

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 06<sup>th</sup>/26 meeting held on 23.03.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/24/26 Online Submission (55085)  CagriSema	M/s. Novo Nordisk India Pvt. Ltd.	<p>The firm presented phase IIIa clinical study protocol no. NN9388-7988, version no. 2.0 dated 22 October 2025.</p> <p>After detailed deliberation, the committee opined the firm shall submit following for further review by the committee.</p> <ol style="list-style-type: none"> <li>1) The firm shall submit the sentinel group data from the ongoing study conducted in other participating countries, along with the recommendations of the Data and Safety Monitoring Board (DSMB).</li> <li>2) A detailed dose justification for cagrilintide and semaglutide (2.4 mg/2.4 mg) in children and adolescents should be provided.</li> <li>3) Dose chart data for cagrilintide and semaglutide (2.4 mg/2.4 mg) in the ongoing study should be based on body weight and/or BMI across children, adolescents, and adults.</li> <li>4) Quantitative Systems Pharmacology (QSP) modelling for dose selection, along with population pharmacokinetic (PK) data with respect to body weight, age, and BMI, should be submitted. This analysis should include a comparison between data from other countries and Indian patients.</li> <li>5) Measurement of glucagon levels is highly desirable when evaluating the efficacy and safety of amylin receptor agonists.</li> </ol>
2.	CT/25/26 Online Submission (55028)  CagriSema	M/s. Novo Nordisk India Pvt. Ltd.	<p>The firm presented phase IIIa clinical study protocol no. NN9838-4968, version no. 4.0 dated 08 September 2025.</p> <p>After detailed deliberation, the committee opined the firm shall submit following for further review by the committee.</p> <ol style="list-style-type: none"> <li>1) The firm shall submit the sentinel group data from the ongoing study conducted in other participating countries, along with the</li> </ol>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>recommendations of the Data and Safety Monitoring Board (DSMB).</p> <p>2) A detailed dose justification for cagrilintide and semaglutide (2.4 mg/2.4 mg) in children and adolescents should be provided.</p> <p>3) Dose chart data for cagrilintide and semaglutide (2.4 mg/2.4 mg) in the ongoing study should be based on body weight and/or BMI across children, adolescents, and adults.</p> <p>4) Quantitative Systems Pharmacology (QSP) modelling for dose selection, along with population pharmacokinetic (PK) data with respect to body weight, age, and BMI, should be submitted. This analysis should include a comparison between data from other countries and Indian patients.</p> <p>5) Measurement of glucagon levels is highly desirable when evaluating the efficacy and safety of amylin receptor agonists.</p>
<b>Biological Division</b>			
3.	<p>BIO/CT18/FF/2024/42 478</p> <p>Semaglutide Injection 0.25 mg/0.5 mg/1 mg/ 1.7 mg/2.4 mg [Wegovy] &amp; Semaglutide Injection 0.25 mg/0.5 mg/1 mg/ 1.7 mg/2.4 mg (Wegovy FlexTouch)</p>	<p>M/s. Novo Nordisk India Pvt. Ltd.</p>	<p>In light of earlier recommendation of SEC (Endocrinology &amp; Metabolism) meeting dated 24 July 2024, the firm has presented India specific PSUR data. The committee also noted the results of Phase-III global clinical trial data (STEP TEENS) conducted by the firm in adolescents (age <math>\geq</math> 12 years) and less than 18 years where India is not the participating country.</p> <p>After the detailed deliberation, the committee recommended for the grant of permission for the additional indication i.e indicated as an adjunct to a reduced calorie diet and increased physical activity for weight management in adolescents aged 12 years &amp; above with obesity and body weight above 60 kgs of the subject drug product with a condition to conduct the Phase-IV clinical trial and the drug shall be prescribed by registered Endocrinologist or pediatrician.</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of permission of additional indication by including the</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>below mentioned parameters also in the proposed Phase-IV clinical trial protocol.</p> <ol style="list-style-type: none"> <li>1. Loss of muscle mass.</li> <li>2. Change in menstrual cycle in females.</li> <li>3. Physical activity performance.</li> </ol>
4.	<p>E-104210</p> <p>Soliqua® SoloStar® (Fixed Ratio Combination of Insulin Glargine and Lixisenatide Injection 100 U/mL + 50/33 mcg/mL)</p>	<p>M/s. Sanofi Healthcare India Pvt Ltd</p>	<p>The firm presented the proposal for update in the Package Insert version v7 dated 22 May 2025 for the Drug Product (Fixed Ratio Combination of Insulin Glargine 100 U/ml + Lixisenatide 33 mcg/ml and Insulin Glargine 100 U/ml + Lixisenatide 50 mcg/ml (Soliqua Solostar)) to include the changes in section 4.4 (warnings or precautions) and Section 9 (Patient Counselling Information) based on US-PI.</p> <p>After detailed deliberation, the committee recommended approval of the updated Package Insert Version v7 dated 22 May 2025 incorporating the proposed changes.</p>
5.	<p>BIO/CT04/FF/2025/51 826</p> <p>Biphasic Insulin Aspart Injection I.P. (30/70)</p>	<p>M/s. G. C. CHEMIE PHARMIE LTD.</p>	<p>In light of earlier recommendation of SEC (Endocrinology &amp; Metabolism) meeting dated 05.02.2026, the firm has presented the justification/data for the subject SEC recommendations for Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence research of Biphasic Insulin Aspart Injection I.P. 30/70 (Mixture of insulin aspart and protamine crystallized insulin aspart) suspension for injection 100 units/mL of G. C. Chemie Pharmie Limited, India comparing with NovoMix 30 100 units/ml suspension for injection (Biphasic insulin aspart I.P. (Mixture of insulin aspart and protamine crystallised insulin aspart) of Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark, in healthy, adult, human male participants using Euglycemic clamp technique under fasting conditions" vide Protocol No. AR 157-24, Version 02 dated 21-Aug 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the presented protocol.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	BIO/CT21/FF/2025/47 384  Insulin Injection, Soluble (Neutral) IP 100 IU/mL	M/s. Regenix Drugs Ltd.	<p>In light of earlier recommendation of SEC (Endocrinology &amp; Metabolism) meeting dated 23 Sep 2025; the firm has presented the additional data.</p> <p>After detailed deliberation, the committee recommended for the grant of approval for manufacture &amp; market the Insulin Injection, Soluble (Neutral) IP 100 IU/mL for the treatment of patients with Diabetes mellitus who require Insulin for the maintenance of glucose homeostasis subject to the condition that firm should conduct Phase-IV study for type-1 and type-2 diabetes mellitus in significant number of patients.</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product.</p>
<b>SND Division</b>			
7.	SND/MA/26/000007  Magnesium Sulfate in 5% Dextrose Injection USP (10.000mg/ml)	M/s. Otsuka Pharmaceutical India Pvt. Ltd.	<p>The firm presented the proposal for marketing and manufacturing Magnesium Sulfate in 5% Dextrose Injection USP (10.000 mg/ml) for proposed indication along with CT waiver before the Committee.</p> <p>After detailed deliberation, the committee accepted CT waiver and recommended for grant of permission for marketing and manufacture Magnesium Sulfate in 5% Dextrose Injection USP (10.000 mg/ml) for the applied indication subject to condition that firm should conduct PMS study.</p> <p>Accordingly, firm should submit PMS study protocol within 3 months from the date of approval of the product to CDSCO for further review by the committee.</p>
8.	SND/CT/26/000008  Trelagliptin Tablets 50 mg and 100 mg	M/s. Hetero Labs Limited	<p>The firm presented the PMS study protocol of Trelagliptin Tablets 50 mg and 100 mg for treatment of type II diabetes before the Committee.</p> <p>After detailed deliberation, the Committee opined to submit revised PMS</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>study protocol with following changes:</p> <ol style="list-style-type: none"> <li>1) Inclusion of efficacy parameters in the study objectives.</li> <li>2) Incorporation /justification of sample size calculation.</li> </ol> <p>Accordingly, firm should submit revised PMS study protocol within 30 days to CDSCO for further review by the committee.</p>
<b>FDC Division</b>			
9.	FDC/89/2025-eoffice Empagliflozin + Linagliptin (10 mg+5 mg, 25 mg+5 mg) tablet	M/s Boehringer Ingelheim India Pvt. Ltd.	The firm did not attend the meeting.