COVID-19 Vaccine AstraZeneca

European Medicines Agency's Pharmacovigilance Risk Assessment Committee preliminary view suggests no specific issue with batch used in Austria

11/03/2021 | Circular Number P01/2021

Information on COVID-19 Vaccine AstraZeneca

In Malta the COVID-19 Vaccine AstraZeneca is authorised through the centralised procedure

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
ChAdOx1-S	COVID-19 Vaccine AstraZeneca	Suspension for injection	POM	EU/1/21/1529/001-002	AstraZeneca AB

Information about the safety concern and the situation in Malta

The Malta Medicines Authority is aware that Austria has suspended a single batch for COVID-19 Vaccine AstraZeneca regarding deep vein thrombosis (DVT; a blood clot in a leg vein) reported on 2 spontaneous adverse reports as a precautionary measure. These cases are being investigated in Austria and at the level of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee.

Today, the Danish Ministry of Health in Denmark has issued a press release that on a precautionary basis they have paused their vaccination campaign at a product level pending investigation of these cases.

In Malta to date 11/03/2021 no deep vein thrombosis cases with COVID-19 Vaccine AstraZeneca have been reported to the Malta Medicines Authority or by the Marketing Authorisation Holder directly to Eudravigilance (the European Union's database of adverse drug reactions). It is important to point out that European Union Directives codifies that if a

national suspension of a medicinal product occurs in any member state at the level of the marketing authorisation an article 107i procedure has to be triggered at the level of the European Union and the European Medicines Agency. To date, this required procedure has not been triggered by Denmark or Austria, and therefore the benefit/risk of the COVID-19 Vaccine AstraZeneca remains positive in the authorised indications.

As per the European Medicines Agency's press release of 10/3/2020:

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 European Union 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.

European Medicines Agency's safety committee Pharmacovigilance Risk Assessment Committee 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 reported among the 3 million people vaccinated with COVID-19 Vaccine AstraZeneca in the European Economic Area.

The Pharmacovigilance Risk Assessment Committee will continue its assessment of any potential issue with the batch as well as its review of thromboembolic events and related conditions.

The European Medicines Agency will further communicate as the assessment progresses.

For more information please see the European Medicines Agency's press release

[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

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on COVID-19 Vaccine AstraZeneca. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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