India approves two COVID-19 vaccines for emergency use

Regulator grants nod to Covishield by Serum Institute, Covaxin by Bharat Biotech

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The Central Drugs and Standards Committee (CDSCO) on Sunday formally approved the COVID-19 vaccines by Bharat Biotech and the Serum Institute of India (SII).

This allows the vaccines – Covishield by SII and based on the Oxford AstraZeneca vaccine, and Covaxin by Bharat Biotech – to be offered to healthcare workers and frontline workers in India. The Health Ministry had said that 3 crore such personnel, considered at the highest risk for COVID-19, would be given the vaccine for free. It isn't yet known which vaccine will be made available to these personnel though officials said roll-outs could begin in less than a fortnight.

Yet to complete trials

Neither Covishield nor Covaxin has completed the crucial Phase-3 trial, under which a vaccine candidate is administered to volunteers at multiple locations across the country. The approval was based on a recommendation by a Subject Expert Committee which deliberated for two days on granting approvals to the vaccines.

The minutes of the SEC meeting aren't yet available. However, a Health Ministry statement said the vaccine's efficacy in Indian volunteers was "comparable" to that tested in overseas trials.

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.

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Vaccines out, but data missing

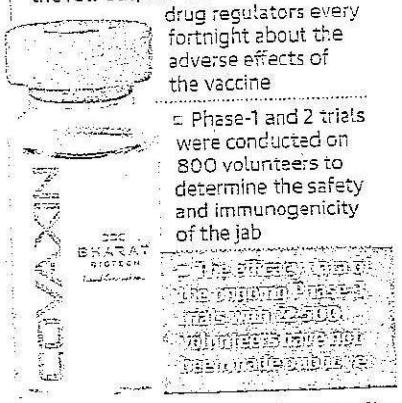
The efficacy data of the Phase-3 trials conducted in India for the two vaccines approved for restricted public use on Sunday have not been made public yet

COVISHIELD

- A vaccine developed by the Serum Institute-Pune based on the AstraZeneca-Oxford vaccine has been given 'conditional approval'
- The vaccine's efficacy is reported to be 70.4% based on the Phase-3 trials conducted in the U.K. and Brazil
- The efficacy data of the Phase-3 trials conducted on 1,600 volunteers in 17 Indian cities have not been made public yet

COVAXIN

- A vaccine developed by Bharat Biotech and the Indian Council of Medical Research has been approved for restricted emergency use in clinical trial mode
- During the first two months after the roll-out, the firm has to inform drug regulators every fortnight about the adverse effects of the vaccine
- Phase-1 and 2 trials were conducted on 800 volunteers to determine the safety and immunogenicity of the jab
- The efficacy data of the Phase-3 trials conducted on 25,800 volunteers have not been made available yet



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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 primarily 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."

Historically there was evidence for this from polio vaccines. An interim analysis of the vaccine's efficacy would happen around March, he added.