

Recommendations of the SEC (Endocrinology & Metabolism) made in its 20th/26 meeting held on 08.09.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/107/26 Online Submission (58252) Zenagamtide B	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase IIIa clinical trial protocol no. NN9490-8665 Version 1.0 dated 17 April 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Beatrice Anne didn't participate in the discussion.
2.	CT/109/26 Online Submission (58203) LY3502970	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical trial protocol no. J2A-MC-GZVA, amendment dated 12 Jun 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/112/26 Online Submission (58383) 0.6 MI AZD6234 Solution for injection 2.5 mg/MI (1.5mg/vial) or 7.5 mg/MI (4.5 mg/vial) or 15mg/MI (9.0 mg/vial) or 30 mg/MI (18mg/vial) or Placebo	M/s. AstraZeneca Pharma India Limited.	The firm presented phase III clinical trial protocol no. D8750C00019 version no. 1.0 dated 12 JUN-2026 and Clinical Study Protocol – Addendum, INDIA, Version 1.0 dated 29 June 2026. After detailed deliberation, the committee opined that the firm shall submit safety data of subjects/patients administered different/multiple dose levels, (with specific focus on safety of patients with renal impairment and eGFR in the range of 15–30 mL/min, for further review by the committee.
4.	CT/114/26 Online Submission (58466) Zenagamtide B	M/s. Novo Nordisk India Pvt. Ltd	The firm presented phase IIIa clinical trial protocol no. NN9489-8034 Version: 1.0 dated 24 April 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition to constitute an independent DSMB/Safety Surveillance Committee for periodic evaluation of safety of subjects during the conduct of the clinical trial. Dr. Beatrice Anne didn't participate in the discussion.

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5.	CT/117/26 Online Submission (58519) Zenagamtide B	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase IIIa clinical trial protocol no. NN9490-8731 Version: 1.0 dated 24 JUNE 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: - Subjects who have received steroid therapy within the last 3 months should be excluded from the clinical trial, except subjects receiving inhaled corticosteroids up to 400 µg/day. - Subjects with a known diagnosis of Cushing's syndrome or those with clinical suspicion of hypercortisolism should be excluded from the trial. - An 8:00 AM serum cortisol test should be included as part of the screening investigations to identify subjects with possible exogenous Cushing's syndrome/hypercortisolism.
Biological Division			
6.	E-139591 Semaglutide Injection 0.25mg / 0.5mg /1mg /1.7mg /2.4mg [Brand name: Wegovy® (Single dose Pen injector)] & Semaglutide Injection 0.25mg/0.5mg/1mg/1.7mg/2.4mg [Brand Name: Wegovy® FlexTouch® & Poviztra® FlexTouch®]	M/s. Novo Nordisk India Pvt. Ltd	The firm presented the proposal for update in Package Insert based on EMA approval for the drug product Semaglutide Injection 0.25mg/ 0.5mg/ 1mg/ 1.7mg/ 2.4mg to include safety updates of "Gastroparesis" and "NAION" under Section 4.4 and Section 4.8 of the package insert. The firm also proposed for the removal of MA condition stating that "The duration of treatment should be up to 104 weeks based on the available study data" from Section 4.2 of the package insert based on 4 years of sustained efficacy and safety data from the SELECT trial. After detailed deliberation, the committee recommended for approval of proposed updates in the package insert of the said drug product.
7.	E-143616 Semaglutide Injection	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented the proposal for update in Package Insert based on EMA approval for the drug product Semaglutide Injection

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	0.25/0.5mg/1mg, solution for injection (r-DNA Origin) in pre-filled pen (Ozempic®)		0.25/0.5mg/1mg, solution for injection (r-DNA Origin) in pre-filled pen (Ozempic®) to include safety updates of “Dysaesthesia” under Section 4.8 of the package insert. The firm also presented the proposal for update in Package Insert based on EMA approval for the drug product Semaglutide 3 mg, 7 mg and 14 mg tablets (Rybelsus®) to include safety updates of “Gastroparesis” and “Dysaesthesia” under Section 4.4 and Section 4.8 of the package insert. After detailed deliberation, the committee recommended for approval of proposed updates in the package insert of the said drug products.
8.	BIO/CT04/FF/2026/56 934 Semaglutide Tablets 14 mg (r-DNA origin)	M/s. Dr. Reddy's Laboratories Limited.	The firm presented the proposal for grant of permission to conduct Bioequivalence and immunogenicity study of Semaglutide tablets 14 mg titled “A double blind, balanced, randomized, two treatments, two sequences, four periods, fully replicate, cross over, single dose, oral bioequivalence study of Semaglutide tablets 14 mg of Dr. Reddy's Laboratories Limited, India and PrRYBELSUS® (Semaglutide) tablets 14 mg of Novo Nordisk A/S Denmark in healthy adult human study participants under fasting condition.” vide Protocol no. - AZBE052525 Version: 4.0, dated 14.08.2026. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence and immunogenicity study of Semaglutide tablets 14 mg for export purpose as per the protocol presented by the firm.