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# Pune-based Gennova Biopharmaceuticals' mRNA vaccine gets DCGI nod

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Written by [Anuradha Mascarenhas](#) | Pune |

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A healthcare worker administers a dose of Covid-19 vaccine to a student. (PTI, file)

The country's first homegrown mRNA Covid-19 vaccine developed at Pune's Gennova Biopharmaceuticals has received emergency use for the age group 18 and above. In a late-night development, the Drug Controller General of India (DCGI) approved the two-dose mRNA vaccine on Tuesday. The vaccine is stable for storage at 2-8 degree C.

At the Pune-based firm, officials say they are excited and eager for a roll out. "We have to go for scientifically sound and the most advanced technology, which has been proven safe and effective. The challenge in front of Gennova was to make it stable at 2-8 °C to enable the democratisation of the mRNA-based vaccine globally. We are confident that the product will speak on its own merit for acceptability, given the proven track record of safety and efficacy of mRNA vaccines," Dr Sanjay Singh, CEO, Gennova Biopharmaceuticals, told *The Indian Express*.

Gennova already has a license from the Central Drug Standard Control Organisation (CDSCO) to manufacture and sell the vaccine and has produced 70 lakh doses at risk. "Now that we have received the EUA, we can ship the material soon after completing all formalities. Our current production capacity is around 40-50 lakh of doses per month, which will be upgraded by two to three fold soon," Dr Singh said.

The fact that the novel mRNA vaccine candidate, GEMCOVAC™-19, is stable at 2-8 degrees makes it amenable for ease of deployment across the nation. The vaccine will be available for adults above 18 years of age. The two-dose vaccine will have to be administered intramuscularly, 28 days apart. “This has been a learning experience for all of us. Gennova and the subject expert committee have had several discussions on the safety and immunogenicity of GEMCOVAC-19 to ensure that this new technology is safe and effective for Indians,” Dr Singh said.

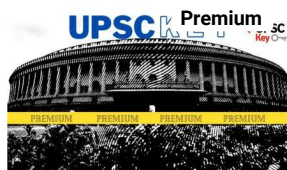
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Vaccines based on mRNA require ultra-low temperature conditions for storage and distribution. India already has a cold supply-chain infrastructure that can handle refrigeration conditions for deployment of the vaccine. “Gennova intended to make an mRNA-vaccine formulation that is stable at 2- 8 °C and can be distributed through the already existing refrigeration supply chain pan-India. Given that early mRNA vaccine developers couldn't materialise such a product, freeze-drying the large and unstable mRNA molecule with the nanoparticle was a daunting challenge,” an official at the firm said.

## EXPLAINED

### Challenge met

mRNA-based vaccines require ultra-low temperature conditions for storage and distribution. India already has a cold supply-chain infrastructure that can

handle refrigeration conditions at 2-8°C, so the novel mRNA vaccine candidate, GEMCOVAC-19, which is stable at 2–8°C, can be distributed through the existing refrigeration supply chain across the country.

“At Gennova, we have invested hundreds of man hours in the hope of lyophilizing the mRNA vaccine in a single vial within a year, thanks to cutting-edge science and our highly dedicated team. This thermostable vaccine was thoroughly tested in various animal models to ensure its safety and immunogenicity before entering human clinical trials involving nearly ~ 4,000 participants. CDSCO approved the vaccine for EUA based on its safety and robust immunogenicity (both humoral and cellular),” Dr Singh said.

While more than 197 crore vaccine doses have been given to citizens 91 crore of whom are fully vaccinated, officials at Gennova said that there still was a potential demand for vaccine for one-third of the population. “There is a need of additional dose vaccination to control the infectivity of the ongoing pandemic and we are very positive that this vaccine will add another tool to the Indian vaccination programme,” Dr Singh added.

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