



FREQUENTLY ASKED QUESTIONS (FAQs) on Authorization of COVID-19 Vaccines

Why do vaccines matter?

Vaccines are an important part of stopping the spread of COVID-19 in Ghana. This is because they offer protection to an individual, by reducing their risk of infection or the severity of their symptoms. Vaccines also provide protection at a population level, referred to as herd immunity. The vaccination programme is a priority in the fight to prevent the spread of COVID-19.

How were the current COVID-19 vaccines developed so quickly?

Medicines including vaccines are highly regulated – and that is no different from the approved COVID-19 vaccines. There are a number of enablers that have made this ground-breaking medical advancement possible and faster compared to other medicines;

1. The different phases of the clinical trial were delivered to overlap instead of run sequentially which sped up the clinical process;
2. Considering the preponderance of the pandemic, the clinical trials had a positive response with thousands of people willing to volunteer;
3. Some of the vaccines used proven and well-studied platforms such as the adenovirus vector platform for the development.

How are COVID-19 vaccines authorized worldwide?

There are a number COVID-19 vaccines approved under Emergency Use Authorization by different National Regulatory Authorities (NRA) worldwide.

What is Emergency Use Authorization (EUA)?

This is when a medical product is authorized for use during a pandemic to ensure **timely** access to much needed health products. The objective is to make medicines, vaccines and diagnostics available as rapidly as possible to address the emergency, while adhering to stringent criteria of safety, efficacy and quality. This authorization is given for the duration of the pandemic. In the EUA manufactures are requested to submit any additional documentation on the product as and when it becomes available.

EUA is given only when the NRA is satisfied that the product has met all efficacy, safety and quality specifications.

How efficacious are COVID-19 vaccines?



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At the moment, vaccines available for COVID-19 have efficacy of between 60-94%, and are efficacious in preventing symptomatic disease.

The World Health Organization guidance is that COVID-19 vaccines should demonstrate at least 50% efficacy against severe disease.

Have COVID-19 vaccines been approved for use in Ghana?

Yes. The Food and Drugs Authority (FDA) has given Emergency Use Authorization to two COVID-19 vaccines:

- (i) Sputnik V vaccine from Generium Joint Stock Company, Russia; and
- (ii) Covishield from the Serum Institute of India.

The FDA, a WHO Maturity Level 3 regulatory agency, has reviewed both of these vaccines and concluded that they are efficacious, safe and of good quality

Will vaccines authorized in Ghana be as effective as the ones in other countries?

Yes. The COVID-19 vaccine authorized in Ghana will be as effective as any vaccine authorized by other countries. This is because various phases of clinical trials data reviewed by the FDA showed that the vaccines are safe and efficacious.

How long will the vaccine be effective for?

We expect these vaccines to work for at least a year – if not longer. This will be updated when information becomes available.