Recommendations of the SEC (Endocrinology & Metabolism)made in its 01th/26meeting held on 06.01.2026at 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 Clinical Trials Eli Lilly and Company India Pvt.Ltd	The firm presented protocol amendment (c) dated 06 May 2025 protocol no. I8F-MC-GPIJ. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
2.	SND/MA/25/000230 Semaglutide Injection 2mg/1.5ml, 4mg/3ml and 8mg/3ml,	M/s Cipla Limited	The firm did not turn up for the presentation.
3.	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 the light of earlier SEC recommendations dated 14.05.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/3mL (0.68 mg/mL), 4 mg/3mL (1.34 mg/mL) & 8mg/3ml (2.68 mg/ml) (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
4.	SND/MA/22/000288 Semaglutide Solution for Injection, Multi-dose Prefilled Pens	M/s. Natco Pharma Limited	In the light of earlier SEC recommendations dated 11.12.2024, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	2mg/1.5ml (1.34mg/ml), 4mg/3ml (1.34mg/ml) & 8 mg/3 ml (2.68 mg/ml) (Synthetic Origin)		After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/1.5mL (1.34 mg/mL), 4 mg/3mL (1.34 mg/mL) & 8mg/3ml (2.68 mg/ml) (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
5.	SND/MA/25/000019 Semaglutide Tablets 3mg, 7 mg & 14 mg (Synthetic origin)	M/s. Torrent Pharmaceuticals Limited	In the light of earlier SEC recommendations dated 25.03.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Tablets 3mg, 7 mg & 14 mg (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes
FDC Division			

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	FDC/CT/25/000078 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg + Metformin Hydrochloride IP (as SR) 500mg/1000mg film coated bilayered tablets	M/s Mascot Health Series Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 29.01.2024; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee
7.	FDC/CT/25/000103 Empagliflozin 10mg/25mg + Linagliptin 5mg/5mg + Metformin Hydrochloride IP (ER) 1000mg/1000mg film coated tablet	M/s Pure & Cure Healthcare Pvt. Ltd.	The firm did not turn up for the presentation.