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

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Dear Healthcare Professional,

IMPORTANT SAFETY INFORMATION

RARE EVENTS OF THROMBOSIS AND THROMBOCYTOPENIA FOLLOWING VACCINATION WITH COVID-19 VACCINE ASTRAZENECA

The Food and Drugs Authority (FDA) has followed closely and reviewed information on a few reports, from Europe, of thrombotic events in people who received *COVID-19 Vaccine AstraZeneca*. These rare reports consisted of blood clots associated with thrombocytopenia, with or without bleeding, including rare cases of cerebral venous sinus thrombosis (CVST) i.e. clots in the vessels draining blood from the brain.

After extensive in-depth review and assessment, both the European Medicines Agency (EMA) and the World Health Organization (WHO) have concluded that the benefits of using the AstraZeneca COVID-19 Vaccine far outweigh the potential risk of thrombotic events.

So far over 50 million doses of the AstraZeneca Covid-19 vaccine have been administered in countries such as India, UK, Ghana and countries in the European Union and in all these countries, the vaccines have been shown to be well tolerated with a few minor adverse events.

Whilst no causal link has been found between the reported thrombotic events and the AstraZeneca Covid-19 vaccine, it is important to have heightened vigilance by identifying, investigating and assessing all serious adverse events that occur after vaccine administration irrespective of whether they are suspected to be caused by the vaccine or not.

In view of the above, the FDA advises health care professionals to closely monitor persons vaccinated and ask them to seek immediate medical attention if they develop any of the underlisted after vaccination:

- shortness of breath, chest pain, leg swelling, persistent abdominal pain.
- neurological symptoms including severe or persistent headaches or blurred vision, headache for more than 4 days after vaccination, or experiences skin bruising (petechia) beyond the site of vaccination after a few days.

The Authority further wishes to inform all healthcare workers that it has established the Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) that regularly assess all reported adverse events and makes recommendations on the safety of COVID-19 vaccines. The Committee, which meets in-person every 2 weeks continuously assesses the latest available safety data for all FDA authorised COVID-19 vaccines. After each in-person meeting, the Committee communicates its findings to the public.

The Authority is also in regular contact with the WHO, EMA and regulators around the world for the latest information on COVID-19 vaccine safety.

The FDA and the JCVSRC sees healthcare workers as key partners in ensuring safe vaccines and healthcare products in Ghana and welcomes any enquiries or suggestions.

Healthcare professionals should report adverse events to the FDA's SafetyWatch Adverse Event Reporting programme through the following:

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at http://adr.fdaghana.gov.gh/patient.php;
- Call Mobile No. 024 4310 297
- Download and complete the AEFI Form, then submit it at the nearest heath facility

Yours faithfully,

Signed

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CHIEF EXECUTIVE OFFICER