



Identification Number: FDA/CSD/CPE/PRS/21/010 TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY

4th October 2021

JOINT COVID-19 VACCINE SAFETY REVIEW COMMITTEE- SAFETY MONITORING

UPDATE 10

The Food and Drugs Authority (FDA) continues to maintain high vigilance during the deployment of COVID-19 vaccines in Ghana as part of its regulatory mandate to ensure public health and safety. As of 29th September 2021, there have been no major safety concerns in relation to COVID-19 vaccine deployment in Ghana.

Four vaccines namely, Oxford/AstraZeneca vaccine (Covishield, Vaxzeveria), Sputnik V, Johnson & Johnson vaccine (COVID-19 Vaccine Janssen) and Moderna vaccine (Spikevax) have been deployed in Ghana to combat the pandemic. The total doses of the four vaccines administered is 1,659,884 consisting of 1,474,721 doses of Oxford/AstraZeneca vaccine, 165,699 doses of Johnson & Johnson vaccine, 16,570 doses of Sputnik V and 2,894 of Moderna vaccine.

To date, side effects received by the FDA for the four vaccines deployed are still mild and resolve within a day or two, with the top five reported side effects still being headache, fever, chills, pain at injection site and body pains.

The FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) reviewed all safety reports received from the vaccinations in Ghana and from international sources at the 11th meeting held on 20th and 21st September 2021. This meeting included a full day's meeting with in-depth discussions and experience sharing with the Netherlands Pharmacovigilance Centre, Lareb, to ensure that Ghana's safety monitoring strategies were well aligned with those of similar world-leading regulators.

The JCVSRC recommended the continued vaccination with COVID-19 vaccines granted Emergency Use Authorization by the FDA as vaccination continues to be the most effective way to reduce severe illness and prevent deaths from COVID-19.



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