Recommendations of the SEC (Renal) made in its 12th/25 meeting held on 22.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/10/25 Online Submission (47645) LNP023	M/s. Novartis Healthcare Private Limited.	The firm didn't turn up for presentation.
2.	CT/50/25 Online Submission (49274) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited.	In light of earlier SEC Recommendation dated 20.05.2025, the firm presented phase III clinical study protocol no.: CVAY736L12301 version no. 00 dated 04-FEB-2025. Now the firm presented revised protocol and dose modification. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/171/25 Online Submission (53260) BI 764198	M/s. IQVIA RDS (India) Private Limited.	The firm presented phase III clinical study protocol no.: 1434-0017 version no. 1.0 dated 09-SEP-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government site shall be included in the study.
BA/BE Division			
4.	BABE/CT05/FF/2025/ 47823 Tiopronin ER Pellets 1000 mg	M/s AZIDUS LABORATORIES LIMITED, CHENNAI (India).	The firm presented their BE protocol No. AZBE012505, Version: 1.0. Dated 06-FEB-2025 for export purposes. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for export purposes only.
Biological Division			
5.	BIO/CT04/FF/2025/ 52219 Eculizumab Concentrate for solution for infusion 300 mg (10 mg/ml) (r-DNA origin)	M/s. AstraZeneca Pharma India Limited	Under Discussion

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
6.	ND-11012/7/2025-eoffice Mycophenolate Sodium Tablets 180 mg and 360 mg Tablets U.S.P	M/s Novartis Healthcare Private Limited	The firm presented proposal for updating the current approved India specific package insert dated 13 Oct 2022 of Mycophenolate Sodium Tablets 180mg and 360 mg Tablets U.S.P based on the Germany Pack insert dated 15 Aug 2022 into proposed India specific package insert dated 30 Jan 2024 based on Germany Pack insert dated 06 Dec 2024 before the committee. The key changes in the proposed package insert are related to changes in the fertility, pregnancy and lactation, undesirable effects, patient counseling information and product name and label claim etc. After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm
7.	ND/MA/25/000049 Voclosporin capsule 7.9 mg	M/s. Zydus Lifesciences Limited	In light of earlier SEC recommendation dated 21.08.2025, firm has re-deliberated their proposal for the Phase-III CT waiver of Voclosporin capsule 7.9 mg, before the committee. The committee noted that there is no unmet medical need for proposed indication, as other drugs for the treatment of Lupus Nephritis are already available in the country. The committee also noted that there are concern over the safety profile of drug, as the published study data included only Asian Patients and did not include any patients from India and opined that dose titration in Indian population is required. Furthermore, firm has not adequately addressed the concern raised during previous SEC meeting dated 21.08.2025 w.r.t. substantial ethnic variability. After detailed deliberation, the committee did not agree for Phase-III CT waiver
SND Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
8.	SND/MA/23/000292 Solifenacin Succinate Oral Solution 1 mg/ml	M/s Pure and Cure Healthcare Pvt. Ltd	The firm presented the Proposal for grant of manufacturing and marketing permission Solifenacin Succinate Oral Solution 1mg/ml for additional indication for the treatment of neurogenic detrusor over activity in pediatric patients aged 2 years and older with CT waiver before the Committee. The committee noted that Solifenacin Succinate Oral Solution 1mg/ml is already approved for applied indication by US-FDA from year 2020. After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Solifenacin Succinate Oral Solution 1 mg/ml for Proposed indication subject to the condition to conduct Active PMS study. Accordingly, the firm should submit active PMS Protocol to CDSCO within 3 months of drug product approval.