Recommendations of the SEC (Cardiovascular) made in its 08th/26 meeting held on 09.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/183/25 Online Submission (53767) Amlodipine + Indapamide + Telmisartan	M/s. Cliantha Research Limited.	In light of earlier SEC recommendation dated 07.04.2026. The firm presented revised protocol, protocol no. C2A06071 version no. 02 dated 01 -May-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/14/26 Online Submission (54631) Ferric derisomaltose	M/s. Pharmaceutical Research Associates India Private Limited.	In light of earlier SEC recommendation dated 05.03.2026, the firm presented phase III clinical study protocol No P-Monofer-CHF-02 version no. 3.0, amendment 2 dated 09-APR- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/27/26 Online Submission (55043) Lerodalcibep	M/s. Medpace Clinical Research India Pvt. Ltd.	In light of earlier SEC recommendation dated 05.03.2026, the firm presented phase IIIb clinical study Protocol No.: LIB003-008 version no. 1.1 dated 28-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/64/26 Online Submission (56532) Elecoglipron (AZD5004)	M/s. AstraZeneca Pharma India Limited.	The firm presented phase III clinical study protocol No. D7266C00001 version no. 1.0 dated 16 March 2026 and Local CSP – Addendum version 1.0 India, dated 09 Apr 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
BA/BE Division			
5.	BABE/CT05/FF/2025/ 52521 Bempedoic acid/ Ezetimibe/ Atorvastatin tablets 180/10/40 mg	M/s. Advity Research Private Limited.	In light of the earlier SEC recommendation dated 05-03-2026, the firm presented the study Protocol No. AR179-25 Version No. 01 Protocol Date 22-SEP-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
6.	SND/MA/24/000140 Colchicine Tablet 0.5 mg	M/s. Pure and Cure Healthcare Pvt. Ltd.	In the light of earlier recommendation dated 05.03.2025, the firm presented additional clinical data for grant permission for manufacture and marketing of Colchicine Tablets 0.5 mg for the proposed indication i.e. to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease along with BE and CT waiver before the committee. After detailed deliberation, the committee accepted the presented additional data and recommended to grant permission for manufacture and marketing of Colchicine Tablets 0.5 mg for applied additional indication.