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COVID-19: EMA recommends conditional marketing authorisation for Paxlovid

EMA's human medicines committee (CHMP) has recommended granting a conditional marketing authorisation for the oral antiviral medicine Paxlovid (PF-07321332 / ritonavir) for the treatment of COVID-19. The applicant is Pfizer Europe MA EEIG.

The Committee recommended authorising Paxlovid for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

Paxlovid is the first antiviral medicine to be given by mouth that is recommended in the EU for treating COVID-19. It contains two active substances, PF-07321332 and ritonavir, in two different tablets. PF-07321332 works by reducing the ability of SARS-CoV-2 (the virus that causes COVID-19) to multiply in the body while ritonavir prolongs the action of PF-07321332 enabling it to remain longer in the body at levels that affect the multiplication of the virus.

In reaching its conclusion, the CHMP evaluated data from a study involving patients with COVID-19 showing that treatment with Paxlovid significantly reduced hospitalisations or deaths in patients who have at least one underlying condition putting them at risk of severe COVID-19. The analysis was done in patients who received Paxlovid or placebo (dummy treatment) within 5 days after COVID-19 symptoms began and who did not receive, nor were expected to receive, treatment with antibodies. Over the month following treatment, the rate of hospitalisation or death[1] was 0.8% (8 out of 1,039) for patients who received Paxlovid, compared with 6.3% (66 out of 1,046) for those who received placebo. There were no deaths in the Paxlovid group and 12 deaths[2] in the placebo group.

The majority of patients in the study were infected with the Delta variant. Based on laboratory studies, Paxlovid is also expected to be active against Omicron and other variants.

The safety profile of Paxlovid was favourable and side effects were generally mild. However, ritonavir is known to affect the action of many other medicines, and warnings and advice have been included in Paxlovid's product information. In addition, the company has provided a drug interaction tool on its website which can be accessed through a QR code included in the product information and on the outer carton. A letter will be sent to relevant healthcare professionals' organisations to further remind them of the issue. The CHMP concluded that the medicine's benefits are greater than its risks for the

[1] On 28 January 2022, this sentence was amended to make reference to hospitalisation or death (and not hospitalisation only) to fully describe the results
[2] On 28 January 2022 this figure was corrected to reflect the data analysed: there were 12 deaths (and not 9) in the placebo group.

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approved use and will now send its recommendations to the European Commission for a rapid decision applicable in all EU Member States.

Where to find more information

The product information for Paxlovid contains information for healthcare professionals, a package leaflet for members of the public and details of conditions of the medicine's authorisation.

An assessment report with details of EMA's evaluation of Paxlovid and the full risk management plan will be published shortly. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's clinical data website in due course.

More information will also be made available in an overview of the medicine in lay language, including a description of the medicine's benefits and risks and why EMA recommended its authorisation in the EU.

Conditional marketing authorisation

The European Commission will now fast-track the decision-making process to grant a decision on the conditional marketing authorisation for Paxlovid, allowing this medicine to be marketed across the EU.

Conditional marketing authorisation (CMA) is used as the fast-track authorisation procedure to speed up approval of medicines during public health emergencies in the EU. CMAs allow authorisation of medicines that fulfil an unmet medical need on the basis of less complete data than normally required. This happens if the benefit of a medicine immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available.

A CMA guarantees that the approved medicine meets rigorous EU standards for efficacy, safety and quality and is manufactured in approved, certified facilities in line with high pharmaceutical standards for large-scale production.

Once a CMA has been granted, companies must provide further data within pre-defined deadlines to confirm that the benefits continue to outweigh the risks.

For Paxlovid the company that markets the medicine will provide further data to reinforce the assurance on the pharmaceutical quality of the medicine.

Assessment of Paxlovid

During the assessment of Paxlovid, CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of Paxlovid, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

Paxlovid was evaluated as part of 'OPEN', an initiative started in December 2020 with the aim of increasing international collaboration in the EU review of COVID-19 vaccines and therapeutics. More information can be found on the EMA website.