Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 March 2022

PFIZER, INC.
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Poblacion 1210 Makati City, Metro Manila

Emergency Use Authorization (EUA) for COVID-19 Drug Nirmatrelvir 150 mg Film-Coated Tablet + Ritonavir 100 mg Film-Coated Tablet *(Co-Packaged in Alu/Alu Push-Through Blister Pack)* [PAXLOVID]

This refers to the application for the issuance of Emergency Use Authorization (EUA) for the COVID-19 Drug Nirmatrelvir 150 mg Film-Coated Tablet + Ritonavir 100 mg Film-Coated Tablet *(Co-Packaged in Alu/Alu Push-Through Blister Pack)* [PAXLOVID] (COVID-19 Drug PAXLOVID).

The details of the COVID-19 Drug PAXLOVID are as follows:

Product Name:	Paxlovid 150mg/100mg film coated tablets
Dosage Strength and Form:	Nirmatrelvir 150 mg Film-Coated Tablet + Ritonavir 100 mg Film Coated Tablet (Co-Packaged in Alu/Alu Push-Through Blister Pack)
Pharmacologic category:	Drug
Storage:	Store below 25ºC. Do not refrigerate or freeze.
Shelf Life:	12 months
Packaging:	Alu/Alu push-through blister pack x 6 tablets [4 Nirmatrelvir tablets + 2 Ritonavir tablets] in Box of 30 tablets [20 Nirmatrelvir tablets + 10 Ritonavir tablets]
Manufacturer:	see list in *Section III. Manufacturer*
Indication:	Indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults 18 years old and above and who are at increased risk for progression to severe 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 drug or vaccine may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the drug or vaccine, when used to diagnose, prevent, or treat COVID-19, outweigh the known and potential risks of the drug or 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 authorization of mature and established National Regulatory Authorities of the United Kingdom, United States of America and Japan. Consideration has also been given to the emergency use authorization of the National Regulatory Authority of India. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement recognition processes of 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 drug 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. shall supply the COVID-19 Drug PAXLOVID only to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) consistent with the terms and conditions of this EUA.

   The DOH or the NTF is authorized to procure or purchase COVID-19 Drug PAXLOVID in line with the COVID-19 management and prevention program.

B. The COVID-19 Drug PAXLOVID shall be delivered to healthcare facilities and administered only by the healthcare providers, and used only for COVID-19 according to the approved indication stated herein.

   Healthcare facility, and healthcare provider, including physicians and nurses, as used in this EUA refer to those designated by the DOH or the NTF to receive and dispense the COVID-19 Drug PAXLOVID, in accordance with the COVID-19 management and treatment program.

II. Posology and Method of Administration

Nirmatrelvir must be co-administered with Ritonavir. Each Nirmatrelvir is a pink film coated tablet which contains 150 mg of Nirmatrelvir, while each Ritonavir-film coated tablet contains 100 mg of Ritonavir. The recommended dose for the COVID-19 Drug

PAXLOVID is Nirmatrelvir 300mg (two 150 mg tablets) with 100 mg Ritonavir (one 100 mg tablet) all taken together orally twice daily for 5 days. This should be given as soon as possible after a diagnosis of COVID-19 has been made and within 5 days of symptom onset.

COVID-19 Drug PAXLOVID is not recommended for women with childbearing potential, pregnant and lactating women.

III. Storage and Supply Chain Management

In the absence of agreement with the DOH or NTF, Pfizer, Inc. shall ensure that appropriate storage, transport, distribution, handling and supply chain is maintained until the product is delivered to FDA licensed establishments and dispensed by healthcare providers consistent with the terms of this letter, and ensure that a contingency plan is in place.

IV. Pharmacovigilance

Pfizer, Inc. shall have a comprehensive pharmacovigilance system for the COVID-19 Drug PAXLOVID 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. 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 drug or when an important milestone is reached.

Pfizer, Inc. shall submit monthly adverse drug reaction and safety reports as planned and discussed in the RMP.

V. Responsibility of FDA Licensed Establishments and Healthcare 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. Healthcare facilities and healthcare providers shall have the following responsibilities.

A. Healthcare facilities shall:

    1. Receive the COVID-19 Drug PAXLOVID in sites identified by DOH, and ensure appropriate storage and supply chain management is maintained in said facilities, in the absence of an agreement with Pfizer, Inc.
    2. Ensure administration of the COVID-19 Drug PAXLOVID is consistent with the terms of this Letter, latest product information and the COVID-19 management and treatment program; and

3. Ensure that healthcare providers of the COVID-19 Drug PAXLOVID 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 dispense the COVID-19 Drug PAXLOVID, and provided with approved fact sheets.

B. On the other hand, healthcare providers shall:

1. Administer the COVID-19 Drug PAXLOVID, in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 management and treatment program;
2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving the dosing regimen;
3. Obtain written informed consent from the recipient of the COVID-19 Drug PAXLOVID prior to administration;
4. Report any Adverse Drug Reaction (ADR) on the use of the COVID-19 Drug PAXLOVID;
5. Monitor and comply with drug management requirements (e.g. obtaining, tracking and handling drug) 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. has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Drug PAXLOVID.

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 No. 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.