16 March 2020
EMA/163893/2021

Investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events continues

EMA's safety committee (PRAC) made further progress today, Tuesday 16 March, in its detailed evaluation of cases of blood clots, some with unusual features such as low numbers of platelets, in recipients of COVID-19 Vaccine AstraZeneca. As previously stated, 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.

The evaluation is looking at the available data related to all thromboembolic events reported after vaccination. National agencies are providing additional support to gather missing and incomplete information as quickly as possible, particularly where it relates to these unusual cases. Rapid and thorough analysis of the available data and clinical circumstances surrounding specific cases is continuing, to determine whether the vaccine might have contributed or if events are likely to have been due to other causes.

PRAC will conclude on the information available at its meeting on Thursday 18 March, and issue any necessary recommendations for further action.

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.

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