Recommendations of the SEC (Cardiovascular) made in its 02nd/26 meeting held on 04.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1)	CT/07/26 Online Submission (54207) NNC0487-0111 B 0.80 mg/mL NNC0487-0111 B 1.67 mg/mL NNC0487-0111 B 3.35 mg/mL NNC0487-0111 B 6.7 mg/mL NNC0487-0111 B 13.4 mg/mL NNC0487-0111 B 26.8 mg/mL	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase IIIb clinical study protocol no. NN9490-8266 version no. 1.0 dated 31 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Patients Information sheet (PIS) shall provide the anticipated adverse events and precautions related to hypoglycemia. Same shall be submitted to CDSCO. 2. Standard of care should be provided below HbA1 (10)
Medical Devices Division			
2)	IMP/MD/2025/145135 Cool line Intravascular Heat Exchange Catheter Kit (ZOLL), ICY Intravascular Heat Exchange Catheter Kit (ZOLL), Quattro Intravascular Heat Exchange Catheter Kit (ZOLL), Solex 7 Intravascular Heat Exchange Catheter Kit (ZOLL)	M/s. ZOLL MEDICAL INDIA PRIVATE LIMITED	The firm presented their proposal for grant of permission to import and market the medical device viz Intravascular Heat Exchange Catheter Kits, manufactured by M/s ZOLL Circulation Inc., USA. After detailed deliberation, the committee opined that the proposal may be further deliberated along with the specialist from Critical care and anesthesiology, before taking further necessary action in the matter.
BA/BE Division			
3)	BABE/CT05/FF/2025/52204 Atorvastatin/Ezetimibe /acetylsalicylic acid 40/10/100 mg capsules	M/s. Lambda Therapeutic Research Limited.	Firm presented the BA/BE study Protocol No. 0241-24 Version No. 2.0 Protocol Date 10-JUN-2025before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
4)	BABE/CT05/FF/2025/51525 Sacubitril, Valsartan and Dapagliflozin tablets 97 mg/103	M/s. Aizant Drug Research Solutions Private Limited.	Firm presented the BA/BE study Protocol No. C25161 Version No. 00 Protocol Date 28-JUL-2025 before the committee. After detailed deliberation, the committee opined that the firm has not presented the

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	mg/10 mg		suitable justification/rationale for this combination. Firm need to present the proposal again along with suitable justification/rationale for this combination.
New Drugs Division			
5)	ND-11/6/2025-eoffice Inclisiran Solution for injection in pre-filled syringe 284 mg/1.5 ml	M/s. Novartis Healthcare Ltd.	The firm presented the proposal for amendment in the warning statement mentioned in import and market permission of Inclisiran Solution for injection in pre-filled syringe 284 mg/1.5 ml from 'To be sold by retail only under the prescription of cardiologist only' to 'To be sold by retail under the prescription of cardiologist and physician with post graduate qualification in medicine only' before the committee. The committee reviewed the proposal and did not find enough scientific justification for amendment in warning statement. After detailed deliberation, the committee did not recommend for the amendment in warning statement proposed by firm and reiterated earlier SEC recommendation dated 06.11.2024 "The drug Inclisiran solution for injection to be sold by retail under the prescription of cardiologist only".
6)	ND-11012/5/2025-eoffice Mavacamten Capsules: 2.5 mg, 5 mg, 10 mg, 15 mg	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented their proposal for update in Prescribing Information of drug Mavacamten Capsules 2.5 mg, 5 mg, 10 mg, and 15 mg (Version: 03, Dated: 04-July-2025), before the committee. After detailed deliberation, the committee considered the proposal, for update in prescribing Information, as presented by firm.
FDC Division			
7)	FDC/CT/26/000001 Amlodipine Besylate IP eq. to Amlodipine 2.5 mg/2.5 mg + Bisoprolol Fumarate IP 2.5 mg/5 mg film coated tablets	M/s. Exemed Pharmaceuticals	In light of the condition mentioned in permission in Form CT-23 dated 28.05.2025; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.

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			Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
8)	FDC/MA/23/000110 Bisoprolol Fumarate 5 mg/2.5 mg + Cilnidipine 10 mg/10 mg + Telmisartan 40 mg/40 mg tablets	M/s. Windlas Biotech Ltd.	In the light of earlier SEC recommendation dated 13.05.2025, the firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. Accordingly, the firm should submit the Phase III clinical trial report to CDSCO for further review by the committee.