Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 June 2022

FABERCO LIFE SCIENCES INC.

Third Amendment to the Emergency Use Authorization (EUA) for SARS-CoV-2 rS Protein Nanoparticle Vaccine [Covovax][1]

This pertains to the request to amend the Emergency Use Authorization (EUA) of the SARS-CoV-2 rS Protein Nanoparticle Vaccine [Covovax] (COVID-19 Vaccine Covovax) to expand the indication to adolescents ages 12 to <18 years.

After due consideration, and taking into consideration the similar regulatory actions of counterpart National Regulatory Authorities in India and Thailand, the Food and Drug Administration (FDA) hereby amends the EUA granted to the COVID-19 Vaccine Covovax.

The foregoing amendment is made pursuant to the discretionary power of the FDA under Section 6 of Executive Order (EO) No. 121, 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 Therefor, and for Other Purposes,"* to revisit any issued EUA as may be appropriate to protect the general public health and safety.

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

Product Name:	SARS-CoV-2 rS Protein Nanoparticle Vaccine [Covovax]
Dosage Strength and Form:	5 micrograms of SARS-CoV-2 recombinant spike protein antigen with 50 micrograms of Matrix-M1 adjuvant
Pharmacologic category:	Vaccine
Approved Shelf Life:	9 months* *The extended shelf life of the product shall apply retroactively to batches already released and distributed, manufactured within nine (9) months prior to the authorization of this variation.*

[1] We refer you to the EUA dated 17 November 2021, Amended EUA dated 31 December 2021 and Second Amendment to the EUA dated 02 May 2022 to extend product shelf life

Storage:	Store at temperatures between 2-8^{o}C. Do not freeze. Keep vials on the outer carton to protect from light.
Packaging:	Type I clear tubular siliconized glass vial x 0.5mL (1 dose) and 5 mL (10 doses)
Manufacturer:	Serum Institute of India Private Limited (see Section III- Manufacture for the manufacturing sites)
Indication:	For active immunization of individuals 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

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 Therefor, 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 Covovax may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine Covovax, 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, consideration has been given to the National Regulatory Authority (NRA) of Indonesia and India. 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. Faberco Life Sciences Inc. shall supply the COVID-19 Vaccine Covovax 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 the COVID-19 Vaccine Covovax 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 Covovax shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals ages 12 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 Covovax in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

The COVID-19 Vaccine Covovax is a colorless to slightly yellow, clear to mild opalescent, free to practically free from visible particle, suspension for injection. The vaccine course consists of two separate doses of 0.5ml each. The second dose should be administered not less than 21 days after the first dose. The COVID-19 Vaccine Covovax is intended for intramuscular (IM) injection only, preferably in the deltoid muscle. Do not dilute.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, Faberco Life Sciences Inc. 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.

Faberco Life Sciences Inc. 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.

Faberco Life Sciences Inc. 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). Faberco Life Sciences Inc. shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

Faberco Life Sciences Inc. shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine Covovax 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.

Faberco Life Sciences Inc. 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.

Faberco Life Sciences Inc. 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 Covovax, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with Faberco Life Sciences Inc.;
    2. Ensure administration of the COVID-19 Vaccine Covovax 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 Covovax 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 Covovax, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

    1. Administer the COVID-19 Vaccine Covovax, 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 Covovax prior to vaccination;
    4. Report any Adverse Events Following Immunization on the use of the COVID-19 Vaccine Covovax;
    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, Faberco Life Sciences Inc. has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Vaccine Covovax.

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.