

DCGI approves Biological E's protein sub-unit COVID-19 vaccine

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CORBEVAX is India's 1st indigenously developed protein sub-unit COVID-19 vaccine



Hyderabad-based Biological E has announced that its CORBEVAX™, India's first indigenously developed protein sub-unit vaccine against COVID-19, has received the approval from the Drugs Controller General of India (DCGI).

CORBEVAX™ is a "recombinant protein sub-unit" vaccine, developed from the receptor binding domain (RBD) of the spike protein on the virus's surface combined with Dynavax's CpG 1018 adjuvant with alum, which helps the body build the immune response against the virus.

The vaccine has been developed by Biological E. Limited in collaboration with Texas Children's Hospital Center for Vaccine Development (Texas Children's CVD) and Baylor College of Medicine (Baylor) in Houston, Texas.

The vaccine will be effective both in scale and affordability, providing sustainable access to low-and middle-income countries.

Biological E. Limited's CORBEVAX™ has completed two Phase III clinical trials involving more than 3000 subjects between the ages of 18 and 80 at 33 study sites across India. The vaccine was found to be safe, well tolerated and immunogenic.

Biological E. Limited plans to complete production at a rate of 75 Million doses per month, anticipating 100+ million doses per month from February 2022. These capacities will enable the Hyderabad-based company to deliver 300 Million doses as promised to the Government of India. Soon, the company plans to deliver more than one billion additional doses globally.