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Gennova Biopharma seeks EUA for first needle-free mRNA vaccine as omicron booster

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Unlike other approved mRNA vaccines requiring ultra-low temperature storage, this vaccine uses the existing refrigeration supply chain

Following assessment of the primary endpoints of the Phase II/III study, Pune-based Gennova Biopharmaceuticals (in partnership with US-based PharmaJet) has submitted data for its mRNA-based Omicron specific COVID-19 booster shot for Emergency Use Authorisation (EUA) to the office of the Drug Controller General of India (DCGI).

The submission corresponds with an increase in COVID-19 cases in India and is the first booster in India targeted specifically for the Omicron variant. The vaccine, GEMCOVAC-OM, will be delivered exclusively with the PharmaJet Tropis Precision Delivery System (PDS).

GEMCOVAC-OM is a lyophilised vaccine, stable at 2-8 °C, which means it can be distributed through the existing refrigeration supply chain Pan-India and in low- and middle-income countries (LMICs). Unlike other approved mRNA vaccines, it does not require ultra-low temperature storage conditions. GEMCOVAC-OM was assessed for its safety and immunogenicity when administered as a booster in participants who have received two doses of COVISHIELD and COVAXIN, the two main COVID-19 vaccines used in India.

The vaccine is delivered needle-free, intradermally with the PharmaJet Tropis Precision Delivery System which has been shown to reliably enhance nucleic acid vaccine immune response.