

Frequently Asked Questions (FAQs) on the Safety of COVID-19 Vaccines

Are there any side effects to COVID-19 vaccines?

Just like any other vaccines or medicine, COVID-19 vaccines have side effects but so far most of these are minor. These include chills, feeling feverish, tenderness, warmth pain or swelling where the injection is given, headache, joint or muscle ache, tiredness, generally feeling unwell.

Most of these common side effects are signs of the body's normal immune response triggered by the vaccines. They are typically seen with most types of vaccines and tend to resolve within a day or two. The vaccines will not give you COVID-19.

What do I do when I experience a suspected side effect after vaccination?

In general report any side effects or health problem that is of concern to you after COVID-19 vaccination. Provide as much information as is known to you when reporting.

How will my side effect be managed?

Healthcare professionals in the districts and regions are trained to handle and manage these side effects when they occur. There are District and Regional Teams in place to investigate any serious side effects which may be reported.

How do I report a suspected side effect?

The FDA, in collaboration with the Ghana Health Service, has put in place reporting pathways for healthcare workers and anyone who gets vaccinated to report suspected side effects of vaccines. This includes making a report

- to your nearest community pharmacy or health facility
- by telephone 024 431 0297
- using the Med Safety Mobile App available to download on iOS or Google Play Store on android devices.
- reporting online <u>http://adr.fdaghana.gov.gh/patient.php</u>
- report using an AEFI reporting form

What happens to reports sent to FDA?

The FDA has in place an independent committee of experts (Joint COVID-19 Vaccine Review Committee) that reviews (performs causality assessment of) all suspected serious side effects received. This is done to find the possible link between the vaccine and the side effects. The Expert Committee is made up of experienced practitioners in



the field of safety, geriatrics, cardiology, internal medicine, epidemiology, pulmonology etc.

Are there any groups that shouldn't receive COVID-19 vaccines?

Currently pregnant women and children below 18 years of age will not be vaccinated. People with history of severe allergy to the ingredients of the vaccines should not be vaccinated with COVID-19 vaccines.

What are the long-term safety issues of the vaccines?

Large numbers of vaccines administered round the world during trials and since introduction and the vaccines have so far shown excellent safety results. There is currently no evidence that vaccines approved for use during the pandemic can cause long-term side effects. Meanwhile, Ghana's robust safety monitoring system and ongoing worldwide safety monitoring and safety studies will ensure that any unexpected side effects (if they happen) are promptly investigated.

Would the vaccine change my genetic material?

Currently there is no evidence that vaccines including those for COVID-19 can lead to changes in genetic materials.

Does the FDA have the capacity to monitor the safety of COVID-19 vaccines?

The FDA has effectively coordinated the introduction of new vaccines including the pneumococcal/rotavirus vaccines, measles rubella, malaria vaccine into the routine immunization programme without major safety concerns. The FDA has been a member of the World Health Organization (WHO) Programme for International Drug Monitoring since 2001 and its safety monitoring function was adjudged by the WHO as Maturity Level 4, the highest attainable for any regulatory function.