# Safety Monitoring Strategy for COVID-19 Vaccines

**Food and Drugs Authority and Ghana Health Service**

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## Acronyms

| | |
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| AEFI | Adverse Event Following Immunisation |
| AESI | Adverse Event of Special Interest |
| AU-3S | African Union Smart Safety Surveillance |
| BC | Brighton Collaboration |
| EPI | Expanded Programme on Immunisation |
| FDA | Food and Drugs Authority |
| GHS | Ghana Health Service |
| MAHs | Marketing Authorisation Holders |
| RMP | Risk Management Plan |
| PAES | Post Authorisation Efficacy Study |
| PASS | Post Authorisation Safety Study |
| PSUR | Periodic Safety Update Report |
| WHO | World Health Organisation |

## 1.0 Background

The COVID-19 pandemic has caused significant morbidity and mortality throughout the world, as well as major social, educational and economic disruptions. As the global community discover vaccines and make them available at scale across countries, there is urgent need for preparedness for vaccine deployment and safety monitoring.

The Ministry of Health plans to commence the roll out of COVID-19 vaccines in Ghana by the end of first quarter of 2021 with a total of an initial 20 million persons targeted to receive the vaccines in a phased approach. This will be one of the largest vaccination campaigns to be held in Ghana.

As with all new vaccines, there is some information on the safety of the COVID-19 vaccines during clinical trials but there are potential safety issues in real life use among relatively larger populations and settings different from those for the clinical trials. For example, limited number of participants are included in clinical trials of these vaccines and follow up is relatively short under controlled conditions. As a result, certain adverse events following immunisation (AEFIs), particularly those that are rare will emerge during large scale and real-life use in different populations. It is, therefore, essential to closely monitor safety of the COVID-19 vaccines to be deployed.

The FDA has, since 2001, been a member of the World Health Organisation Programme for International Drug Monitoring and has had experience in the safety monitoring of new vaccines including the introduction of Pneumococcal and Rotavirus vaccines into the routine immunisation programme in 2012 and an ongoing Malaria Vaccine Pilot Implementation Programme which has gone on for close to two years without any significant safety concerns. The FDA partners with the Expanded Programme on Immunisation and some Development Partners, notably the World Health Organisation (WHO) in vaccine safety monitoring.

For COVID-19 vaccines, the FDA has constituted an independent committee of experts from the three Technical Advisory Committees of the FDA, namely, Clinical Trials, Safety of Medicines and Safety of Vaccines and Biological Products and other experts not available on the three Committees. This committee, known as the Joint COVID-19 Vaccine Safety Review Committee for the purpose of quick and expedited review of all safety information received during the deployment.

The FDA in collaboration with the EPI, Ghana Health Service (GHS), will employ both passive and active systems to ensure those who receive the vaccines report any safety concerns to ensure quick review and possible regulatory action to ensure safety of vaccine recipients.

The document provides a high-level overview of the post-approval safety monitoring strategy to be implemented by the FDA in collaboration with the Ghana Heath Service during the deployment.

Activities by the Marketing Authorisation Holders (MAHs) as required by Section 125 of the Public Health Act 2012, Act 851 and applicable guidelines are also outlined.

## 2.0 Objectives of the safety monitoring

The objectives of the safety monitoring strategy are to:

- Rapidly detect, investigate and manage AEFIs during the introduction of COVID-19 vaccine(s) in Ghana.
- Assess the magnitude of COVID-19 vaccine-associated AEFIs
- Assess causality of AEFIs in relation to COVID-19 vaccine(s)
- Identification of possible signals.
- Evaluate the benefit-risk balance of the vaccines.
- Proactively engage and collaborate with stakeholders including vaccinees, healthcare professionals, MAHs and international partners to collate and share safety data on COVID-19 vaccines;
- Promptly and effectively communicate new safety information arising from the safety monitoring of COVID-19 vaccine(s).

## 3.0 Safety monitoring strategies to be employed

The FDA is employing three underlisted strategies:

- nationwide enhanced (stimulated) passive AEFI reporting led by the FDA and EPI to collect AEFI data on COVID-19 vaccines
- active collection of AEFI data in selected districts/facilities
- formal epidemiological studies to further characterise safety concerns, identify potential risks and investigate missing information during the clinical trials of COVID-19 vaccines.

Additional, strategies and activities to ensure safety of COVID-19 vaccines are:

- Submission of Periodic Safety Update Reports (PSURs)/Periodic Safety Risk Evaluation Reports (PBRERs) by MAHs
- Data analysis and causality assessment
- Signal management
- Communication and information sharing

### 3.1 Enhanced spontaneous reporting

The national AEFI reporting system will be enhanced through training for healthcare professionals, dissemination of updated AEFI monitoring tools/guidelines and constant reminders sent to promote diagnosis, management and reporting of AEFIs.

All serious and non-serious AEFIs will be reported. Causality assessment will be done for all serious cases, clusters and AEFIs of community concern by the Joint COVID-19 Vaccine Safety Review Committee in line with the procedure outlined by the WHO to ascertain the causal link between the vaccine and the reported AEFI.

Regional AEFI investigation Teams will lead investigation of all serious AEFI cases in their respective regions.

AEFI reports will be received through AEFI reporting form, the Med Safety Mobile App, Telephone Call and Online Reporting Form.

## 3.2 Active safety monitoring

### 3.2.1 Cohort event monitoring

Active monitoring of AEFIs will be done in five selected districts led by the FDA in collaboration with the Ghana Health Service. This will be designed as a cohort event monitoring study with vaccinees in the selected districts followed up on specified time intervals after each of the two doses of the vaccine to help further characterise the safety profile of COVID-19 vaccines.

The choice of the five hospitals is based on the districts with the highest rate of COVID-19 infections.

In addition to cohort event monitoring, at least 10,000 vaccinees will be sent SMS reminders to report AEFIs.

## 3.3 Formal epidemiological studies

Post-authorization safety studies (PASS) and Post Authorization Efficacy Studies (PAES) will be conducted to gather additional data on the safety of the vaccines post-approval to further characterize, identify potential risks and investigate missing information during the clinical trials of COVID-19 vaccines.

## 3.4 Additional strategies and activities

### 3.4.1 Risk management plan

Marketing Authorisation Holders (MAHs) of approved COVID-19 vaccines will be required to submit Risk Management Plans (RMPs) in line with the Section 3.2 of the FDA's Guidelines on Safety Monitoring of Medicinal Products; additional details may be required acknowledging uncertainties of the pandemic.

The FDA will follow-up to ensure implementation of all risk minimisation measures outlined in the RMP and their effectiveness.

### 3.4.2 Periodic safety update reports

MAHs will be required to submit monthly summary of safety reports received in addition to the six-monthly submission of PSUR within the first two years, in line with Section 3.1 of the Guidelines on Safety Monitoring of Medicinal Products.

The monthly summary will include, amongst others, information on all AEFIs, AESIs received by the MAH and data on the number of doses distributed or given.

### 3.4.3 Data analysis and signal management

A team of dedicated Ghanaian scientists will review all safety information received daily to look for safety issues or unexpected, rare adverse events. The reports will be presented to the Joint COVID-19 Vaccine Safety Review Committee at their bi-weekly meeting or a meeting to be held more frequently when needed.

The Committee will review safety information from Ghana and globally in order to arrive at risk-benefit decision on the vaccinations.

### 3.4.5 Communication and information sharing

The FDA will provide weekly update on the safety information received during the vaccinations