

FOOD AND DRUGS AUTHORITY **REGULATORY UPDATE**



Identification Number: FDA/CSD/CPE/PRS/22/013 TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY

11th February 2022

JOINT COVID-19 VACCINE SAFETY REVIEW COMMITTEE - SAFETY MONITORING

UPDATE NO. 13

The Food and Drugs Authority (FDA) continues to undertake robust safety monitoring of all Covid-19 vaccines deployed in the country. The Committee meets regularly to review safety information and to design strategies that help to ensure that all COVID-19 vaccines used in Ghana remain safe and are deployed safely across the country. This ensures that the benefits of vaccination continue to outweigh any risks.

As at 2nd February 2022, over 10 million doses of the five Covid-19 vaccines granted Emergency Use Authorization (EUA) by the FDA had been administered to combat the pandemic. The cumulative doses of the five vaccines consist of 6,979,491 doses of Oxford/AstraZeneca, 1,354,527 of Pfizer, 1,054,371 of Moderna, 883,772 doses of Johnson & Johnson and 17,982 doses of Sputnik V COVID-19 vaccines.

The Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) at its 14th meeting held on 3rd February 2022, reviewed all safety reports received from the vaccinations in Ghana including those from pregnant women and persons aged 15-17-years old who have recently been included in the vaccinations. The Committee concluded that there were no safety concerns with the vaccinations in the two newly included groups. The safety reports and reporting patterns after these groups were included have not changed. Nonetheless, the Committee will have closer attention to these 2 new groups so that no safety issues that occur are missed.

Monitoring of all vaccinees will continue with the same rigour as the FDA and EPI have done since COVID-19 vaccination started.

The JCVSRC also reviewed cases of "appetite loss" reported as a side effect following vaccination with Janssen COVID-19 Vaccine. The Committee concluded that there was no evidence for a causal relationship between the Janssen COVID-19 vaccine and "appetite loss" but recommended continuous monitoring of this event by the FDA and FPI.

The Committee, after careful and exhaustive review of the accumulating safety data on Covid-19 vaccines since vaccination started in Ghana, concluded that the COVID-19 vaccines being deployed in Ghana are safe and effective, and advises continuous use of the vaccines as well as continuous dissemination of information to vaccine recipients on how to report any side effects they may experience.

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