

CORBEVAX bags DCGI nod as heterologous COVID-19 booster dose

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Hyderabad-based Biological E (BE) has announced that its CORBEVAX COVID-19 vaccine has been approved by the Drug Controller General of India (DCGI) as a heterologous COVID-19 booster dose to individuals aged 18 years and above after six months of administration of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccines for restricted use in an emergency. BE's CORBEVAX is the first such vaccine in India to be approved as a heterologous COVID-19 booster.

Recently, BE has furnished its clinical trials data to the DCGI who after a detailed evaluation and deliberations with the Subject Experts Committee, granted their approval for administering the CORBEVAX vaccine as a heterologous booster dose to people who have already taken two doses of either COVISHIELD or COVAXIN. BE's clinical trial data showed that the CORBEVAX booster dose provided significant enhancement in immune response and the excellent safety profile required for an effective booster.

BE has conducted a multicentre Phase III placebo-controlled heterologous booster clinical trial in 416 subjects from 18 to 80 years of age who were previously vaccinated with two doses of either COVISHIELD or COVAXIN at least 6 months before the administration of CORBEVAX as a booster dose.

The booster dose of CORBEVAX increased the neutralising antibody titers in the COVISHIELD and COVAXIN groups significantly when compared to the placebo.