



Publication: The Economic Times (print)

**Date** : August 27, 2021

**Page** : 05

Title : Reliance Life Gets Regulatory

Nod for Trials of 2-dose Vax

Reliance jab similar to Biological E's

## Reliance Life Gets Regulatory Nod for Trials of 2-dose Vax

Teena.Thacker@timesgroup.com

New Delhi: The drug regulatory authority on Thursday approved Reliance Life Sciences, part of India's largest private sector enterprise-application, seeking to conduct clinical trials of its recombinant protein-based Covid-19 vaccine candidate.

The subject expert committee (SEC) reviewed its application at a meeting on Thursday and gave its approval. Reliance has approached drug regulator seeking phase-1 trial for its proposed two-dose vaccine, people in the know told ET.

The aim of phase-1 clinical trials are to obtain reliable information on safety, tolerability, pharmacokinetics (PK), and mechanism of action of drugs with the objective of determining the maximum tolerated dose (MTD).

"Phase-1 trials are usually conducted for 58 days to check the tolerated dose strength. Once it's done, the company can apply for conducting phase-2/3 trials," added a person.

So far in India there are six vaccines which have got emergency use authorisation (EMA). Zydus Cadila's vaccine became the sixth to get EUA in India last week, after Serum Institute of India's Covishield, Bharat Biotech's Covaxin, Russia's Sputnik V, and the vaccines of US companies Moderna and Johnson & Johnson.

The vaccine by Reliance Life Sciences will be a recombinant protein vaccine, similar to the one which is being developed by Biological E.

An email sent to Reliance Life Sciences did not elicit any response. Mean-

while, vaccination is picking pace in the country.

The Union health secretary Rajesh Bhushan on Wednesday chaired a high-level meeting with all states to review progress of Covid-19 vaccination.

The states were advised to focus on enhancing second dose coverage as well as immunization of school teachers and staff.

"We know that these vaccines are disease modifying vaccines, they are not disease preventive vaccines and, therefore, it is important to continue to use the mask even after one or two doses. We know that vaccines reduce the disease severity, they reduce the possibility of hospitalisation and also avert death to the tune to 98-99 %," DG ICMR Balram Bhargava said on Thursday.

