

FOOD AND DRUGS AUTHORITY REGULATORY UPDATE



Identification Number: FDA/CSD/CPE/PRS/21/006 TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY

26th May 2021

JOINT COVID-19 VACCINE SAFETY REVIEW COMMITTEE- SAFETY MONITORING UPDATE 6

The Food and Drugs Authority (FDA) has successfully carried out safety monitoring of the first round of COVID-19 vaccinations in Ghana without any safety concerns. The Authority has continued to proactively monitor the second dose deployment because vaccination is the only proven means to reduce death and severe illness from COVID-19.

As of Thursday, 20th May 2021, the Expanded Programme on Immunization (EPI) had administered 852,047 first doses and 107,744 second doses of Covishield Vaccine in Ghana with few and mild side effects reported. The most common side effects after the second dose were headache, fever, pain at injection site, body pains and vomiting which resolved within a day or two. Information received from the second dose deployment so far indicates that side effects reported were milder and fewer compared to the first dose.

The FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) held its 7th meeting on Friday, 20th May 2021 and based on information currently available from the FDA's safety monitoring

activities of Covishield as well as from international sources, the JCVSRC continues to be satisfied that the benefits of using Covishield to vaccinate against COVID-19 far exceed any risks the vaccine may pose.

The Committee therefore recommends the continued use of the vaccine and advise that the 2nd dose deployment by the Ghana Health Service should continue and those due to receive their 2nd dose go forward for their vaccine.

The FDA will continue to monitor the safety of Covishield vaccinations and any other approved vaccine that will be deployed to fight the pandemic.



DELESE A. A. DARKO (MRS)

CHIEF EXECUTIVE OFFICER