Recommendations of the SEC (Cardiovascular) made in its 12th/25 meeting held on 09.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2024/115829 ADVARING Mitral (Bovine Annuloplasty Ring Mitral) , ADVARING Tricuspid (Bovine Annuloplasty Ring Tricuspid)	M/s Advanced Medtech Solutions Private Limited.	The firm presented their study protocol, protocol no. AMS/ADVARING/001/2025, Version 2.0 to conduct Clinical Investigation on the devices viz. Bovine Annuloplasty Ring Mitral (Brand name: ADVARING Mitral) and Bovine Annuloplasty Ring Tricuspid (Brand name: ADVARING Tricuspid) in the country. The firm proposed for manufacture of said devices which is developed in Russia. After detailed deliberation, the committee observed that the innovator device is approved for marketing only in the country of origin. The firm was unable to produce the pre-clinical studies data and published literatures to demonstrate the safety and performance of the device. Therefore, the committee recommended that the firm shall submit the following documents for further deliberation: 1. All the preclinical study data generated on the device. 2. Copy of the first approval obtained from the National Regulatory Authority in the country of origin for the device. 3. The proof of the number of units used in the patient along with the longest clinical follow-up on the device used. 4. Adequate published literature/data on the safety and performance of the device.
BABE Division			
2.	BABE/CT05/FF/2025/52007 Three Test Products: Oral ER Milrinone 14 mg Capsule	M/s. Veeda Clinical Research Limited.	The firm presented the BA/BE study protocol, vide No.: 25-VIN-0413, Protocol Version 01 dated 19-Aug-2025 for export purpose only, before committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission for conduct of the BA/BE study for export purpose only.
New Drugs Division			
3.	E-22737 Trimetazidine, Modified Release tablets 35 mg.	M/s Servier India private Limited.	The firm presented proposal for updating the prescribing information from version 5.0 (April 2022) to version 6.0 (April 2025) for drug product, Trimetazidine Modified Release tablets 35 mg before the committee. The key changes in the proposed prescribing information are inclusion of drug reaction with eosinophilia and systemic symptoms (DRESS) under Severe cutaneous adverse reactions (SCARs) and undesirable effects, paraesthesia as an uncommon adverse reaction and other administrative changes. After detailed deliberation, the committee recommended for grant of approval for the proposed updates in prescribing information as presented by the firm.
FDC Division			
4.	FDC/CT/20/000074 Carvedilol IP 3.125mg/6.25mg/12.5 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg/5mg/5 mg film coated tablet	M/s Sun Pharma Laboratories Limited.	In light of earlier SEC recommendation dated 19.04.2021, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report with condition that firm shall update prescribing information (product information leaflet) and label in bold letter with the followings: 1. The product is approved for patients who are stable with both these drugs individually/ separately prescribed. 2. Heart rate monitoring is required while using this combination. Accordingly, firm should submit revised above mentioned Prescribing Information (PI) and Label to CDSCO.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	FDC/MA/24/000232 Bisoprolol Fumarate IP 2.5 mg/5 mg + Cilnidipine IP 10 mg/10 mg + Telmisartan IP 40 mg/40 mg film coated tablet	M/s Ravenbhel Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 13.05.2025, the firm presented the proposal along with BE study report and Phase III CT study protocol before the committee. After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee recommended for grant of permission to conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.
6.	FDC/MA/22/000115 FDC/78/2025-eoffice Pantoprazole Sodium IP eq. to Pantoprazole (as gastro resistant tablet) + Aspirin (as gastro resistant tablet) (20 mg + 81 mg & 20 mg + 150 mg) hard gelatin capsules	M/s. Akums Drugs and Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 20.12.2023; the firm presented an active post-marketing surveillance protocol. After detailed deliberation, the committee recommended for conducting the Active PMS study with the condition that firm should include Endoscopy test at the discretion of the investigator. Accordingly, the revised active post-marketing surveillance protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit results of the study for further review by the Committee.