FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233)-302-233200/235100
(+233)-551-112223/4/5 (Hotline)
Email: fda@fda.gov.gh
Digital Address: GA-237-7316

FDA/HPT/SMC/SMD/VGU/22/0399 24th August 2022

Dear Healthcare Professional,

SAFETY ALERT: COVID 19 VACCINE JANSSEN

The Food and Drugs Authority (FDA) would like to update healthcare professionals on the following adverse events following immunization (AEFI) to COVID-19 vaccine Janssen, namely, capillary leak syndrome (CLS), thrombosis with thrombocytopenia syndrome (TTS), thrombocytopenia (ITP) and venous thromboembolism (VTE).

The FDA has not received any report of these AEFIs to COVID-19 vaccine Janssen or any COVID-19 vaccine being deployed through its rigorous safety monitoring system.

COVID-19 Vaccine Janssen suspension for injection is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Capillary leak syndrome (CLS):

- Very rare cases of CLS have been reported in the first days after vaccination with COVID-19 Vaccine Janssen, in some cases with a fatal outcome. For all the cases reported, at least one had a history of CLS.
- COVID-19 Vaccine Janssen is now contraindicated in individuals who have previously experienced episodes of CLS.
- CLS is characterized by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Patients with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted.

Thrombosis with thrombocytopenia syndrome (TTS)

- Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.
- TTS requires specialized clinical management. Healthcare professionals should consult specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.

Immune thrombocytopenia (ITP):

- Cases of ITP, some with very low platelet levels (<20,000µL), have been reported very rarely, usually within the first four weeks after receiving COVID-19 Vaccine Janssen. This included cases with bleeding and cases with a fatal outcome. Some of these occurred in individuals with a history of ITP.

- If an individual has a history of ITP, the risks of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination.

- Individuals should be alert to signs and symptoms of ITP, such as spontaneous bleeding, bruising or petechiae.

- Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialized clinical management.

Venous thromboembolism (VTE):

- Venous thromboembolism has been observed rarely following vaccination with COVID-19 Vaccine Janssen.

- The risk of VTE should be considered for individuals with increased risk for thromboembolism.

- Healthcare professionals should be alert to the signs and symptoms of VTE. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination.

- Individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) that requires specialized clinical management

The FDA would like to reiterate that COVID-19 vaccine Janssen have been shown to be safe and effective and the benefits of vaccination continue to outweigh any potential risks of side effects.

Healthcare professionals are encouraged to report adverse events following immunization to COVID-19 vaccine Janssen and any other health products to FDA by completing the AEFI form or call **024 431 0297** or send email to drug.safety@fda.gov.gh or through the Med Safety App which is available for free on Google play store or App Store.

Yours faithfully,

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER