

**Recommendations of the SEC (Cardiovascular) made in its 05<sup>th</sup>/25 meeting held on 05.03.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/03/23 Online Submission (37471)  ISIS 678354 (Olezarsen)	M/s Medpace Clinical Research India Pvt. Ltd.	The firm presented protocol amendment 5 dated 03 December 2024 protocol no. ISIS 678354-CS6.  After detailed deliberation, the committee opined that the firm shall submit more justification for amendment in statistical analysis and secondary endpoints after last patient recruited for further review by the committee.
<b>BA/BE Division</b>			
2.	BABE/CT05/FF/2024 /44013  FDC of Torsemide and Spironolactone 5mg/25 mg	M/s Cipla Limited	In light of the earlier SEC recommendation dated 22/10/2024, the firm presented literature for proposed FDC. After detailed deliberation, the committee opined that the data/literature submitted by the firm is not relevant. Therefore the firm should present again the relevant literature as required in the last deliberation and updates, if any.
<b>Medical Devices Division</b>			
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 said device (EluNIR-PER), has been deliberated before the expert committee.  After detailed deliberation, the expert committee recommended that the firm has produced the clinical data generated globally on the previous version of the device, however the clinical data for the applied device is not produced before the committee.  Therefore, the committee recommended that the firm should carry out Clinical study in the Indian population to establish the safety and performance of the applied device at least on 100 patients before taking appropriate action in the matter.
<b>New Drugs Division</b>			

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4.	ND/MA/24/000125 Esaxerenone Tablets 1.25, 2.5 and 5 mg	M/s Sun Pharma Laboratories Limited	<p>In the light of earlier recommendation dated 06.11.2024 the firm presented revised phase III CT protocol (Protocol No. ICR/24/016, Version No. 1.0, dated 10th December 2024) before the committee.</p> <p>After detailed deliberation, the committee noted that some of the investigators are MD, Medicine.</p> <p>Accordingly, committed recommended for grant of permission to conduct Phase III clinical trial for New Drug Esaxerenone tablets as per protocol presented subject to the condition that all the Investigators should be Cardiologist and list of the investigators should be submitted to CDSCO accordingly.</p>
5.	ND/MA/24/000105 Esaxerenone Tablets 1.25, 2.5 and 5 mg	M/s Eris Lifesciences Limited	<p>In light of earlier recommendations dated 15.10.2024, the firm has presented the BE study report before the committee.</p> <p>After detailed deliberation, the committee noted the results of BE study and recommended for grant of permission to initiate Phase III clinical trial for New Drug Esaxerenone tablets.</p>
<b>SND Division</b>			
6.	SND/MA/24/000140 Colchicine Tablet 0.5mg	M/s PURE & CURE HEALTHCARE Pvt. Ltd	<p>The firm presented their proposal for grant of permission to manufacture and market Colchicine Tablets 0.5 mg for additional Indication to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease with BE and CT waiver before the committee.</p> <p>Firm has informed that, the proposed drug product is approved in US for the proposed indication since June 2023.</p> <p>After detailed deliberation, the committee recommended to present additional</p>

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			clinical data for the proposed indication to support waiver for the clinical studies.
<b>FDC Division</b>			
7.	FDC/MA/22/000248  Bisoprolol Fumarate IP + Telmisartan IP + Chlorthalidone IP (2.5mg/5mg/10mg + 20mg/40mg/80mg + 6.25mg/12.5mg/12.5 mg) uncoated tablets	M/s. Windlas Biotech	<p>In light of earlier SEC recommendation dated 17.09.2024, the firm presented the proposal along with amended BE protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per presented amended BE protocol.</p> <p>Accordingly, the firm should submit BE study report along with Phase-III CT protocol to CDSCO for further review by the committee.</p>