Recommendations of the SEC (Renal) made in its 08th/25 meeting held on 21.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/09/24 Online Submission (38720) Zibotentan 0.25 mg + Dapagliflozin 10 mg Zibotentan 0.75 mg + Dapagliflozin 10 mg	M/s AstraZeneca Pharma India Limited	In light of earlier SEC Recommendation dated 20.05.2025. The firm presented more detailed justification for Increase the number of sample size from 1500 to 1800 for protocol amendment version 2.0 dated 14 Feb 2025 protocol no. D4325C00010. After detailed deliberation, the committee recommend for approval of protocol amendment as presented by the firm.
2.	CT/54/25 Online Submission (49480) Felzartamab	M/s PPD Pharmaceutical Development India Private Limited	In light of earlier SEC Recommendation dated 19.06.2025. The firm has clarified the points raised in earlier SEC meeting dated 19.06.2025. As there is no consensus on the standard treatment for Primary Membranous Nephropathy (PMN), tacrolimus monotherapy as a comparator may be reasonable, though it is not the most suitable, for protocol no. 299PN301 version no. 1.0 dated 24 Jan 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with subject to following conditions. 1. In view of the concerns over the Tacrolimus monotherapy as the comparator, the rescue medication treatment should be at the discretion of treating physician and it may be instituted before 24 weeks of the open label treatment phase if there are signs of clinical deterioration. In addition, the rescue medication must be provided by the sponsor during the trial. 2. The sponsor will provide the vaccines after successful study screening and prior to randomization of the participants who are not covered by any personal health insurance.
3.	CT/26/24 Online Submission (40325)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 17 June 2025 protocol no. CTIN816B12202.

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	TIN816		After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/166/22 Online Submission (40412) SNP-ACTH (1-39) Gel	M/s Cliantha Research Limited	The firm presented protocol amendment 3 version 4 dated 28 May 2025 protocol no. ACTH-PMN-301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/103/25 Online Submission (50793) BAY 3401016	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented phase IIa clinical study protocol no. 22419 version no. 1.0 dated 26 Jun 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
6.	CT/126/23 Online Submission (40691) BION-1301 (zigakibart)	M/s PPD Pharmaceutical Development (India) Pvt. Ltd.	The firm presented protocol amendment 6 version 7.0 dated 14 April 2025 protocol no. CHK02-02. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
New Drugs Division			
7.	ND/CT/25/000057 Sodium Zirconium Cyclosilicate powder for oral Suspension 5/ 10 g	M/s AstraZeneca Pharma India Limited	The firm presented Phase IV clinical trial protocol of drug Sodium Zirconium Cyclosilicate powder for oral Suspension 5/ 10 g (Protocol no. D9480L00025, Ver. 1.0 dated 30.05.2025), before the committee. The firm presented study objective, study design, inclusion & exclusion criteria, risk assessment and mitigation strategy, dose modification criteria, management and reporting of AE, safety evaluation, statistical analysis methodology and sample size to be enrolled in study etc. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV Clinical trial as per protocol presented by the firm.
8.	ND/MA/25/000049 Voclosporin capsule 7.9 mg	M/s Zydus Lifesciences Limited	The firm presented BE study report and justification of Phase-III local clinical trial waiver, before the committee. The Committee considered BE study results. The committee noted that the data

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			presented with respect to orphan drug status is anecdotal. Therefore, the firm is requested to submit adequate data to substantiate the Orphan drug status in Indian context. Further, there are concerns over the safety profile of drug in Indian population as the published study data included Asian patients but not patients from India specifically. The committee also noted that dose titration on drug in Indian population is required. The committee is of opinion that there is lack of sufficient efficacy and safety data to prove that the dose requirement in Indian population is adequate. In addition, the data on the course of dose titration is also inadequate considering the safety profile of the drug. The firm is therefore, required to submit data proving that there is no substantial ethnic variability. After detailed deliberation, the committee didn't agree for Phase-III CT waiver at this stage.