EU watchdog approves Pfizer COVID pill

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The EU's drug watchdog approved Pfizer's coronavirus pill on Thursday, making it the first oral antiviral treatment for the disease to be authorised in Europe.

Studies showed the drug called Paxlovid reduces hospitalisation and death in patients at risk of severe COVID, and may also be effective

against the Omicron variant.

Pills are seen as a potentially huge step in ending the pandemic as they can be taken at home, rather than in hospital.

"Paxlovid is the first antiviral medicine to be given by mouth that is recommended in the EU for treating COVID-19," the European Medicines Agency (EMA) said in a statement.

The United States, Canada and Israel are among a handful of countries to have already given the green light to the Pfizer treatment.

The European Commission must now formally authorise the drug but that is a rubber-stamp procedure that usually takes hours or days.

"Paxlovid is the first oral antiviral for home use in our portfolio, and has the potential to make a real difference for persons at high risk of progression to severe COVID," EU Health Commissioner Stella Kyriakides said in a statement.

"We have also seen the promising evidence regarding Paxlovid's effectiveness against Omicron and other variants."

The Pfizer treatment is a combination of a new molecule, PF-07321332, and HIV antiviral ritonavir, that are taken as separate tablets.

The EMA said it "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".

EMA experts looked at a study "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".

Patients were given the pill within five days of developing symptoms and over the following month only 0.8 percent of the 1,039 people studied ended up in hospital, compared with 6.3 percent of those who received a placebo.

There were no deaths in the Paxlovid group and nine deaths in the placebo group, the EMA said.

In December the EMA cleared individual states to decide whether to make early emergency use of Paxlovid, but held off on deciding on full authorisation across the 27-nation bloc.

The watchdog is still weighing a similar application for US drugmaker Merck's anti-COVID pill.

Unlike vaccines, the Pfizer treatment does not target the ever-evolving spike protein which the coronavirus uses to invade cells.

It should therefore in theory be more variant-proof, and the company has said preliminary lab studies have backed up that hypothesis.