

Recommendations of the SEC (Endocrinology & Metabolism) made in its 22nd/26 meeting held on 23.09.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/26 Online Submission (59065) Petrelintide	M/s. Roche Products (India) Private Limited	The firm presented phase III clinical trial protocol no. CC46368 version no. 1.0 dated 27 May 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/133/26 Online Submission (59094) Petrelintide	M/s. Roche Products (India) Private Limited	The firm presented phase III clinical trial protocol no. CC46369 version no. 1.0 dated 27 May 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Fundus examination should be conducted at the screening stage for all subjects. The results of these examinations must not be older than one month for subjects being screened and planned for enrollment in the study. 2. Standard procedures and guidelines should be defined across all sites to manage subjects experiencing hypoglycemia episode during the trial.
3.	CT/132/26 Online Submission (59110) Petrelintide	M/s. Roche Products (India) Private Limited	The firm presented phase III clinical trial protocol no. CC46446 version no. 2 dated 06 July 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Fundus examination should be conducted at the screening stage for all subjects. The results of these examinations must not be older than one month for subjects being screened and planned for enrollment in the study. 2. Standard procedures and guidelines should be defined across all sites to manage subjects experiencing

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			hypoglycemia episode during the trial.
Biological Division			
4.	BIO/CT21/FF/2026/56 833 Liraglutide Injection (r-DNA origin) 6 mg/mL (3 mL cartridge)	M/s. Virchow Biotech Private Limited	The firm presented the proposal for grant of permission to manufacture and market the Drug Product Liraglutide Injection (r-DNA origin) 6 mg/mL based on the results of Phase III Clinical Trial (Protocol Number: VBLG01/2024-CT1), Report No. 01/ VBLG01/2026-CT1 conducted by the firm to Compare Efficacy, Safety and Immunogenicity of VBLG01 to Victoza in adults with Type 2 Diabetes Mellitus. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Liraglutide Injection (r-DNA origin) 6 mg/mL for the indication “as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus” subject to conduct of Phase IV Study.
5.	BIO/CT04/FF/2026/57 136 Semaglutide Tablets 1.5 mg, 4 mg and 9mg	M/s. Torrent Pharmaceuticals Ltd.	The firm presented proposal to conduct Phase III Clinical Trial Study titled “A randomized, multi-centric, double-blind, double-dummy, active-controlled, parallel-group, phase-III, clinical trial to evaluate the efficacy and safety of semaglutide oral tablets in adult patients of type 2 diabetes mellitus” on Semaglutide Tablets 1.5 mg, 4 mg & 9 mg, Vide Protocol Number: CT/SEMA/DM/2026/3_1, version no. 1, version date: 11.05.2026. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical trial as presented by the firm.
6.	BIO/CT04/FF/2026/57 151 1.Semaglutide solution for Injection 4mg/3mL (1.34mg/mL) pre-filled pen 2.Semaglutide solution for Injection 8 mg/3 mL (2.68 mg/mL) pre-filled pen	M/s. LevimLifetech Private Limited.	The firm presented a proposal to conduct a clinical trial titled, “A Prospective, Randomized, Assessor-blinded, Multicentric, Parallel Group Phase-I/III Clinical Study to Evaluate the Efficacy, Safety, Immunogenicity, Pharmacokinetics and Pharmacodynamics of Biosimilar Semaglutide of LevimLifetech Pvt. Ltd. with Reference Product (Ozempic® of Novo Nordisk) injection in Type 2 Diabetes Mellitus” vide protocol no. ICS/LEV/2026-005 version 2.0 dated 10

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			June 2026. After detailed deliberation, the committee recommended to conduct Phase I/III clinical study as per the protocol presented by the firm subject to the condition that the sponsor should constitute a Drug Safety Monitoring Board (DSBM) and submit an interim safety analysis report at Week 13 to CDSCO for further evaluation. Accordingly, firm shall submit revised protocol incorporating the aforesaid provision to CDSCO.
7.	BIO/CT18/FF/2026/57858 Semaglutide Tablets (r-DNA Origin) 1.5 mg/4 mg/9 mg/25 mg	M/s. Novo Nordisk India Pvt. Ltd	The firm presented the proposal for grant of permission to import and market the Drug Product Semaglutide Tablets (rDNA Origin) 1.5mg/4mg/9 mg/25 mg (WEGOVY®) are indicated in combination with a reduced calorie diet and increased physical activity: • To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition. • To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight. Firm presented the Clinical Study results of “Pioneer Plus” in which Indian subjects were participated. The Primary objective of the study is “To confirm superiority of oral Semaglutide 25mg and 50mg once daily versus oral Semaglutide 14mg once daily on HbA1c reduction in subjects with T2D on stable dose of 1-3 OADs” and Secondary objective is “To confirm superiority of oral Semaglutide 25mg and 50mg once daily versus oral Semaglutide 14mg once daily on body weight reduction in subjects with T2D on stable dose of 1-3 OADs”. The study is conducted in three Cohorts with initial dose Semaglutide 3 mg tablets once daily, then escalation dose of Semaglutide 7 mg tablets once daily

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			followed by Semaglutide 14 mg tablets once daily finally the maintenance dose of either Semaglutide 14 mg tablets once daily or Semaglutide 25 mg tablets once daily or Semaglutide 50 mg tablets once daily. The firm also presented other Clinical Studies of Semaglutide Tablets 25 mg & 50 mg conducted in abroad. After detailed deliberation, the committee recommended the firm to submit the following for further evaluation before the committee: 1. Any BA/BE study for Semaglutide Tablets (rDNA Origin) 1.5 mg/4 mg/9 mg/25 mg (R2 formulations) conducted in India. If not, firm is recommended to conduct BA/BE study in Indian Participant. 2. Any clinical trial data for Semaglutide Tablets (rDNA Origin) 1.5 mg/4 mg/9 mg/25 mg (R2 formulations) conducted in India. 3. The study results to justify or correlate SNAC in varying concentration in Semaglutide Tablets (rDNA Origin) 1.5 mg/4 mg/9 mg/25 mg (WEGOVY®).
8.	BIO/Post/Appr/R-DNA/2026/4609 CEREZYME® (Imiglucerase powder for concentrate for solution for infusion 400 Units)	M/s. Sanofi Healthcare India Private Limited	The firm presented the proposal for an update in the Package Insert; based on EU SmPC dated 16th Oct 2025 for the drug product CEREZYME® (Imiglucerase powder for concentrate for solution for infusion 400 Units), under sections 4.4 (special warnings & precautions for use) and 4.8 (undesirable effects). After detailed deliberation, the committee recommended approval of the proposed Package Insert dated April 2026, in line with EU SmPC dated 16th Oct 2025.