EU agency backs Pfizer COVID pill for emergency use

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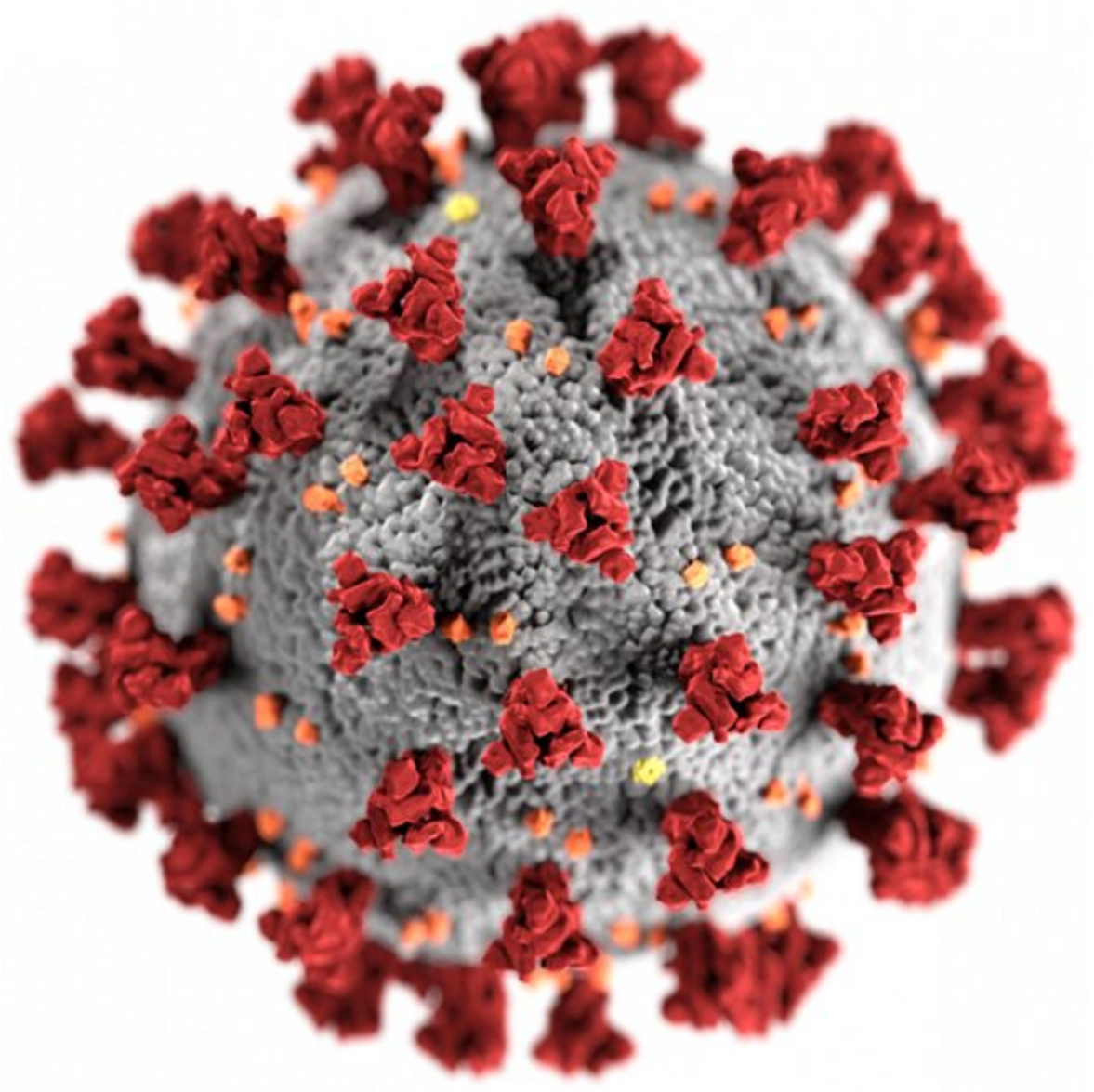

Image of the ultrastructural morphology exhibited by the 2019 Novel Coronavirus (2019-nCoV). Credit: CDC

The EU's drug regulator on Thursday allowed member states to use Pfizer's new COVID pill ahead of its formal approval, as an emergency measure to curb an Omicron-fuelled wave.

Pills like those by US pharma giant Pfizer and rival Merck have been hailed as groundbreaking because they do not need to be injected or taken intravenously, making them more accessible.

Pfizer said this week that its Paxlovid pill reduced hospitalisations and deaths in vulnerable people by almost 90 percent.

"The medicine, which is not yet authorised in the EU, can be used to treat adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe disease," the EMA said in a statement.

"EMA issued this advice to support national authorities who may decide on possible early use of the medicine... for example in emergency use settings, in the light of rising rates of infection and deaths due to COVID-19 across the EU."

Pfizer CEO Albert Bourla said the decision "signifies the strength of our data for Paxlovid in the treatment of high-risk adults diagnosed with COVID-19."

"If authorised, Paxlovid has the potential to help save lives and reduce hospitalisations," he said in a statement.

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

The Amsterdam-based EMA said it should be taken as soon as possible after a diagnosis and within five days of the start of symptoms, with the treatment lasting five days.

'Combined effect'

Possible side effects were taste changes, diarrhoea and vomiting. Pregnant women should not use the drug.

The EMA said it also launching a "rolling review" of the Pfizer pill that could lead to its full approval in months.

Merck's pill received EMA emergency approval in November. It is already authorised in Britain and is in the process of being approved in the United States.

Denmark on Thursday became the first EU country to approve its use.

However the full results of a clinical trial released by Merck were disappointing as they showed a much lower efficacy than earlier reports based on interim data.

Separately, the EMA approved GlaxoSmithKline's Xevudy drug and the treatment Kineret, made by Swedish Orphan Biovitrum, for patients at risk of developing severe COVID.

EU Health Commissioner Stella Kyriakides said the new drugs were "crucial" as the "combined effect of Delta and Omicron will unfortunately bring severe disease and hospitalisations up".

The EMA also announced a special meeting on Monday to decide whether to approve the bloc's fifth vaccine, made by US firm Novavax.

Novavax uses so-called protein subunit technology that is similar to that used in the decades-old Hepatitis B and whooping cough vaccines that are widely used around the world.

Experts hope using this tried-and-tested technology has raised hopes that it could reduce the vaccine hesitancy that still dogs the newer, genetically-engineered methods used in the four vaccines currently approved by the EU.