

US FDA concerned over potential Novavax myocarditis risk

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The Food and Drug Administration voiced concern Friday about myocarditis being potentially linked to the Novavax COVID-19 vaccine, just as experts are to weigh its use in the United States.

The Novavax vaccine is already authorized in other countries, particularly in Europe. In the United States, an independent committee

convened at the request of the FDA is to meet Tuesday to evaluate data from the clinical trials of Novavax and give its recommendation.

In advance of that, the agency published a lengthy document on Friday analyzing these results, as it had done for the three other vaccines already authorized in the country.

Shortly afterwards, Novavax stock dropped 20 percent on the New York Stock Exchange.

Novavax's vaccine was found to be 90 percent effective against symptomatic cases of the disease, in trials conducted before the appearance of the Omicron variant, according to the FDA.

But six cases of myocarditis, an inflammation of the heart muscle, were detected in the group that received the vaccine, against one case in the [placebo group](#), the agency pointed out.

Five cases occurred within two weeks of vaccination.

"Identification of multiple potential vaccine-associated cases" out of 40,000 clinical trial participants "raises concern that if causally associated, the risk of myocarditis following" the Novavax shot "could be higher than reported" on other vaccines such as Pfizer or Moderna, the FDA said.

A small risk of myocarditis had in fact been identified after Pfizer or Moderna vaccinations, which are based on Messenger-RNA, particularly in young men and adolescent boys.

But the FDA noted that during clinical trials of these vaccines, no cases had yet been detected, and the agency appeared concerned that the risk is higher with Novavax.

The company issued a statement in response to the FDA report on Friday, saying "we believe there is [insufficient evidence](#) to establish a [causal relationship](#)", adding that it was normal "to see natural background events of myocarditis in any sufficiently large database."

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