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13th October 2021

Re: 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 Health Products Regulatory Authority (HPRA), 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:

HPRA Pharmacovigilance
Website: www.hpra.ie and include the batch/lot number if available.

Adverse events should also be reported to AstraZeneca Patient Safety on 1800 812456.

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

Company contact point

AstraZeneca Medical Information
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Yours Faithfully

DocuSigned by:
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Daniel Wygal
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