Ref: 04/2021/PLD

02/06/2021

Direct Healthcare Professional Communication

**VAXZEVRIA/COVID-19 Vaccine AstraZeneca: Risk of thrombosis in combination with thrombocytopenia – Updated information**

Dear Healthcare Professional,

Please refer to previous Direct Healthcare Professional Communications (DHPCs) of 24th March and 13th April 2021.

AstraZeneca AB in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

## Summary

- **Vaxzevria is contraindicated in individuals who have experienced Thrombosis with Thrombocytopenia Syndrome (TTS) following previous vaccination with Vaxzevria.**

- **TTS requires specialised clinical management. Healthcare professionals should consult applicable guidance and/or consult specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.**

- **Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with Vaxzevria should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.**

The Vaxzevria Summary of Product Characteristics (SmPC) has been updated accordingly with this information.

## Background on the safety concern

Vaxzevria is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Vaxzevria. This includes severe cases presenting as venous thrombosis, including in unusual sites, such as cerebral venous sinus thrombosis and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. Some cases had a fatal outcome. The majority of these cases occurred in the first three weeks following vaccination and occurred mostly in women under 60 years of age.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, blurred vision, confusion or seizures after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Individuals presenting with thrombocytopenia within 3 weeks after vaccination should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

## Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions associated with Vaxzevria in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.

Please note the importance of reporting the vaccine product name and batch details.

## Company contact point

Should you have any questions or require additional information, please contact AstraZeneca Medical Information at:

| Company | Product Name | Website | Phone |
|---|---|---|---|
| **Associated Drug Company Limited**<br>Triq l-Esportaturi, Zone 1,<br>Central Business District,<br>Birkirkara CBD 1040<br>Malta | Vaxzevria | www.azcovid-19.com | +356 22778134 |

Yours faithfully,
**Post-Licensing Directorate**
**Medicines Authority**

***Disclaimer***
*This Direct Healthcare Professional Communication has been submitted to you on behalf of AstraZeneca AB and their local representative Associated Drug Company Limited*