



## Identification Number: FDA/CSD/CPE/PRS/22/014 TYPE OF COMMUNICATION: COVID-19 VACCINE SAFETY

4<sup>th</sup> May 2022

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

### UPDATE NO. 14

The Food and Drugs Authority (FDA) continues to perform its mandate of ensuring the safety of COVID-19 vaccine recipients through a comprehensive and robust safety monitoring of all COVID-19 vaccines deployed in Ghana.

As of 13<sup>th</sup> April 2022, 13,714,484 doses of the five COVID-19 vaccines granted Emergency Use Authorization (EUA) by the FDA had been administered in Ghana. The administered vaccines are as follows:

- 8,780,589 doses of Oxford/AstraZeneca Covid-19 vaccines,
- 2,495,708 doses of Pfizer Covid-19 vaccines,
- 1,356,808 doses of Johnson & Johnson Covid-19 vaccines,
- 1,063,397 of Moderna Covid-19 vaccines and
- 17,982 doses of Sputnik V COVID-19 vaccines

The Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) at its 15<sup>th</sup> meeting held on 13<sup>th</sup> April 2022, reviewed all safety reports received from the vaccinations in Ghana as well as reports

from international sources and found that generally, reports on side effects received in Ghana are rare and consistent with what is expected from the vaccinations. The commonly reported side effects including headache, fever, chills, pain at injection site and body pains, are usually minor and resolved within a day or two.

The JCVSRC also carefully reviewed the preliminary data from the ongoing active monitoring of mRNA COVID-19 vaccines (i.e., Pfizer and Moderna COVID-19 vaccines) in pregnancy across Ghana and concluded that there were no safety concerns. The Committee, therefore, encourages pregnant women to get their vaccinations because available evidence indicate that the benefits of receiving the mRNA COVID-19 vaccines in pregnancy far outweigh any potential risks.

The FDA would like to continue to encourage all those who receive Covid-19 vaccines and all other vaccines to report any side effects to the Authority to help in the early identification and quick mitigation of any potential safety issues.



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