Recommendations of the SEC meeting to examine COVID-19 related proposalunder accelerated approval process made in its 144th meeting held on 24.02.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/21/000021 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) Phase III clinical trial (in the age group of ≥5years to ≤18 years)	M/s Bharat Biotech, International Limited	Firm presented its proposal for conduct of phase III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) in the age group of ≥ 5years to ≤18 years along with clinical trial protocol. After detailed deliberation, the committee recommended that:- 1. Firm should submit Efficacy and Safety data of the ongoing Phase III clinical trial in adults along with the age subgroup analysis. 2. The design of trial should be revised to Phase II/III. Sample size and other consequential changes should be made to the protocol, accordingly. Accordingly firm shall submit revised clinical trial protocol for review of the committee.
2.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) Addendum to Factsheet	M/s Bharat Biotech, International Limited	In light of the recommendations of the SEC meeting dated 03.02.2021, firm presented Addendum to Factsheet for Whole Virion, Inactivated Corona Virus Vaccine (BBV152) [COVAXIN] . After detailed deliberation, the committee recommended that there may be no objection for the supporting guidance provided in addendum to Factsheet.
3.	BIO/MA/20/000102 ChAdOx1 nCov-19 Corona Virus Vaccine (Recombinant) Amendment in Factsheet	M/s Seum Institute of India Pvt. Ltd,	In light of the recommendations of the SEC meeting dated 03.02.2021, firm presented amended Factsheet forChAdOx1 nCov-19 Corona Virus Vaccine (Recombinant) [COVISHIELD]. After detailed deliberation, the committee recommended that the recommendation for vaccine administration in bleeding disorders should be more elaborated. There should not

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
			be any change in "reporting of side effects". Accordingly, the firm may submit the revised factsheet to CDSCO for approval.
4.	BIO/CT04/FF/2020/23436 Etanercept	M/s Lupin Limited	In light of the recommendations of the SEC meeting dated 18.01.2021 and 19.01.2021, firm presented the revised protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct of Phase II clinical trial subject to following: 1. In treatment arm 2 the word "Etanercept placebo" should be replaced to "placebo" 2. Primary endpoints should be evaluated at 14 days. 3. The clinical trial sites should be geographically distributed. Accordingly, firm should submit revised protocol to CDSCO for approval.
5.	BIO/IMP/21/000010 Gam COVID Vac Combined Vector vaccine (Component one and component two) MA (Emergency use)	M/s Dr. Reddy's Laboratories Ltd	Firm presented its proposal for grant of permission to import (marketing authorization) for emergency use of Gam COVID Vac Combined Vector vaccine (Component one and component two) along with the safety & immunogenicity data of Phase II part of Phase II/III clinical trial in India and interim safety, efficacy & immunogenicity data from overseas Phase III clinical trial. After detailed deliberation, the committee recommended that firm should submit immunogenicity and safety data of Phase II and III trial as per approved protocol for further consideration of the Committee. Further the firm is requested to present its data with more clarity.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
GCT Division			
6.	CT/15/21 online submission (23729) ATR-002	M/s Clinexel Life Science	Firm presented its proposal for conduct of phase II clinical trial. After detailed deliberation, the committee recommended that 1. Firm should submit clinical phase I PK/PD data, animal toxicology data . 2. Justification for using loading dose - 900mg OD on day 1 and maintenance dose 600mg OD on day 2 to 6. 3. Inclusion criteria should be modified as per ICMR guidelines and include only cases of moderate severity. 4. Subject with inadequately controlled hyper tension and history of recent thrombo-embolic events should be excluded. Accordingly exclusion criteria should be modified. 5. Safety should be co-primary endpoint. 6. Efficacy should be atleast 2 point improvement as per 7 point WHO ordinal scale. 7. Sample size should be restricted to 40 subjects only. Accordingly, the firm submit the data/ justification/revised protocol for further review.