Recommendations of the SEC (Cardiovascular) made in its 08th/25 meeting held on 05.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/148/24 Online Submission (39118) Selatogrel 16 mg/0.5mL aqueous solution	M/S Mylan Pharmaceuticals Private Limited	The firm presented protocol amendment version 6.0 dated 21 Jan 2025 protocol no. ID-076A301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/52/25 Online Submission (49488) Vicadrostat (BI 690517)	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. 1378-0018 version no. 1.0 dated 14-JAN-2025. After detailed deliberation, the committee opined the following: 1. PI for CVOT trial should have qualification of DM/DNB Cardiology. 2. The firm shall submit details of phase 2 trial data with Vicadrostat in relation to drug interaction with beta blockers and ARNI (which are used for heart failure with reduced EF) for further review by the committee.
3.	CT/06/24 Online Submission (39265) Ziltivekimab C 30 mg/ml/ placebo	M/s Novo Nordisk India Pvt Ltd	The firm presented for Increase the number of subjects from India 700 to 1000 protocol no. EX6018-4979. After detailed deliberation, the committee recommended for approval of Increase the number of subjects from India 700 to 1000.
4.	CT/166/23 Online Submission (39263) Ziltivekimab C 30 mg/ml / placebo	M/s Novo Nordisk India Pvt Ltd	The firm presented protocol amendment version 5.0 dated 02 April 2025 protocol no. NN6018-4914. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/95/24 Online Submission (39311) Olezarsen (ISIS 678354)	M/s. Medpace Clinical Research India Pvt. Ltd.	The firm presented Protocol Amendment 3 dated 11-Feb-2025 protocol no. ISIS 678354-CS15. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
6.	BABE/CT05/FF/2025/47447 Ramipril and Amlodipine Capsules 10mg/10mg	M/s Unison Pharmaceuticals Pvt Ltd	Firm presented the BA/BE study Protocol No. C1B05256 Version No. 01 Protocol Date 27-DEC-2024 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only
Medical Devices Division			
7.	CI/MD/2024/140804 Defibrillation Lead, Slitter, Delivery Catheter	M/s. St. Jude Medical India Pvt. Ltd.	The proposal of the firm for the grant of permission to conduct Global Clinical Investigation (Protocol number: ABT-CIP-10549 version A dated 20.11.2024) of Defibrillation Lead, Delivery Catheter and Slitter device was further deliberated before the expert committee. The safety evaluation data and pilot study data generated on the device was presented before the SEC by the firm. After detailed deliberation, the expert committee recommended for grant of permission to conduct the said study in the country
SND Division			
8.	SND/MA/23/000282 Cilnidipine Extended Release Tablets 20mg	M/s. Unique Pharmaceutical Laboratories (A Division of J.B. Chemical & Pharmaceuticals Limited)	The firm did not turn up for the presentation.