Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

26 JAN 2022

FDA ADVISORY : 20220024

TO : ALL CONCERNED STAKEHOLDERS

SUBJECT : APPLICATIONS FOR COMPASSIONATE SPECIAL PERMIT (CSP) OF COVID-19 DRUGS

The Food and Drug Administration (FDA) received reports of limited access to COVID-19 Drugs granted with Emergency Use Authorization (EUA) such as Molnupiravir and Casirivimab + Imdemivab due to the increase in demand of these drugs following the recent surge of COVID-19 cases due to virus mutation and high transmissibility of the virus.

In reference to the Administrative Order No. 2021-0053 entitled "Guidelines on the procurement, Distribution and Rational Drug Use of COVID-19 under Emergency Use Authorization (EUA)" which states that COVID-19 Drugs granted with EUA shall no longer be applied for CSP after a specified time period determined by the Philippine FDA, the FDA shall approve CSP applications for the time being to augment the supply of COVID-19 Drugs in the country.

The application for CSP of COVID-19 Drugs shall be accepted within the next 3 months. This is subject to re-evaluation of current availability of supplies and status of registration of these COVID-19 Drugs. Please be informed that current CSPs are still valid and in effect.

The FDA continues to work with the government and health care industry to ensure access to these lifesaving commodities during this public health emergency.

For inquiries or clarification, you may email the FDA Clinical Research Section at clinicalresearch@fda.gov.ph.

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