FDA/CSD/CPE/PRS/24/008

FDA ALLAYS CONCERNS OVER ASTRAZENECA COVID-19 VACCINE SAFETY IN GHANA

FOR IMMEDIATE RELEASE

ACCRA, 21st May 2024 - In light of renewed concerns about the AstraZeneca COVID-19 vaccine, the Food and Drugs Authority (FDA) hereby updates the public on the vaccine's safety status in Ghana. The AstraZeneca vaccine, sold as Covishield and Vaxzevria, is one of six COVID-19 vaccines granted Emergency Use Authorization (EUA) by the FDA in February 2021. The EUA process allows for the availability of essential medical products during public health emergencies through a stringent, expedited process that ensures safety, quality, and efficacy.

During the rollout of COVID-19 vaccines, the FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) received various reports of adverse events. These reports were anticipated and managed according to national procedures. The JCVSRC also monitored global reports of vaccine side effects, including thrombosis with Thrombocytopenia Syndrome (TTS).

TTS is a rare condition associated with adenoviral COVID-19 vaccines like AstraZeneca's Vaxzevria and the Johnson & Johnson/Janssen vaccine.

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Symptoms appear between 4 and 42 days after vaccination. The estimated risk of TTS after the first dose of the AstraZeneca vaccine is about 2 per 100,000 people vaccinated, with higher rates in individuals under 60. The risk decreases after the second dose.

Current safety update

As of the end of March 2024, 10,545,038 people in Ghana had received the AstraZeneca vaccine. The FDA investigated 4,149 reported adverse events following immunization (AEFIs), and thrombosis with TTS was not among them.

In Ghana, the Emergency Use Authorization granted for the AstraZeneca vaccines expired in May 2023 in line with Section 4.4 of the FDA's guidelines on EUA when the COVID-19 pandemic was no longer listed as a global public health emergency of international concern.

Globally, the AstraZeneca vaccine's manufacturers have suspended its production due to the development of new vaccines for emerging COVID-19 strains. The vaccine will therefore no longer be available for use globally.

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Despite this, the FDA remains vigilant in monitoring the safety of all vaccines used in Ghana, including COVID-19 vaccines, through its Safety Monitoring Department and its Technical Advisory Committee on Safety of Vaccines and Biological Products.

During the pandemic, the JCVSRC, established by the FDA, worked with the Ghana Health Service Expanded Programme on Immunization to oversee vaccine safety. The JCVSRC suspended its regular meetings in 2023 as the number of adverse event reports declined, corresponding with reduced vaccine uptake.

What the public should know

The FDA assures the public that it is dedicated to the continuous and proactive monitoring of all regulated products to ensure they remain safe, effective, and of high quality. Should any product present an unacceptable risk, the FDA will take swift regulatory action to safeguard public health.

For further information, please contact the FDA via the contacts below.

Signed
Chief Executive Officer
Food and Drugs Authority

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