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EMA's safety committee continues investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events – further update

Several authorities responsible for national vaccine campaigns in EU countries have temporarily paused vaccination with COVID-19 Vaccine AstraZeneca. This is a precaution taken in the light of their national situation while EMA investigates a number of events of blood clots in people who had received the vaccine, as previously reported.

Events involving blood clots, some with unusual features such as low numbers of platelets, have occurred in a very small number of people who received the vaccine. Many thousands of people develop blood clots annually in the EU for different reasons. The number of thromboembolic events overall in vaccinated people seems not to be higher than that seen in the general population.
EMA is working closely with the company, with experts in blood disorders, and with other health authorities including the UK's MHRA based on its experience with around 11 million administered doses of the vaccine.

EMA's investigation has been continuing over the weekend, and rigorous analysis of all the data related to thromboembolic events will be carried out in the coming days. Experts are looking in great detail at all the available data and clinical circumstances surrounding specific cases to determine whether the vaccine might have contributed or if the event is likely to have been due to other causes. EMA's safety committee (PRAC) will further review the information tomorrow (Tuesday) and has called an extraordinary meeting on Thursday 18 March to conclude on the information gathered and any further actions that may need to be taken.

The COVID-19 pandemic is a global crisis, with devastating health, social and economic impact, and continues to be a major burden on EU health systems. Vaccines for COVID-19 help to protect individuals from becoming ill, especially healthcare professionals and vulnerable populations, such as older people or those with chronic diseases. While its investigation is ongoing, EMA currently remains of the view that **the benefits of the AstraZeneca vaccine in preventing COVID-19, with its associated risk of hospitalisation and death, outweigh the risks of side effects**.

EMA will continue to communicate further as appropriate. In the meantime, anyone who has received the vaccine and has any concerns should contact an appropriate healthcare professional. It is important that people who suspect they may have a side effect after vaccination report this to the national medicines regulator, or to a healthcare professional who can help them do so.

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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 such as a vaccine 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.