

Recommendations of the SECmeeting to examine (COVID-19) related proposal under accelerated approval process made in its 247th meeting held on 18.04.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	<p>BIO/MA/23/000022</p> <p>Lyophilized mRNA Vaccine for Injection (COVID-19) [10 µg/dose [10 µg/0.1 mL] [GEMCOVAC[®]-OM]</p>	<p>M/s Genova Biopharmaceuticals Limited.</p>	<p>In light of the recommendations of SEC (Covid) meeting dated 06.04.2023, the firm presented its proposal for grant of permission to manufacture and market Lyophilized mRNA Vaccine for Injection (COVID-19) [10 µg/dose [10 µg/0.1 mL] [GEMCOVAC[®]-OM] indicated as a single booster dose (intradermal) in individuals aged ≥18 years administered at least 4 months after completion of primary vaccination with either COVISHIELD[™] or COVAXIN[®] for Restricted use in Emergency situation along with additional 90 days safety data of Phase III clinical trial before the committee.</p> <p>The firm presented the preclinical data including immunogenicity study data in Guinea pig and skin irritation study data in Rabbits. The firm also presented the interim Phase III clinical trial data for approx. 3000 subjects including safety data up to 90 days & immunogenicity data for 420 subjects up to 29 days measuring GMT by IgG-ELISA against SARS-CoV-2 Spike protein, Seroconversion rate (≥ 2 fold rise in neutralizing antibodies), neutralizing antibody titers against SARS-CoV-2 (omicron variant) using PRNT assay & surrogate virus assay (cPASS[™]), Th1 biased cellular response and BA.1 specific, BA.5 specific and BF.7-specific B cells response,.</p> <p>The committee noted that the safety data upto 90 days of Phase III clinical trials was satisfactory and also noted that the vaccine is observed to be non-inferior to COVISHIELD[™] vaccine.</p> <p>The committee also reviewed the package insert, factsheet and SmPC of the Lyophilized mRNA Vaccine for Injection (COVID-19) [10 µg/0.1 mL] [GEMCOVAC[®]-OM].</p> <p>After detailed deliberation, as the trial was conducted during the period when Omicron variant - sub lineage BA.1 was dominant variant in the country and in the</p>

			<p>light of current pandemic situation, the committee recommended for grant of permission for manufacture and marketing of Lyophilized mRNA Vaccine for Injection (COVID-19) [10 µg/0.1 mL] [GEMCOVAC[®]-OM] for restricted use in emergency situation subject to various regulatory provisions including following:</p> <ol style="list-style-type: none"> 1. The vaccine is indicated as a single booster dose in individuals aged ≥18 years administered at least 4 months after completion of primary vaccination with either COVISHIELD[™] or COVAXIN[®]. 2. The firm should submit revised PI, SmPC & Factsheet to CDSCO after incorporating the latest safety, immunogenicity data and other suggestions made during the meeting. 3. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the health care provider 4. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine. 5. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. 6. The firm should submit safety & immunogenicity data from the ongoing clinical trials in the country for review as and when available. 7. The firm should submit safety data including the data on AEFI and AESI with due analysis every 15 days for the first two months & monthly thereafter till the completion of the ongoing clinical trial in the country. Thereafter, the firm should submit the safety data as per the provisions and standard procedures. 8. The firm should submit Risk management plan.
2.	BIO/MA/23/000008 LS SARS-CoV-2 Recombinant Protein	M/s Reliance Life Sciences Pvt. Ltd	In light of the recommendations of SEC (Covid) meeting dated 07.02.2023, the firm presented its proposal for grant of permission to conduct Phase II clinical trial protocol of

	Subunit Vaccine		<p>RLS SARS-CoV-2 Recombinant Protein Subunit Vaccine (10mcg) for administration of heterologous booster (third)dose to adult subjects (≥ 18 years to ≤ 80 years) with CORBEVAX (as comparator) who are fully vaccinated with COVAXIN or COVISHIELD after 6 months .</p> <p>After detailed deliberation and as requested by the firm for review of the Phase II clinical trial design for heterologous booster and recalculation of sample size, the proposal was deferred for the next meeting.</p>
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