COVID-19 Vaccine AstraZeneca

Review of very rare cases of unusual blood clots concluded

Possible link between the vaccine and the occurrence of thrombosis in combination with thrombocytopenia

08/04/2021 | Circular Number P04/2021

Information on COVID-19 Vaccine AstraZeneca

COVID-19 Vaccine AstraZeneca is authorised by the European Commission

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

Information about updated recommendations following further discussions held at the level of the Pharmacovigilance Risk Assessment Committee (PRAC) with regards the signal of COVID-19 Vaccine AstraZeneca and thromboembolic events

The European Medicines Agency (EMA) concluded the evaluation of a signal procedure of rare and unusual blood clots and Vaxzevria. The outcome of the evaluation resulted in a conclusion that there could be a possible link between combined thrombosis and thrombocytopenia with the COVID-19 Vaccine AstraZeneca in rare cases.

The signal procedure is expected to result in an update to the Summary of Product Characteristics (SmPC) sections 4.4 (Special warnings and precautions for use) and 4.8 (Undesirable effects).

Furthermore, a direct healthcare professional communication (DHPC) is being proposed to update and inform HCPs with the current knowledge of the safety issue as well as a number of studies to further investigate and characterise the possible link. The product risk management plan (RMP) will also be updated with this new information.

To date the marketing authorisation as issued by the European Commission is still valid and restrictions in the vaccine's use, from a regulatory perspective, <u>are not being proposed.</u>

More information on the European Medicines Agency's press release is available here:

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:

We thank you for your interest and look forward to hearing your opinion.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000