Recommendations of the SEC (Cardiovascular & Renal) made in its 122nd meeting held on 29.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000055 Bisoprolol Fumarate Tablets USP 3.75mg/7.5mg	M/s. Akums Drugs & Pharmaceuticals Pvt. Ltd.	The firm presented its proposal for manufacture and marketing of Bisoprolol Fumarate Tablets USP 3.75mg & 7.5mg (Additional strengths) for the indication "Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides" along with justification for waiver of BE study and clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should conduct comparative BE study with already approved product. Accordingly, the firm should submit the protocol for comparative BE study to CDSCO for further review by the committee. Committee also opined that clinical trial waiver would be considered after submission of the results of the comparative BE study.
FDC Division			
2.	FDC/MA/22/000302 Rosuvastatin + Bempedoic acid (5mg+180mg, 10mg + 180mg, 20mg + 180mg) tablet	M/s. Exemed	The firm did not turn up for presentation.
3.	FDC/MA/23/000008 Ezetimibe 10mg+ Atorvastatin Calcium 80mg tablets	M/s. Windlas	The firm did not turn up for presentation.
GCT Division			
4.	CT/134/22 Online Submission (34602) TIN816	M/s. Novartis	The firm presented the proposal of grant of permission to conduct Phase IIa clinical trial Protocol No. CTIN816A12201; version no. 00 dated 23-Aug-2022 before the committee. After detailed deliberation, the committee recommended to submit

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			literature on CKD diagnosis and accordingly the inclusion & exclusion criteria in study protocol to be revised. After protocol revision, the proposal should be re-deliberated before the committee.
5.	CT/63/21 Online Submission (23315) Ziltivekimab	M/s. Novo-Nordisk	The firm has presented protocol amendment version 9.0 dated 30-Nov-2022 (Protocol No. EX6018-4758) before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm. Further, the committee recommended that the patients diagnosed as latent tuberculosis, during screening for exclusion, to be reported by PI to appropriate authorities as per guidelines of Ministry of Health and Family welfare under National tuberculosis eradication program.
6.	CT/28/21 Online Submission (22561) Semaglutide 2.4mg	M/s. Novo-Nordisk	The firm presented protocol amendment 6 version 7.0 dated 09-09-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
7.	CT/98/22 Online Submission (33732) Tenecteplase lyophilized	M/s. JSS Medical Research	In light of earlier SEC held on 24.11.2022, the firm presented updated safety and efficacy data of study drug Tenecteplase before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. The Phase of trial should be revised from Phase III to Phase II. 2. Initially the trial should be conducted in 15 subjects from India and applicant should submit their safety data along with updated global safety and efficacy data for further review by the committee. These 15 subjects should be randomized from both Govt. and Private sites.