Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 206th meeting held on 31-01-2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/21/000004 Equine Anti Covid antibody Fragments F (ab') 2 (Phase I/II Clinical trial protocol amendment)	M/s JSS Medical Research India Pvt. Ltd.	The firm presented its proposal for amendment in ongoing Phase I/II clinical trial of Equine Anti Covid antibody Fragments F (ab') 2 before the committee. After detailed deliberation, the committee recommended to continue the ongoing clinical trial as per the protocol in moderate patients and accordingly, the sample size may be revisited as per the statistical plan. Further, prevention of hospitalization to be clearly defined in the protocol. Accordingly, the firm should submit revised clinical trial protocol for further review by the committee.
2.	BIO/CT/21/000148 Adenoviral –Vector Based Vaccine (VXA-CoV2-1.1-S) Expressing a SARS-CoV-2S Protein and dsRNA Adjuvant (Phase Ib clinical trial)	M/s Syngene International Limited	The firm presented its proposal for conduct of Phase Ib study 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. After detailed deliberation, the committee recommended that: 1. One additional cohort to be added for sero positive subjects in addition to two Cohorts in the protocol. 2. Exploratory endpoint for T cell response to be clearly specified in the protocol. Accordingly, the firm should submit revised clinical trial protocol for further review by the committee.
3.	BIO/CT/22/000004 Lyophilized mRNA Vaccine for injection (Covid- 19) (Phase II/III clinical trial)	M/s Gennova Biopharmaceuticals Limited	The firm presented its proposal for conduct of Phase II study seamlessly followed by a Phase III study of GEMCOVAC-19 (COVID-19 vaccine) in healthy subjects of 5 to 17 years along with interim safety and immunogenicity data of Phase II part & safety data of 7 days of all subjects of Phase III part of ongoing Phase II/III clinical trial of HGCO19 Lyophilized

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			mRNA Vaccine for Injection (COVID-19) in adults before the committee. The committee noted the interim safety & immunogenicity data in adult age group in ongoing Phase II/III trial. After detailed deliberation, the committee recommended that: 1. The age group to be mentioned as 12 to less than 18 years instead of 12 to 17 years. 2. Safety data of 12 to 17 years should be assessed by DSMB for 2 days post 2nd dose (Day 30) before proceeding to Phase III part of the trial. 3. In the light of COVAXIN Whole Virion Inactivated COVID-19 vaccine being proposed as a comparator, neutralizing antibody titres by surrogate assay & $PRNT_{50}$ should be assessed for all subjects & interim Phase II safety & immunogenicity data of all immunogenicity cohorts should be submitted before proceeding to Phase III part of the trial. Accordingly, firm should submit revised Phase II/III clinical trial protocol to CDSCO for approval.
4.	BIO/CT/22/000003 COVAXIN & COVISHIELD (Clinical Trial)	ICMR & National Institute of Epidemiology, Chennai.	The firm presented its proposal for conducting clinical trial of safety and immunogenicity of the third dose of COVISHIELD/COVAXIN vaccine using homologous and heterologous regimen in immunocompromised patients before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed trial with the conditions that 1. Subject age group has to be stratified. 2. T and B cell response parameters need to be clearly defined in the protocol. 3. Safety follow up may be continued till the end of the study.
5.	BIO/IMP/21/000056 Recombinant human adenovirus serotype number 26 (rAd26) COVID-19 vaccine	M/s Dr. Reddy's Laboratories Ltd., Hyderabad	In light of recommendations of SEC meeting dated 27.12.2021 and 04.01.2022, the firm presented: 1. Efficacy data from Russian Phase III clinical trial data after unblinding.

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	(Sputnik Light Vaccine) (Marketing Authorisation)		2. Updated data of SARS-CoV-2 glycoprotein antibodies and neutralizing antibodies at Day 90 in Phase III Indian study. 3. Virus neutralization data of Sputnik Light vaccine as a booster against Omicron variant in Sputnik V vaccinated subjects of Russian study. 4. Proposal for consideration of booster dose of Sputnik Light to Sputnik V vaccine. The committee noted that the firm has not submitted neutralization activity data of sputnik light vaccine against Omicron variant as a standalone component. Therefore, after detailed deliberation, the committee recommended that the firm should produce the neutralization activity data of sputnik light vaccine against Omicron variant as a standalone component along with additional safety, efficacy and immunogenicity data from Russian and Indian studies for further review by the committee.
New Drug Division			
6.	ND/CT/20/000046 Umifenovir	CSIR-CDRI	In light of earlier recommendation of the SEC (COVID-19) meeting held on 26.08.2021, the applicant requested for reconsideration of the proposal and presented the data before the committee. After detailed deliberation, the committee considered its earlier recommendation dated 29.07.2021 and recommended that the applicant should conduct Phase III clinical trial in statistically significant number of patients and as proposed by the Institute, evidence of efficacy against Omicron variant should be produced.