

# INDIA APPROVES TWO COVID-19 VACCINES

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

Both approvals accorded are for “restricted use in emergency situation” and in the case of Bharat Biotech, the approval wording notes that it is in “...public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains”. These conditions were not specified.

Bharat Biotech, whose vaccine candidate is being tested in large Phase-3 trials in India, has provided safety and immunogenicity data.

This data is proof that the inoculation doesn't harm and is capable of stimulating an immune response in the body — but no efficacy data, that shows the vaccine achieves its primary goal of protecting against disease. Doing such a trial would have, according to the company's timeline, taken some more months.

The head of the CDSCO, V.G. Somani, read out a prepared statement according approval and on the sidelines of the briefing told reporters that the vaccine was “110% safe” and that every adverse event, were they to happen, would be diligently followed up.

Samiran Panda, head of the Epidemiology and Communicable Diseases Division, ICMR, defended the emergency approval granted to Covaxin on the ground that the existence of the pandemic, the detection of the U.K. strain and the vaccine's safety profile meant that it could approved in “clinical trial mode”.

“This isn't the standard approval given to a vaccine. The scheduled trial (on 26,000) will continue and every person who gets the vaccine will be followed up and monitored for risk as well as benefit. It can also be withdrawn. This vaccine, as of now is not for everybody, and is being given under restricted use condition,” he said.

Covaxin has been developed based on an inactivated SARS-CoV-2 strain cultured at the National Institute of Virology, an ICMR body. Because it was a whole virus (and therefore, more of it would be exposed to the immune system) the chances that it would mount a response against a variety of mutant virus types or strains were higher.

“I would say scientifically Covaxin offers much better antigen presentation (and a consequent immune response) than a vaccine developed as a specific part of the (viral) protein,” Dr. Panda told *The Hindu*. “So this is potentially more effective against mutant strains.”

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