



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



19 August 2021

2 WORLD TRADERS INC.

No. 285 El Grande Ave., BF Homes
Parañaque, Metro Manila

**Emergency Use Authorization (EUA) for COVID-19 Vaccine (Vero Cell),
Inactivated manufactured by Sinopharm/China National Pharmaceutical Group/
Wuhan Institute of Biological Products Co., Ltd.**

This applies to the application for the issuance of Emergency Use Authorization (EUA) for COVID-19 Vaccine (Vero Cell), Inactivated manufactured by Sinopharm/China National Pharmaceutical Group/ Wuhan Institute of Biological Products Co., Ltd. [“COVID-19 Vaccine Sinopharm (Wuhan)”].

The details of the COVID-19 Vaccine Sinopharm (Wuhan) are as follows:

Vaccine Type:	COVID-19 Vaccine (Vero Cell), Inactivated
Pharmaceutical Form:	Suspension for injection
Presentation:	0.5 ml per vial containing 200 WU of inactivated SARS-CoV-2 antigen 0.5 ml per syringe containing 200 WU of inactivated SARS-CoV-2 antigen
Number of doses:	2 dose regimen
Diluent:	Not applicable
Route of administration:	Intramuscular
Shelf- life:	6 months
Storage Temperature:	2-8°C
Manufacturer:	Sinopharm/China National Pharmaceutical Group/ Wuhan Institute of Biological Products Co., Ltd
Indication:	For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years old and above



After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA has been satisfied that all the conditions for the issuance of an EUA exist as provided under EO No. 121, s. 2020, particularly:

1. Based on the totality of evidence available to date, including data from adequate and well-known controlled trials, it is reasonable to believe that the COVID-19 Vaccine Sinopharm (Wuhan) may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine Sinopharm (Wuhan), when used to diagnose, prevent, or treat COVID-19, outweigh the known and potential risks of said Vaccine as of date; and
3. There is currently no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

In issuing this EUA, reliance has been accorded to the emergency use authorization given by the National Medical Products Administration (NMPA) of the People's Republic of China. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement reliance and recognition processes, and accept regulatory decisions of recognized and established regulatory authorities.

This EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, this EUA cannot be used as an authorization to market the vaccine commercially.

While the evaluation process was facilitated, strict conditions on the authorization granted in this Letter shall be imposed as follows:

I. Scope

The scope of the EUA shall be limited as follows:

- A. 2 World Traders Inc. (2WTI) shall supply COVID-19 Vaccine Sinopharm (Wuhan) only to emergency response stakeholders consistent with the terms and conditions of this EUA.

"Emergency response stakeholders" shall refer to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) or their designees authorized to procure or purchase COVID-19 Vaccine Sinopharm (Wuhan) in line with the COVID-19 vaccination program. Designees may include hospitals (public and private), health facilities of other National Government Agencies, Local Government Units (LGUs) and other members of the Private Sector.

- B. The COVID-19 Vaccine Sinopharm (Wuhan) shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals ages 18 and above.

"Vaccination providers" shall refer to the facility, organization, or a healthcare provider, including non-physician healthcare providers such as nurses or pharmacists, authorized by the DOH or the NTF to administer the COVID-19

Vaccine Sinopharm (Wuhan) in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

The COVID-19 Vaccine Sinopharm (Wuhan) should be supplied as a slightly milky white suspension liquid. This is a 2-dose regimen at an interval of 21-28 days, each dose is 0.5ml. The recommended administration is through an intramuscular route.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, 2WTI shall provide appropriate cold chain requirements for storage, transport and handling until it is delivered to the inoculation sites, and ensure that a contingency plan is in place.

2WTI shall have a system of monitoring to ensure traceability and that the vaccine is consistent with the storage requirements from the manufacture and transport to the inoculation sites.

2WTI shall observe strict compliance with the standards for Good Distribution Practices (GDP) and Good Storage Practices (GSP) adopted pursuant to Administrative Order No. 2013-0027 including supplements thereto (i.e. WHO Technical Report Series No. 961, 2011, Annex 9 and Technical Report Series No. 992, 2015, Annex 5). 2WTI shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

2WTI shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine Sinopharm (Wuhan) following system or protocol for a registered drug and biologic product as stated in the FDA Circular No. 2020-003. Submission of serious and non-serious adverse reaction reports is mandatory.

2WTI shall ensure compliance with the Risk Management Plan (RMP) along with the Philippine-specific Annex. Additional pharmacovigilance activities such as interventional and non-interventional studies (ongoing or new studies, or additional activities) shall be implemented as stated in the RMP. The RMP must be updated whenever there is a significant change which may affect the benefit-risk profile of the vaccine or when an important milestone is reached.

2WTI shall submit monthly summary safety reports as planned and discussed in the RMP.

V. Responsibility of Emergency Response Stakeholders and Vaccination Providers

Under FDA Circular No. 2020-036 or the Guidelines for the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19, the pharmacovigilance obligations and post-authorization commitments imposed in the Letter shall be shared to the fullest extent possible and applicable by the national procurer and health program

implementors, and their designees. Emergency response stakeholders and vaccination providers shall have the following responsibilities.

A. Emergency response stakeholders shall:

1. Identify inoculation sites to receive the COVID-19 Vaccine Sinopharm (Wuhan), and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with 2WTI;
2. Ensure administration of the COVID-19 Vaccine Sinopharm (Wuhan) is consistent with the terms of this Letter, latest product information and the COVID-19 Vaccination Program; and
3. Ensure that vaccination providers of the procured COVID-19 Vaccine Sinopharm (Wuhan) are aware of this Letter of Authorization and the terms herein and any subsequent amendments thereof, instructed about the means which they are to obtain and administer the COVID-19 Vaccine Sinopharm (Wuhan), and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the COVID-19 Vaccine Sinopharm (Wuhan), in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 Vaccination Program;
2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving their second dose;
3. Obtain written informed consent from the recipient of the COVID-19 Vaccine Sinopharm (Wuhan) prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of COVID-19 Vaccine Sinopharm (Wuhan);
5. Monitor and comply with vaccine management requirements (e.g. obtaining, tracking and handling vaccine) of the DOH; and
6. Ensure that records associated with this EUA are maintained until notified by FDA. Such records shall be made available to DOH and FDA for inspection upon request.

Notwithstanding the foregoing, 2WTI has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Vaccine Sinopharm (Wuhan).

VI. Validity

Unless otherwise revoked, this EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of a marketing authorization/CPR.

In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, this EUA shall have a provisional validity for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

This EUA is subject to revocation, suspension or cancellation due to violations of pharmacovigilance obligations and post authorization commitments, as well as any violation of the EO No. 121, and RA 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.