Recommendations of the SEC (Cardiovascular) made in its 03rd/25 meeting held on 06.02.25. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/01/25 Online Submission (47120) Baxdrostat Tablets 1mg/2mg and Dapagliflozin Tablets 10 mg	M/s AstraZeneca Pharma India Limited	The firm presented phase 3 clinical trial protocol no. D6973C00001 CSP Version 2.0 dated 25 Nov 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/06/24 37019 Online Submission (37019) Ziltivekimab	M/s Novo Nordisk India Pvt. Ltd	The firm presented protocol amendment version 5.0 dated 02 December 2024 protocol no. EX6018-4979. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/166/23 37211 Online Submission (37211) Ziltivekimab	M/s Novo Nordisk India Pvt. Ltd.	The firm presented recruitment of additional 60 patients to achieve randomization of 150 patients from India, protocol no. NN6018-4914. After detailed deliberation, the committee recommended for approval of recruitment of additional 60 patients from India as presented by the firm.
4.	CT/02/24 P Online Submission (37213) Ravulizumab	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment 3.0 dated 02 December 2024 protocol no. D928DC00001. After detailed deliberation, the committee opined that the firm should submit rationale and more justification for the amendments proposed for further review by the committee.
BA/BE Division			
5.	BABE/CT05/FF/2024 /45127 Torsemide and Eplerenone Tablet 20 mg/25 mg	M/s Cipla Limited	The firm did not turn up for the presentation.
Medical Devices Division			
6.	MFG/MD/2024/132452 Mitral Heart Valve (Brand Name: TRIA)	M/s. Dolphin Life Science India LLP	Under Discussion

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
7.	FDC/MA/23/000231 Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (ER) + Telmisartan IP 40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg film coated bilayered tablet	M/s Ajanta Pharma Ltd.	In light of the earlier SEC recommendation dated 07.05.2024, the firm presented the proposal along with BE study report and justification for CT waiver based on their phase III Clinical Trial report on higher strength i.e. Metoprolol succinate 50 mg + Amlodipine 5 mg + Telmisartan 40 mg tablets, before the committee. After detailed deliberation, the committee considered the BE study report as well as the request for Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC.
8.	04-01/2022-DC (Misc. 2) (Pt.1) Ramipril + Amlodipine 2.5mg+5mg, 5mg+5mg, 10mg+5mg tablets	M/s Sanofi India Limited.	In light of the earlier SEC recommendation dated 22.05.2024, The firm presented the proposal for update prescribing information of the FDC changes based on the updated company core data sheet (CCDS) version 5 dated 28.09.2023. After detailed deliberation, the committee considered and approved the changes in prescribing information.