EU Says Novavax COVID Vaccine Must Carry Heart Inflammation Warning

The European Medicines Agency (EMA) is requesting more data from U.S. vaccine maker Novavax and said its COVID-19 vaccine — marketed under the brand names "Nuvaxovid and Covovax" — carry a warning of two types of heart inflammation after a small number of cases were reported in those who received the vaccine.

According to a statement issued Aug. 3 by the EMA, the agency's Pharmacovigilance Risk Assessment Committee (PRAC) — responsible for assessing and monitoring the safety of human medicines — concluded that "myocarditis and pericarditis can occur following vaccination with Nuvaxovid."

"The Committee is therefore recommending listing myocarditis and pericarditis as new side effects in the product information for Nuvaxovid, together with a warning to raise awareness among healthcare professionals and people receiving this vaccine," the statement said.

PRAC also requested that the "marketing authorization holder of Nuvaxovid provides additional data on risk of side effects occurring."

Novavax was hoping that people who opted not to take Pfizer and Moderna's vaccines – both of which are associated with a risk of heart inflammation – would favor their shot because it "relies on technology used for decades," Reuters reported.

The U.S. Food and Drug Administration (FDA) flagged a risk of heart inflammation from the Novavax vaccine in early June. Yet, the agency on July 13 granted Novavax's request for Emergency Use Authorization of the vaccine for adults 18 and over in the U.S.

The FDA's "Fact Sheet for Healthcare Providers Administering Vaccine" now reflects the warning.

The agency's "Fact Sheet for Recipients and Caregivers" states that for most people who have had myocarditis or pericarditis after receiving the vaccine, symptoms began within 10 days following vaccination and that vaccine recipients should seek medical attention right away if they experience chest pain, shortness of breath, feelings of having a fast-beating, fluttering or pounding heart.

Myocarditis is inflammation of the heart muscle that can lead to cardiac arrhythmia and death. According to the National Organization for Rare Disorders, myocarditis can result from infections, but "more commonly the myocarditis is a result of the body's immune reaction to the initial heart damage."

Pericarditis is inflammation of the tissue surrounding the heart that can cause sharp chest pain and other symptoms.

Unlike the Pfizer and Moderna vaccines that use mRNA technology, and the Johnson & Johnson (J&J) vaccine that uses adenovirus vector technology, the Novavax vaccine uses a more conventional vaccine technology.

One reason the FDA's vaccine advisory panel recommended the vaccine was because they hoped the "unvaccinated holdouts" would be more likely to get the Novavax shot.

Despite a unanimous vote by the FDA's vaccine advisory panel, members raised several concerns about heart-related adverse events that occurred during the clinical trials.

FDA documents show multiple instances of myocarditis and pericarditis reported after the administration of the Novavax vaccine:

> *"Multiple events of myocarditis/ pericarditis were reported in temporal relationship to NVX-CoV2373 [the Novavax vaccine used during the trials] administration, similar to myocarditis following mRNA COVID-19 vaccines and raising concern for a causal relationship to NVX-CoV2373.*
>
> *"Events of lymphadenopathy were infrequent but reported by a higher proportion of participants in the NVX arm, with the highest rate observed after Dose 2 (0.2%).*
>
> *"Review of the data also identified small imbalances in certain thromboembolic events, including cardiac and neurovascular events, hypersensitivity events, cholecystitis, uveitis, cardiac failure, and cardiomyopathy.*
>
> *"Data from passive surveillance during post-authorization use in other countries also indicate a higher-than-expected rate of myocarditis and pericarditis (mainly pericarditis) associated with the vaccine."*

In a safety database encompassing data from 40,000 Novavax vaccine recipients, four men, ages 16 through 28, reported myocarditis or pericarditis within 20 days of vaccination.

According to the FDA, there were 26,000 people in the Novavax

clinical trial. Yet, only 21,000 of the 26,000 people who received the vaccine during the trial were "followed for at least 2 months."

It is unknown if any participants developed heart inflammation after the 2-month follow-up period, why the other 5,000 clinical trial participants were not followed or whether those individuals experienced heart inflammation.

In briefing documents released June 3, the FDA wrote:

"These events raise the concern for a causal association with this vaccine, similar to the association documented with mRNA COVID-19 vaccines."

The FDA asked Novavax to "flag" myocarditis and pericarditis as an "important identified risk" in its materials accompanying the vaccine. However, Novavax has not yet agreed to do so.

"Based on our interpretation of all the clinical data supporting NVX-CoV2373 … we believe there is insufficient evidence to establish a causal relationship," the company said in a statement.

Novavax claimed that "natural background events" of myocarditis can be expected in any large database and the "totality of the clinical evidence" is "not enough to establish an overall causal relationship with the vaccine."

Novavax is already seeking to expand its vaccine for use in the 12 to 17 adolescent age group.