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Sweden, Denmark Pause Moderna's COVID Vaccine for Younger Age Groups Citing Reports of Myocarditis

Sweden will pause Moderna's COVID vaccine for people under age 30, while Denmark said it will halt use of Moderna's vaccine in people under age 18.

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Global Research, October 07, 2021
Children's Health Defense 6 October 2021

Region: Europe
Theme: Science and Medicine

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Sweden and Denmark on Wednesday said they will pause the use of Moderna's COVID vaccine for younger age groups after reports of possible rare side effects, including myocarditis.

The Swedish health agency said it would pause the vaccine for people born in 1991 and later, as data pointed to an increase of myocarditis and pericarditis among youths and young adults who had been vaccinated, Reuters reported.

> "The connection is especially clear when it comes to Moderna's vaccine, 'Spikevax,' especially after the second dose," the health agency said in a statement.

The health agency said it now recommends Pfizer/BioNTech's Comirnaty vaccine instead. People born 1991 or later who received a first Moderna dose — approximately 81,000 people — will not get a second Moderna jab.

Earlier this week, the Swedish health agency said 12- to 15-year-olds would only get Pfizer's COVID vaccine.

Denmark said that, while it was already using the Pfizer/BioNTech vaccine as the main option for 12- to 17-year-olds, it had decided to pause the Moderna vaccine for people under 18 as a "precautionary principle."

> "In the preliminary data … there is a suspicion of an increased risk of heart inflammation, when vaccinated with Moderna," the Danish Health Authority said in a statement.

The agency referred to data from a yet unpublished Nordic study, which will be sent to the European Medicines Agency (EMA) for further assessment once the data is finalized, the agency added.

Norway, which already recommends the Comirnaty vaccine for minors, reiterated Wednesday rare side effects could happen, particularly in boys and young men, and mainly after receiving a second dose.

The EMA approved the use of Comirnaty in May, while Spikevax was approved for use in children over 12 in July, U.S. News reported.

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.

According to the the Vaccine Adverse Event Reporting System, there have been 6,561 cases of myocarditis and pericarditis reported following COVID vaccines, with 5,874 cases attributed to Pfizer, 1,515 cases to Moderna and 161 cases to Johnson & Johnson's COVID vaccine between Dec. 14, 2020 and Sept. 24, 2021.

Among 12- to 17-year-olds, there have been 617 reports of myocarditis and pericarditis, with 603 cases attributed to Pfizer's vaccine.

VAERS is the U.S. government-run system for reporting vaccine adverse events, but some of the reports sent to the system come from outside the U.S.

> Another sad story! Mom so proud that her 14-year-old son could get the COVID vaccine… but now doctors confirm her son meets the criteria for having post-vaccine myocarditis.
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> SUBSCRIBE #TheDefender: https://t.co/zL66Edfiw5https://t.co/CmRUHc8QMr
>
> — Robert F. Kennedy Jr (@RobertKennedyJr) August 11, 2021

On June 25, the U.S. Food and Drug Administration (FDA) added a warning to patient and provider fact sheets for both Pfizer and Moderna COVID vaccines suggesting an increased risk of myocarditis and pericarditis — particularly following the second dose and with onset of symptoms within a few days after vaccination.

The FDA's update followed a June 23 meeting which included a review of information and discussion by the Advisory Committee on Immunization Practices — a committee within the Centers for Disease Control and Prevention (CDC) that provides advice and guidance on effective control of vaccine-preventable diseases.

During the meeting, the committee acknowledged 1,200 cases of heart inflammation in 16- to 24-year-olds, and said mRNA COVID vaccines should carry a warning statement.

Health officials said the benefits of receiving a COVID vaccine still outweigh any risks. But physicians and other public commenters during the June 23 meeting accused the CDC of exaggerating the risk of COVID to young people, and minimizing the risk of the vaccines.

The FDA approved Pfizer's COVID vaccine for emergency use in the 12 to 15 age group in May, and approved a biologics license application for the Pfizer Comirnaty vaccine Aug. 23 — leaving the Pfizer/BioNTech vaccine under Emergency Use Authorization.

A third booster dose of Pfizer's COVID vaccine was approved for the immunocompromised and those in "high risk" professions in September — in what was deemed a controversial move by the CDC and FDA, both of which overruled the recommended guidance issued by their vaccine advisory committees.

In June, Moderna asked the FDA to expand emergency use of its COVID vaccine in adolescents aged 12 to 17. A decision has yet to be made.

Both Moderna and Johnson & Johnson (J&J) have asked the FDA to approve booster doses of their COVID vaccines for emergency use. The FDA will convene its advisory panel next week to review booster data from both J&J and Moderna.

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