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EMA receives application for conditional marketing authorisation for Paxlovid (PF-07321332 and ritonavir) for treating patients with COVID-19

EMA has started evaluating an application for a conditional marketing authorisation for the oral antiviral medicine Paxlovid (PF-07321332 and ritonavir). The applicant is Pfizer Europe MA EEIG.

The application is for the treatment of mild-to-moderate COVID-19 in adult and adolescent patients (12 years of age and older weighing at least 40 kg) who are at high risk of progression to severe COVID-19.

EMA will assess the benefits and risks of Paxlovid under a reduced timeline and could issue an opinion within weeks, depending on whether the data submitted are sufficiently robust and whether further information is required to support the evaluation.

Such an expedited timeframe is only possible because EMA's human medicines committee (CHMP) has already started a review of the data on the medicine during a rolling review, which included data from laboratory, animal and clinical studies, as well as data on the quality of the medicine. In addition, CHMP assessed interim results from the main study on the use of Paxlovid in non-hospitalised, unvaccinated patients with COVID-19 who had symptomatic disease and at least one underlying condition putting them at risk of severe disease.[1]

In parallel, EMA's safety committee (PRAC) started the assessment of the risk management plan (RMP) proposed by the company, which outlines measures to identify, characterise and minimise the medicine's risks. Furthermore, in accordance with the accelerated timelines for COVID-19 products EMA's committee for medicines for children (PDCO) issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children.

Should the additional data submitted with the conditional marketing authorisation application be sufficient for CHMP to conclude that the benefits of Paxlovid outweigh its risks in the treatment of COVID-19, EMA will liaise closely with the European Commission to fast track the decision granting a conditional marketing authorisation in all EU and EEA Member States.

EMA will communicate further at the time of CHMP's opinion.

[1] Based on an interim analysis of this study EMA issued advice on the use of Paxlovid for treating COVID-19 in December 2021.

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How is the medicine expected to work?

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 supplies 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. Paxlovid is expected to reduce the need for hospitalisation in patients with COVID-19.