

Recommendations of the SEC (Cardiovascular) made in its 10th/25 meeting held on 23.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/09/23 Online Submission (39916) Ziltivekimab B 15 mg/ml/placebo	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 7.0 dated 19 March 2025 protocol no. EX6018-4915. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/82/25 Online Submission (50212) TQJ230	M/s Novartis Healthcare Private Limited	The firm presented phase IIIb clinical study Protocol No.: CTQJ230A12301E1 Version No. 00 dated 19-DEC-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/88/25 Online Submission (50347) Vicaurostat (BI690517)	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. 1378-0041 version 1.0 dated 02 May 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Medical Devices Division			
4.	IMP/MD/2025/160442 Aveir Leadless Pacemaker (LP)	M/s St. Jude Medical India Pvt. Ltd.	The firm presented proposal for Grant of permission to import the device viz, (Aveir Leadless Pacemaker (LP)) manufactured by M/s St. Jude Medical India Pvt. Ltd, USA for marketing in the country. The product is approved by the National Regulatory Authority of the country of origin. The firm has presented safety data, clinical data and PMS data generated on the said device globally before committee. After detailed deliberation the committee recommended for grant of permission to import and market the said device in the country with the following conditions: 1. The firm shall conduct Post Marketing Clinical Investigation on at least 30 subjects in the country on Indian Population.

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			<p>2. Out of total study sites, 70% of the study sites should be from Government hospitals and 30% from Private hospitals.</p> <p>Accordingly, the firm shall submit the Post Marketing Clinical Investigation Plan to this office within 6 months from the date of launch of the said device in the country for necessary action.</p>
FDC Division			
5.	FDC/CT/25/000056 Bisoprolol Fumarate IP 5 mg/5 mg + Perindopril Arginine 5 mg/10 mg film coated bilayered tablet	M/s Servier India Pvt. Ltd.	The firm did not turn up for presentation.
6.	FDC/MA/25/000146 Nebivolol Hydrochloride IP eq. to Nebivolol 2.5 mg + Telmisartan IP 40 mg uncoated bilayered tablet	M/s Windlas Biotech Limited	<p>The firm presented the proposal along with BE study protocol and justification for Phase III CT waiver before the committee.</p> <p>The committee noted that the NOC for continued manufacturing and marketing under 18 month policy decision for the higher strength i.e., Nebivolol HCl 5 mg + Telmisartan 40 mg tablets issued on 16.07.2015.</p> <p>After detailed deliberation, the committee considered the request for Phase III CT waiver and recommended to conduct BE study.</p> <p>Accordingly, the firm should submit BE study report to CDSCO for further review by the committee.</p>