

Recommendations of the SEC (Cardiovascular) made in its 13th/25 meeting held on 15.10.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/129/25 Online Submission (51567) KJX839 (Inclisiran)	M/s. Novartis Healthcare Private Limited	The firm presented phase IIIb clinical study protocol no.: CKJX839A12309 version no. 00 dated 09-JUL-2025. After detailed deliberation, the committee recommended grant of permission to conduct the trial as presented by the firm. Dr. Ajay Mahajan didn't participate.
2.	CT/138/25 Online Submission (52084) Zilebesiran	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no.: ALN-AGT01-008 version no. original protocol dated 15-JUL-2025. After detailed deliberation, the committee recommended grant of permission to conduct the trial as presented by the firm. Dr. Sandeep Bansal didn't participate.
3.	CT/117/25 Online Submission (51380) Enlicitide Decanoate	M/s. MSD Pharmaceuticals Private Limited	The firm presented phase III clinical study protocol no.: MK-0616-038 version no. 00 dated 20-JUN-2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee: 1) The comparative statement (in tabular form) of applied phase III protocol (MK-0616-038) with global ongoing/ completed study protocol (P013, P017, P018) with respect to study design, primary objective/ endpoint, secondary objective/ endpoint, inclusion & exclusion criteria, safety and efficacy endpoint. 2) Status of ongoing global clinical

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			trial vides study code no.: P013, P017, P018, P015, and P019.
Medical Devices Division			
4.	IMP/MD/2025/14719 6 Clip Delivery System (TriClip G4 Clip Delivery System), Steerable Guide Catheter (TriClip Steerable Guide Catheter)	M/s. St. Jude Medical India Pvt Ltd	<p>The firm presented proposal for grant of permission to import for marketing of said medical device manufactured by M/s Abbott Medical, USA. The said device is intended for reconstruction of the insufficient tricuspid valve through tissue approximation.</p> <p>The said device is approved and marketed in major countries for more than two years. The firm presented the global clinical evidence and post marketing data demonstrating the safety and effectiveness of said device.</p> <p>After detailed deliberation the committee recommended for the grant of permission to import for marketing of the said medical device in the country with the condition that the firm shall submit the study protocol to conduct Post Market Clinical Investigation on at least 20 Indian subjects, within 3 months from the date of approval.</p>
New Drugs Division			
5.	ND/119/2025-eoffice Clopidogrel Bisulphate IP 75 mg tablet	M/s. Sanofi healthcare India private limited	<p>The firm presented proposal for updating the prescribing information for drug product, Clopidogrel Bisulphate IP 75 mg tablet (Plavix) from current PI as per CCDS V21 dated 23.06.2016 to propose PI as per CCDS Version 32 dated 17.02.2022 before the committee.</p> <p>The key changes in the proposed prescribing information are related to editorial changes in the indication, dosage and administration, warnings and precautions, special population, clinical</p>

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			<p>efficacy/clinical studies adverse reactions etc.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed updates in prescribing information as presented by the firm.</p>
6.	<p>E-22737</p> <p>Trimetazidine Modified Release tablets 35 mg</p>	M/s. Servier India private Limited	The firm did not turn up for presentation.
FDC Division			
7.	<p>FDC/CT/25/000056</p> <p>Bisoprolol Fumarate IP 5 mg/5 mg + Perindopril Arginine 5 mg/10 mg film coated bilayered tablet</p>	M/s. Servier India Pvt. Ltd.	<p>In light of the condition mentioned in permission in Form CT-23 dated 18.09.2024; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
8.	<p>FDC/CT/25/000091</p> <p>Combi-kit of Dapagliflozin Tablet 10 mg/10 mg/ 10 mg/ 10 mg + Bisoprolol Fumarate Tablet 1.25 mg/2.5 mg/5 mg/10 mg + Sacubitril and Valsartan Tablet 100 mg/100 mg/200 mg/ 200 mg per strip</p>	M/s. Eris Lifesciences Limited	<p>In light of the condition mentioned in permission in Form CT-23 dated 30.05.2025; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>

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9.	FDC/MA/25/000203 Telmisartan IP 40 mg/40 mg + Amlodipine Besilate IP eq. to Amlodipine 5 mg/5 mg + Bisoprolol fumarate IP 2.5 mg/5 mg film coated bilayered tablet	M/s. Windlas Biotech Limited	<p>The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial.</p> <p>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.</p>