Recommendations of the SEC (Endocrinology & Metabolism) made in its 11th/25 meeting held on 14.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/53/23 Online Submission (38019) LY3437943	M/s Eli Lilly And Company	The firm presented protocol amendment (e) dated 23 Jan 2025 and protocol addendum 2.1 dated 11 Feb 2025 protocol no. J1I-MC-GZBJ. After detailed deliberation, the committee recommended for approval of protocol amendment and protocol addendum as presented by the firm.
Biological Division			
2.	E-60351 Recombinant Alglucosidase alfa (Myozyme 50 mg)	M/s. Sanofi Healthcare India Pvt Ltd	The firm presented the proposal for approval of Updated Package insert (Oct 2024) of Recombinant Alglucosidase alfa (Myozyme 50 mg) for the updates in the sections of Posology and Method of Administration, special warnings and precautions for use, drug interactions, undesirable effects, overdose, pharmacological properties and other administrative changes based on EU SmPC dated 14 March 2024. After detailed deliberation, the committee recommended for the approval of updated Package Insert of drug product Myozyme 50 mg with the condition to include following statement in Section 4.2- Posology and method of administration- In case of any infusion related reaction if required the patient should be transferred to nearby hospital/clinical facility for treatment. Accordingly, firm should submit revised Package insert to CDSCO for further evaluation.
BA/BE Division			
3.	BABE/CT05/FF/2024/45881 Vitamin D3 liposomal oral solution 60000IU/5ml	M/s SpinoS Lifescience And Research Private Limited	In light of the earlier SEC recommendation dated 08.04.2025, the firm presented the revised Protocol No.SLS-CT-0007-24-VITA Version No.04 Protocol Date 24 Apr 25.

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			After detailed deliberation the committee recommended for conduct of proposed BE study for export purpose only, with the following conditions- 1) Screening of volunteers for Vit-D baseline levels and volunteers having normal Vit-D levels shall only be enrolled in the study. 2) Before check-in of period II, Vit-D levels shall be monitored and volunteers having normal Vit-D levels only be continued in the study. Accordingly the firm shall submit the revised protocol to CDSCO for further review.
SND Division			
4.	SND/CT/25/000026 Semaglutide Injection (Synthetic Origin) 0.68 mg/mL (1 mg/1.5 ml), 1.34 mg/mL (2 mg/1.5 ml), 1.34 mg/mL (4 mg/3 ml), 2.27 mg/ml (6.8 mg/3ml) and 3.2 mg/ml (9.6 mg/ 3 ml) prefilled pen	M/s INTAS PHARMACEUTICALS LTD	Firm has presented the proposal for the grant of permission to conduct phase III clinical trial of Semaglutide injection as per protocol no. 0130-24, version no. 1.0, dated 03.02.2025 for the proposed indication of Type 2 Diabetes Mellitus along with Bioequivalence study report. After detail deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase III clinical trial as per presented protocol. **Note : Dr. Sanjay Saran did not participated in the deliberation of proposal**
5.	SND/CT/25/000029 Semaglutide Injection 8 mg/3 mL (2.68 mg/mL)	M/s Dr. Reddys Laboratories Limited	The firm presented the proposal to include additional strength of Semaglutide Injection 8mg/3ml (delivers 2mg/dose for each injection) in the ongoing Phase III clinical trial study as per protocol no.: DRL-IND-NDA23-SEM/2024, which was approved vide permission no. CT/SND/13/2024 dated 18.09.2024 & subsequent amendment dated 26.11.2024. In the matter, firm presented the revised Phase III clinical trial protocol vide no.: DRL-IND-NDA23-SEM/2024, version no. 2.2, dated 05.03.2025 before the committee. After detailed deliberation, the committee

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			recommended for approval of inclusion of additional strength as per the revised protocol vide no.: DRL-IND-NDA23-SEM/2024, version no. 2.2, dated 05.03.2025 with condition to 50% Clinical Trial Sites should be Government sites
6.	SND/MA/25/000047 Semaglutide Injection, 1 mg/1.5 ml (0.68 mg/ml), 2 mg/1.5 ml (1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), 6.8 mg/3 ml (2.27 mg/ml) and 9.6 mg/3 ml (3.2 mg /ml)	M/s Cipla	Firm presented BE study protocol vide no. 0103-01-25 Version No. 03, Dated 14.02.2025 and Phase III CT study protocol vide no. CP/08/24 Version No. 1.0, dated 07.01.2025 for Chronic Weight Management before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III Clinical Trial as per the Protocol presented. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III Clinical Trial.
7.	SND/MA/24/000172 Semaglutide Injection 2mg/3ml (0.68mg/ml), 4mg/3ml (1.34mg/ml) & 8mg/3ml (2.68mg/ml)	M/s. MSN Laboratories Private Limited	In light of earlier SEC recommendation dated 13.01.2025, the firm has presented the Bioequivalence study report and revised clinical trial protocol vide no. MSN/SEMA/Phase-III/2024-2025, Version No. 2.0, Dated 03.03.2025 for Type 2 Diabetes Mellitus before the committee. After detailed deliberation, the committee recommended to accept the BE Study report and recommended to conduct Phase III clinical trial as presented by the firm
FDC Division			
8.	FDC/MA/24/000266 Dapagliflozin propanediol monohydrate (10mg + 10mg) + Pioglitazone hydrochloride (15mg + 15mg) + Metformin hydrochloride ER (500mg + 1000mg) Tablets	M/s Alkem Laboratories Ltd	The firm presented the proposal along with BE & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. As regard to Phase III clinical trial protocol, the committee opined that the Control and test arms should have equal

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			number of drugs. Accordingly, the firm should submit BE study report along with revised Phase III clinical trial protocol to CDSCO for further review by the committee.
9.	FDC/CT/25/000037 Gliclazide SR 30mg/60mg + Sitagliptin 100mg/100mg tablets	M/s Eris Lifesciences Limited	In light of the condition mentioned in permission in Form CT-23 dated 07.12.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined the following modification: 1. Inclusion and exclusion criteria should be revised with scientific justification. 2. Withdrawal criteria should be mentioned in the protocol. 3. Study duration should be 24 weeks. 4. Patient not controlled with Metformin alone should be given two drugs with stratification that who is going to receive 30mg and who is going to receive 60mg. Accordingly, the firm should submit the revised Phase IV clinical trial protocol to CDSCO for further review by the committee.