Ministry of Health and Family Welfare
Government of India

Help us to help you

General FAQs

1 Which COVID-19 vaccines are licenced in India?

Two vaccines that have been granted emergency use authorization by the Central Drugs Standard Control Organization (CDSCO) in India are

Covishield® *(AstraZeneca's vaccine manufactured by the Serum Institute of India)* **&** **Covaxin®** *(manufactured by Bharat Biotech Limited)*

2 What is Emergency Use Authorization (EUA)/ Permission for restricted use?

Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of vaccines and medicines to prevent and/or reduce the impact of life-threatening diseases or conditions as caused by COVID-19. However, before the grant of the EUA, there are rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy. Safety is a particularly critical aspect of this scrutiny and a risk-versus-benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Indian regulators is aligned with global guidelines.

3 Is the EUA a new process introduced for the COVID-19 Vaccine?

The concept of EUA always existed to save the lives of people all over the world with vaccines and medicines for life-threatening diseases while companies continue to obtain additional safety and effectiveness information to enable full licensure. Previously, EUAs have been granted to vaccines for outbreaks due to anthrax, Ebola, enterovirus, H7N9 influenza, and Middle East respiratory syndrome. As of January 2021, nine COVID-19 vaccines were in emergency use in numerous countries around the globe.

4 Have the vaccines undergone the needed clinical trials before EUA?

Both of the Indian COVID-19 vaccines have completed their phase I & II trials. Covishield® has completed its phase III trials in the UK and the bridging trial in India.

5 What are Phase I, II and III of a clinical trial for a vaccine?

Clinical Trial > Phase 1 > Phase 2 > Phase 3

Phases of vaccine development/trial	Purpose
Pre-clinical	Vaccine development in laboratory animals
Phase 1 Clinical trial (a small number of participants)	Assess vaccine safety, immune response and determine right dosage (short duration)
Phase 2 Clinical trial (few hundred participants)	Assess safety and the ability of the vaccine to generate an immune response (short duration)
Phase 3 Clinical trial (thousands of participants)	Determine vaccine effectiveness against the disease and safety in a larger group of people (duration 1-2 years)

6 Why vaccination is not provided to children who are the usual target?

COVID-19 affects all age groups; however, morbidity & mortality is several times higher in adults, particularly in those above the age of 50 years. Children have an either asymptomatic or mild infection. The general practice is to first evaluate any new vaccine in the older population and then age reduction is done to assess the safety and effectiveness in the paediatric population. The currently available vaccines have not been evaluated in children so far. There are some clinical trials now underway to test the effectiveness and safety of the COVID-19 vaccines on children.