Recommendations of the SEC (Nephrology & Urology) made in its 04th/26 meeting held on 16.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/144/25 Online Submission (52037) LY3502970	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	In light of earlier SEC Recommendation dated 18.12.2025, the firm presented phase III clinical study protocol no.: J2A-MC-GZPS, amendment (a) dated 12-SEP-2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the SEC committee in presence of two Endocrinologist experts. 1. Interim analysis data from the ongoing same clinical trial in other participating countries, along with the recommendations of the DSMB. 2. The Co-Principal Investigator of this study shall be an endocrinologist. 3. Data from the completed and ongoing studies in India and in other countries to be analyzed with respect to weight reduction in lean muscle mass, as well as loss of intramuscular and pelvic muscle mass.
2.	CT/177/25 Online Submission (53470) Utreglutide (GL0034) Solution for injection 1.0 mg/mL	M/s. Sun Pharmaceutical Industries Limited	In light of earlier SEC Recommendation dated 13.01.2026, the firm presented phase I clinical study \protocol no. UTRE-25-01 version no. 1.0 dated 19 Nov 2025. Now the firm presented revised protocol for protocol no. UTRE-25-01 amendment 01/IND-1 dated 24th February 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition to enroll hemodialysis patients from India.
Biological Division			
3.	BIO/CT04/FF/2025/53256 Alteplase 2 mg Lyophilized powder	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented the proposal to conduct Phase III clinical trial titled "A Prospective, Multi-center, Open label, Two-arm, Comparative Clinical study to Evaluate the Efficacy and Safety of RLS-

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	for reconstitution in single use vial for intracatheter instillation		Alteplase 2 mg with Cathflo® Activase® 2 mg in Complete Restoration of Patency and Flow in Dysfunctional Central Venous Access Devices" vide Protocol No.: RLS/VAS/2025/07, Version 1.0, dated 15 Sep 2025. After detailed deliberation, the committee recommended following changes in the presented protocol**:** 1. The protocol should clearly specify the different types of catheters to be used in the study. *2.* The exact volume of the investigational drug to be administered must be defined for each type of catheter. 3. The number of study sites should be increased to improved data robustness and recruitment. 4. With an increase in catheter types and study sites, the sample size should be appropriately increased. 5. Study sites should be selected based upon the availability of: • C-arm (CR) or ultrasound-guided catheterization facilities. • Adequate infrastructure to support such procedures. 6. Each site must have experiences and trained personnel capable of performing catheterization procedures. 7. The protocol should specify that the catheterization procedure is to be performed by qualified personnel to maintain consistency**.** Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation by the committee.
4.	BIO/CT04/FF/2025/53304 NM5072	M/s. Ablenio Sciences Private Limited	The firm presented the proposal to conduct Phase II clinical trial titled "A Phase II, Open-Label Study of NM5072 in Patients with Immunoglobulin A Nephropathy (IgAN)" vide Protocol Number: NM5072-IgAN-601**.** After detailed deliberation, the committee recommended following changes in the presented protocol**:**

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			1. Being a global phase 2 trial, to keep Generalizability and data integrity, the study should be conducted at multiple centers. 2. The protocol must clearly define inclusion criteria with respect to proteinuria, hematuria, glomerular filtration rate (GFR). 3. Patients should have received at least 90 days of standardized maximum ACE inhibitor therapy, with or without SGLT2 inhibitor therapy, prior to enrollment. 4. Patients should be on 90 days of stable supportive therapy before inclusion. 5. The protocol should clearly specify whether patients on immunosuppressive therapy are include or excluded. 6. Study endpoints, statistical considerations, and study rationale need to be adequately defined. 7. The sponsor has registered multiple phase 2 trials for a similar molecule (NM8074) in last 12-14 months for different indications (PNH, ANCA Associated Vasculitis, Dermatomyositis, IgA nephropathy: https://clinicaltrials.gov/search?intr=NM8074&viewType=Card. Status for all the trials needs to be submitted. 8. Status of the another similar registered phase 2 trial for IgA nephropathy which was apparently approved in 2024 by FDA - NCT06454110 for NM8074 (https://www.hcplive.com/view/fda-clears-initiation-of-phase-2-efficacy-trial-for-ruxoprubart-in-igan) 9. Details of phase 1 trial for NM5072 need to be submitted along with the published literature. 10. Rationale for conducting the trial exclusively in India since the molecule was developed in USA and USA being a leading recruiting country for the clinical trial. Accordingly, the revised protocol shall be submitted to CDSCO for further

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			evaluation by the committee.
FDC Division			
5.	FDC/MA/23/000293 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan (10 mg+ 40 mg/ 10 mg+80 mg) film coated tablet	M/s Eris Lifesciences Limited	In light of earlier SEC recommendation dated 15.01.2025, the firm presented justification on Phase III clinical trial report before the committee. After detailed deliberation, the committee noted that firm did not submitted adequate justification/supporting data. In view of above, the committee reiterated its earlier recommendation dated 15.01.2025. Accordingly, firm should submit Phase III CT protocol for both the strengths (10 mg + 40 mg) and (10 mg + 80 mg) to CDSCO for further review by the committee.
6.	FDC/MA/23/000309 Mirabegron Ph. Eur. (ER tablets) 25 mg/50 mg + Tamsulosin Hydrochloride IP (ER pellets) 0.4 mg/0.4 mg in capsule	M/s. Sun Pharma Laboratories Limited	In light of the earlier SEC recommendation dated 18.06.2025, the firm presented the proposal along with BE study report and Phase III CT study protocol before the committee. After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee recommended for grant of permission to conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.
7.	FDC/MA/23/000323 Mirabegron (ER tablets) 25 mg/50 mg + Silodosin JP (as granules) 8 mg/8 mg in capsule	M/s. Sun Pharma Laboratories Limited	In light of the earlier SEC recommendation dated 29.11.2023 & 30.11.2023, the firm presented the proposal along with BE study report wherein BE study under fasting condition did not meet the bioequivalence criteria. In view of above, the firm presented the fresh BE study protocol under both fasting and fed condition with individual innovator product as reference along with request for Phase III CT waiver before the committee.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the fresh BE study protocol under both fasting and Fed condition. Further, the committee did not consider the request for Phase III CT waiver and recommended to conduct Phase III CT study as per the protocol already presented before SEC dated 29.11.2023 & 30.11.2023. Accordingly, the results of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial.
8.	FDC/MA/25/000166 Acetylcysteine 150 mg + Taurine 500 mg film coated tablets	M/s. Fourts (India) Laboratories Pvt. Limited	In light of the earlier SEC recommendation dated 13.01.2026, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for following modification in the Phase IV CT protocol: 1. Study duration should not be less than 3 years. 2. Standard of care should include medication as per the latest guidelines. 3. The inclusion and exclusion criteria should be modified to include UACR reduction apart from micro albuminuria and use GFR criteria instead of serum creatinine. Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.