Pfizer seeks conditional EU authorization for COVID-19 pill

January 10 2022

Credit: Pixabay/CC0 Public Domain

The European drug regulator said Monday it has started evaluating an application by Pfizer for its pill to treat the effects of COVID-19.

The announcement comes as countries in much of the 27-nation bloc are reporting soaring numbers of infections as the highly transmissible omicron variant sweeps across the continent.

The European Medicines Agency said in a statement that it could decide within weeks whether to approve Pfizer's application for a conditional marketing authorization for the drug Paxlovid, "depending on whether the data submitted are sufficiently robust and whether further information is required to support the evaluation."

Late last month, U.S. health regulators authorized the pill that patients will be able to take at home to ward off the worst effects of the virus. At the time, Pfizer said it had 180,000 treatment courses available worldwide, with roughly 60,000 to 70,000 allocated to the U.S. The company said it expected to have 250,000 available in the U.S. by the end of January.

Pfizer's application to the EMA covers use of the pill to treat mild to moderate COVID 19 in patients aged 12 years and older who are at risk of developing severe symptoms of the disease.

The EMA last month issued advice on use of the drug to EU nations that wanted to begin using it before official authorization. The agency said it based its advice on a study of non-hospitalized, unvaccinated patients who had COVID-19 and at least one underlying condition that put them at risk of developing severe COVID-19 symptoms.

"These data showed that Paxlovid reduced the risk of hospitalization and death when treatment started within five days of the start of symptoms," the agency said.