Recommendations of the SEC (Cardiovascular & Renal) made in its 128th meeting held on 20.06.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000043 Roxadustat Tablets 20mg/50mg/70mg/100 mg/ 150mg	M/s. Akums Drugs & Pharm. Ltd.	The firm presented the proposal to conduct Bioequivalence study and requested for clinical trial waiver before the committee. After detailed deliberation, the committee recommended to revise & submit the protocol w.r.t inclusion criteria, exclusion criteria & methodology to CDSCO for further review by the committee. The committee opined that the decision to waive of the clinical trial will be taken after the review of Bioequivalence study report.
2.	ND/MA/23/000083 Roxadustat Tablets 20mg/50mg/70mg/100 mg/ 150mg	M/s. Synokem Pharmaceutical Ltd.	The firm presented the proposal to conduct Bioequivalence study and requested for clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the presented protocol with the condition that the firm should mention smokers and alcoholic subjects in exclusion criteria. The firm should submit Bioequivalence study report for further review by committee. The committee opined that the decision to waive of the clinical trial will be taken after the review of Bioequivalence study report.
SND Division			
3.	SND/IMP/23/000012 Sodium citrate 0.136mmol/ml USP solution for infusion	M/s. Fresenius Medical Care India Pvt. Ltd.	The firm presented the proposal for import and marketing permission of Sodium Citrate 0.136 mmol/ml USP solution for infusion, for regional citrate anticoagulation (RCA) in continuous venovenous haemodialysis (CVVHD), continuous venovenous haemodiafiltration (CVVHDF), sustained low efficacy (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) viamembrane plasma separation with clinical trial waiver, before the committee.

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			The firm informed that the proposed product is already marketed in about 40 countries and presented clinical evidence in support of the applied drug product. Based on clinical evidence and marketing authorization of the applied drug product in various countries, the committee considered local Phase III clinical trial waiver and recommended for grant of import and marketing permission of the applied drug product for proposed indication subject to condition that the firm should conduct a Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol within 3 months of grant of permission for the drug product in India for further evaluation by the committee.
4.	SND/IMP/23/000010 Bisoprolol Fumrate 1.25mg/3.75mg/7.5mg	M/s. Windlas Biotech Limited	The firm did not turn up for presentation.
GCT Division			
5.	CT/47/23 Online Submission (37376) Secukinumab	M/s. Novartis Healthcare	The firm has withdrawn their application.
6.	CT/37/23 Online Submission (37060) Milvexian	M/s. IQVIA	The firm presented Phase III clinical trial protocol no 70033093AFL3002, dated 09-12-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that 50% sites should be Govt. sites and 50% trial subjects should be enrolled in these Govt. sites.
Medical Device Division			
7.	CI/MD/2023/83213 Paclitaxel Eluting PTA Balloon Catheter (Mozec™ PEB PTA)	M/s. Meril Life Sciences Pvt. Ltd.	In light of earlier SEC recommendation dated 10.05.2023, the firm presented the four study case, conducted globally before the committee. After detailed deliberation, the committee agreed with the proposed protocol for conduct the Pharmacokinetic study. The approval may be given as per the Provisions of Medical Devices rules 2017.