

Recommendations of the SEC (Cardiovascular) made in its 06th/25 meeting held on 09.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/43/23 Online Submission (38041) Milvexian	M/s IQVIA RDS India Private Limited	The firm presented for Increase in the number of subjects from 487 to 700 in India. protocol no. 70033093ACS3003. After detailed deliberation, the committee recommended for approval of increase in number of subjects from 487 to 700 in India as presented by the firm.
2.	CT/92/24 Online Submission (38107) BI690517	M/s IQVIA RDS India Private Limited	The firm presented protocol amendment version 3.0 dated 18 -Dec-2024 protocol number: 1378-0020. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/64/24 Online Submission (38184) AZD5462	M/s Parexel International Clinical Research Private Limited	The firm presented waiver of the conditions (1) Amendment is approved except the exclusion criteria regarding ferritin level (2) More geographically distributed Govt. sites shall be included. Protocol Version 2.0 / Local CSP India-2, dated 04-Dec-2024 protocol no. D9090C00008. After detailed deliberation, the committee recommended for approval of waiver of the conditions as presented by the firm (1) Amendment is approved except the exclusion criteria regarding ferritin level (2) More geographically distributed Govt. sites shall be included.
4.	CT/63/21 Online Submission (38233) Ziltivekimab 15 mg/ml	M/s Novo nordisk India Pvt Ltd.	The firm presented protocol amendment version 14.0 dated 16 December 2024 Protocol no. EX6018-4758. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/37/23 Online Submission (38318) Milvexian	M/s IQVIA RDS India Private Limited	The firm presented Protocol Amendment 3 dated 05 Feb 2025 protocol no. 70033093AFL3002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			

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6.	CI/MD/2024/140804 Defibrillation Lead, Slitter, Delivery Catheter	M/s. St. Jude Medical India Pvt. Ltd.	<p>The proposal for the grant of permission to conduct Global Clinical Investigation (Protocol number: ABT-CIP-10549 version A dated 20.11.2024) of said device has been deliberated before the expert committee.</p> <p>After detailed deliberation, the expert committee opined that the applicant need to submit the following details for taking further necessary action in the matter:</p> <p>(1) Pilot study data generated on the applied device specifically use on the device on the Left bundle branch area of the heart of the patient.</p> <p>(2) Safety evaluation data of the device carried out on the South Asian population, if any.</p>
New Drugs Division			
7.	ND/CT/24/000086 Vericiguat film coated tablets 2.5 mg, 5 mg and 10 mg	M/s Bayer Pharmaceuticals Pvt. Ltd.	<p>The firm presented the proposal to carry out a Retrospective, non-interventional database study for the evaluation of real-world drug use patterns of drug Vericiguat film coated tablets 2.5 mg, 5 mg and 10 mg (Study No. 22613; v 1.0, 06 SEP 2024), before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct proposed Retrospective, non-interventional database study as per the protocol presented by the firm.</p>
8.	ND-11/3/2025-eoffice Rosuvastatin Calcium Tablets IP 5mg, 10 mg, 20 mg and 40 mg (Crestor®)	M/s Astrazeneca Pharma India Limited	<p>The firm presented proposal for update in Prescribing Information (Version 6 & 7), before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval for update in Prescribing Information of drug Rosuvastatin Calcium Tablets IP 5mg, 10 mg, 20 mg and 40 mg (Crestor®), as presented by firm.</p>
SND Division			
9.	SND/MA/23/000282 Cilnidipine Extended Release Tablets 20 mg	Unique Pharmaceutical Laboratories (A Division Of J. B. Chemicals & Pharmaceuticals Limited)	Firm did not turn up for the presentation.

