COVID-19 Vaccine AstraZeneca

Update following extraordinary meeting of the Pharmacovigilance Risk Assessment Committee (PRAC) to review thromboembolic events

Benefits still outweigh the risks

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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 outcome of discussions held at the level of the Pharmacovigilance Risk Assessment Committee with regards the COVID-19 Vaccine AstraZeneca and thromboembolic events

The benefit / risk of the COVID-19 Vaccine AstraZeneca remains positive although very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets have been observed in patients who had received the vaccine.

After a detailed analysis and long discussions held at the level of the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) with participation of representatives from Malta, it was decided that a description of the data should be included in the summary of product characteristics (SmPC), which is used by healthcare professionals.

A causal link of such cases with the vaccine is not proven and will be analysed further, but as is normally done in such procedures, the product information will be updated with information on cases of blood clots that have occurred.

The vaccination campaign should continue since the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself can result in clotting problems) continue to

outweigh the risk of side effect. If the benefit / risk, following this careful review, was negative the AstraZeneca COVID-19 vaccine would have been suspended by the European Medicine Agency.

As per the European Medicines Agency's press release of 18/3/2021:

EMA's safety committee, PRAC, concluded its preliminary review of a signal of blood clots in people vaccinated with COVID-19 Vaccine AstraZeneca at its extraordinary meeting of 18 March 2021. The Committee confirmed that:

- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it;
- there is no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites;
- however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets (elements in the blood that help it to clot) with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (CVST).

These are rare cases – around 20 million people in the UK and EEA had received the vaccine as of March 16 and EMA had reviewed only 7 cases of blood clots in multiple blood vessels (disseminated intravascular coagulation, DIC) and 18 cases of CVST. A causal link with the vaccine is not proven but is possible and deserves further analysis.

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

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)

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Pharmacovigilance Section

Post-Licensing Directorate

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