REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press Release

EMA starts review of Paxlovid for treating patients with COVID-19

EMA is reviewing currently available data on the use of Paxlovid (PF-07321332/ritonavir), an oral treatment for COVID-19 developed by Pfizer. EMA is starting this review to support national authorities who may decide on its early use for COVID-19, for example in emergency use settings, prior to marketing authorisation.
EMA's human medicines committee (CHMP) will look at data from a study comparing the effect of Paxlovid with that of a dummy treatment (placebo) in non-hospitalised patients with mild to moderate COVID-19 who were at high risk of progressing to severe disease. The preliminary results indicate that Paxlovid reduced the risk of hospitalisation or death compared with placebo when treatment was given within 3 or five days of the start of symptoms. The CHMP will also review data on the medicine's quality and safety.

While a more comprehensive rolling review is anticipated to start ahead of a possible application for a marketing authorisation, this current review will provide EU-wide recommendations in the shortest possible timeframe so they can be used by national authorities who wish to take evidence-based decisions on the early use of the medicine.

Authorities in the EU 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 once it concludes.

More about the medicine

Paxlovid is an oral antiviral medicine that reduces the ability of SARS-CoV-2 (the virus that causes COVID-19) to multiply in the body. The active substance PF-07321332 blocks the activity of an enzyme needed by the virus to multiply. Paxlovid also contains a low dose of ritonavir (a protease inhibitor), which slows the breakdown of PF-

07321332, enabling it to remain longer in the body at levels that affect the virus. The medicine is expected to reduce the need for hospitalisation in patients with COVID-19.

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 a formal marketing authorisation is issued.

Ministry of Health
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