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COVID-19 Vaccine Safety FDA/CSD/CPE/PRS/21/0007

FOR IMMEDIATE RELEASE

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COVID-19 VACCINES: SAFETY MONITORING UPDATE 1

On 26th February 2021, the Food and Drugs Authority constituted a Committee of Experts – the Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) – which meets bi-weekly to assess all reported adverse events and make recommendations on the safety of COVID-19 vaccines.

At its meeting held on 12th March 2021, the JCVSRC discussed reports received through the FDA's robust safety monitoring system since vaccinations started. The most commonly reported adverse events are headaches, fever, chills, body pains, pain at injection site, weakness, nausea and dizziness. These adverse events are expected from the vaccination and in most cases, resolved within a day or two.

Additionally, the JCVSRC discussed reports of blood clots in some countries in Europe following vaccination with the AstraZeneca COVID-19 vaccine, leading to the suspension of vaccination for further investigations. It concluded that there is currently no causal link between the event and the vaccine, a position that was subsequently upheld by the European Medicines Agency and the World Health Organization.

In view of the above, the FDA would like to reassure the public that it is closely monitoring this situation locally and to date, no events of blood clots linked to the Covishield vaccine have been reported among those who have been vaccinated in Ghana. Generally, vaccines and medicines tend to have some side effects and this needs to be continually balanced against the expected benefits in preventing illnesses.

The Authority continues to work with its Committee of Experts, other regulators globally and will use its established safety monitoring system to support the vaccine program to ensure public health and safety. A weekly safety update will be made public on the FDA website: www.fdaghana.gov.gh

For any vaccine safety related information or to report side effects of 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: Med Safety App –

apple store/play store

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