Recommendations of the SEC (Endocrinology & Metabolism) made in its 04th /25 meeting held on 06.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/23 36953 Online Submission (36953) TP-102	M/s JSS Medical Research Asia Pacific Private Limited	The firm presented Increase the number of subjects from India (10) protocol no. TP-102_102. After detailed deliberation, the committee opined that the firm has to submit following for further review by the committee. 1. Statistical calculation and scientific explanation for increasing sample size in India only. 2. Impact on recruitment in other countries because of change in sample size.
SND Division			
2.	SND/MA/24/000220 Semaglutide solution for injection 0.25mg {(1mg /1.5ml)(0.68 mg/ml)}, 0.5mg{(2mg/1.5ml) (1.34mg/ml)}, 1mg {(4mg/3ml)(1.34 mg/ml)}, 1.7mg{(6.8mg/3ml) (2.27mg/ml)} & 2.4mg{(9.6mg/3ml) (3.2mg/ml) (Synthetic origin)	M/s. Alkem Laboratories Ltd.	Firm presented the BE study waiver based on earlier BE study report compared with Ozempic (RLD) and Phase-III CT (Protocol no. ALK39-SEM2, Version 1.0, Dated 23/Jul/2024) for weight management before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the Phase III CT Study with following change in the CT protocol: • Retinal examination (fundoscopy) shall be done periodically.
3.	SND/MA/24/000166 Semaglutide Tablets 3mg, 7mg & 14mg (Synthetic origin)	M/s. Alkem Laboratories Ltd.	Firm presented BE study protocol vide no. BIOS/2024/128, Version No. 01, Dated 17.07.2024 and Phase III CT study protocol vide no. ALK40/SEM3 Version No. 1.0, dated 16.08.2024 for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following changes in the CT protocol:

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			• Retinal examination (fundoscopy) shall be done periodically. • Rescue criteria and medication need to be defined in the protocol. 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.
4.	SND/MA/24/000104 Semaglutide Injection 15mg/3ml (Synthetic origin)	M/s. Zydus Lifesciences Limited	In light of earlier SEC recommendation dated 13.08.2024, the firm presented Bioequivalence study report 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 with following change in the study protocol: • Retinal examination (fundoscopy) shall be done periodically.
5.	SND/MA/24/000105 Semaglutide Injection 15mg/3ml (Synthetic origin)	M/s. Zydus Lifesciences Limited	In light of earlier SEC recommendation dated 13.08.2024, the firm presented Bioequivalence study report for weight management before the committee. After detailed deliberation, the committee recommended to accept the BE Study report and recommended to conduct Phase III clinical trial with following change in the study protocol: • Retinal examination (fundoscopy) shall be done periodically.
6.	SND/MA/24/000214 Semaglutide Tablet 3mg/7mg/ 14 mg (Synthetic origin)	M/s Macleods Pharmaceuticals Ltd.	Firm presented BE study protocol vide no. BEQ-3818-SEMA-2024, Version No. 01, Dated 22.05.2024 and justification for Phase III CT waiver for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study for the protocol presented. Further, the firm should submit BE Study report to CDSCO and BE report should be presented before the committee for further evaluation.

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7.	SND/CT/24/000094 Semaglutide Injection 2mg/1.5ml & 4mg/3ml (1.34mg/ml) (synthetic origin)	M/s Hetero Labs Limited	Firm presented BE study protocol vide no. AZBE112405, Version No. 01, Dated 15.11.2024 and Phase III CT study Protocol (Protocol no. HCR/III/SEMADM/10/2024, Version no. 01, dated 02.11.2024) for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following change in the CT protocol: • Retinal examination (fundoscopy) shall be done periodically. 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.
8.	SND/MA/24/000227 Liraglutide Injection 6mg/ml solution for injection prefilled pen (synthetic peptide)	M/s. Eris Lifesciences Limited	The firm presented the proposal for grant of permission to manufacture and marketing of synthetic Liraglutide 6mg/ml solution for injection in pre-filled pen indicated for the treatment of weight management along with Bioequivalence study report and justification for waiver of Phase-III clinical trial before the committee. The firm has informed that Liraglutide 6mg/ml solution for injection in pre-filled pen has already been approved by UK MHRA for the applied indication. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Liraglutide 6mg/ml solution for injection in pre-filled pen with Phase-III CT waiver subject to condition that the firm should conduct Phase-IV clinical trial. In addition to above, firm should fulfil the requirement of CMC data in compliance with NDCT Rules, 2019. Accordingly, the firm should submit Phase IV Clinical trial protocol to

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			CDSCO within three months from date of approval of the drug for further review by the committee.