SAFETYWATCH UPDATE No. 03

COVID-19 Vaccine Safety Monitoring Weekly Update
(16th March to 22nd March 2021)

Summary

This Update No. 3 provides the safety overview of the COVIID-19 vaccine in Ghana for the period 16th to 22nd March 2021. Since publication of Update No. 02 (9th-15th March 2021) (LINK for 2nd update) which provided safety overview for up to the second week of the vaccine deployment, an additional 49,652 doses of the Covishield Vaccine have been given with 140 persons reporting adverse events (commonly known as *side effects)* which are mostly mild flu-like symptoms; headache, fever, chills, weakness and body ache.

The Covishield Vaccine continues to be safe and its benefits outweigh possible risks. The reported *side effects* experienced after vaccination usually resolve within a day or two. Cumulatively, the reporting rate is about 3 adverse event reports for every 1000 persons vaccinated, which signifies that the FDA has in place, a well-established/robust safety monitoring system.

Highlights

- After 3 weeks of vaccinations, a total of 474,419 doses of Covishield Vaccine have been given with 1,629 persons reporting adverse events following immunization (AEFIs); this gives a reporting rate of about 3 reports per 1,000 doses administered.

- Additional 6 serious AEFI[1] reports were received in the third week bring the cumulate number of serious AEFIs to 11 serious reports. The additional serious AEFI reports received will be assessed by the Joint COVID-19 Vaccine Safety Review Committee at the third meeting scheduled for Friday, 26th March 2021.

Demographic Characteristics of Persons Who Reported Adverse Events

- Report by gender and age

The details on those who reported AEFIs were:

- Females 907(55.7%)
- Males 721 (44.3%)
- Unknown 1 (0.1%)
- Mean age 40 (SD =14.2)

Adverse Events Report by Monitoring Type

- Enhanced spontaneous reporting 1250 (76.7%)
- Cohort event monitoring 379 (23.3%)

[1] An AEFI that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a birth defect.

Description of Adverse Events

The top ten most commonly reported adverse events based on the number of times these were reported during the three weeks of vaccinations is shown in Figure 1:

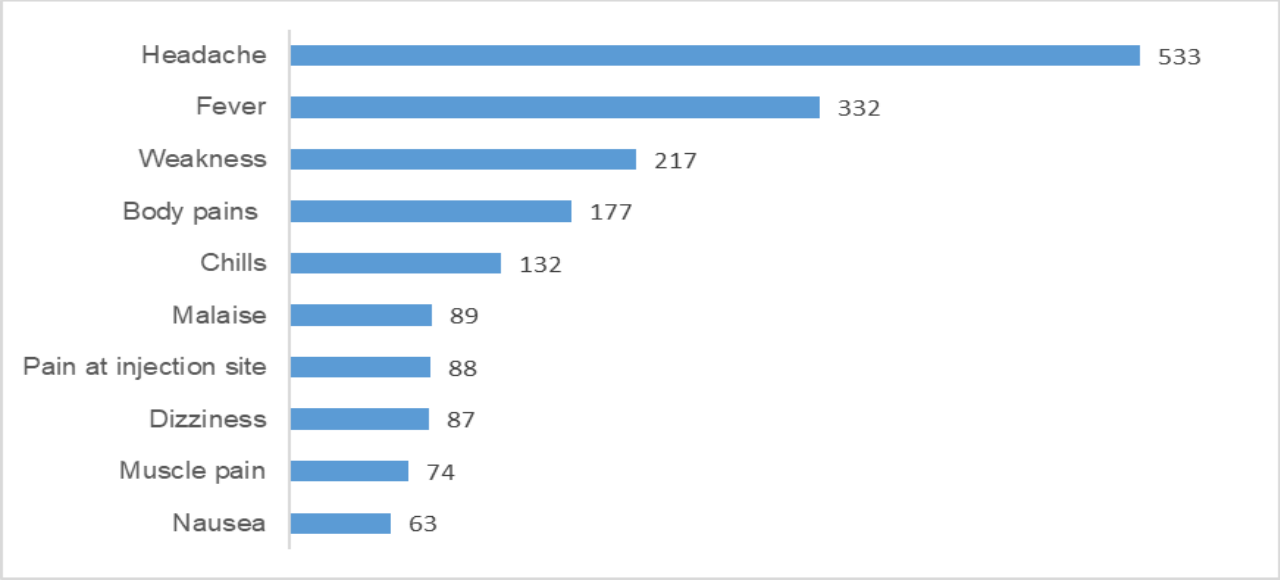

Fig. 1: The top ten most commonly reported events during the two weeks of vaccinations

Assessment of Adverse Event Reports

There might be no relationship between the AEFIs and the vaccine - it may be a coincidence that the adverse events occurred when the vaccine was given.

All adverse event reports received by the FDA are reviewed by the JCVSR Committee to find out the possible link between the events and the vaccine.

How to Report Adverse Events to COVID-19 Vaccines to the FDA

Reporting AEFIs help the FDA have more details about the safety of vaccines to enable any needed regulatory action to be taken to ensure public health and safety.

For any vaccine safety related information or to report AEFIs to COVID-19 vaccines, please contact the FDA through the following:

Mobile: 024 4310 297	**Email:** drug.safety@fda.gov.gh
Hotlines:055 1112 224/ 055 1112 225	**Online:** http://adr.fdaghana.gov.gh/patient.php
WhatsApp: 055 1112 225	**Med Safety App:** Download from the Apple store or Google play store