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EU Regulators Call on Pfizer, Moderna, AstraZeneca for More Data on Heart Inflammation, Guillain–Barré Syndrome

The European Medicines Agency also wants Pfizer and Johnson & Johnson to update warnings and lists of side effects relating to face swelling (Pfizer) and blood clots (J&J).

By Megan Redshaw
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EU regulators Friday called on Pfizer and Moderna to provide additional data related to the companies' COVID vaccines and a potential link to heart inflammation, after the agency completed a safety review of all four COVID vaccines authorized for emergency use in the EU.

The European Medicines Agency's safety committee, (PRAC), also asked AstraZeneca for data related to reports of Guillain–Barré syndrome in people who received the AstraZeneca vaccine, and they recommended Pfizer and Johnson & Johnson (J&J) update their labels with side effect warnings.

In a report issued May 7, PRAC disclosed its members were aware of cases of myocarditis and pericarditis following Pfizer vaccination. Regulators said they didn't see an indication the vaccine caused these cases, but as a prevention, PRAC requested Pfizer provide further data, including an analysis of events according to age and gender in its next pandemic summary safety report and will consider if any other regulatory action is needed.

Because Moderna and Pfizer use the same mRNA technology for their vaccines, the committee asked Moderna to monitor for similar cases of heart inflammation.

Myocarditis, or inflammation of the heart muscle, can lead to cardiac arrhythmia and death. Pericarditis is inflammation of the membrane around the heart.

A search in the CDC's Vaccine Adverse Events Reporting System (VAERS) revealed 213 cases of pericarditis and myocarditis reported in the U.S following COVID vaccination. Of the 213 cases reported, 105 cases were attributed to Pfizer, 93 cases to Moderna and 15 cases to Johnson & Johnson's (J&J) COVID vaccine.

On April 27, Reuters reported the U.S. Department of Defense was investigating 14 cases of heart inflammation among people who were vaccinated through the military's health services.

Of the 14 cases, one patient developed myocarditis after their first dose of vaccine. The remaining 13 patients developed myocarditis after their second vaccine doses. Eleven received the Moderna vaccine and three received Pfizer.

Israel's Health Ministry is also examining cases of heart inflammation in people who received Pfizer's COVID vaccine. As The Defender reported April 26, a preliminary report by the committee tasked with monitoring vaccine side effects in Israel identified 62 cases of myocarditis, including two deaths, after recent vaccination with Pfizer. Fifty-five of the cases occurred in men — most between ages 18 and 30.

In the case of AstraZeneca, PRAC said it is examining reports of Guillain–Barré syndrome and asked for more detailed data and an analysis of all reported Guillain–Barré syndrome cases.

Guillain–Barré syndrome is a rare immune disorder in which the body's immune system attacks the nerves resulting in paralysis. It had been previously identified by regulators as a potential adverse side effect that required monitoring following AstraZeneca's shot.

EMA recommends updates to labels, lists of side effects

The EMA's May 7 report also included the recommendation that Pfizer add a new side effect to its product information for people with dermal fillers — soft, gel-like substances injected under the skin.

After reviewing all available evidence, including cases reported to the European database for suspected side effects and data from scientific literature, PRAC said there is at least a "reasonable possibility of a causal association between the vaccine and the reported cases of facial swelling in people with a history of injections with dermal fillers."

The safety committee also said it would update its warning for J&J's COVID vaccine after EU regulators in April identified a link between the shot and blood clots.

Though PRAC said the benefits of the vaccine outweigh the risks, the label will now include advice that patients diagnosed with thrombocytopenia within three weeks of vaccination be actively investigated for signs of thrombosis and that patients who present with thromboembolism within three weeks be evaluated for thrombocytopenia.

Thrombosis with thrombocytopenia syndrome will also be added as an "important identified risk" in the risk management plan for J&J's vaccine. The committee asked the company to provide a plan to further study the possible underlying mechanisms for these events.

Additionally, PRAC looked at clotting risks with Pfizer and Moderna vaccines. Though several cases of low blood platelets and blood clots were identified, the committee concluded that for the moment there does not seem to be any evidence of a safety signal for the mRNA shots.

Utilizing a search criteria that included reports of blood clots associated with blood clotting

disorders, VAERS yielded a total of 2,808 reports in the U.S for all three vaccines from Dec. 14, 2020, through April 30. Of the 2,808 cases reported, there were 1,043 reports of blood clotting disorders attributed to Pfizer.

As The Defender reported Monday, a Utah teen remains hospitalized with three blood clots in and near his brain that developed after he received the first dose of Pfizer's COVID vaccine.

On May 7, Pfizer became the first COVID vaccine producer to request full approval by the U.S Food and Drug Administration for ages 16 and up. Pfizer requested priority review, which asks the FDA to take action within six months, compared to 10 months designated under standard review.

The FDA is expected to amend Pfizer's Emergency Use Authorization (EUA) this week to authorize use of the vaccine in adolescents aged 12 to 15. The company announced plans to further expand EUA for its vaccine for children ages 2 to 11 in September.

If approved, Pfizer will be the first experimental vaccine to receive full approval by the FDA.

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***Megan Redshaw** is a freelance reporter for The Defender. She has a background in political science, a law degree and extensive training in natural health.*

Featured image is from Children's Health Defense
