Date: (XX October 2021)

VAXZEVRIA™/COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia (including immune thrombocytopenia) with or without associated bleeding

Dear Healthcare professional,

AstraZeneca AB, in agreement with the European Medicines Agency and the <National Competent Authority >, would like to provide you with the following updated information:

Summary

- **Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination.**
- **Very rarely, these events of thrombocytopenia presented with very low platelet levels (<20,000 per µL) and/or were associated with bleeding.**
- **Some of these cases occurred in individuals with a history of immune thrombocytopenia.**
- **Cases with fatal outcome have been reported.**
- **If an individual has a history of a thrombocytopenic disorder, such as immune thrombocytopenia, the risk of developing low platelet levels should be considered before administering the vaccine and platelet monitoring is recommended after vaccination.**

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.

Cases of thrombocytopenia, including the autoimmune condition of immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination. Very rarely, these events of thrombocytopenia presented with very low platelet levels (<20,000 per microliter) and/or were associated with bleeding. Cases with fatal outcome have been reported.

The European Medicines Agency has recommended an update to the product information of the Vaxzevria suspension for injection to reflect the current knowledge of the safety topic.

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.

Please note the importance of reporting the vaccine product name and batch details.
<include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

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	Thrombocytopenia (including immune thrombocytopenia) with or without associated bleeding: To communicate updated information on the topic
DHPC recipients	General practitioners, specialists in internal medicine, haematology 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 COVID-19 Vaccine AstraZeneca is marketed.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	30 September 2021
DHPC and communication plan (in English) agreed by CHMP	1 October 2021
Submission of translated DHPCs to the national competent authorities for review	4 October 2021
Agreement of translations by national competent authorities	8 October 2021
Dissemination of DHPC	13 October 2021