The Arab Republic of Egypt
Egyptian Drug Authority
Central Administration for Pharmaceutical Care
General Administration for Pharmaceutical Vigilance

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للرعاية الصيدلية
الإدارة العامة لليقظة الصيدلية

Direct Healthcare Professional Communication

24-October-2021

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

Dear Healthcare Professional,

Please refer to previous Direct Healthcare Professional Communications (DHPC) of 8 April, 2021, 6 June, 2021 and 27 June, 2021.

VACSERA in agreement with the Egyptian Pharmaceutical Vigilance Center in The Egyptian Drug Authority would like to inform you of the following:

Summary

- **Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Covid-19 vaccine AstraZeneca, typically within the first four weeks after vaccination.**

■ **Very rarely, these events of thrombocytopenia presented with very low platelet levels (<20,000 per ttL) 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.**

The Covid-19 Vaccine AstraZeneca Summary of Product Characteristics (SmPC) has been updated accordingly with this information.

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The Egyptian Drug Authority is following closely all safety updates outside Egypt and along with the ministry of health is evaluating all reported adverse events cases within Egypt to detect any change in the vaccine safety profile.

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

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of COVID-19 Vaccine AstraZeneca. Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@ edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Company contact point:

Name: VACSERA (The Holding Company for Biological Products and Vaccines) **Address:** 51 Wezaret El-Zeraa-Agouza-Giza-Egypt **Telephone:** +202 37603922 +202 37611111, Extension: 7222,7134

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