

Recommendations of the SEC (COVID-19) made in its 01st/25 meeting held on 06.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Vaccine Division			
1.	BIO/PostAppr/2025/37 220 BIO/CT/23/000008 RLS Protein Subunit Vaccine	M/s Reliance Lifesciences	<p>The firm presented Phase II clinical trial report titled, “A prospective, multi-center, randomized, open label, active control, Phase II clinical study to evaluate immunogenicity, safety and tolerability of single heterologous booster dose of RelCoVax® (Protein Subunit Vaccine of Reliance Life Sciences against SARS-CoV-2 Virus) with Corbevax® (Protein Subunit Vaccine of Biological E Ltd. against SARS CoV-2 Virus)”</p> <p>After detailed deliberation, the committee observed that immunogenicity results of the test vaccine did not meet the primary objective of the study as compared with the reference vaccine. The lower bound of 95% CI of difference in proportion of seroconversion rate in test v/s reference group did not meet the non-inferiority criteria of -10 % as defined in the protocol. Hence, the vaccine did not demonstrate non-inferiority with the comparator vaccine.</p>
2.	BIO/MA/25/000028 SARS-CoV-2 (Covid-19) Vaccine [CORBEVAX]	M/s Biological E. Ltd.	<p>Firm has requested for updation of the status of approval of Corbevax: SARS-CoV-2 (Covid-19) Vaccine, RBD antigen of SARS-CoV-2 (Covid-19) excluding the conditions of permission for restricted use in emergency situation.</p> <p>Firm presented following study titled:</p> <ol style="list-style-type: none"> 1. Phase II/III clinical study titled “A prospective, multicentre, Phase II seamlessly followed by Phase III clinical study to evaluate the immunogenicity and safety of Biological E’s CORBEVAX Vaccine for protection against COVID-19 disease when administered to COVID-19-negative adult subjects”. 2. Phase III Clinical Study titled “A prospective, single-blind, randomized, active controlled Phase III clinical study to evaluate the immunogenicity and safety of Biological E’s CORBEVAX Vaccine for protection against COVID-19 Disease when administered to RT-PCR negative adult subjects”.

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			<p>3. Phase II / III Clinical Study titled “A prospective, randomised, double-blind, placebo controlled, phase-II by III study to evaluate safety, reactogenicity, tolerability and immunogenicity of CORBEVAX Vaccine in children and adolescents.”</p> <p>4. Phase III Clinical Study titled “A prospective double-blind randomised phase III clinical study to evaluate the immunogenicity and safety of single booster of Biological E’s CORBEVAX vaccine when administered to COVID-19-negative adult volunteers previously vaccinated with 2-doses of either Covishield or Covaxin.”</p> <p>The committee noted that :</p> <ol style="list-style-type: none"> 1. Firm presented safety and immunogenicity data of Phase II/III and Phase III clinical trials along with information of serious adverse events and safety data from the vaccination program. 2. Risk Management Plan has been submitted. 3. Humoral response was found persistent in terms of binding antibody titers against the RBD protein and neutralizing antibody titers against SARS-CoV-2 or Pseudovirus till one year post vaccination. 4. Cross-neutralization was demonstrated in terms of nAb titers against variants Beta, Delta and Omicron strains. 5. Firm has supplied more than 85 million doses, out of which 32.5 million received two doses of Corbevax in India for vaccination program in the age group of 12-14 years. 6. The vaccine has received WHO-EUL in Jan 2024. <p>The committee reviewed safety and immunogenicity data of Phase II/III & Phase III clinical trials conducted in the country &</p>

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			<p>safety data of approximately 100 million doses of vaccine administered in the vaccination program of India and globally.</p> <p>The committee noted that there has been no additional safety concerns upto now.</p> <p>After detailed deliberation, the committee recommended to update the status of approval of Corbevax SARS-CoV-2 (Covid-19) Vaccine, RBD antigen of SARS-CoV-2 (Covid-19) from restricted use in emergency situation to the new drug permission as per rules in individuals aged 5 years and above with conditions that the vaccine to be supplied for programmatic settings & AEFI, AESI shall be continued to be monitored.</p>