FOOD AND DRUGS AUTHORITY
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SAFETYWATCH UPDATE No. 01

COVID-19 Vaccine Safety Monitoring Weekly Update
(2nd March to 8th March 2021)

Background

The Food and Drugs Authority, (FDA) Ghana, has granted Emergency Use Authorization to two COVID-19 vaccines for use in Ghana; Covishield (Serum Institute of India) and Sputnik V Vaccines (Generium Joint Stock Company, Russia)
Covishield vaccine is currently being deployed by the Ghana Health Service's Expanded Program on Immunization.

An independent committee of experts, the Joint COVID-19 Vaccine Safety Review Committee, has been put in place by the FDA to review safety information from the COVID-19 vaccinations in Ghana. This expert Committee will make recommendations on the benefit-risk balance of the vaccines to ensure that the COVID-19 vaccines continue to protect people against coronavirus disease and are safe.

COVID-19 vaccines are safe and provide protection against severe disease, however, just like other vaccines, there may be Adverse Events Following Immunization[1] (commonly known as side effects). Most of those reported following COVID-19 vaccination are minor and go away after a day or two. These however need to be continuously balanced against the expected benefits of preventing illness.

The FDA Safety Monitoring Department, in order to obtain as much safety information on the COVID-19 vaccines during the deployment, is supplementing its enhanced spontaneous reporting system with active follow up (cohort event monitoring) of vaccine recipients in five selected health facilities in the Greater Accra, Central and Ashanti regions where the vaccine deployment is currently ongoing.

Highlights

- After 7 days of vaccinations, a total of 262,335 doses have been given with 707 persons reporting adverse events following immunization (AEFIs); this gives a reporting rate of about 3 reports per 1000 doses administered.

- Three serious AEFIs[2] were received during the period.

[1] An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.
[2] An AEFI that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect.

Demographic characteristics

- Report by gender and age

The details on those who reported AEFIs were:

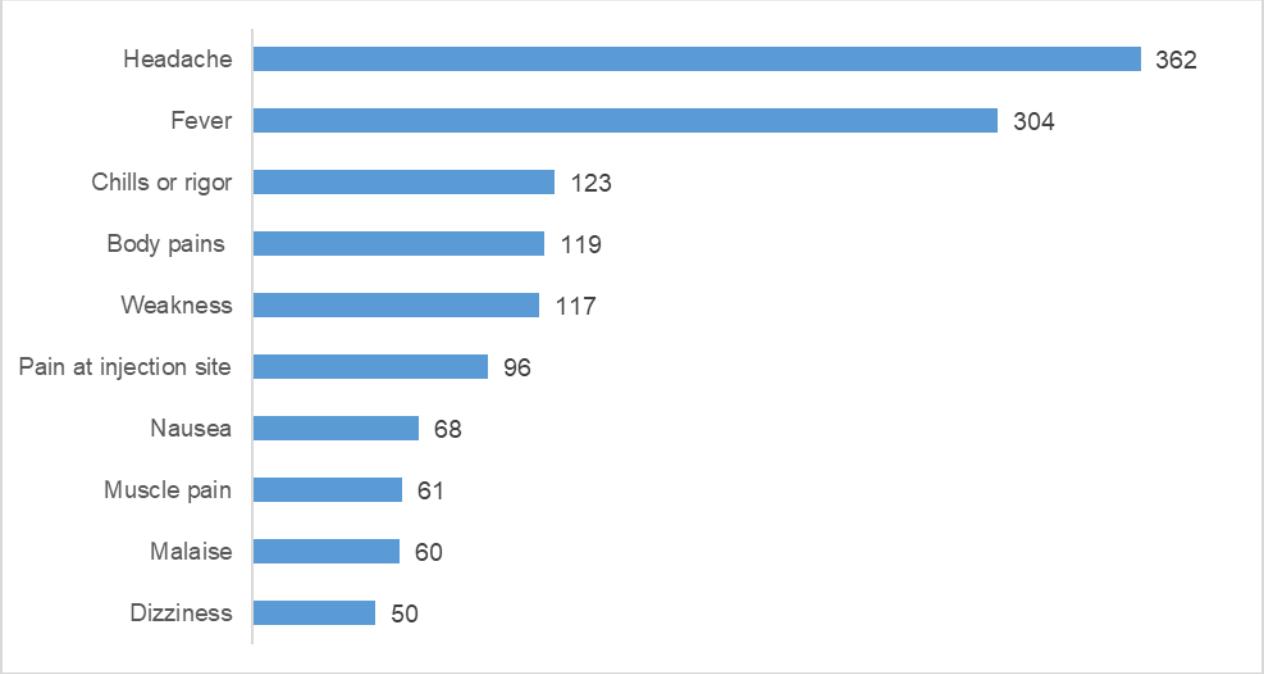
- Females 400(56.6%)
- Males 306 (43.3%)
- Unknown 1(0.1%)
- Mean age 41 (SD =14)

Report by monitoring type

- Enhanced spontaneous reporting 537 (76%)
- Cohort event monitoring 170 (24%)

Description of AEFIs

The top ten most commonly reported AEFIs based on the number of counts in the first week is shown in Figure 1:



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 Joint COVID-19 Vaccine Safety Review Committee to find out the possible link between the events and the vaccine.

How to Report AEFIs 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

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