MedicalXpress

AstraZeneca vaccine approval unlikely in January: EU

December 31 2020

The coronavirus vaccine developed by AstraZeneca and Oxford University, which was approved Wednesday in Britain, is unlikely to get a green light in the European Union in the next month, according to the European Medicines Agency (EMA).

The regulator, charged with overseeing vaccines' authorisation in the EU before they can be marketed, approved the Pfizer-BioNTech vaccine on December 21. It is expected to rule on Moderna's vaccine on January 6.

But an EU ruling on the AstraZeneca-Oxford jab will take some time.

"Additional scientific information on issues related to quality, safety and efficacy of the vaccine is deemed necessary to support the rigour required for a conditional marketing authorisation (CMA) and this has been requested from the company," the EMA said in a statement.

"Further information from the ongoing clinical trials is also expected from January."

The Amsterdam-based agency earlier told AFP that it had not yet received any formal marketing authorisation and that it had set no timetable for approving the vaccine.

The regulator's deputy executive director Noel Walthion told Belgian newspaper Het Nieuwsblad on Tuesday that a possible approval in January is "unlikely".

The AstraZeneca-Oxford vaccine is currently undergoing a "rolling review" which allows the EMA to examine safety and efficacy data as they are released, even before a formal application for authorisation is filed by the manufacturer.

This procedure speeds up the evaluation of a marketing authorisation application once it is made, the EMA said.

The agency said Wednesday it is "aware that the UK MHRA has granted a temporary authorisation of supply of the vaccine in the emergency use setting, which is distinct from a marketing authorisation."

An AstraZeneca spokesperson told AFP it "has submitted a full data package to support an application for conditional marketing authorisation for the AstraZeneca COVID-19 vaccine to the European Medicines Agency."

The spokesperson added: "AstraZeneca has been submitting data on a rolling basis and will continue to work closely with the EMA to support the start of a formal CMA application process."

Britain is the first country in the world to approve the vaccine, which is cheaper to produce and easier to store and transport than the Pfizer-BioNTech jab.

For EU countries, it is up to the European Commission in Brussels to issue the final green light after EMA approval.

Inoculations with the Pfizer-BioNTech vaccine began in the 27-member bloc over the weekend.