EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

COVID-19 Vaccine AstraZeneca: PRAC investigating cases of thromboembolic events - vaccine's benefits currently still outweigh risks - Update

News 11/03/2021

EMA is aware that the Danish Health Authority has paused its vaccination campaign with COVID-19 Vaccine AstraZeneca. This was decided as a precautionary measure while a full investigation is ongoing into reports of blood clots in people who received the vaccine, including one case in Denmark where a person died. Some other Member States have also paused vaccination with this vaccine.

There is currently no indication that vaccination has caused these conditions, which are not listed as side effects with this vaccine. The position of EMA's safety committee PRAC is that the vaccine's benefits continue to outweigh its risks and the vaccine can continue to be administered while investigation of cases of thromboembolic events is ongoing. PRAC is already reviewing all cases of thromboembolic events, and other conditions related to blood clots, reported post-vaccination with COVID-19 Vaccine AstraZeneca.

The number of thromboembolic events in vaccinated people is no higher than the number seen in the general population. As of 10 March 2021, 30 cases[1] of thromboembolic events had been reported among close to 5 million people vaccinated with COVID-19 Vaccine AstraZeneca in the European Economic Area.

EMA will further communicate as the assessment progresses.

More about the medicine

COVID-19 Vaccine AstraZeneca is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus. COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2. COVID-19 Vaccine AstraZeneca does not contain the virus itself and cannot cause COVID-19.

The most common side effects with COVID-19 Vaccine AstraZeneca are usually mild or

moderate and improve within a few days after vaccination.

More about the procedure

The review of thromboembolic events with COVID-19 Vaccine AstraZeneca is being carried out in the context of a safety signal, under an accelerated timetable. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation.

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.

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[1] Cases reported in EudraVigilance, the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA)

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