Recommendations of the SEC (Urology) made in its 09th/25 meeting held on 13.11.2025 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.	The firm did not turn up for the presentation.
Medical Devices Division			
2.	CI/MD/2025/145443 BPH Pulse field Ablation device	M/s. Trialguna Private Limited	The proposal for the grant of permission to conduct Clinical investigation on the device viz. BPH Pulse field Ablation device was re-deliberated in the SEC (Urology). The firm has presented the safety and performance data generated on the device before the experts. After detailed deliberation, the experts recommended for the conduct of the proposed study vide Protocol no. CS00001 with date: 02/12/2024, which is a part of Global Clinical study subject to the condition that the firm shall submit Clinical study data of every six subjects enrolled in the study and also, the Principal Investigator should be Urologist.
New Drugs Division			
3.	ND/CT/25/000094 Methenamine Hippurate Tablets USP 1 gm	M/s. Lyrus Life Sciences Pvt Ltd	In line with the condition of permission for manufacturing and marketing of drug Methenamine Hippurate Tablets USP 1gm, the firm presented a Protocol titled "A Post Marketing Surveillance, Observational, Prospective, Multicenter, Non-Interventional study to Evaluate the Safety and Efficacy of Methenamine Hippurate 1g Tablets in Patients with Recurrent Urinary Tract Infection". (LYR-MHP-002-25, Version No.: 01 and Date 27 Jun, 2025) before the committee. After detailed deliberation, the committee recommended that firm should revise protocol to include the following: 1. Firm needs to justify Inclusion criteria w.r.t catheterized patients & maintenance of adequate pH of urine and adequate exposure of

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			drug. 2. Clear parameters of monitoring of urine pH and concentration of excreted drug should be defined in the protocol. 3. Sample size shall be defined considering the protocol design for Phase IV study and efficacy parameters & same shall be certified by bio-statistician. Accordingly, the firm should submit the revised structured Phase IV CT protocol as per the approved indication and conditions of MA within one month to CDSCO for further review by the committee.
FDC Division			
4.	FDC/MA/23/000018 Silodosin 8 mg + Solifenacin Succinate 5 mg Capsule	M/s. MSN Laboratories Private Limited	The firm presented their proposal along with justification for BE waiver and Phase III Clinical trial protocol before the committee. After detailed deliberation, the committee opined the following: 1. Firm has not submitted sufficient data for bio waiver justification related to Mannitol used in Silodosin blend which may affect the absorption of the drug. 2. Size of the prostate and residual urine should be defined in the inclusion criteria of the Phase III CT Protocol. Accordingly, the firm should submit revised Phase III CT protocol along with bio waiver justification to CDSCO for further review by the committee.