REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

COVID-19: EMA and Heads of Medicines Agencies update on molnupiravir

EMA starts review to support possible national decisions on early use

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA)[1] have agreed on the need for additional guidance on COVID-19 treatments in light of rising rates of infection and deaths due to COVID-19 across the EU.

To this end, EMA is reviewing available data on the use of molnupiravir (also known as MK 4482 or Lagevrio) to support national authorities who may decide on the use of this medicine for COVID-19 treatment prior to its authorisation.

While the more comprehensive rolling review is ongoing ahead of a possible application for a marketing authorisation, EMA's Committee for Medicinal Products for Human Use (CHMP) will provide EU-wide recommendations in the shortest possible timeframe to help national authorities decide on possible early use of the medicine, for example, in emergency use settings.

Molnupiravir is an oral antiviral medicine developed by Merck Sharp & Dohme in collaboration with Ridgeback Biotherapeutics.

EMA and HMA remain committed to expediting the evaluation of much needed COVID-19 treatments and vaccines, while ensuring these meet the EU's high standards of safety and efficacy. EMA will communicate on the outcome of this review and that of the rolling review once they conclude.

[1] The Heads of Medicines Agencies (HMA) is a network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the countries of the European Economic Area.

More about the medicine

Molnupiravir is oral antiviral medicine that reduces the ability of SARS CoV 2 (the virus that causes COVID-19) to multiply in the body. It does this by increasing the number of alterations (mutations) in the virus's genetic material (known as RNA), in a way that impairs the ability of SARS-CoV-2 to multiply.

More about the procedure

EMA's Executive Director requested the review under Article 5(3) of Regulation 726/2004 following preliminary discussions with EMA's COVID-19 pandemic task force (COVID-ETF), which brings together experts from across the European medicines regulatory network.

The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. The Committee will issue a scientific opinion within the shortest possible timeframe, for EU Member States to consider when making decisions on the use of this medicine at national level before formal marketing authorisation is issued.

The review is being carried out alongside a rolling review of the data on quality, efficacy and safety, which when sufficient will allow a possible application for authorisation.

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Ministry of Health
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