Recommendations of the SEC (Cardiovascular & Renal) made in its 97th meeting held on 17.02.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New DrugDivision			
1.	ND/CT-21/FF/2022/29946 Bempedoic Acid Tablets 180mg & Ezetimibe 10mg tablets	M/s. Ravenbhel Healthcare Pvt. Ltd	The firm presented Phase III clinical trial and bioequivalence study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study andcommittee also opined that the firm should submit bioequivalence study results before the committee for further consideration of the proposed clinical trial.
SND Division			
2.	12-257/2010-DC (Pt-C-Novartis) Everolimus tablet 0.25mg, 0.5mg, 0.75mg and 1mg	M/s. Novartis Healthcare	The firm presented the updated package insert for Everolimus Tablets 0.25mg, 0.5mg, 0.75mg and 1mg before the committee. After detailed deliberation, the committee recommended for approval of updating the proposed package insert .
3.	SND/MA/20/0000221 Ticagrelor SR tablets 120mg/180mg	M/s. Akums	The firm didn't turn up for presentation.
FDC Division			
4.	FDC/MA/20/000160 Metoprolol IP 50mg + Chlorthalidone IP 12.5 mg +Cilnidipine IP 10 mg tablets	M/s. Pure & Cure Healthcare	In light of earlier SEC recommendation dated 15.07.2021, 16.07.2021& 19.07.2021, the firm presented revised Phase-III CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial subject to condition that patients who developed hyponatremia during the study should be discontinued after assessing the urine/serum osmolality.
GCT Division			
5.	CT/45/21 Online Submission (14416) Iptacopan (LNP023)	M/s. Novartis	In light of earlier recommendation dated 11.01.2022 & 12.01.2022, the firm presented their amended clinical trial protocol before the committee. After detailed deliberation, the committee

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			recommended for grant of permission for approval of the proposed protocol amendment V00.IN.0 dated 01.11.2021.
6.	CT/49/21 Online Submission (14705) LN P023	M/s. Novartis	In light of earlier recommendation dated 10.06.2021, 11.06.2021 & 14.06.2021, the firm presented their amended clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for approval of the proposed protocol amendment V00-IN.01 dated 06.12.2021.