



14 June 2022

**PFIZER, INC.**

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**Third Amendment to the Emergency Use Authorization (EUA) for Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified) 30 micrograms/dose Dispersion for Injection (IM) [Comirnaty]<sup>1</sup>**

This refers to the request to amend the Emergency Use Authorization (EUA) for (EUA) for Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified) 30 micrograms/dose Concentrate for Dispersion for Injection (IM) [Comirnaty] (COVID-19 Vaccine Pfizer) to change outer carton packsize and allow booster administration to individuals 12 years of age and older.

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 change is 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 COVID-19 Vaccine Pfizer are as follows:

<b>Product Name:</b>	Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty]
<b>Dosage Strength and Form:</b>	30 micrograms/dose Dispersion for Injection (IM) One dose (0.3 mL) contains 30 micrograms of Tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
<b>Pharmacologic category:</b>	Vaccine

<sup>1</sup> We refer you to the EUA dated 24 December 2021, Amended EUA dated 28 December 2021, and Second Amendment to the EUA dated 26 April 2022



<b>Shelf Life and Storage:</b>	12 months frozen at -90° to -60°C. Once thawed, this can be stored at 2° to 8°C for 10 weeks within the 12-month shelf life* <i>*The extended shelf life of this product shall be applied retroactively to batches already released and distributed, manufactured within 12 months prior to the authorization of the variation.</i>
<b>Packaging:</b>	10 and 195 Multidose vial. No dilution required. One (1) vial (2.25 mL) contains 6 doses of 0.3 mL.
<b>Manufacturer:</b>	Pfizer Manufacturing Belgium NV- Rijksweg 12, Puurs, 2870 Belgium
<b>Indication:</b>	For active immunization for the prevention of COVID-19 caused by SARS-COV-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:

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 Pfizer may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine Pfizer, 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 authorizations given by mature and established National Regulatory Authorities (NRAs) such as the United States of America, and the European Union. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement reliance on 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 COVID-19 Vaccine Pfizer 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 Pfizer 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 Pfizer 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 Pfizer in accordance with the COVID-19 vaccination program.

## **II. Dosage Strength, Form and Administration**

COVID-19 Vaccine Pfizer should be supplied as a white to off-white frozen dispersion of 30 micrograms/dose administered intramuscularly. The dosing regimen is two (2) doses (0.3 mL each). The second dose should be given after three (3) weeks from the first dose.

A booster dose (third dose) of Comirnaty 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 the COVID-19 Vaccine Pfizer 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.

As committed, Pfizer, Inc. (Philippines) shall submit the Philippine Specific Annex of the RMP on or before 15 January 2022.

#### **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 Pfizer, 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 COVID-19 Vaccine Pfizer 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 Pfizer 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 Pfizer, and provided with approved fact sheets.

##### **B. On the other hand, vaccination providers shall:**

1. Administer the COVID-19 Vaccine Pfizer, 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 Pfizer prior to vaccination;

4. Report any Adverse Events Following Immunization on the use of COVID-19 Vaccine Pfizer;
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 COVID-19 Vaccine Pfizer.

## **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.