REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

COVID-19 Vaccine AstraZeneca: PRAC preliminary view suggests no specific issue with batch used in Austria

The Austrian national competent Authority has suspended the use of a batch of COVID-19 Vaccine AstraZeneca (batch number ABV5300) after a person was diagnosed with multiple thrombosis (formation of blood clots within blood vessels) and died 10 days after vaccination, and another was hospitalised with pulmonary embolism (blockage in arteries in the lungs) after being vaccinated. The latter is now recovering. As of 9 March 2021, two other reports of thromboembolic event cases had been received for this batch.

There is currently no indication that vaccination has caused these conditions, which are not listed as side effects with this vaccine.

Batch ABV5300 was delivered to 17 EU countries[1] and comprises 1 million doses of the vaccine. Some EU countries[2] have also subsequently suspended this batch as a precautionary measure, while a full investigation is ongoing. Although a quality defect is considered unlikely at this stage, the batch quality is being investigated.

EMA's safety committee PRAC is reviewing this issue; it is investigating the cases reported with the batch as well as all other cases of thromboembolic events, and other conditions related to blood clots, reported post-vaccination. The information available so far indicates that the number of thromboembolic events in vaccinated people is no higher than that seen in the general population. As of 9 March 2021, 22 cases of thromboembolic events had been

[1] Austria, Bulgaria, Cyprus, Denmark, Estonia, France, Greece, Iceland, Ireland, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Spain, Sweden.
[2] As of 9 March 2021: Estonia, Lithuania, Luxembourg, Latvia

reported among the 3 million people vaccinated with COVID-19 Vaccine AstraZeneca in the European Economic Area.

PRAC will continue its assessment of any potential issue with the batch as well as its review of thromboembolic events and related conditions.

EMA will further communicate as the assessment progresses.

_____

Ministry of Health
11 March 2021