Recommendations of the SEC (Cardiovascular) made in its 03rd/26 meeting held on 18.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2025/167839 Abbott Sensor Based Monitoring System	M/s. Abbott Healthcare Pvt. Ltd	The firm has presented study protocol to conduct clinical investigation on the device "Abbott Sensor Based Monitoring System" intended to quantitatively measure and monitor elevated interstitial fluid lactate levels in New York Heart Association (NYHA) Class II, III or IV heart failure patients (18 years and older) by M/s. Abbott Diabetes Care Ltd, U.K. After detailed deliberation, the committee has opined that, the applicant shall submit adequate justification/ rationale for the measurement of lactate as potential biomarker in the disease pathogenesis and its severity in heart failure patients. The firm should submit the patient data generated in the country of origin with respect to the following for further appropriate action: a) The correlation of lactate levels with the conventional risk factors/clinical parameters of different stages of heart failure patients; b) The specificity and sensitivity of lactate as a prognostic/diagnostic biomarker as against the gold standard clinical marker of NTProBNP or BNP; c) The data on the correlation levels of lactate from intestinal fluid versus blood.
BA/BE Division			
2.	BABE/CT05/FF/2025/ 52521 Bempedoic acid/Ezetimibe/ Atorvastatin tablets 180/10/40 mg	Advity Research Private Limited	The firm did not attend the meeting.
FDC Division			
3.	FDC/MA/25/000205 Bempedoic Acid 180	M/s Exemed Pharmaceuticals	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the

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	mg/180 mg/180 mg + Atorvastatin Calcium IP eq. to Atorvastatin 10 mg/20 mg/40 mg film coated tablet		committee. Committee noted that FDC in higher strength i.e. Bempedoic acid 180mg + Atorvastatin Calcium eq. to Atorvastatin 80mg tablets is already approved. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of the BE study should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.
4.	FDC/MA/25/000152 Bisoprolol Fumarate IP 5mg + Trimetazidine Hydrochloride IP 80 mg (ER) film coated bilayered tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present enough scientific justification for the rational of the FDC. 2. There is no unmet need for the FDC. 3. There is no Pharmacological synergism as mechanism of action of the component of the FDC is totally different. 4. The product is not approved internationally. 5. FDC is not recommended in any standard treatment guideline. In view of above, the committee did not recommend for approval of the proposed FDC.
5.	FDC/CT/26/000003 Bisoprolol Fumarate IP 1.25 mg/2.5 mg + Dapagliflozin Propanediol Monohydrate 10 mg/10 mg eq. to Dapagliflozin film coated tablet	M/s. Akums Drugs and Pharmaceutical Limited	In light of the condition mentioned in permission in Form CT-23 dated 28.03.2025; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. The sample size should be increased to at least 250 patients. 2. More sites to be included which should be geographically

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			distributed. 3. Principal investigator in all the study sites should be Cardiologist. Accordingly, the revised Phase IV clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase IV clinical trial report for further review by the committee.