Recommendations of the SEC (Cardiovascular & Renal) made in its 126th meeting held on 24.05.2023 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/23/000029 Dapagliflozin Tablet 10mg	M/s. Astrazeneca Pharma India Limited	The firm presented the proposal for import and marketing of Dapagliflozin tablet 10mg for the additional indication i.e for the treatment of heart failure in adult. The firm in support of the additional indication presented the global clinical trial data along with the justification of the local clinical trial waiver. The committee noted that the proposed indication for the Dapagliflozin tablet 10mg has been approved in around 55 countries. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Dapagliflozin tablet 10mg for the additional indication i.e for the treatment of heart failure in adult.
GCT Division			
2.	CT/66/22 Online Submission (33152) Crovalimab 340 mg/2ml	Ms. Roche	In light of earlier SEC recommendations dated 24.11.2022 & 21.12.2022, the firm presented the justification before the committee. The committee noted that the applicant had not complied with the previous SEC recommendations. After detailed deliberation, the committee reiterated its earlier recommendations.
3.	CT/77/22 Online Submission (33262) Crovalimab	Ms. Roche	In light of earlier SEC recommendations dated 24.11.2022 & 21.12.2022, the firm presented the justification before the committee. The committee noted that the applicant had not complied with the previous SEC recommendations. After detailed deliberation, the committee reiterated its earlier recommendations.
4.	CT/149/21 Online Submission	M/s. Parexel	The firm presented the proposal for protocol amendment version 4.0 dated

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	(23501) BI 690517		19Aug 2022 before the committee. After detailed deliberation, the committee recommended for grant of approval for amendment section 4.1.5.1 (blinding) of the proposed protocol version 4.0 dated 19 Aug 2022. The committee also recommended that the rest of other proposed changes in the proposed protocol amendment are not approved since randomization is already completed.
5.	CT/17/23 Online Submission (36110) Finerenone + Empagliflozin	M/s. Labcorp	The firm presented the proposal for Phase II clinical trial of protocol number 21839 dated 15 Nov 2021 before the committee. After detailed deliberation, the committee recommended for grant of permission for the proposed Phase II clinical trial subject to the following conditions: 1. Acute urinary tract infection should be included as exclusion criteria. 2. More than two hypoglycemic episodes in past six months should be included as exclusion criteria. 3. The lower limit of Hb1Ac is required to be defined in the inclusion criteria. 4. The proposed clinical trial sites should be geographically distributed of which 50 percent should be government sites.
6.	CT/133/22 Online Submission (24127) Sodium Zirconium Cyclosilicate	M/s. AstraZeneca	The firm presented the proposal for waiver No.1&2 of the clinical permission for protocol number D9488C00001 version 2.0 dated 08June 2022 before the committee. After detailed deliberation, the committee recommended for waiver of condition No.2 of the clinical trial permission. However, the condition No.1 of the clinical trial permission should be read as- “All investigators should follow CKD guidelines for dietary restriction and high potassium diet should be restricted for trial subjects”. Accordingly, the applicant should revise the India specific protocol addendum w.r.t protocol section 5.3.1.

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7.	CT/88/21 Online Submission (25255) Flnerernone	M/s. Bayer	The firm presented the proposal for increasing the number of subjects from 50 to 65 under protocol amendment 1 version No: 3.0 dated 01 Dec 2021 from India before the committee. After detailed deliberation, the committee recommended for increasing the number of subjects from 50 to 65 from India.