Recommendations of the SEC (Endocrinology & Metabolism)made in its 05th/26meeting held on 05.03.2026at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/19/26 Online Submission (54866) NNC0487-0111/zenagamtide	M/s. Novo Nordisk India Pvt Ltd	The firm presented Phase IIIa clinical study protocol no. NN9490-8028 version no. 1.0 dated 07 January 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the more geographically distributed government sites shall be included in the study. Dr. Beatrice Anne didn't participate in the discussion.
2.	CT/23/26 Online Submission (55030) Orforglipron(LY3502970)	M/s. IQVIA RDS (India) Private Limited	The firm did not attend the meeting.
SND Division			
3.	SND/MA/25/000139 Eliglustat Sublingual Film 8 mg and 16 mg	M/s. Amneal Pharmaceuticals Pvt. Ltd	In light of earlier SEC recommendation dated 06.11.2025, firm has presented the Phase-III Clinical Study Report of study no.CE-24-03 (Cohort 1 & Cohort 2) before the committee. After detailed deliberation, the committee accepted the Phase-III clinical trial results of Cohort 1 &Cohort 2 and recommended for the grant of permission for manufacture and market of Eliglustat Sublingual Film 8 mg and 16 mg for the following indication: **Adults:** Indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1), who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs), or extensive metabolisers (EMs). **Paediatric (from 12 to <18 years):** Indicated for long-term treatment of paediatric patients with Gaucher disease type 1 (GD1), who are 12 years and older, who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs), or extensive metabolisers (EMs).

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	SND/MA /25/000153 Diazoxide capsules 25 mg	M/s. Ekam Pharma	In light of the earlier recommendation, the firm presented a reference literature regarding usage and method of administration of Diazoxide Capsule 25 mg before the Committee. After detailed deliberation, the Committee observed that the firm has not submitted any regulatory approved prescribing information on usage and method of administration of Diazoxide Capsule 25 mg in pediatric populations for the proposed indication. Accordingly, the Committee did not recommend the proposal for grant of permission for manufacturing and marketing of Diazoxide Capsules 25 mg in applied indication.
5.	SND/MA/25/000228 Semaglutide Injection 2mg/1.5mL, 4mg/3mL & 8mg/3mL Prefilled Pens (Synthetic Origin)	M/s. Hetero Labs Limited	The firm did not attend the meeting.
FDC Division			
6.	FDC/MA/22/000360 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + Glimepiride IP 1mg/2mg + Metformin Hydrochloride IP (as ER) 1000mg/1000mg film coated tablet	M/s. Exemed Pharmaceutical	The firm did not attend the meeting.
7.	FDC/MA/24/000108 Glimepiride 1mg/2mg + Linagliptin 5mg/5mg Tablets	M/s. Pure and Cure Healthcare Pvt. Ltd	In light of the earlier SEC recommendation dated on 09.01.2025, 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 considered the BE study report. As regard to Phase III clinical trial protocol, the committee opined that:

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			1. The exclusion criteria should mention that fasting glucose more than equal to 200mg/dl will be excluded from the study. 2. Details regarding how hypoglycemic episodes will be captured should be mentioned in the protocol. 3. HbA1C should be checked at baseline at 12th week and 24th week. 4. Periodic self-monitoring of blood glucose should be done and recorded by the patients withstandard glucometer. Accordingly, firm should submit revised Phase III CT Protocol to CDSCO. After approval from CDSCO, firm should submit Phase III CT report to CDSCO for further review by the committee.
8.	FDC/CT/25/000037 Gliclazide SR 30mg/60mg + Sitagliptin 100mg/100mg tablets	M/s. Eris Lifesciences Limited	The firm did not attend the meeting.