Recommendations of the SEC (Renal) made in its 06th/25_meeting held on 19.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/54/25 Online Submission (49480) Felzartamab	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical trial protocol no. 299PN301 version no. 1.0 dated 24 Jan 2025. After detailed deliberation, the committee is opined that the proposed comparator arm as presented in protocol is not appropriate.In addition, the proposed rescue medication at 24 weeks,i.e, tacrolimus monotherapy may not appropriate anticipating better clinical response with treatment either Rituximab or the combination of tacrolimus with adequate dose of glucorticooids. Further, explanation deliberated by the firm regarding use of study drug (Frlzartamab) dose of 16mg/kg is inappropriate. Firm should produce adequate justification/evidence to use 16mg/kg in Membranous Glomerulonephropathy. The vaccination schedule for the treatment and comparator arm must be same as it may potentially influence the outcome assessments between the groups. In addition, this should be explicitly detailed prior to the start of the trial keeping in mind the conduct of trial in Indian setting. The firm has agreed during the deliberations, the vaccines would be provided by the sponsor. Accordingly, the firm shall modify the protocol for further review by committee.
2.	CT/49/21 Online Submission (39321) Iptacopan (LNP023)	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 03 dated 13 November 2024 protocol no. CLNP023F12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/160/24 Online Submission (39355)	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented protocol amendment 6.0 version 7.0 dated 07 April 2025 protocol no. 19920

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	BAY 94-8862 /Finerenone		After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
4.	CT/22/24 Online Submission (39589) Baxdrostat Tablets 1mg/Placebo Baxdrostat Tablets 2mg/ Placebo Dapagliflozin Tablets 10 mg	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 5.0 dated 20 February 2025 protocol no. D6972C00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
5.	e-Receipt No.: 80394 & No. 87012 Eculizumab concentrate for solution for infusion 300 mg (10mg/ml) [Soliris]	M/s. AstraZeneca Pharma India Limited	Under Discussion.