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FDA/HPT/VVC/SMD/VGU/23/0330

10th October 2023

Dear Healthcare Professional,

CANCELLATION OF EMERGENCY USE AUTHORIZATION FOR MOLNUPIRAVIR 200MG CAPSULES FOR THE TREATMENT OF COVID-19

The Food and Drugs Authority (FDA) wishes to inform you about the cancellation of the Emergency Use Authorization (EUA) granted for the underlisted brands of Molnupiravir 200mg capsules for the treatment of COVID-19.

- Movfor 200mg capsules
- Molflu 200mg capsules

This cancellation is based on the following reason: the marketing authorization holder, Merck Sharp & Dohme B.V has taken the decision to withdraw its application for marketing authorisation of Lagevrio (Molnupiravir), 200mg capsules from the European Medicine Agency (EMA).
This withdrawal is because the EMA's Committee for Medicinal Products for Human Use (CHMP) concluded, from all data made available at the time of the advice and subsequently provided by the company, that the clinical benefit of Lagevrio in the treatment of adults with Covid-19 who are not receiving supplemental oxygen and who are at a risk of developing severe Covid-19, could not be demonstrated.

Molnupiravir was granted EUA for the treatment of mild to moderate COVID-19 in an adult with a positive SARS-COV-2 diagnostic test and has at least one risk factor for developing severe illness.

The FDA, in collaboration with the importers, has instituted the recall of Movfor and Molflu from the Ghanaian market.

Patients and healthcare professionals are, therefore, requested to take note of the following information:

Advice to patients

- Patients taking Movfor or Molflu for the treatment of COVID-19 should return the product to the hospital where they obtained them, or to the nearest Food and Drugs Authority Office for safe disposal.

Advice to healthcare professionals

The FDA wishes to advice all healthcare professionals to:

- Stop using Movfor or Molflu capsules for the management of COVID-19 in adults.
- Return any samples of these products to the importer or the nearest FDA office for safe disposal.

FOOD AND DRUGS AUTHORITY

Patients and healthcare professionals may call the FDA on Mobile No: 024 431 0297/ 055 111 2224 or email to drug.safety@fda.gov.gh for enquiries or further guidance.

Meanwhile, you are reminded to report adverse reactions to all medicinal products including **lack of therapeutic effect, medication errors, suspected product quality, and substandard or falsified medicinal products:**

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at *http:adr.fdaghana.gov.gh/*
- Download and complete the Adverse Reaction reporting form and submit it at the nearest health facility.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER