b. research clinical trials under a WHO-recommended protocol; and/or
- c. a WHO-recommended emergency use protocol under the MEURI (Monitored Emergency Use of Unregistered and Experimental Interventions) framework; (all of the foregoing hereinafter collectively referred to as “**the Purpose**”).

3. The Undersigned NRA undertakes to regard all of the Information that is disclosed or otherwise made available by WHO as confidential and the property of WHO and/or the collaborating third parties. The Undersigned NRA shall use the Information only for the Purpose, and shall make no other use of the Information for any other purpose unless and until a further written agreement is signed by WHO and/or the relevant owner of the Information in question.

4. The Undersigned NRA shall maintain any and all Information in strict confidence. In this respect, the Undersigned NRA shall take all reasonable measures to ensure that the Information: (a) shall not be used for any purpose other than the Purpose; and (b) shall not be disclosed, made available or otherwise transmitted to any person or entity (including, but not limited to, to any other government, national regulatory authority and/or other body or authority), except for a person/entity who needs to know the Information for the Purpose and who is legally bound by similar obligations of confidentiality and restrictions on use as contained in this Undertaking, in which case the Undersigned NRA shall ensure that the Information shall only be disclosed to such person/entity to the extent strictly necessary to achieve the Purpose.

5. The obligations of confidentiality and restrictions on use contained in this Undertaking shall not apply to any part of the Information which the Undersigned NRA is clearly able to demonstrate (as evidenced by written records or other competent proof) that:

- a. was lawfully in its possession and known to the Undersigned NRA without any legal obligation of confidentiality or restriction on use, prior to any disclosure by WHO; or
- b. was in the public domain or the subject of public knowledge at the time of disclosure by WHO; or

- c. becomes part of the public domain or the subject of public knowledge through no fault of the Undersigned NRA and/or of any third persons or entities to whom the Undersigned NRA has disclosed any Information; or
- d. becomes available to the Undersigned NRA from a third party not in breach of any legal obligations of confidentiality or restriction on use; or
- e. was subsequently and independently developed by or on behalf of the Undersigned NRA without access to any Information.

6. Upon the earlier to occur of (a) the completion of the Purpose, or (b) a written request from WHO to that effect, the Undersigned NRA shall immediately cease all use of and make no further use of any and all Information disclosed or otherwise made available to it. In addition, upon request to do so by WHO, the Undersigned NRA agrees to promptly return to WHO or destroy all of the Information (including any and all copies of the Information), except that the Undersigned NRA may retain one copy of the Information in its files to determine any continuing obligations hereunder.

7. Nothing in this Undertaking shall be construed as granting the Undersigned NRA any rights to any Information, other than those rights which are expressly set forth in this Undertaking. This Undertaking shall not be construed as: (a) conveying to the Undersigned NRA and/or any third parties any rights under any patents or other intellectual property which WHO and/or any collaborating third parties may now have or hereinafter obtain; and/or (b) placing WHO and/or any collaborating third party under any obligation to enter into any subsequent agreements.

8. The obligations of the Undersigned NRA set forth in this Undertaking shall not cease on termination of the Purpose.

9. The Undersigned NRA warrants and represents that it has, and will hereinafter maintain, adequate technical and organizational measures and procedures in place to ensure compliance with its obligations under this Undertaking.

10. Any dispute relating to the interpretation or application of this Undertaking 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.

11. Nothing contained in or relating to this Undertaking shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO or any of its officials under national and international law, and/or as submitting WHO to the jurisdiction of any national, regional or local court or tribunal.

12. Below are the details of the Undersigned NRA's focal point to be provided access to the WHO database with the Information. The Undersigned NRA hereby confirms that the named focal point is legally bound by similar obligations of confidentiality and restrictions on use as contained in this Undertaking:

Mr/Mrs/Ms/Dr

First name: _____

Family name: _____

Position in the Undersigned NRA: _____

Email: _____

Telephone: _____

13. This Undertaking constitutes the understanding between WHO and the Undersigned NRA with respect to the subject matter hereof, and supersedes any prior agreements, arrangements and/or other understandings concerning that subject matter. This Undertaking shall not be modified, except by a written amendment signed by duly authorized representatives of WHO and the Undersigned NRA.

Agreed and accepted in the name and on behalf of the Undersigned NRA:

Signature: _____

Full Name: _____

Position in the NRA: _____

Full Name of NRA: _____

Place: _____

Date: _____