Welcome to the Reuters.com BETA. Read our Editor's note on how we're helping professionals make smart decisions.

Read more





July 10, 2021 12:40 AM PST Last Updated 6 days ago

# **Healthcare & Pharmaceuticals**

# EU finds potential link between heart inflammation and mRNA COVID shots

#### Pushkala Aripaka



4 minute read



EU finds potential link between heart inflammation and mRNA COVID shots | Reuters

Vials with Pfizer-BioNTech and Moderna coronavirus disease (COVID-19) vaccine labels are seen in this illustration picture taken March 19, 2021. REUTERS/Dado Ruvic/Illustration/File Photo

Summary

Says possible link to myocarditis and pericarditis

Says cases occurred more in younger adult men

Also advices against J&J shot for those with rare blood disorder

July 9 (Reuters) - Europe's drug regulator has found a possible link between very rare heart inflammation and COVID-19 vaccines from Pfizer-BioNTech (PFE.N), (22UAy.DE) and Moderna (MRNA.O), it said on Friday, stressing that the benefits of the shots outweighed any risks.

The conditions, myocarditis and pericarditis, must be listed as side-effects of the two mRNA vaccines, the safety committee of the European Medicines Agency (EMA) said, adding that such cases primarily occurred within 14 days of inoculation.

It said cases occurred more often after the second dose and in younger adult men. This is in line with U.S. findings last month. <u>read more</u>

Symptoms from the conditions include breathlessness, palpitations and chest pain.

EMA's safety panel also advised that people with a history of the rare blood disorder capillary leak syndrome (CLS), must not be vaccinated with Johnson & Johnson's <u>(JNJ.N)</u> shot.

While the regulator cautioned healthcare professionals and people to be on the lookout for post-vaccine symptoms, it said it was continuously monitoring the safety of approved

>

vaccines as they are rolled out more widely.

"EMA confirms that the benefits of all authorised COVID-19 vaccines continue to outweigh their risks," it said.

EMA in total reviewed more than 300 cases of myocarditis and pericarditis in the European Union, Iceland, Norway and Liechtenstein - together referred to as the European Economic Area (EEA).

Most cases occurred with Pfizer's vaccine, called Comirnaty, the watchdog said.

#### SIDE-EFFECTS

Roughly 177 million doses of Comirnaty had been given in the EEA as of May 31, compared to 20 million doses of Moderna's Spikevax vaccine, EMA said.

The cases of myocarditis and pericarditis were "generally mild," and individuals "tend to recover within a short time following standard treatment and rest," Pfizer said in a statement.

EMA had also been looking into such cases with J&J and AstraZeneca <u>(AZN.L)</u> vaccines, but on Friday said it had not found any causal relationship so far and had asked for more data from the drugmakers.

Both J&J and AstraZeneca vaccines use similar technology but with different versions of a cold virus to deliver immunity-building instructions to the body.

EMA in June asked CLS to be added as a side-effect of AstraZeneca's shot, Vaxzevria. <u>read</u> <u>more</u>

The regulator then too said people who had previously sustained the condition, in which fluids leak from the smallest blood vessels causing swelling and a drop in blood pressure, should not receive the shot. <u>read more</u>

For J&J, EMA reviewed three cases of CLS which occurred within two days of vaccination.

The developments could put pressure on vaccination plans in Europe and on the U.S. company after millions of doses of the vaccine were banned for EU use over safety concerns following a contamination incident in the United States.

J&J did not immediately respond to a request for comment.

Reporting by Pushkala Aripaka in Bengaluru; additional reporting by Trisha Roy; Editing by Arun Koyyur, Nick Macfie, Kirsten Donovan

Our Standards: The Thomson Reuters Trust Principles.

### **More from Reuters**



### Sign up for our newsletter

Subscribe for our daily curated newsletter to receive the latest exclusive Reuters coverage delivered to your inbox.

Sign up

# Healthcare & Pharmaceuticals