



14 February 2023

**PFIZER, INC.**

18F-20F, 8 Rockwell Building  
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Manila Philippines 1200

**Amendment to the Emergency Use Authorization (EUA) for  
Tozinameran+Famtozinameran [Comirnaty Original/Omicron BA.4-5]  
(15mcg/15mcg/ 0.3ml Dispersion for Injection (IM) COVID-19 mRNA Vaccine  
(nucleoside modified)<sup>1</sup>**

This refers to the request to amend the Emergency Use Authorization (EUA) for (EUA) for COVID-19 vaccine Tozinameran+Famtozinameran [Comirnaty Original/Omicron BA.4-5] [15mcg/15mcg/ 0.3ml Dispersion for Injection (IM) COVID-19 Vaccine (nucleoside modified)] “COVID-19 Vaccine Pfizer Bivalent” to extend the 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 COVID-19 Vaccine Pfizer Bivalent are as follows:

<b>Product Name:</b>	Tozinameran+Famtozinameran [Comirnaty Original/Omicron BA.4-5]
<b>Dosage Strength and Form:</b>	15mcg/15mcg/0.3ml dose Dispersion for Intramuscular (IM) Injection
<b>Pharmacologic category:</b>	Vaccine
<b>Storage and Shelf Life:</b>	Store in freezer at -90 <sup>0</sup> C to -60 <sup>0</sup> C for 18 months. Protect from light.

<sup>1</sup>We refer you to the EUA dated 02 December 2022.



<b>Packaging:</b>	Thaw and store undiluted vials in the refrigerator, 2 <sup>0</sup> C to 8 <sup>0</sup> C for up to 10 weeks. 195 Multiple Dose Vials. 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, 2870 Puurs, 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 who have previously received at least a primary vaccination against 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 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, 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 COVID-19 Vaccine Pfizer Bivalent 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 Bivalent 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 Bivalent 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 Bivalent should be supplied as a white to off-white frozen dispersion of 15mcg/15mcg/ 0.3 mL dose administered intramuscularly. There should be an interval of at least 3 months between administration of COVID-19 Vaccine Pfizer Bivalent and the last prior dose of COVID-19 vaccine. COVID-19 Vaccine Pfizer Bivalent is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

## **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 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.