

Recommendations of the SEC (Cardiovascular) made in its 09th/25 meeting held on 12.06.2025 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/59/25 Online Submission (49542) AZD0780 30mg Tablet	M/s AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D7960C00015 Version No. 1.0 Protocol dated 11-APR-2025; Local CSP Addendum IND-1: Version 1.0, dated 14 Apr 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/62/25 Online Submission (49590) LY3502970	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd	The firm presented phase III clinical study Protocol No.: J2A-MC-GZPL Version No. Initial dated 24-JAN-2025. The firm has presented the said protocol and related data in respect to obesity/overweight, diabetic etc., however, the clinical study data is not provided related with the proposed indication of hypertension. Therefore, the committee opined that the firm need to submit data in hypertension patients only for the further review by the committee.
Medical Devices Division			
3.	IMP/MD/2024/13145 8 Ridaforolimus Eluting Coronary Stent System (Brand Name : EluNIR-PERL™)	M/s. Translumina Therapeutics LLP	The proposal of the firm for import of the applied device (EluNIR-PERL), has been further deliberated before the expert committee along with Clinical data generated on 1000 patients globally. After detailed deliberation of safety and performance data of the device, the expert committee recommended for grant of permission to import the device with the condition that the firm shall carryout Post marketing clinical Investigation on 100 patients in the country, accordingly a study protocol shall be submitted within a period of 03 months from date of launch of product in the market.
FDC Division			
4.	FDC/MA/25/000127	M/s Ajanta Pharma Limited	The firm did not turn up for presentation.

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	Cilnidipine IP 20mg + Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate 50 mg (ER) film coated bilayered tablet		