

# FOOD AND DRUGS AUTHORITY **REGULATORY UPDATE**

## Identification Number: FDA/CSD/CPE/PRS/21/011 **TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY**

#### 9<sup>th</sup> November 2021

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

### **UPDATE 11**

The Food and Drugs Authority (FDA), as part of its regulatory mandate to ensure public health and safety continuously monitors the side effects of all medical products including vaccines deployed for use in Ghana using a robust monitoring, assessment and communication strategy.

The FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) reviews all suspected safety reports received from the vaccinations that are being deployed to combat COVID-19 to ensure comprehensive and effective vaccination in Ghana. All COVID-19 vaccines deployed so far have proven to be safe with almost three million doses administered without any major safety concerns.

Four vaccines namely, Oxford/AstraZeneca vaccine, Sputnik V, Johnson & Johnson vaccine and Moderna vaccine have been used in Ghana to combat the pandemic as at 28<sup>th</sup> October 2021. The total doses of the four vaccines consist of 2,926,669 doses of Oxford/AstraZeneca vaccine, 166,878 doses of Johnson & Johnson vaccine,16,455 doses of Sputnik V and 12,237 of Moderna vaccine.

Side effects reported to date, including headache, fever, chills, pain at injection site and body pains, continue to be mild and resolve within a dav or two.

The Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) at its 12<sup>th</sup> meeting held on 28<sup>th</sup> October 2021, reviewed safety reports received from the vaccinations in Ghana and other countries using the same vaccines.

The Committee concluded that extensive safety monitoring in Ghana and worldwide have proven that the COVID-19 vaccines deployed in Ghana are safe and effective, and therefore advises all Ghanaians who are eligible for the vaccination to turn up in their numbers to receive their COVID-19 vaccine to prevent becoming sick or dying from the disease.

The general public is to contact the nearest Public Health Facility and/or District Health Directorate for information on how they can receive their COVID-19 vaccination.

Meanwhile, the FDA would like to encourage the general public and healthcare professionals to report side effects of all medicines and vaccines using the Med Safety App which can be downloaded from the App Store or Google Play or call Mobile No: 0244 310 297 or Call Centre: 030 825 0070 or send an email to drug.safety@fda.gov.gh.

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**DELESE A. A. DARKO (MRS) CHIEF EXECUTIVE OFFICER** 

