Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

7 June 2021

DEPARTMENT OF HEALTH
Sta. Cruz, Manila

Emergency Use Authorization (EUA) for COVID-19 Vaccine (Vero Cell), Inactivated manufactured bv Sinopharm/China National Pharmaceutical Group

This applies to the application for the issuance of Emergency Use Authorization (EUA) for donated COVID-19 Vaccine (Vero Cell), Inactivated manufactured bv Sinopharm/China National Pharmaceutical Group ("COVID-19 Vaccine Sinopharm").

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

Vaccine Type:	Inactivated COVID-19 Vaccine (Vero Cell)
Pharmaceutical Form:	Suspension for injection
Presentation:	2ml vial presentation containing 0.5 ml vaccine, mono dose
Number of doses:	2 dose regimen
Diluent:	Not applicable
Route of administration:	Intramuscular
Shelf- life:	24 months
Storage Temperature:	2-8^{o}C
Manufacturer:	Beijing Institute of Biological Products (BIBP) 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 Executive Order (EO) No. 121, s. 2020 entitled *"Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefore, and for Other Purposes,"* 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 may be effective to prevent, diagnose, or treat COVID-19;

2. The known and potential benefits of the COVID-19 Vaccine Sinopharm, when used to diagnose, prevent, 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, recognition has been accorded to the Emergency Use Listing (EUL) of the World Health Organization (WHO). Consideration was also given to emergency use authorizations given by counterpart National Regulatory Authorities (NRAs) such as China and the United Arab Emirates. 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 covers donated vaccines and 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. The Department of Health (DOH) shall supply the COVID-19 Vaccine Sinopharm only to emergency response stakeholders consistent with the terms and conditions of this EUA.

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

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

   "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 in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

The COVID-19 Vaccine Sinopharm should be supplied as a semi-transparent suspension in a lightly white color. 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

DOH 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.

DOH 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.

DOH 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). DOH shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

DOH shall have a comprehensive pharmacovigilance system for the COVID-19 Vaccine Sinopharm 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.

DOH 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.

DOH shall submit six (6) monthly summary safety reports as planned and discussed in the RMP.

V. Responsibility of Emergency Response Stakeholders and Vaccination Providers

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, and ensure appropriate storage and cold chain management is maintained in said sites,
2. Ensure administration of the COVID-19 Sinopharm 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 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, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the COVID-19 Vaccine Sinopharm, 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 prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of the COVID-19 Vaccine Sinopharm;
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.

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/Certificate of Product Registration.

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.