

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



FDA ADVISORY No. 20220005

1 2 JAN 2022

TO:

ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Alleged Rampant Selling of Molnupiravir in the Market

The Food and Drug Administration (FDA) warns all healthcare professionals and the public on significant risks associated with the growing sales of the drug product Molnupiravir in the market. The recent surge of COVID-19 infections due to the Omicron variant created an increased demand on this investigational drug product, which is used in the treatment of COVID-19. This sudden demand has attracted unscrupulous individuals or organizations from distributing and selling this drug product in the market at a much higher price even without the required authorizations from this Office.

Molnupiravir has been made available in the country through Compassionate Special Permit (CSP) which is being granted by the FDA to an applicant hospital/institution or licensed physician with a named patient through an FDA-licensed Drug Manufacturer or Drug Importer. On 22 December 2021, an Emergency Use Authorization (EUA) for Molnupiravir (Molnarz) 200 mg Capsule has been issued. However, this is to emphasize that EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, it cannot be used as an authorization to market the drug commercially. The procurement and distribution of drugs under EUA like Molnupiravir shall follow the guidelines issued by the Department of Health.

Buying medicines in unlicensed establishments or over the internet can pose serious health risks. Furthermore, a medicine bought in an unlicensed establishment or online cannot be guaranteed as genuine and may contain no active ingredient, too much or too little active ingredient which may result in conditions/ailments not being treated correctly. Also, this medicine may not be stored correctly in accordance with its appropriate storage condition.

Healthcare professionals, patients and consumers are strongly advised to access Molnupiravir only through the Department of Health as the national procurer for drug products under EUA or to hospitals/institutions granted with CSP.

To report on the illicit and illegal distribution and selling of this product, kindly email us at <a href="report@fda.gov.ph">report@fda.gov.ph</a> or eReport at <a href="www.fda.gov.ph/ereport">www.fda.gov.ph/ereport</a>. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For the suspected adverse drug reactions (ADR), kindly report immediately through this link: <a href="https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH">https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH</a> by filling out the required fields.

For more information and inquiries, please email us at info@fda.gov.ph.

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