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Biological E's COVID-19 vaccine receives EUA for 12-18 yrs old

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CORBEVAX is India’s 1st indigenously developed Receptor Binding Domain Protein sub-unit vaccine againstCOVID-19

Hyderabad-based Biological E (BE) has announced that its CORBEVAX vaccine, which is India's first indigenously developed Receptor Binding Domain (RBD) Protein sub-unit vaccine against COVID-19, has received emergency use authorisation (EUA) from India's drug regulator for the 12 to 18-year age group.

The Drugs Controller General of India (DCGI) has already approved CORBEVAX for restricted use in emergency situation among adults on December 28, 2021.

BE received the approval for restricted use in an emergency situation in adolescents aged 12 to less than 18 years based on interim results (of the ongoing phase II/III clinical study).

Last September, BE received approval to conduct a Phase II/III clinical trial on CORBEVAX in children and adolescents aged 5 to 18 years. Based on the no-objection certificate, BE initiated the clinical study in October 2021 and evaluated the available safety and immunogenicity results of the ongoing phase II/III study, which indicated that the vaccine is safe and immunogenic.

The CORBEVAX vaccine is administered through intramuscular route with two doses scheduled 28 days apart and is stored at 2 to 8 degrees’ Celsius temperature and presented as 0.5 ml (single dose) and 5 ml (10 doses) vial and 10 mL (20 doses) vial pack

BE conducted phase I/II, II/III clinical trials of its CORBEVAX vaccine for adults in the country. In addition, it conducted a Phase III active comparison clinical trial to evaluate superiority over Covishield vaccine.