SFDA
Safety Communication

3 August 2021

The Saudi Food and Drug Authority Statement on reports of Guillain-Barré Syndrome Following AstraZeneca COVID-19 Vaccine

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about the potential risk of Guillain-Barré syndrome (GBS) following the use of AstraZeneca COVID-19 vaccine.

GBS is a rare neurological disorder affecting primarily peripheral nerves, which can cause muscle weakness and in severe cases can progress to complete paralysis and even death. Symptoms may include difficulty in walking; difficulty with facial movements; double vision or inability to move eyes; or difficulty controlling bladder or bowel functions.

The SFDA reviewed all the measures that have been established by the international regulatory bodies on the potential risk of GBS with AstraZeneca COVID-19 vaccine. Based on the available evidence, the SFDA considered that relationship between AstraZeneca COVID-19 vaccine and GBS is possible.

Overall, the potential benefits of AstraZeneca COVID-19 vaccine continues to outweigh any potential risks, and based on that, the SFDA recommends the following:

1- Cases of GBS have occurred very rarely after vaccination with the AstraZeneca COVID-19 vaccine.

2- Healthcare providers should advise people receiving AstraZeneca COVID-19 vaccine to seek immediate medical attention if they develop symptoms suggestive of GBS, including weakness, tingling and paralysis in the extremities that may progress to other parts of the body including the chest and face.

3- The product information of AstraZeneca COVID-19 vaccine will be updated to include GBS risk.

The SFDA is carefully monitoring all the safety data of registered COVID-19 vaccines, including AstraZeneca COVID-19 vaccine, and will update any advice as necessary.

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:

SFDA Call Center: 19999

COVID Vaccine adverse event electronic reporting form:

(https://ade.sfda.gov.sa/Covid/CovidRequest)

Email: NPC.drug@sfda.gov.sa