

CORONAVIRUS

India's First mRNA-Based Omicron Booster Vaccine Gets Emergency Use Authorisation; To Be Rolled Out in 2-3 Weeks

The Drugs Controller General of India (DCGI) has granted Emergency Use Authorisation (EUA) to India's first mRNA-based Omicron booster vaccine, and it is likely to be rolled out in 2-3 weeks, Gennova Biopharmaceuticals announced on Tuesday.

The Pune-based firm's GemCovac-OM is a monovalent needle-free booster shot. It will be delivered intradermally with the PharmaJet Tropis Precision Delivery System (PDS) to adults of 18 years of age and older; and to those who have previously taken the primary vaccine shots from either Covishield or Covaxin, the two major COVID-19 vaccines administered in the country.

The GemCovac-OM is a lyophilised (freeze-dried) vaccine that remains stable at 2-8°C, and is safe and compatible with the current refrigeration supply chain across India, along with other low and middle-income countries (LMICs), said Dr Sanjay Singh, Chief Executive Officer, Gennova Biopharmaceuticals, at a virtual press conference held on Tuesday.

"Even though the WHO has declared that COVID is no longer a public health emergency, our booster dose holds relevance as COVID, specifically, Omicron and its sub-lineages, are still prevalent. It has been scientifically proven that the existing vaccines are not effective in tackling specific variants. The need is for a tailor-made vaccine to target specific variants," Dr Sanjay Singh said.

"We are proud to announce that India now has its own Omicron-based vaccine that has passed clinical trials," he added.

The mRNA vaccine was developed in association with the Department of Biotechnology. It was evaluated for its safety and immunogenicity as a booster in about 3,000 people from across 13 cities in India who received two doses of Covishield and Covaxin.

The clinical trial results showed that the single booster dose is safe and well tolerated with mild to moderate side effects. No serious adverse events were reported.

Importantly, GemCovac-OM as a booster also showed a "significantly higher immune response than Covishield," Singh added.

The company is yet to disclose the price.