EUROPEAN MEDICINES AGENCY
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COVID-19 vaccines: update on ongoing evaluation of myocarditis and pericarditis

EMA's safety committee (PRAC) is continuing its assessment of reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) in a small number of people following vaccination with COVID-19 vaccines.

The PRAC started its review in April following cases of myocarditis after vaccination with Comirnaty in Israel. Most of these cases were mild and resolved within a few days. They mainly affected males under 30 years of age, with symptoms mostly starting within several days of vaccination with the second dose.

Cases of myocarditis[1] and/or pericarditis[2] were also reported in the EEA following vaccination with all COVID-19 vaccines.

Currently further analysis is needed to conclude on whether there is a causal relationship with the vaccines, and the PRAC is requesting additional data from the companies marketing them.

Myocarditis and pericarditis are inflammatory diseases of the heart that can occur following infections or immune diseases. Depending on the source, the incidence of myocarditis and pericarditis in the EEA ranges from 1 to 10 in 100,000 people per year. Symptoms of myocarditis and pericarditis can vary but often include shortness of breath, a forceful heartbeat that may be irregular, and chest pain. The conditions usually improve on their own or with treatment.

The PRAC encourages all healthcare professionals to report any cases of myocarditis or pericarditis and other adverse events in people having these vaccines. Patients who have symptoms such as shortness of breath, a forceful heartbeat that may be irregular, and chest pain following vaccination should consult their doctor.

EMA is working closely with other medicines authorities including the Israeli medicines authority. Any new data that become available will feed into PRAC's ongoing evaluation, and EMA will update its advice as necessary.

[1] As of end of May 2021, cases of myocarditis reported in the EEA from EudraVigilance database were: 122 (Comirnaty), 16 (COVID-19 Vaccine Moderna), 38 (Vaxzevria) and 0 for COVID-19 Vaccine Janssen. The exposure in the EEA for each vaccine was around 160 million doses for Comirnaty, 19 million doses for Moderna, 40 million for Vaxzevria and 2 million for Janssen.
[2] As of end of May 2021, cases of pericarditis reported in the EEA from EudraVigilance database were: 126 (Comirnaty), 18 (COVID-19 Vaccine Moderna), 47 (Vaxzevria) and 1 (COVID-19 Vaccine Janssen).
The exposure in the EEA for each vaccine was around 160 million doses for Comirnaty, 19 million doses for Moderna, 40 million for Vaxzevria and 2 million for Janssen.

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More about the vaccines

COVID-19 vaccines work by preparing the body to defend itself against COVID-19. Comirnaty and COVID-19 Vaccine Moderna contain a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

Vaxzevria and COVID-19 Vaccine Janssen are made up of another virus (adenovirus) that has been modified to contain the gene for making the spike protein.

Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells to attack it.

More about the procedures

For Comirnaty and COVID-19 Vaccine Moderna the PRAC is reviewing cases of myocarditis and pericarditis in the context of a safety signal, under an accelerated timetable (finalisation expected in July). A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine such as a vaccine and that warrants further investigation.

For Vaxzevria and COVID-19 Vaccine Janssen, the PRAC is reviewing the cases in the context of the vaccines' Monthly Summary Safety Reports, also referred to as pandemic summary safety reports, which are compiled by the marketing authorisation holders to support timely and continuous benefit-risk evaluations of COVID-19 vaccines used during the pandemic.

These reports complement the submission of Periodic Safety Update Reports (PSURs), the vaccines' routine benefit-risk assessment.

The review is being carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the committee responsible for the evaluation of safety issues for human medicines. Once the review is completed, PRAC will make any recommendations necessary to minimise risks and protect patients' health.

The rare cases of myocarditis and pericarditis were also considered by EMA's human medicines committee (CHMP) when evaluating the use of Comirnaty in children.[3]

[3] https://www.ema.europa.eu/en/news/first-covid-19-vaccine-approved-children-aged-12-15-eu