

Recommendations of the SEC (Cardiovascular) made in its 03rd/24 meeting held on 13.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/02/24 Online Submission (41274) Ravulizumab 10mg/mL (300mg/30mL	M/s. AstraZeneca	The firm presented Phase III clinical study protocol No. D928DC00001, protocol amendment 1.0, dated 12 June 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/21/000063 Online Submission (30731) Ziltivekimab15 mg/ml	M/s. Novo Nordisk	The firm presented recruitment of additional 100 patients for ongoing study protocol No. EX6018-4758 (ZEUS). After detailed deliberation, the committee recommended approval for recruitment of additional 100 patients in ongoing study as presented by the firm.
3.	CT/13/24 Online Submission (41557) Baxdrostat Tablets 1mg &2mg	M/s. AstraZeneca	The firm presented phase 3 clinical study protocol No. D6970C00008 CSP version 1.0 dated 27 Oct 2023. After detailed deliberation, the committee recommended that the applicant shall submit more justification in inclusion criteria for including two different subject's population in study for further review by the committee.
4.	CT/06/24 Online Submission (41420) Ziltivekimab C 30mg/ml	M/s. Novo Nordisk	The firm presented Phase III clinical study protocol No. EX6018-4979 version No. 1.0 dated 04 December 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Medical Device Division			
5.	IMP/MD/2023/96704 Vascular Closure System	M/s. Teleflex Medical Private Limited	The proposal of Teleflex Medical Private Limited for import and marketing of "Manta Vascular Closure Device" manufactured by M/s Essential Medical Inc., USA deliberated before the SEC committee with regard to its safety aspects. The firm presented the clinical study data

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			<p>carried out in USA (351 patients) and EU (50 patients) and regulatory approval of the device by Health Canada, USFDA, TGA and EU and comparison data with respect to predicate device.</p> <p>After detailed deliberation, the committee considered the proposal. However, the committee suggested that since the proposed product is not used in Indian population. Therefore, safety data on Indian population need to be generated by the applicant. Accordingly, firm need to submit study protocol to CDSCO to conduct the safety study on Indian population within 3 months atleast on first 50 patients from the date of import of the product.</p>
SND Division			
6.	SND/MA/23/000156 Sacubitril and Valsartan Tablets 25mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm did not turn up for presentation.
New Drugs Division			
7.	ND/IMP/23/000057 Mavacamten capsules 2.5mg, 5mg, 10mg, 15 mg	M/s. Bristol Myers Squibb	<p>The firm presented their proposal for grant of permission to import and market Mavacamten capsules 2.5mg, 5mg, 10mg, 15 mg for the proposed indication of obstructive hypertrophic cardiomyopathy (oHCM) in adult patients along with the request for local Phase-III Clinical Trial waiver before the committee.</p> <p>After detailed deliberation, the committee opined that there is an unmet medical need in the country. The drug Mavacamten capsules met orphan drug status in many countries.</p> <p>Accordingly, the committee recommended for the grant of permission to import and market of the drug Mavacamten capsules 2.5mg, 5mg, 10mg, 15 mg with local Phase III clinical trial waiver subject to the condition that</p> <ol style="list-style-type: none"> 1. The drugs should be sold by retail

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			<p>under the prescription of cardiologist only.</p> <p>2. Firm should conduct Phase IV clinical trial. Accordingly, the firm should submit phase IV CT protocol within 3 months of approval for the review by the committee.</p>