

Recommendations of the SEC (Cardiovascular) made in its 07th/26 meeting held on 05.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/117/25 Online Submission (51380) Enlicitide Decanoate	M/s. MSD Pharmaceuticals Private Limited	In light of earlier SEC recommendation dated 15.10.2025, the firm presented phase III clinical study protocol no.: MK-0616-038, version no. 00 dated 20-JUN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm shall provide Investigational Medicinal Product for Post-Trial Access (free of cost) till market authorization in India.
Medical Devices Division			
2.	CI/MD/2024/115829 ADVARING Mitral (Bovine Annuloplasty Ring Mitral) , ADVARING Tricuspid (Bovine Annuloplasty Ring Tricuspid)	M/s. Advanced Medtech Solutions Private Limited	The proposal for grant of permission to conduct Clinical investigation on the device viz. Bovine Annuloplasty Ring Mitral (Brand name: ADVARING Mitral) and Bovine Annuloplasty Ring Tricuspid (Brand name: ADVARING Tricuspid) was further deliberated in the SEC (Cardiovascular). After detailed deliberation, the committee opined to take final concurrence from Cardiac surgeon on the said proposal for taking necessary action in the matter
3.	CI/MD/2025/167839 Abbott Sensor Based Monitoring System	M/s. Abbott Healthcare Pvt. Ltd	The proposal for grant of permission 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) was further deliberated in the SEC(Cardiovascular). After detailed deliberation, the committee recommended for consideration of the proposal with condition that the patients enrolled in the said study should be adequately compensated in comparison with other participating countries
BABE Division			

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4.	BABE/CT05/FF/2025/51525 Sacubitril, Valsartan and Dapagliflozin tablets 97 mg/103 mg/10 mg	Aizant Drug Research Solutions Private Limited	<p>In light of the earlier SEC recommendation dated 04.02.2026, the firm presented the Protocol No. C25161 Version No. 00 Protocol Date 28-JUL-2025.</p> <p>After detailed deliberation the committee recommended for conduct of proposed BE study for export purpose only. Additionally, the firm should perform an additional BE study with 5 mg Dapagliflozin in combination with 97 mg Sacubitril and 103 mg Valsartan by filing a separate application with CDSCO.</p>