Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 227th meeting held on 25.05.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000054 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 CORBEVAX vaccine	M/s Biological E Ltd., Hyderabad	The firm presented its proposal for grant of market authorization permission to administer heterologus booster (third) dose of SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 to individuals of age >18 years after 6 months of administration of primary vaccination (two doses) of COVAXIN & COVISHIELD vaccines alongwith the Phase III clinical trial data conducted in the country. The firm presented safety & immunogenicity data for all (416) subjects post 28 days of administration of booster dose after 6 & 9 months after primary vaccination. The committee noted that the vaccine is approved in the age of 5 years and above for primary vaccination (two doses at day 0 & 28) for restricted use in emergency situation. During presentation the firm submitted that they will present up to date safety data within few days for presentation. After detailed deliberation, the committee agreed for the update and review of safety data till date and meeting was deferred till such time.
2.	BIO/CT/22/000056 Novel Corona Virus 2019-nCoV Vaccine (Recombinant)	M/s Cadila Healthcare Limited	The firm presented its proposal for grant of permission to conduct Phase III clinical trial to administer heterologus booster (third) dose of Novel Corona Virus 2019-nCoV Vaccine (Recombinant) [single dose of 3 mg formulation to be administered in three shots of 0.1ml intradermally] to individuals of age >18 years after 6 months of administration of primary vaccination (two doses) of COVAXIN & COVISHIELD vaccines. The committee noted that the vaccine is approved in the age of 12 years and above for primary vaccination (two doses at day 0 & 28) for restricted use in emergency situation. After detailed deliberation, the committee recommended that firm should revise the clinical trial protocol as follows:

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			1. The enrollment criteria for booster dose vaccination should be 6 months+1 month after primary vaccination. 2. The assessment of Interferon gamma & TH1 / TH2 response for cell mediated immunogenicity analysis to be included in the protocol. 3. Assessment of Variant of concerns including Omicron in the study objective should be defined. 4. Clinical trial sites should be geographically distributed across the country. Accordingly, the firm should submit revised clinical trial protocol to CDSCO for approval.
3.	BIO/CT/21/000149 Whole Virion Inactivated Coronavirus (SARS-CoV-2) Vaccine [COVAXIN]	M/s Bharat Biotech International Limited (BBIL)	In continuation to earlier SEC committee recommendation dated 24.11.2021, the firm presented its proposal to carry out Phase II/III clinical trial of Whole Virion Inactivated Corona virus (SARS-CoV-2) Vaccine along with developmental toxicity study (gestational and lactation phase). The committee noted that there is variability in pre and post natal IgG titre value in developmental toxicity study (gestational and lactation phase) conducted in Newzealand Rabbit. After detailed deliberation, the committee recommended that the firm should submit additional preclinical toxicity study & teratogenicity data conducted in suitable animal model. Further, committee also recommended that the firm should revise the clinical trial protocol for inclusion of following: 1. Immunogenicity of vaccinated maternal participants throughout the gestational period should be co-primary endpoint. 2. Variant of concern including omicron, cell mediated immunity, AESI assessment should be included in the protocol. 3. Study objective, endpoint and assessment for Phase II part and Phase III should be clearly defined in the protocol. Accordingly, firm should submit the above preclinical toxicity data along with the revised clinical trial protocol for further evaluation by the committee.
4.	4-18/Roche/PAC-R/Tocilizumab/2021-BD	M/s Roche Products(I) Pvt ltd.	The firm presented its proposal for grant of approval for additional indication in COVID-19. After detailed deliberation, the committee

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	Tocilizumab Injection 80mg/4ml, 200mg/10ml, 400mg/20ml		observed that the data presented by the firm was inadequate for the proposed additional indication, hence the committee did not recommend the grant of approval for the proposed additional indication.
New Drug Division			
5.	ND/MA/20/0000166 Aviptadil for injection 500 mcg/vial(100mcg/ml)	M/s MSN Lab Pvt. Limited	In light of the earlier SEC recommendations dated 01.06.2021, 02.06.2021 and 03.06.2021, the firm presented 28 days interim report of phase III clinical trial of 71 subjects and also requested for emergency approval of the drug Aviptadil for injection 500 mcg/vial(100mcg/ml). During deliberation the committee noted that the study did not meet primary efficacy end point i.e. recovery from respiratory failure or ARDS by day 28 as per the approved protocol. After detailed deliberation, the committee recommended that firm should submit complete clinical trial report for further review by the committee.
GCT Division			
6.	CT/19/22 INO-4800	M/s Inovio Clinical Trials	The firm did not turn up for presentation.
7.	CT/15/21 ATR-002	M/s Clinexal Life Science	In light of previous SEC recommendation, the firm presented DSMB recommendation and safety data before the committee. After detailed deliberation the committee recommended for approval of the proposal for increase of subjects from 40 to 80 in India as proposed by the firm.
8.	CT/09/22 ES16001 COVID-19	M/s Cliantha	The applicant presented phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that the applicant should present pre-clinical and clinical study data with the active bio-constituent(s) of the proposed IP as proof of concept for the proposed Covid-19 indication before the committee for deliberation along with experts from phytopharmaceuticals.
9.	GCT/CT04/FF/2022/31520	M/s Veeda Clinical Research	The applicant presented phase III clinical trial protocol of booster dose of Anti-COVID-19 AKS Vaccine before the committee. The committee noted that one phase II/III study is going on in India, therefore, the committee

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			opined that the applicant should submit efficacy, immunogenicity & safety data of primary vaccination series (Phase III part) of this on-going trial for further review by the committee. Further on satisfactory results and evaluation of primary vaccination, the committee opined that in the given immunization situation in India mostly with COVISHIELD and COVAXIN, it would be appropriate that the applicant may also include COVAXIN Vaccine arm apart from COVISHIELD Vaccine arm and accordingly, the data and revised protocol should be submitted for further review by the committee.