

**Recommendations of the SEC (Cardiovascular & Renal) made in its 121<sup>st</sup> meeting held on 14.03.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/23/000052 Sacubitril/Valsartan (as sodium Complex) Extended Release 100mg + Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg tablets	M/s. Bajaj Healthcare Ltd.	In light of the earlier SEC recommendation dated 08.12.2022& 09.12.2022, the firm presented its proposal before the Committee. After detailed deliberation, Committee recommended that firm could not present adequate rationality, justification, clinical proof of concept as Dapagliflozin because of its PK and Pharmacological diuretics effects, could not be prepared as FDC with Sacubitril/Valsartan for twice daily administration.  Therefore the, firm is required to present the justification/documents before presenting the PK study protocol and CT study protocol.
<b>GCT Division</b>			
2.	CT/144/22 Online Submission (33999) ARO-APOC3	M/s. Medpace	The applicant presented Phase III Clinical trial protocol no. AROAPOC3-3001, amendment 3.0 dated 22 Nov 2022 before the committee. The Committee noted that the proposed indication i.e. Familial Chylomicronemia Syndrome is a rare disease. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the condition that the applicant should submit safety and efficacy data of double blind period (first 12 months) along with IDMC recommendations to CDSCO for further review by the committee and once the data is reviewed by the committee, trial might be continued with open label extension parts of the study.
3.	CT/64/21 Online Submission (18643) Tirzepatide	M/s. Eli Lilly	The applicant has presented protocol amendment (b) dated 21-01-2022 of protocol no-I8F-MC-GPID, Protocol addendum (1.1) dated 17-12-2021, protocol addendum (3.1) dated 25-01-2022 and India specific protocol addendum No- 6 dated 17-11-2022 before the committee. After detailed deliberation, the committee recommended for approval of proposed

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			protocol amendment and addendums.
4.	CT/24/21 Online Submission (23236) Atrasentan	M/s. IQVIA	The applicant has withdrawn the proposal.
5.	CT/10/23 Online Submission (35934) Sibeprenlimab (VIS649)	M/s. George	<p>The proposal of open label extension (OLE) of ongoing two trials, Phase-2 and Phase-3 was first presented in SEC (Cardiovascular &amp; Renal) dated 28.07.2022. There were many concerns raised by the committee during the presentations and those were duly communicated to the firm. The firm presented its proposal and committee noted that there was no point wise clarification given on the concerns raised in the previous SEC meeting.</p> <p>The committee opined that Open label extension study is not justified for Phase-2 study patients and for Phase-3 study patients it is planned to start after two years if permission is granted.</p> <p>The key inclusion criteria for open label extension study that is “Investigator assessment that the subject may derive benefit from treatment with Sibeprenlimab for up to an additional 26 doses” cannot be assessed without unblinding the subject. As such open label extension studies are not for efficacy but primarily for assessing long-term safety.</p> <p>In view of current circumstances, the committee did not recommend open label extension study of Phase-2/3.</p>
<b>Medical Device Division</b>			
6.	CI/MD/2022/77755  BIP Central Venous Catheter	M/s. Biosphere Clinical Research Private Limited	<p>In light of earlier SEC recommendation dated 21.02.2023, the firm presented its proposal before expert of anesthesia and critical care.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with the following condition:</p> <ol style="list-style-type: none"> <li>1. The firm needs to exclude the ongoing infection in the inclusion criteria.</li> </ol>

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			2. The firm needs to exclude the ongoing infection and they should also need to form a subgroup to mention the average duration of the catheter.
7.	CI/MD/2022/72489 Sterile Intraosseous Access / Infusion Device (Ozyn-D™)	M/s. Rcupe Lifesciences Private Limited	In light of earlier SEC recommendation dated 21.02.2023, the firm presented its proposal before expert of anesthesia and critical care. After detailed deliberation the committee recommended for grant of permission to conduct the proposed study in Indian population
8.	CI/MD/2021/51498 BioMime Branch Sirolimus Eluting Side branch	M/s. Meril Life Sciences Private Limited	The firm presented its protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct post market clinical investigation in the country with protocol version 4.0 dated 29-Dec-2022.
9.	IMP/MD/2022/53336 LKT Disposable Perfusion Circuit, Kidney Transporter	M/s. Renovate Biologicals Private Limited	The firm did not turn up for presentation.
10.	CI/MD/2022/62891 Transcatheter Heart Valve(THA) Model 3	M/s. Meril Life Sciences Pvt. Ltd.	The firm presented its amended protocol before the committee. After detailed deliberation, the committee recommended for approval of the protocol version 1.0.1 dated 07-Dec-2022.