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 <XX> March and <XX> April, 2021.

AstraZeneca AB in agreement with the European Medicines Agency and the <National Competent 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

Healthcare professionals should report any suspected adverse reactions associated with the use of Vaxzevria in accordance with the national spontaneous reporting system *<include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>*.

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

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address (company contact point in the concerned EU MS should be included, respectively)>

Yours Faithfully

Medical Director of AstraZeneca AB

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	VAXZEVRIA/COVID-19 Vaccine AstraZeneca suspension for injection (ChAdOx1-S [recombinant])
Marketing authorisation holder(s)	AstraZeneca AB
Safety concern and purpose of the communication	To communicate the addition of the contraindication, the need for expert consultation for diagnosis and treatment, and the need of a high level of suspicion for thrombosis if thrombocytopenia is diagnosed and vice versa.
DHPC recipients	General practitioners, specialists in internal medicine, haematology, emergency medicine and vaccination centres. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	All EU member states where VAXZEVRIA/COVID-19 Vaccine AstraZeneca is marketed.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	20th May 2021
DHPC and communication plan (in English) agreed by CHMP	20th May 2021
Submission of translated DHPCs to the national competent authorities for review	24th May 2021
Agreement of translations by national competent authorities	26th May 2021
Dissemination of DHPC	2nd June 2021