Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

18 MAY 2022

**FDA ADVISORY**
No. 2022 - 1067

**TO:** **ALL HOLDERS OF EMERGENCY USE AUTHORIZATIONS (EUA) WITH CONDITIONAL MARKETING AUTHORIZATIONS (CMA) OF COVID-19 DRUGS, FDA LICENSED DRUGSTORES AND WHOLESALERS, PRESCRIBING PHYSICIANS AND DISPENSING PHARMACISTS**

**SUBJECT:** **Reminders regarding the conditions on the prescription and dispensation of oral COVID-19 Drugs under EUA with CMA**

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To allow greater access of the public, the Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUA) with Conditional Marketing Authorization (CMA) for Molnupiravir (several brand names) and Ritonavir + Nimratrelvir (Paxlovid) (collectively referred to as "COVID-19 Drugs"). Under the EUA with CMA, COVID-19 drugs may be prescribed and dispensed at FDA licensed drugstores provided conditions to protect the patient are strictly met.

Holders of EUA with CMA of COVID-19 Drugs are required to make available to all relevant stakeholders the terms of the EUA, including the provisions of the CMA. These stakeholders include FDA licensed drugstores and wholesalers, physicians and pharmacists which are required to comply with requirements on dispensation and prescription of the COVID-19 Drugs.

FDA licensed drugstores and wholesalers are expected to ensure that the physicians and pharmacists are aware of the terms of the EUA with CMA, and instructed about the means to prescribe and dispense the COVID-19 Drugs.

Considering the investigational nature of the COVID-19 Drugs, the prescribing physicians are reminded to thoroughly read the labels of such products. As with all medicines, these drugs have the potential to cause side effects and health problems especially if not used properly or when used beyond the instructions stated in the medicine leaflet. Under no circumstance that the COVID-19 Drugs be prescribed to pregnant women, breastfeeding or lactating women, women with child bearing potential, and the immunocompromised. The use of the COVID-19 Drugs must be thoroughly discussed between the patient and the prescribing physicians. All treatment options should be considered, taking into account comorbidities and special precautions. Lastly, the physician should obtain a positive RT-PCR test result and a written informed consent or conforme from the patient prior to the prescription of the COVID-19 Drugs.

Furthermore, pharmacists shall dispense the COVID-19 drug only upon presentation of the valid prescription. All prescriptions of the dispensed COVID-19 drugs shall be recorded in the prescription record book.

The FDA also reiterates the reporting of suspected adverse drug reactions associated with the use of the COVID-19 Drugs.

For the information and guidance of all.

**DR. OSCAR G. GUTIERREZ, JR.**
Officer-In-Charge, Director General

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph