Safety Communication

[09/4/2021]

Oxford/AstraZeneca COVID-19 Vaccine: Potential Risk of Thrombosis and Thrombocytopenia

The Saudi Food and Drug Authority (SFDA) is issuing this safety communication to aware healthcare professionals about the possibility of very rare cases of thrombosis combined with thrombocytopenia occurring within 2 weeks of vaccination with Oxford/AstraZeneca COVID-19 Vaccine.

The vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2. Cases of thromboembolic events have been reported following administration of the vaccine in several countries worldwide including Saudi Arabia. A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Oxford/AstraZeneca COVID-19 Vaccine. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first 4 to 20 days following vaccination. Some cases had a fatal outcome.

The SFDA has conducted a comprehensive investigation of locally and internationally reported cases related to thrombosis and thrombocytopenia in individuals who received the vaccine taking in consideration all information related to sex, age, risk factors, time-to-onset, outcome, and clinical condition.

The investigation has also included literature review of available data and documents submitted by the manufacturing company.

Based on the available evidence, the benefits of Oxford/AstraZeneca Vaccine in preventing COVID-19 outweigh potential risks. No specific risk factors, so far, have been found to be correlated with risk of thrombosis and thrombocytopenia with the vaccine. It is important to note that this type of adverse event can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease.

Advice for healthcare providers:

- Vaccinees should be instructed to seek medical attention if they develop the following symptoms:
  - Shortness of breath.
  - Chest pain.
  - Leg swelling.
  - Persistent abdominal pain.
  - Neurological symptoms, such as severe and persistent headache or blurred vision.
  - Petechiae beyond the site of vaccination after few days of administration.

- The benefit/risk in individuals at increased risk of thromboembolic events (including autoimmune disease, oral contraceptive use, or prior history of thromboembolic events) should be evaluated before vaccination.

Call for reporting:

Healthcare professionals should report any suspected adverse events related to the use of COVID-19 vaccines to the National Pharmacovigilance Center via below reporting channels:

COVID Vaccine adverse event electronic reporting form:
(https://ade.sfda.gov.sa/Covid/CovidRequest)

Email : NPC.drug@sfda.gov.sa