Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 March 2022

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Fifth Amendment to the Emergency Use Authorization (EUA) for COVID-19 Vaccine (ChAdOx1-S[recombinant]) [VAXZEVRIA][1]

This pertains to the request to amend the Emergency Use Authorization for COVID-19 Vaccine (ChAdOx1-S[recombinant]) [VAXZEVRIA]. The request seeks to extend the shelf life of the batches A1076, A1106, A1115, A1166, A1140, A1173 and A1175 manufactured at Siam Bioscience Co., Ltd., and batches ACB9704, ACB9712, and ACC 1392 manufactured at Catalent Anagni S.R.L.

After due consideration, the Food and Drug Administration (FDA) hereby revises the EUA granted to the COVID-19 Vaccine AstraZeneca to reflect the requested changes.

The foregoing revision is made pursuant to the discretionary power of the Food and Drug (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 AstraZeneca are as follows:

Product Name:	COVID-19 Vaccine (ChAdOx1-S[recombinant]) [VAXZEVRIA]
Dosage Strength and Form:	0.5mL Solution for Injection (IM)
Pharmacologic category:	Vaccine
Storage and Shelf Life:	Unopened multidose vial Store in a refrigerator (2^0 to 8^0C) for 6 months.

[1] We refer you to the EUA dated 28 January 2021, the Amended EUA dated 10 September 2021, the Second Amendment to the EUA dated 15 November 2021, Third Amendment to the EUA dated 28 December 2021 and Fourth Amendment to the EUA dated 22 February 2022

	Expiry date for batches A1054 and A1065 manufactured by Siam Bioscience Co., Ltd. shall be 31 March 2022. The batches manufactured in Siam Bioscience Co., Ltd. shall have the following expiry dates: A1076 on 30 April 2022; A1106 and A1115 on 31 May 2022; A1140 on 30 June 2022; A1166 on 31 August 2022; and A1173 and A1175 on 31 July 2022. The batches manufactured in Catalent Anagni S.R.L. shall have the following expiry dates: ACB9704, and ACB9712 on 30 June 2022, and ACC1392 on 31 July 2022. Do not freeze.
Packaging:	5mL of solution in a 10-dose vial (clear type I glass) with stopper (elastomeric with aluminum overseal) with a plastic flip off-cap. Packs of 10 vials.
Manufacturer:	See list of sites
Indication:	For active immunization of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19)

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 AstraZeneca may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine AstraZeneca, 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, recognition and reliance have been accorded to the Emergency Use Listing (EUL) of the World Health Organization (WHO), and emergency use authorizations given by mature and established National Regulatory Authorities (NRAs) such as the United Kingdom, Australia, Canada, Japan and South Korea. 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. AstraZeneca Pharmaceuticals (Phils.), Inc. shall supply COVID-19 Vaccine AstraZeneca 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 AstraZeneca 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 AstraZeneca 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 AstraZeneca in accordance with the COVID-19 vaccination program.

II. Dosage Strength, Form and Administration

The COVID-19 Vaccine AstraZeneca vaccination course consists of two separate doses of 0.5mL each. The second dose should be administered between four (4) and twelve (12) weeks after the first dose.

COVID-19 Vaccine AstraZeneca is for intramuscular (IM) injection only, preferably in the deltoid muscle.

A third dose of COVID 19 Vaccine AstraZeneca may be administered at least 6 months after the second dose of COVID 19 Vaccine AstraZeneca when the potential benefits outweigh any potential risks for individuals 18 years of age and older.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, AstraZeneca Pharmaceuticals (Phils.), 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.

AstraZeneca Pharmaceuticals (Phils.), 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.

AstraZeneca Pharmaceuticals (Phils.), 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). AstraZeneca Pharmaceuticals (Phils.), Inc. shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

AstraZeneca Pharmaceuticals (Phils.), Inc. shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine AstraZeneca 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.

AstraZeneca Pharmaceuticals (Phils.), 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.

AstraZeneca Pharmaceuticals (Phils.), 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 AstraZeneca, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with AstraZeneca Pharmaceuticals (Phils.), Inc.;
2. Ensure administration of the COVID-19 Vaccine AstraZeneca 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 AstraZeneca 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 AstraZeneca, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the COVID-19 Vaccine AstraZeneca, 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 AstraZeneca prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of COVID-19 Vaccine AstraZeneca;
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, AstraZeneca Pharmaceuticals (Phils.), Inc. has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Vaccine AstraZeneca.

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.