Recommendations of the SEC (Cardiovascular & Renal) made in its 112th meeting held on 20.10.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000137 Icosapent Ethyl Capsule 500 mg & 1000 mg	M/s. BDR	The firm didn't turn up for presentation.
Biological Division			
2.	BIO/CT/22/000096 Darbepoetin alfa	M/s. Dr. Reddy's Laboratories Limited	Firm presented proposal for conduct of study titled "A Single Dose, Double-Blind, Two-Period, Two-Sequence, Crossover, Comparative Pharmacokinetic Study of DRL_DA and EU approved Reference Medicinal Product (Aranesp®), Administered by the Intravenous Route to Male Healthy Volunteers" Protocol no. DA-01-005, Version 1.0, dated 21st July 2022. The committee noted that the drug is already approved in India since 2011. After detailed deliberation, the committee recommended for grant of permission for conduct of study as per presented protocol.
SND Division			
3.	SND/MA/22/000083 Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm didn't turn up for presentation.
4.	SND/MA/22/0000261 Ticagrelor SR Tablets 120/180 mg	M/s. Torrent Pharmaceuticals	The firm presented their proposal of manufacture and market of Ticagrelor ER Tablets 120/180 mg with pilot BE study reports of higher strength of the drug product in fasting and fed condition and Phase III Clinical Trial protocol before the committee. After detailed deliberation, the committee opined that Phase III protocol needs to be forwarded to the experts for further review and necessary comments. Additional comments may be forwarded to the applicant as final recommendation. Further the firm should conduct BE study

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			for 120 mg SR tablets Vis-à-vis 60 mg b.i.d Ticagrelor SR Tablets.
FDC Division			
5.	FDC/MA/22/000132 Bempedoic acid 180mg + Ezetimibe 10mg tablets	M/s. Optimus Pharma Pvt. Ltd.	In light of earlier recommendations of SEC dated 09.06.2022, the firm presented their proposal along with BE study report before the committee. The committee noted that some other firm was earlier asked to conduct Phase III clinical trial by the committee when Bempedoic acid molecule was not approved. The committee also noted that Bempedoic acid tablet has been approved on 09.05.2022. Further, the proposed FDC is already approved in EU, UK, USA etc. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing with the condition to conduct Phase IV clinical trial. Accordingly Phase IV trial protocol should be submitted within 3 months from the date of approval. Committee also recommended that the earlier application of other applicants may also be considered provided that the applicant has conducted BE study as per the protocol approved by the committee with the same condition of Phase IV clinical trial.
6.	FDC/MA/22/000035 Bempedoic acid 180mg + Ezetimibe IP 10mg tablets	M/s. Mascot	In light of earlier recommendations of SEC dated 09.06.2022, the firm presented their proposal along with BE study report before the committee. The committee noted that some other firm was earlier asked to conduct Phase III clinical trial by the committee when Bempedoic acid molecule was not approved. The committee also noted that Bempedoic acid tablet has been approved on 09.05.2022. Further, the proposed FDC is already approved in EU, UK, USA etc. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing with the

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			condition to conduct Phase IV clinical trial. Accordingly Phase IV trial protocol should be submitted within 3 months from the date of approval. Committee also recommended that the earlier application of other applicants may also be considered provided that the applicant has conducted BE study as per the protocol approved by the committee with the same condition of Phase IV clinical trial.
GCT Division			
7.	CT/98/22 Online Submission (33732) Tenecteplase lyophilized	M/s. JSS Medical Research	The firm presented clinical trial protocol TNCTPL_IM_Ph_3-202, Version 2.0, dated 05.07.2022 before the committee. After detailed deliberation, the committee recommended that as the study is for myocardial infarction, hence applicant needs to provide supportive data with reference to safety and efficacy of the said product in country of origin.
8.	CT/109/20 Online Submission (20748) Finerenone/BAY 94-8862	M/s.Bayer	The firm didn't turn up for presentation.