FDA GHANA

FOOD AND DRUGS AUTHORITY

Your Well-being, Our Priority.

EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS

As the technical agency of the Ministry of Health responsible for the regulation of medical products including vaccines, the Food and Drugs Authority wishes to respond to recent media coverage on issues of vaccines and medicines approvals, registrations and Emergency Use Authorization (EUA). The FDA therefore provides the following explanations with the aim of ensuring that the public is fully appraised of our processes, which are in line with global best practices.

The EUA Guideline is an international guideline that is activated following the declaration of a public health emergency and represents a fundamental step towards ending a pandemic, protecting public health and safety and helping to restore a country's social and economic liberties. An EUA is a risk-based procedure designed to expedite the evaluation and authorization of medical products, including vaccines, during a public health emergency, such as the current COVID-19 pandemic, to diagnose, treat, or prevent serious or life-threatening conditions or diseases when there are no adequate, approved, and available alternatives to save lives.

In Ghana, in response to COVID-19 being declared a Public Health Emergency of International Concern (PHEIC) by the Director General of the World Health Organization (WHO), the Minister of Health of Ghana, based on the authority reposed in him by the Public Health Act 2012, Act 851, declared COVID-19 as a Public Health Emergency in Ghana.

In response to the declaration, the FDA activated its mandate as part of the national effort towards the management of the Public Health Emergency as provided in sections 169 to 173 of the Public Health Act2012, Act851 and activated the Emergency Use Authorization Guideline for Medical Products (FDA/GEN/GL-EUA/2021/04; first adoption March 4 2019), intended to provide guidance to applicants in the preparation of their applications.

Under an EUA, the FDA authorizes the use of, hitherto an unregistered medical product or an unapproved use of a registered medical product, which has been evaluated by the FDA to have met the minimum requirements for product quality, safety, efficacy and systems for post-authorization product safety monitoring.

Like all routine applications, the FDA subjects EUA applications to its stringent, rigorous and transparent evaluation processes to ascertain whether the minimum regulatory requirements have been met, taking into account the totality of the scientific evidence on the medical product available to FDA. The Authority then subsequently makes a decision on the application within 15 working days of receipt. This evaluation procedure is guided by a set of published regulatory tools adjudged by the WHO to have met International Standards in medical product regulation in emergency situations.

Unlike routine authorization which has a validity period of three (3) years, EUA has a validity of one (1) year or when the declaration of the Public Health Emergency has ceased to exist or whichever is earlier. The limited validity has been instituted to strictly control product deployment and use since the authorization is granted to address an emergency. The one year validity period is renewable.

Generally, the FDA ensures that the underlisted criteria are met before a EUA application is approved:

1. That the disease causative agent/item (e.g., pathogen) specified in the declaration of public health emergency can cause a serious or life-threatening disease or condition;

2. That based on the totality of scientific evidence available, including data from adequate and well-controlled Clinical Trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by the agent specified in the declaration of emergency;

3. That the known and potential benefits outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration;

4. That the medical product is manufactured in compliance with current Good Manufacturing Practices (GMP); and

5. That there is no approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition.

Applying the criteria presented above, the FDA has successfully granted EUA to six (6) COVID-19 vaccines out of eight (8) EUA applications received and evaluated. The authorized COVID-19 vaccines include viral-vectored vaccines and mRNA vaccines. These vaccines have unique properties to trigger the immune system of recipients. The vaccines granted EUA as at 20th December 2021 includes:

i. Sputnik V (Gam-COVID-Vac)

ii. Covishield™ (Oxford/AstraZeneca formulation)

iii. COVID-19 Vaccine Janssen (Ad26.COV2. S)

iv. Pfizer – BioNTech Comirnaty (BNT162B2)

v. Moderna Spikevax (mRNA 1273)

vi. Vaxzevira (previously COVID-19 Vaccine AstraZeneca) (AZD1222)

To continually monitor the quality and safety profiles of the vaccines granted EUA, the FDA evaluates the appropriateness of every batch of vaccine imported into the country before they are deployed for vaccination. The Authority has also instituted systems to report, receive and effectively investigate all Adverse Events Following Immunization (AEFI).

To complement the existing structures to monitor the safety of the authorized COVID-19 vaccine, a Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) was also established by the FDA. The committee meets every fortnight to systematically review and make recommendations on AEFI data on authorized COVID-19 vaccines received by the FDA.

In addition, the FDA has published Periodic Safety Updates on authorized COVID-19 vaccines towards public education, and in line with its transparency policy.

The FDA will like to assure the public and all stakeholders that **r**egardless of the regulatory pathway of authorization, be it Routine Market Authorization or Emergency Use Authorization, the single overarching principle is that the FDA must conclude that the potential benefits associated with the use of the product far outweighs the risk posed by the use of the product.

The public should therefore be assured of the safety of the vaccines granted EUA by the FDA, and the FDA will continue to create the enabling environment to facilitate access to all COVID-19 related medical products which Ghanaians can trust and have confidence in.

Based on the evidence available so far including the huge amount of safety data generated in-country, the FDA is satisfied that the processes it has used in making available access to life saving medical products (vaccines, medicines, medical devices) are appropriate and in line with global best practices. The FDA has provided the Ministry of Health and the Government of Ghana the needed tools to combat this pandemic. It is also worthy of note that globally, Ghana is one of the few countries to have accumulated the highest proportion of safety data (compared to its population) to permit decision making based on Ghana's own data. Other initiatives including approval of clinical trials of herbal medicines and vaccines have been undertaken and the FDA awaits the results of these studies to increase the pharmacological armamentarium available to fight and roll back the Covid-19 pandemic.

For further information, please contact the FDA on any of the following:

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