

CONFIDENTIALITY UNDERTAKING BY NATIONAL REGULATORY AUTHORITIES

This Undertaking is given by,

The **NATIONAL REGULATORY AUTHORITY ("NRA")** of Georgia country
Name of the NRA: LEPL Regulation Agency for Medical and Pharmaceutical Activities
Address: 144, Ak. Tsereteli Ave, Tbilisi, 0119
Email: regagency@moh.gov.ge Telephone: (+995 032)251 00 11 (12-11)

1. The World Health Organization ("**WHO**"), 20 Avenue Appia, 1211 Geneva 27, Switzerland, has access to certain information and data relating to the following therapeutics, vaccines, diagnostics or other types of medical products recommended by WHO for use in emergency situations, including application dossiers submitted by applicants ("**the applicants**"), assessment, inspection and testing reports, which information and data are considered confidential and proprietary to the concerned applicants (hereinafter collectively referred to as "**the Information**").

	Name of product	Description/platform	Applicant
1.	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	Inactivated, produced in Vero cells	Sinopharm / BIBP1
2.	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Inactivated, produced in Vero cells	Sinovac
3.			
4.			
5.			

2. WHO, with the written approval of the applicant, or reference regulatory authority (hereinafter collectively "**the concerned parties**"), as the case maybe, is willing to provide access to the Information to the Undersigned to facilitate authorization for use of therapeutics, vaccines, diagnostics or other types of medical products recommended under and emergency use listing (EUL) or prequalified by WHO, or granted Emergency Use Authorization (EUA), conditional or full approval by stringent or other reference regulatory authorities ("**the Purpose**"), provided that the Undersigned undertakes to treat the Information as confidential and proprietary, to use the Information only for the aforesaid Purpose and to disclose it only to persons who have a need to know for the Purpose and are bound by like obligations of confidentiality and non-use as are contained in this Undertaking.

3. The Undersigned undertakes to regard the Information as confidential and the property of WHO and/or the concerned parties and agrees to take all reasonable measures to ensure that the Information is not used, disclosed or copied, in whole or in part, other than as provided in paragraph 2, except that with respect to Information, the Undersigned shall not be bound by any such obligations of confidentiality and restrictions on use, if and to the extent she is clearly able to demonstrate that the Information:

- was known to the Undersigned prior to any disclosure by or on behalf of WHO or by the applicant(s); or
- was in the public domain at the time of disclosure by or on behalf of WHO or by the applicant(s); or
- becomes part of the public domain through no fault of the Undersigned; or

- d. becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.
4. If requested to do so, the Undersigned agrees to return to WHO any and all copies of the Information.
5. The obligations of the Undersigned shall not cease on termination of the Purpose.
6. The Undersigned warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.
7. 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.
8. Nothing contained herein 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.
9. Below are the details of the NRA focal point to be provided access to the WHO database with the Information. The Undersigned confirms that the named focal point is bound by confidentiality provisions in this Undertaking:

Mr/Ms/Dr

First name (and initials):	<u>Ms Tamar</u>
Surname/family name:	<u>Kirvalidze</u>
Position in NRA:	<u>Quality Assessor of Pharmaceutical Products</u>
Email:	<u>tkirvalidze@moh.gov.ge</u>
Telephone:	<u>00 995 555 005 777</u>

Agreed and accepted on behalf of the NRA:

Signature: Z. KAPANADZE

Full Name: Zaal Kapanadze

Position in NRA: Director of Agency

Name of NRA: LEPL Regulation Agency for Medical and Pharmaceutical Activities

Place: Tbilisi, Georgia

Date: 26.03.2021