Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 238th meeting held on 15.11.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000095 ChAd36-SARS-CoV-S COVID-19 Nasal Vaccine (BBV154) [Chimpanzee Adenovirus Vectored) recombinant COVID-19 vaccine]	M/s Bharat Biotech International Limited, Hyderabad	The firm presented its proposal for grant of permission to manufacture and market ChAd36-SARS-CoV-S recombinant COVID-19 vaccine (Nasal) for additional indication for administration of heterologus booster (third) dose to individuals of age ≥18 years after 6 months of primary vaccination (two doses) of COVAXIN & COVISHIELD vaccines alongwith the interim data of Phase III clinical trial conducted in the country. The firm presented clinical trial data for all (875) subjects including safety data up to 180 days & immunogenicity data of day 28 & 56 post administration of booster dose including neutralising antibody titres, spike specific IgA (Saliva) and IgG Titers (Serum), cell mediated immunogenicity and neutralising antibodies against variants of concern (VOC) including BA.1, BA.2, BA.5, BA.2.12. The committee reviewed the clinical trial data for Phase III heterologus booster dose trial along with the safety data from Phase III trial of ChAd36-SARS-CoV-S COVID-19 Nasal vaccine for primary vaccination in 3000 subjects. The committee noted that the vaccine is approved for restricted use in emergency situation in age 18 years and above for primary vaccination (two doses at day 0 & 28). The committee also reviewed summary of product Characteristics (SmPC), prescribing Information (PI) & factsheet presented before the committee. After detailed deliberation, the committee recommended for grant of permission to

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			manufacture and market ChAd36-SARS-CoV-S COVID-19 Nasal Vaccine (BBV154) [Chimpanzee Adenovirus Vector) recombinant COVID-19 vaccine] for additional indication for administration of heterologous booster (third) dose to individuals aged ≥18 years years after 6 months of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccines for restricted use in emergency situation with condition that the firm should continue to review & submit the safety follow up data after heterologous boost. Further, firm is also required to conduct an active post marketing surveillance and submit the interim data after obtaining safety data of first 2000 recipients. Further, the conditions of the original permission to manufacture & market of the said vaccine should remain unchanged.
2.	X-11026/188/2020-BDAnti-Platelet, Anti-Coagulant(APAC) Unfractionated heparin-Serum Albumin Conjugate	M/s Cadila Pharmaceuticals Limited, Ahamdabad	In light of earlier SEC, the Firm has presented the amended protocol no CRSC20007, version 03 dated 04-05-2022 for Phase I clinical study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.
New Drug Division			
3.	ND/MA/20/000166 Aviptadil for Injection 500 mcg/vial	M/s MSN	The firm presented the Phase III clinical trial study report with drug Aviptadil for Injection 500 mcg/vial before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market drug Aviptadil for Injection 500 mcg/vial restricted use in emergency situation for treatment of patients with severe COVID-19 with Acute Respiratory Distress Syndrome (ARDS)

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4.	ND/CT/21/000079101 -PGC-005	M/s Laxai Life Sciences Pvt. Ltd.	In light of earlier SEC (COVID) recommendation dated 09.02.2022 & 04.07.2022, the firm presented the safety study data of Phase I & Phase-II Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-II clinical trial as per protocol presented by the firm.
5.	IND/MA/22/000004 PROlectin M	M/s Murli Krishna Pvt. Ltd.	In light of the earlier SEC COVID-19 meeting recommendation dated 07.09.2022, the firm presented the supportive pharmacokinetic data along with the dose response relationship alongwith their proposal to conduct Phase 1b/2a clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase 1b/2a clinical trial as per the presented protocol.
GCT Division			
6.	CT/22/000070 Asunercept(APG 101)	M/s Pharm Olam	The applicant has presented their Phase III clinical trial protocol no APG_CD_018, version 2.0, FRA/IND/ITA/POL/ZAF-1 dated 26-07-2022 and India Specific Addendum version 1.0 dated 18-10-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.