Recommendations of the SEC (Renal) made in its 08th/24 meeting held on 17.09.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/97/24 Online Submission (44642) NNC0519-0130 B 34 mg/ml / placebo	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase 2 clinical study protocol no. NN9541-7841 version 1.0 dated 22 May 2024. After detailed deliberation, the committee opined that the firm shall submit the evidences for the comments as mentioned below: I. Rationale of the study is not clearly defined as unmet need for chronic kidney disease (CKD) patients is not justified and protocol is not having clarity regarding mechanism of action of the investigative drug in preventing the progression of kidney disease. II. Mention regarding the proposed mechanism of action of investigative drug to achieve the kidney endpoints such as reduction the proteinuria, decrease the GFR etc. III. In addition to existing therapies how does the investigative drug proposed to further improve the kidney endpoints? Any novel mechanism proposed or enhancing the existing mechanism is proposed ? IV. Dose escalation strategy of IMP from 6mg to 35mg is not defined in the protocol based on GFR ≥15 and ≤90ml/min/1.73m2. All the patients in the GFR ranges from 15ml to 90ml proposed to receive the same dose. Any variation of doses proposed for the above GFR range ? V. Submit the data of Phase I study conducted to established rationale of the study for CKD patients. If it's not available, needs to conduct a phase I study initially to gather preliminary

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			evidence. ***VI.*** Rationale for composition of the IMP drugs based on GIP/GLP receptor. How much will be the composition of each GIP/GLPRA in each strength proposed. Are they within the range of established safety dose of each component individually ? For GIP and GLPRA ?
2.	CT/86/24 Online Submission (44106) Sodium zirconium cyclosilicate (SZC)	M/s. Fortrea Development India Private Limited	The proposal may be deliberated before SEC after availability of peadiatric nephrologist as a special invitee.
3.	CT/25/21 Online Submission (34005) Atrasentan	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment 5 version 1.1 dated 05 July 2023 and protocol amendment 6 dated 22 September 2023 protocol no. CHK01-01. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/66/22 Online Submission (34628) Crovalimab 340mg/2ml	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 7.0 dated 01 July 2024 protocol no. BO42353. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/65/23 Online Submission (29991) Atacicept	M/s. Medpace Clinical Research India Pvt. Ltd.	In light of earlier SEC recommendation on 20.02.2024, the firm presented protocol amendment 6, dated 23 August 2023 protocol no. VT001-0050. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.