Recommendations of the SEC (Cardiovascular & Renal) made in its 98th meeting held on 08.03.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000027 Icatibant Injection 30mg/3ml (10mg/ml)	M/s. MSN	The firm presented their proposal along with justification for local clinical trial waiver before the committee. The committee opined that the proposal needs to be evaluated in SEC pulmonary along with experts in Internal medicine.
2.	ND/MA/22/000037 Treprostinil solution for Infusion (1.0 mg/ml, 2.5 mg/ml, 5.0 mg/ml, 10.0 mg/ml)	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal along with justification for local clinical trial waiver before the committee. The committee noted that the drug is already approved in countries like US, EU, Canada & Japan and also drug is designated as orphan drug & indicated for serious and life threatening disorder and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Treprostinil solution for Infusion (1.0 mg/ml, 2.5 mg/ml, 5.0 mg/ml, 10.0 mg/ml.
SND Division			
3.	SND/IMP/20/000105 Empagliflozin 10mg/25 mg tablet	M/s. Boehringer Ingelehlheim	In light of earlier SEC recommendation, the firm presented the detailed clinical trial data of patients with eGFR values between 30ml and 45ml/minute/1.73m^2 . After detailed deliberation, the committee recommended for grant of approval of updated package insert of Empagliflozin 10mg/25 mg tablet.
4.	SND/MA/20/000221 Ticagrelor SR Tablet 120/180 mg	M/s. Akums Drugs	The firm didn't turn up for presentation.
5.	SND/MA/22/000083 Calcium Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm presented their proposal for manufacturing and marketing of Calcium Polystyrene Sulphonate Jelly 20% w/w. After detailed deliberation, the committee opined that the firm should present the details of safety data, advantages and

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			active/inactive ingredients in comparison with innovator product for further review by the committee.
FDC Division			
6.	FDC/MA/22/000012 Combikit of Rivaroxaban 2.5mg tablets (14nos) and Clopidogrel 75mg + Aspirin 75mg hard gelatin capsules (7nos)	M/s. Windlas	In light of earlier recommendation dated 08.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee opined that there are chances of various side effects of the proposed product including the intracranial bleeding as well as misuse. Hence, the committee did not recommend for approval of the FDC.
GCT Division			
7.	CT/24/21Online Submission (24074)	M/s. IQVIA	The firm didn't turn up for presentation.
8.	CT/43/21 Online Submission (14844)	M/s. Medpace	The firm presented protocol amendment version 3, dated 03 December 2021 before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
Medical Device Division			
9.	MD/Post Appr/2021/7704 Pericardial Bioprosthesis (Aortic) (Edwards PERIMOUNT Magna Ease)	M/s. Edwards Lifesciences (India) Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee observed that the proposed IFU is not in line with that approved in the country like USA. Therefore, the committee opined that the firm should submit the current status of the proposed IFU in USA as well as other countries including the reason for such change in IFU with supporting documents for review by the committee.
10.	MFG/MD/2021/51503 Transcatheter Heart Valve System	M/s. Meril Life Sciences Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the product with condition that the firm should conduct post market clinical investigation

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			with proposed device on atleast 30 patients.
11.	MFG/MD/2021/45831 Transcatheter Bicaval Valves System	M/s. Relisys Medical Devices Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing with the condition that the firm should conduct post market clinical investigation with proposed device on atleast 10 patients.
12.	CI/MD/2021/46393 Request w.r.t cost of implant for post market clinical Investigation for MesRes 100	M/s. Meril Life Sciences Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee reiterated the earlier recommendation dated 10.11.2021 and recommended that the firm should provide the medical device for treatment free of cost and conduct follow up investigation for the proposed device.