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Seventh Amendment to the Emergency Use Authorization (EUA) for Pfizer BioNTech COVID-19 Vaccine Suspension for IM Injection Kalamazoo, Michigan, USA Site[1]

This refers to the request to amend the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 (BNT162b2) Suspension for IM injection (Kalamazoo, Michigan, USA Site) (Pfizer- BioNTech COVID-19 Vaccine) to extend shelf life to 18 months.

After due consideration, the Food and Drug Administration (FDA) revises the EUA of the COVID-19 Vaccine Pfizer to reflect the requested changes. In arriving at this decision, the FDA has taken into account similar regulatory actions of the European Medicines Agency (EMA) and the US Food and Drug Administration (USFDA).

The foregoing changes are made pursuant to the discretionary power of the Food and Drug Administration (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 Pfizer- BioNTech COVID-19 Vaccine are as follows:

Product Name:	Pfizer-BioNTech COVID-19 (BNT162b2)
Dosage Strength and Form:	30 mcg Suspension for Intramuscular (IM) Injection
Pharmacologic category:	Vaccine
Storage:	Prior to dilution, store at -90^{0}C to -60^{0}C for 18 months. Protect from light.
Packaging:	25 and 195 Multiple Dose Vials (after dilution each vial contains 6 doses of 0.3 mL)

[1] We refer you to the EUA 29 January 2021, Amended EUA dated 28 May 2021, Second Amendment to the EUA dated 15 November 2021, Third Amendment to the EUA dated 28 December 2021, Fourth Amendment to the EUA dated 26 April 2022, Fifth Amendment to the EUA dated 14 June 2022, and the Sixth Amendment to the EUA dated 10 October 2022.

Manufacturer:	Pharmacia and Upjohn Company LLC Kalamazoo, Michigan, USA See list of sites in Sec. III. Manufacture
Indication:	For active immunization for the prevention of COVID-19 caused by SARS-C0V-2 in individuals 12 years of age and older

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:

l. 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 Pfizer-BioNTech COVID-19 Vaccine may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the Pfizer- BioNTech COVID-19 Vaccine, 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 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 States of America, United Kingdom, Canada, European Union and Singapore, respectively. 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. Pfizer Inc. (Philippines) shall supply Pfizer- BioNTech COVID-19 Vaccine 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 Pfizer- BioNTech COVID-19 Vaccine 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 Pfizer- BioNTech COVID-19 Vaccine 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 PfizerBioNTech COVID-19 Vaccine in accordance with the COVID-19 vaccination program.

II. Dosage Strength, Form and Administration

Pfizer- BioNTech COVID-19 Vaccine should be supplied as a frozen suspension in multiple dose vials. Each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to reconstitute the vaccine. The dosing regimen is two doses of 0.3 mL each. The second dose should be given after three weeks (3) from the first dose.

A booster dose (third dose) of Pfizer- BioNTech COVID-19 Vaccine may be administered intramuscularly at least 6 months after the second dose in individuals 12 years of age and older. The decision when and for whom to implement a third dose of Pfizer- BioNTech COVID-19 Vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, Pfizer, Inc. (Philippines) 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.

Pfizer, Inc. (Philippines) 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.

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

IV. Pharmacovigilance

Pfizer, Inc. (Philippines) shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine Pfizer 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.

Pfizer, Inc. (Philippines) 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.

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

B. On the other hand, vaccination providers shall:

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

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.