

US will likely issue allergy warning over Pfizer vaccine: official

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Moncef Slaoui, who is the chief advisor to the US program for Covid vaccine and treatment development, expects the Food and Drug Administration will issue an allergy warning for the Pfizer vaccine

If the US Food and Drug Administration (FDA) decides to approve the Pfizer-BioNTech COVID vaccine, it will probably ask people with a known history of severe allergic reactions to not take it, a top government scientist said Wednesday.

The news follows a similar warning in Britain after two health care workers suffered <u>allergic reactions</u> and needed treatment.

Both Britain and Canada have already approved the two-dose vaccine regimen on an emergency basis and the US is expected to follow suit within a matter of days, after an FDA advisory panel meets on the issue Thursday.

Moncef Slaoui, who is the chief advisor to the US program for COVID vaccine and treatment development, told reporters: "Looking into the data, patients or subjects with severe allergic reaction history have been excluded from the clinical trial.

"I assume—because the FDA will make those decisions—that tomorrow this will be part of the consideration, and as in the UK, the expectation would be that subjects with known severe reactions, (will be asked) to not take the vaccine, until we understand exactly what happened here."

The FDA will probably also ask providers to watch for whether people develop a rare but temporary and not very serious form of facial paralysis called Bell's palsy, after data showed four people out of about 19,000 in the vaccine arm of the trial got the condition.

Overall, Slaoui said he was impressed by the vaccine data that had emerged in briefing documents submitted to the FDA, including importantly that strong protection began after the first dose—though the recommendation remains to take both injections, 21 days apart.

It isn't known when exactly the regulatory agency could issue its emergency use authorization but health secretary Alex Azar indicated that officials have early next week in mind.

General Gus Perna, who is overseeing logistics nationwide, said he had given the order Wednesday to begin distributing syringes, needles, alcohol wipes and dilutants required for the Pfizer vaccine, a process expected to be completed by Friday.

The US hopes to vaccinate 20 million people this month, with long term care facility residents and health care workers at the front of the line.

The goal is to reach 100 million by the end of February and the whole population by June.

The next vaccines to receive approval might be those made by Moderna, Johnson & Johnson, and AstraZeneca, most likely in that order.



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