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 for the approved COVID-19 vaccines. There are a number of enablers that have made this ground-breaking medical advancement possible 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. Clinical trials managed to recruit people very quickly as a global effort meant thousands of people were 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 issued with Emergency Use Authorization (EUA) by different National Regulatory Authorities (NRA) worldwide.

What is Emergency Use Authorization?

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, manufacturers 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 the product has met all efficacy, safety and quality specifications.

How efficacious are COVID-19 vaccines?

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 suggested 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) granted Emergency Use Authorization to six COVID-19 vaccines listed below.

Name of vaccine	Manufacture
Sputnik V (Gam-COVID-Vac)	Gameleya National Centre of Epidemiology and Microbiology, Russia
Covishield (ChAdOX1Ncov-19 Corona Virus Vaccine (Recombinant)	Serum Institute of India Pvt. Limited, India
COVID-19 Vaccine Janssen Suspension for Injection (Ad26.COV2-S [recombinant])	Janssen Vaccines & Prevention B. V, 2333 CN Leiden, The Netherlands
Moderna's Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]	Moderna Biotech Spain, S.L.
Comirnaty Concentrate for Dispersion for Injection [COVID-19 mRNA Vaccine (nucleoside modified)]	BioNTech Manufacturing GmbH, Germany
COVID-19 Vaccine AstraZeneca Suspension for Injection (ChAdOx1 S [recombinant])	AstraZeneca, United Kingdom

The FDA, a WHO Maturity Level 3 regulatory agency has reviewed all of these vaccines and concluded that they are efficacious, safety and quality assured.

Which vaccines are authorized for use in children?
The FDA has given Emergency Use Authorization for the Pfizer-BioNTech COVID-19 for vaccination in children aged 15 years and above.

Will Vaccines authorized in Ghana be as effective as the ones in other countries?
Yes. The COVID-19 vaccine authorized in Ghana will be 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?
Studies have shown that protection provided by COVID-19 vaccines may decrease over time therefore necessitating booster doses. Currently, a booster dose is recommended after six months for persons who have completed the primary series.

The FDA and other stakeholders will continue to review the evidence and provide guidance on booster dose as soon as more information is available.