

Recommendations of the SEC (Endocrinology & Metabolism) made in its 13th/26 meeting held on 20.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/58/26 Online Submission (56269) Elecoglipron (AZD5004)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no.: D7261C00003 version no. 1.0 dated 18-MAR-2026 CSP Addendum India version 1.0 dated 31 Mar 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the more geographically distributed government site shall be included in the study.
2.	CT/60/26 Online Submission (56271) Elecoglipron (AZD5004)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no.: D7261C00004 version no. 1.0 dated 12-MAR-2026 and CSP Addendum India, version 1.0 dated 28-Mar-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the more geographically distributed government site shall be included in the study.
Biological Division			
3.	BIO/CT18/FF/2026/54713 Biphasic Insulin Aspart Injection I.P. (30:70), 100 IU/ml	M/s. Mankind Pharma Ltd.	The firm presented the proposal for grant of permission to import and market the Drug Product Biphasic Insulin Aspart Injection I.P. (30:70) 100 IU/mL suspension for injection based on the results of PK/PD and Phase-III clinical trial conducted by the firm to compare the Efficacy and Safety of Rapilin™ 30 (30% Insulin Aspart and 70% Insulin Aspart Protamine suspension) Injection with NovoMix® 30 (30% Insulin Aspart and 70% Insulin Aspart Protamine suspension) Injection in Adult Patients of Type 2 Diabetes Mellitus (T2DM). After detailed deliberation, the committee recommended for grant of permission to manufacture and market

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			<p>Biphasic Insulin Aspart Injection I.P. (30:70) 100 IU/mL Suspension for Injection for the indication of improving glycemic control in adults with diabetes mellitus with the condition that firm shall conduct Phase IV study in India.</p> <p>Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.</p>
New Drugs Division			
4.	<p>ND/IMP/26/000028</p> <p>Orforglipron Tablets 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, and 17.2 mg</p>	M/s. Eli Lilly and Company	<p>The firm presented the proposal for grant of permission to import and market the drug Orforglipron Tablets 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, and 17.2 mg along with Phase-III Global Clinical Trial Report in which India is one of the participating countries.</p> <p>The committee noted that the applied drug is approved in USA.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and marketing of Orforglipron Tablets 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, and 17.2 mg subject to following conditions:</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail under prescription of Endocrinologist or internal medicine specialists only. 2. The firm should conduct Phase-IV clinical trial for which the firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee.
SND Division			
5.	<p>SND/MA/25/000052</p> <p>Semaglutide Injection (synthetic origin) 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), 9.6 mg/ 3 mL (3.2 mg/ mL)</p>	M/s. Emcure Pharmaceuticals Limited	<p>In the light of earlier SEC recommendation dated 17.07.2025, the firm presented Phase III CT report for chronic weight management before the Committee.</p> <p>After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide Injection (synthetic</p>

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			<p>origin) 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), 9.6 mg/ 3 mL (3.2 mg/ mL) prefilled pen for the following indication with subject to condition that the firm should conduct PMS study;</p> <p><u>Indication</u></p> <p>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</p> <ul style="list-style-type: none"> • 30 kg/m² or greater (obesity) or • 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) <p>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.</p>