

**Recommendations of the SEC (Covid-19) made in its 235<sup>th</sup> meeting held on 07.09.2022at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT/22/000015 Lyophilized mRNA COVID-19 Vaccine – Omicron Specific	M/s Genova Biopharmaceutical s Limited	The firm presented its proposal for grant of permission to conduct Phase II followed by Phase III clinical trial of Lyophilized mRNA COVID-19 Vaccine (Omicron Specific) for Intradermal administration as heterologous booster dose in adults at least 4 months after primary vaccination with Covishield. The firm also presented immunogenicity study data in Guinea pig and skin irritation study data in Rabbits. After detailed deliberation, the committee recommended for the proposed Phase II/III clinical trial protocol with the opinion to provide details on usage of comparator along with further details of safety cohort. The firm to submit the clinical trial protocol, accordingly.
2.	BIO/CT/21/000148 Adenoviral- Vector Based Vaccine (VXA- CoV2-1.1-S)	M/s Syngene International Limited	In light of the earlier SEC (Covid-19) meeting recommendation dated 31.01.2022, the firm presented the amended Phase Ib clinical trial protocol of Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S) (Enteric Coated Oral Tablet) expressing a SARS-CoV-2S Protein and dsRNA Adjuvant before the committee along with results of Phase I trial. After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase Ib clinical trial as present.
<b>New Drug Division</b>			
3.	IND/CT/20/000037 2-Deoxy-D-Glucose	M/s Dr. Reddy	In light of the earlier SEC(Covid) meeting recommendation dated 1.12.2021 the firm presented the results of Phase III clinical trial along with the detailed data specifically with respect to efficacy parameter. After detailed deliberation, the committee observed that the data is not statistically significant & could not found expected outcome and recommended that the firm should submit more data with increased sample size. Further the committee

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			suggested that the firm may submit a separate protocol for additional indication for other than covid pneumonia, if required.
4.	IND/IMP/22/00004 Glactomannan 1400 mg Tablet	M/s Murli Krishna Pvt. Ltd.	In light of the earlier SEC(Covid) meeting recommendation dated 05.04.2022, the firm presented the supportive In-vitro data, animal data, proof of concept along with the published clinical trial data, justification for Phase III CT.  After detailed deliberation, the committee recommended that the firm should submit Pharmacokinetic data along with the dose response relationship.
<b>GCT Division</b>			
5.	CT/101//21 Ad26.Cov.s	M/s J & J	In light of earlier SEC recommendations held on 06.06.2022, the applicant presented results of ongoing clinical trial before the committee along with protocol amendment 3 dated 28 Feb 2022.  After detailed deliberation, the committee recommended for approval of the proposed protocol amendment subject to the condition that applicant should submit immunogenicity data of primary immunization of group 4-6 prior to administration of booster dose.
6.	CT/144/21 AZD 1222	M/s Siro	In light of earlier SEC recommendations held on 05.01.2022, the applicant has presented Phase II/III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II part of the study with the following conditions:- <ol style="list-style-type: none"> <li>1. Applicant should submit Phase II data for further continuation of the study i.e Phase III part of the protocol and after its review by the committee, trial may be continued.</li> <li>2. SoC should be provided as per ICMR/GoI guidelines.</li> <li>3. More Govt sites should be included.</li> </ol>

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7.	CT/38/22 Anticovid-19-AKS-452 Vaccine	M/s Veeda	<p>In light of earlier SEC recommendations held on 06.07.2022, the applicant presented results of Phase II/III clinical trial along with proposed Phase III booster dose clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee noted that the proposed vaccine is not yet approved for primary vaccination anywhere and the Phase II/III study was conducted in 1500 subjects. Therefore the committee recommended to seek data and defer the proposal for further deliberation for clarity with respect to above.</p>