



## Identification Number: FDA/CSD/CPE/PRS/21/007 TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY

22<sup>nd</sup> June 2021

### JOINT COVID-19 VACCINE SAFETY REVIEW COMMITTEE-SAFETY MONITORING

#### UPDATE 7

The Food and Drugs Authority (FDA) continues the safety monitoring for dose 2 vaccinations and on 17<sup>th</sup> June 2021, a total of 380,829 second doses have been administered with overall fewer and milder side effects received compared to the first dose.

The Expanded Programme on Immunization has to date administered cumulatively **1,232,876** doses of Covishield; out of these **852,047** were **dose 1** and **380,829 dose 2**. The most common side effects continue to be headache, fever, pain at injection site, body pains and vomiting which resolved within a day or two.

At its 8<sup>th</sup> meeting held on **Friday, 18<sup>th</sup> June 2021**, the FDA's Joint COVID-19 Vaccine Safety Review Committee

(JCVSRC) reviewed all safety reports available from the FDA's safety monitoring activities of Covishield as well as from international sources. The JCVSRC was satisfied that the benefits of COVID-19 vaccinations continue to far exceed any risks the vaccine may pose.

The Committee therefore recommends the continued use of the vaccine and advise that the 2<sup>nd</sup> dose deployment by the Ghana Health Service should continue.

The FDA will continue to actively monitor the safety of Covishield and all other vaccines issued with Emergency Use Authorization to be deployed to fight the pandemic.



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