Recommendations of the SEC (Nephrology & Urology) made in its 06th/26 meeting held on 16.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/47/26 Online Submission (55760) Recombinant Human Complement Factor H	M/s. Bionergyx Private Limited	The firm presented phase Ib clinical study protocol no. CPV-104-101 Version 3.0 dated 28-OCT-2025. After detailed deliberation, the committee opined that the proposed trial shall be conducted only in the "patients with C3 glomerulopathy who carry a pathogenic mutation in the CFH gene" Accordingly the firm shall submit revised protocol with change in Inclusion criteria for further review by the committee.
2.	CT/65/26 Online Submission (56530) Elecoglipron (AZD5004)	M/s. Astra Zeneca Pharma India Limited	The firm presented phase III clinical study protocol no: D7265C00001, Version 1.0 dated 16 Mar 2026 and Clinical Study Protocol - Addendum INDIA, version 1.0 dated 06 Apr 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drug Division			
3.	ND/MA/26/000038 Sparsentan Tablets 200 mg and 400 mg	M/s. Zydus Lifesciences Limited	The firm presented the proposal for grant of permission for manufacture and market of the drug Sparsentan Tablets 200 mg and 400 mg along with BE study protocol and request for Phase-III clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented and opined that the firm should submit Bioequivalence study report to the CDSCO for further review by the committee. Further, the committee discussed in detail the need for Phase-III CT waiver and opined that the drug may be useful for the Indian patients. However, the decision should be based on the outcome of the BE study as per the proposed protocol.
4.	ND/MA/26/000032 Daprodustat Tablets 1 mg, 2 mg, 4 mg and 6 mg	M/s. Sun Pharma Laboratories Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Daprodustat tablets 1 mg, 2 mg, 4 mg and 6 mg along with Phase-

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			III Clinical Trial Protocol vide Protocol Number ICR/26/006, Protocol Version No: 1.0, dated 17/FEB/2026 and BE study report (Study No.: 24-ENEM-103, Version No: 01, Dated: 18-JUL-25) of drug Daprodustat tablets 6 mg before the committee. After detailed deliberation, the committee considered the BE study results Daprodustat tablets and recommended for grant of permission to conduct Phase III clinical trial. Accordingly, the firm should submit Phase III clinical trial results to CDSCO for further review by the committee.
5.	ND/MA/26/000050 Sparsentan Tablets 200 mg and 400 mg	M/s. MSN Life Sciences Private Limited	The firm presented the proposal for grant of permission for manufacture and market of the drug Sparsentan Tablets 200 mg and 400 mg along with BE study report and request for Phase-III clinical trial waiver, before the committee. Further, the committee noted that the disease is more common in India than it is in the countries where the previous trials have been conducted. However, the absence of epidemiological data makes it difficult to determine if the drug qualifies as Orphan drug as defined in NDCT, 2019. The committee also noted that there are no other drugs or molecules of this class available in India. Also, the disease affects younger population and it can result in chronic kidney disease. Further, the committee noted that the drug is already approved in USA, EU and UK. The committee noted the results of published international clinical trials and opined that availability of the drug would be beneficial for the Indian patients. After detailed deliberation, the committee considered BE study results. The committee agreed for grant of Phase-III clinical trial waiver with the condition to conduct Phase-IV Clinical Trial to assess the efficacy and safety of applied drug.

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			Accordingly, firm is required to submit Phase-IV study protocol within the period of three months of grant of permission, for further evaluation by the committee. Further, drug should be sold by retail under the prescription of Registered Medical Practitioner only.
SND Division			
6.	SND/CT21/FF/2023/40410 & SND/MA/23/000283 Mirabegron Extended Release Tablets 25 mg and 50 mg	M/s. Sun Pharma Laboratories Limited	Firm has presented BE study report of Mirabegron Extended Release Tablets 50 mg in Fasting and Fed conditions before the committee. After detailed deliberation the committee accepted the BE study report of both the studies and recommended to grant the permission to manufacture Mirabegron Extended Release Tablets for the applied indication.
FDC Division			
7.	FDC/23/2025-eoffice Alfuzosin Hydrochloride IP (as Extended Release) + Tadalafil IP (10 mg +2.5 mg & 10 mg + 5 mg) film coated tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 07.06.2023; the firm presented the Active PMS protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Active PMS study. Accordingly, the firm should submit the Active PMS report to CDSCO for further review by the committee.