Recommendations of the SEC (Endocrinology & Metabolism) made in its 17th/25 meeting held on 07.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/112/22 Online Submission (40312) Tirzepatide	M/s Eli Lilly And Company	The firm did not turn up for the presentation.
Biological Division			
2.	BIO/CT04/FF/2025/48948 Insulin Glargine Injection IP 100 IU/ml,3 ml Cartridge	M/s M. J. Biopharm Pvt. Ltd	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled "A Prospective, Multi-center, Open-Label, Single-Arm, Phase IV Study to Evaluate the Safety and Efficacy of Insulin Glargine 100 IU/mL Injection of M.J. Biopharm Private Limited in the Treatment of Patients Diagnosed with Type 2 Diabetes Mellitus" vide Protocol No. INGLR/MJBL/P4/2025, Version: 1.0; Date: 14 Feb 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm
BA/BE Division			
3.	BABE/CT05/FF/2025/48803 Fludrocortisone Tablets USP 0.2 mg	M/s Advity Research Private Limited	The firm presented the study protocol No. AR053-25 version no 01dated 27.03.25 for export purpose only. After detailed deliberation, the committee opined that the firm shall submit more published literature/data reflecting safety and tolerability of Fludrocortisone Tablets USP 0.2 mg in healthy subjects for further review by the committee
New Drugs Division			
4.	ND/MA/25/000098 Miglustat Capsules 100 mg	M/s Apothecon Pharmaceuticals	Firm presented BE study reports for both fasting and Fed condition (Protocol no. C1B03042 & C1B03043) of drug Miglustat Capsules 100 mg, before the committee. The committee noted that the drug is already approved in USA, EU, Australia and Canada. The committee noted that firm has

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			presented the BE study report. The committee recommended that firm need to submit detailed analysis of the intra individual variability and published literature demonstrating response of drug Miglustate in various ethnic population. Further, firm need to submit the patient exposure data of drug where they are already marketing along with the side effect profile in those patients. Further, committee opined that firm has not submitted any clinical data with respect to ethnicity variation. Therefore, firm should submit a well-structured clinical study plan on Indian Patients for further consideration
SND Division			
5.	SND/MA/25/000079 Cholecalciferol Soft Gelatin Capsules USP 60000.000 IU and 3200.000 IU	M/s. Zuventus Healthcare Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Cholecalciferol Soft Gelatin Capsules USP 3200.000 IU & 60000.000 IU along with justification for waiver of Bioequivalence study and clinical trial study before the committee. After detailed deliberation, the committee opined that firm should submit relevant clinical studies and literature for proposed posology of once daily dosing for up to 12 weeks of Cholecalciferol Soft Gelatin Capsules USP 3200.000 IU in applied indication to CDSCO for further review by committee
6.	SND/MA/25/000139 Eliglustat Sublingual Film 8 mg and 16 mg	M/s. Amneal Pharmaceuticals Pvt. Ltd	The firm has presented interim analysis report for the clinical study CE-24-03 along with revised protocol no. CE-24-03, Version 2.0 dated 19.05.2025 to include Cohort 3 and requested for grant of marketing authorization based on interim clinical study report Firm has informed that Eliglustat capsules are approved by EMEA for paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 PMs, IMs or Ems.

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			After detailed deliberation, the committee recommended for the grant of approval for the revised protocol no. CE-24-03, Version 2.0 dated 19.05.2025 for the addition of Cohort 3 for inclusion of patients with >6 years of age with a minimum body weight of 15 kg. Further, committee recommended that firm shall submit final results of Cohort 1 and 2 for evaluation for grant of marketing authorization
FDC Division			
7.	FDC/MA/23/000367 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg/10 mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 10 mg/20 mg film coated tablet	M/s Pure and Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 24.01.2024, the firm presented their proposal along with BE study report and revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. Raw data of BE study report for pharmacokinetic of each subject should be submitted. 2. The firm should submit Drug-Drug Interactions study as individual drugs have different drug profile in respect of its mechanism. Accordingly, the firm should submit above data for further review by the committee.
8.	FDC/MA/25/000048 Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg/10 mg + Glimepiride IP 0.5 mg/0.5 mg + Metformin Hydrochloride IP (ER) 500 mg/1000 mg film coated tablet	M/s Sun Pharma Laboratories Limited	The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee. Committee opined that utility of this small dose of Glimepiride once daily considering over the Adverse Events of this combination is questionable. Hence, the committee did not recommend for approval of the proposed FDC.