FOOD AND DRUGS AUTHORITY
REGULATORY UPDATE

Identification Number: FDA/CSD/CPE/VSU/21/0002
COVID-19 VACCINES: SAFETY MONITORING UPDATE 2

6th April, 2021

The FDA, as mandated by Section 125 of the Public Health Act 2012, Act 851 continues to monitor Ghana's COVID-19 Vaccination Programme using its robust safety monitoring system.

The Authority as of Friday, 26th March 2021 had received **1,679 reports** of suspected adverse events (side effects) after the administration of approximately **490,000 doses** of Covishield Vaccines in Ghana. The most commonly reported adverse events were headache, fever, weakness, body pains, chills, pains at injection site, malaise and dizziness.

The Joint COVID-19 Vaccine Safety Review (JCVSR) Committee at its 3 rd meeting held on 26th March 2021 discussed these reported adverse events in addition to an in-depth review of nine (9) suspected serious adverse events. Following assessment of causality, the JCVSR concluded that eight (8) of the serious events were unrelated to the vaccine but one (a case of febrile illness) was considered as vaccine product related.

The Committee maintains that based on review of the side effects received and the expected benefit of the vaccine to prevent COVID-19 infections, hospitalization and reduce deaths, the Covishield Vaccine continues to have a positive benefit-risk profile in Ghana and should be used as part of the key strategies to contain Covid-19.

The Committee also endorsed the FDA's continuous education and awareness creation programmes targeted at healthcare professionals and the public to encourage reporting of all suspected adverse events after COVID-19 vaccine administration.

The FDA will continue to promote reporting of adverse events and continuously review all safety data received in Ghana and from all over the world and will update the general public of any changes in the benefit-risk profile of the Covishield Vaccine.

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