Recommendations of the SEC (Endocrinology & Metabolism) made in its 25th/25 meeting held on 09.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/106/25 Online Submission (42540) Utreglutide (GL0034)	M/s .Sun Pharmaceutical Industries Limited	The firm Protocol Amendment 01 dated 20 October 2025 Protocol No.: UTRE-24-01. After detailed deliberation, the committee recommended for protocol amendment as presented by the firm. Dr. Rajesh Khadgawat didn't participate.
Medical Devices Division			
2.	IMP/MD/2024/143435 Parathyroid Detection System	M/s. India Medtronic Private Limited.	The firm presented their proposal for grant of permission to import and market the medical device viz PT eye Parathyroid Detection System, manufactured by M/s Medtronic Xomed Inc., USA. The said device has been approved for marketing in the country of origin for more than two years and also marketed in other major countries. The firm has submitted Post-Marketing Surveillance data, clinical studies data to demonstrate the safety and performance of the device. After detailed deliberation, the committee opined that the firm shall submit the following data for further deliberation with the committee along with the presence of at least two parathyroid surgeons, an Endocrine Surgeon and a Biomedical Engineer, for taking further necessary action: 1. Details on false positive results reported in the Clinical studies conducted. 2. Clarification with documented evidence whether the device will detect de-vascularized parathyroid tissue.

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SND Division			
3.	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 Limited.	In light of earlier SEC recommendation dated 14.05.2025 the firm presented the BE study report before the Committee to initiate Phase III clinical trial. After detailed deliberation, the Committee accepted the BE study results and recommended to initiate Phase III clinical trial as per earlier SEC recommendation.
4.	SND/MA/24/000062 Semaglutide Solution for Injection (Synthetic origin) 0.25 mg/ 0.5 ml, 0.5 mg/ 0.5 ml, 1 mg/ 0.5 ml, 1.7 mg/ 0.75 ml and 2.4 mg/ 0.75 ml	M/s Sun Pharmaceutical Industries Limited.	In the light of earlier SEC recommendation dated 25.03.2025, the firm presented Phase III CT report for chronic weight management before the Committee. After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide Solution for 0.25 mg/ 0.5 ml, 0.5 mg/ 0.5 ml, 1 mg/ 0.5 ml, 1.7 mg/ 0.75 ml and 2.4 mg/ 0.75 ml (Synthetic origin) for the following indication with subject to condition that the firm should conduct PMS study; **<u>Indication</u>** It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of • 30 kg/m^2 or greater (obesity) or • 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.

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5.	SND/MA/24/000220 Semaglutide injection 0.25 mg {(1 mg /1.5 ml) (0.68 mg/ml)}, 0.5 mg {(2 mg/1.5 ml) (1.34 mg/ml)}, 1 mg {(4 mg/3 ml) (1.34 mg/ml)}, 1.7 mg {(6.8 mg/3 ml) (2.27mg/ml)} & 2.4 mg {(9.6 mg/3 ml) (3.2 mg/ml) (Synthetic origin)	M/s Alkem Laboratories Limited.	In the light of earlier SEC recommendation dated 16.02.2025, the firm presented Phase III CT report for chronic weight management before the Committee. After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide injection 0.25 mg {(1mg /1.5ml) (0.68 mg/ml)}, 0.5 mg {(2 mg/1.5ml) (1.34 mg/ml)}, 1mg {(4 mg/3ml) (1.34 mg/ml)}, 1.7 mg {(6.8 mg/3 ml) (2.27 mg/ml)} & 2.4 mg {(9.6 mg/3 ml) (3.2 mg/ml) (Synthetic origin) for the following indication with subject to condition that the firm should conduct PMS study; **<u>Indication</u>** It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of • 30 kg/m^2 or greater (obesity) or • 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee
6.	SND/MA/24/000104 Semaglutide injection 15 mg/3 ml (Synthetic Origin)	M/s Zydus Lifesciences Limited.	In the light of earlier SEC recommendations dated 06.11.2025, the firm presented Phase III CT study report along with clinical data of each clinical trial site 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 15 mg/3 ml

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			(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
7.	SND/MA/24/000105 Semaglutide injection 15 mg/3ml (Synthetic Origin)	M/s Zydus Lifesciences Limited	In the light of earlier SEC recommendation dated 06.02.2025, the firm presented Phase III CT report for chronic weight management before the Committee. After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide injection 15mg/3ml (Synthetic origin) for the following indication with subject to condition that the firm should conduct PMS study; **<u>Indication</u>** It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of • 30 kg/m^2 or greater (obesity) or • 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.

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8.	SND/MA/23/000047 Cholecalciferol Chewable tablets IP 8000 IU	M/s Quality Pharma Products Private Limited.	Under Discussion.