

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 243rd meeting held on 07.02.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000098 Equine Anti Covid Antibody Fragments F(ab) ₂	M/s VINS Bioproducts Ltd.	<p>The firm presented its proposal for grant of permission to manufacture & market Equine Anti Covid Antibody Fragments F(ab)₂ for restricted use in emergency situation along with Phase I/II clinical trial report.</p> <p>The committee noted that the Phase I clinical trial was conducted in 42 subjects and Phase II clinical trial was conducted in 168 subjects.</p> <p>After detailed deliberation, the committee recommended that the firm is required to generate more efficacy and safety data for consideration of the proposal for grant of permission to manufacture & market Equine Anti Covid Antibody Fragments F(ab)₂ for restricted use in emergency situation.</p>
2.	BIO/MA/23/000008 LS SARS-CoV-2 Recombinant Protein Subunit Vaccine	M/s Reliance Life Sciences Pvt.	<p>The firm presented its proposal for grant of permission to conduct Phase II/III clinical trial of RLS SARS-CoV-2 Recombinant Protein Subunit Vaccine (10mcg) for administration of heterologous booster (third) dose to adult subjects (≥18 years to ≤80 years) who are fully vaccinated with COVISHIELD and COVAXIN after 6 months.</p> <p>Firm also presented report of Phase I clinical trial conducted in 72 subjects in primary vaccination with two doses (day 0 & 28) wherein three dose levels were evaluated for safety, tolerability and immunogenicity viz. 2.5 mcg, 5mcg & 10mcg. The clinical trial data include the safety & immunogenicity data (anti RBDIgG, anti Nucleocapsid IgG, Neutralising antibody, T cell response by levels of Interferon γ).</p> <p>The committee reviewed and noted the results of the Phase I clinical trial with primary vaccination schedule.</p> <p>The committee also noted that the firm has proposed to conduct Phase II/III clinical trial with 10mcg formulation for administration of heterologous booster (third) dose of vaccine to adult subjects (≥18 years to ≤80 years) who are fully vaccinated</p>

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			<p>with COVISHIELD and COVAXIN after 6 months.</p> <p>After detailed deliberation, the committee recommended that the firm should revise the Phase II/III clinical trial protocol considering the following points:</p> <p>1) Primary end point should be comparison of neutralizing antibody, GMT and seroconversion with comparator and sample size should be statistically significant.</p> <p>2) Secondary endpoint should be comparison of anti-RBD, GMT and seroconversion with comparator.</p> <p>2) The sample size should be at least 3000 for assessment of safety.</p> <p>Accordingly, the firm should submit the revised Phase II/III clinical trial protocol for review by the Committee.</p>
GCT Division			
3.	CT/101/21 Ad2.CO V2.S COVID vaccine	M/s J & J	<p>The applicant presented protocol amendment 4 dated 15/08/2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed protocol amendment.</p>
4.	CT/38/22 Anti-Covid-19 AKS-452 Vaccine	M/s Veeda	<p>In light of earlier SEC recommendation dated 07/09/2022, the applicant presented data of Phase II/III clinical trial conducted in 1500 subjects in India.</p> <p>After detailed deliberation, the committee recommended that the applicant should submit revised protocol as per WHO guidelines, in which sample size should be at least 3000 for assessment of safety and design should be non inferiority end point with approved comparator. Accordingly, the applicant should submit revised protocol.</p>