Recommendations of the SEC (Endocrinology & Metabolism) made in its 12th/26 meeting held on 19.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/56/26 Online Submission (56089) Elecoglipron (AZD5004)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol No.: D7260C00015 Version no. 1.0 dated 10 March 2026 and CSP Addendum India version 1.0 dated 17 March 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/57/26 Online Submission (56238) Elecoglipron (AZD5004)	M/s. AstraZeneca Pharma India Limited	The firm presented phase III clinical study protocol no.: D7261C00006 version no. 1.0 dated 19 March 2026 and CSP Addendum India version 1.0 dated 26 March 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Medical Devices Division			
3.	IMP/MD/2024/143435 Parathyroid Detection System	M/s. India Medtronic Private Limited	In light of the SEC(Endocrinology & Metabolism) meeting recommendation dated 05.02.2026, the firm has presented the proposal before the Committee along with the experts from Parathyroid surgeon and Biomedical Engineer. After detailed deliberation, the committee observed the following: The clinical study data demonstrated by the applicant has no adequate clinical end point in assessing the vascularity of parathyroid tissue. Also, there is no conclusive clinical evidence demonstrating a reduction in the incidence of Post-total thyroidectomy hypocalcemia and hypoparathyroidism rates with use of this device. Further, the warning section of the Instructions for Use (IFU) with respect to the use of the device in oxygen-rich environments and in the presence of anaesthetic gases contradicts the actual applicable environment. Therefore, the Committee opined that the

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			firm shall conduct Clinical investigation on the device on the Indian population with the study design for assessing the above points in statistically significant sample size. Accordingly, the firm shall submit the Clinical study protocol in application Form MD-22 for taking further necessary action in the matter. Also the IFU shall be revised with respect to its use in the specific end-use environment.
Biological Division			
4.	BIO/CT18/FF/2025/50951 Velaglucerase Alfa (r- DNA Origin)	M/s. Takeda Biopharmaceuticals India Pvt. Ltd	In reference to earlier SEC recommendation dated 23.04.2026, the firm has now presented the subject proposal in presence of pediatric neurologist for grant of approval of extension of indication of Velaglucerase Alfa (r- DNA Origin) Brand name: (VPRIV®); Powder for Solution for Infusion wherein proposed indication is read as: Velaglucerasealfa is indicated for long-term enzyme replacement therapy (ERT) in patients with type-1, and chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant non-neurological manifestations of the disease. The non-neurological manifestations of Gaucher disease include one or more of the following conditions: • anaemia after exclusion of other causes, such as iron deficiency • thrombocytopenia • bone disease after exclusion of other causes such as Vitamin D deficiency • hepatomegaly or splenomegaly Precautions about Indication: • Velaglucerasealfa should be administered only the patients with a confirmed diagnosis of Gaucher disease. • The effectiveness to the neurological symptoms is not expected. • The effects on the symptoms in Type 3 Gaucher disease patients are not sufficiently demonstrated (especially on the bone symptoms) The committee noted that the

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			Gaucherdisease (GD) is a rare disease and type-3 subtype of the same is more prevalent in Asia including India. Further, the committee noted that the subject drug Velaglucerase Alfa (r- DNA Origin) Brand name: (VPRIV®); Powder for Solution for Infusion is approved in India since 21.05.2018 for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease. After detailed deliberation, the committee recommended for the approval of proposed extension of indication; in-line with the approval granted by the Japan, with local clinical trial waiver; subject to the condition that the firm shall conduct a Phase IV clinical trial in the Indian population in the proposed extension of indication for chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant non-neurological manifestations. Accordingly, a protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indication.
5.	BIO/CT04/FF/2025/53840 Insulin Degludec Injection 100 units/mL	M/s. Alkem Laboratories Ltd.	The firm presented the proposal to conduct Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of Insulin Degludec Injection 100 units/mL of Alkem Laboratories Limited, India comparing Tresiba 100 units/mL Flex Touch solution for injection in pre-filled pen Insulin Degludec of Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsvaerd, Denmark, in healthy, adult, human male participants using Euglycemic clamp technique under fasting conditions" vide Protocol No. AR261-25; Version No.: 01; Dated: 11 Dec 2025. After detailed deliberation, the committee recommended the firm to submit the following: 1. The validation data of the ELISA

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			method proposed to be used for the estimation of C-peptide and Insulin. 2. Revised protocol to include the provision for the prospective evaluation of hypersensitivity of proposed test product Insulin Degludec Injection 100 units/mL; during the subject screening. 3. Justification for the maximum sampling duration for estimation of PD parameters as the duration of activity of the proposed drug is more than 24 hrs. Accordingly, the firm should submit the revised protocol along with the data to CDSCO for further evaluation by the committee.
6.	BIO/CT04/FF/2025/53996 Insulin Degludec and Insulin Aspart (70/30) Injection 100 Units/mL	M/s. Alkem Laboratories Ltd	The firm presented the proposal to conduct Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of Insulin Degludec/Insulin Aspart Injection 100 units/mL of Alkem Laboratories Limited, India comparing with Ryzodeg (Insulin degludec/Insulin aspart) 100 units/mL of Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark, in healthy, adult, human male participants using Euglycemic clamp technique under fasting conditions" vide Protocol No. AR262-25; Version No.: 01; dated 11 Dec 2025. After detailed deliberation, the committee recommended the firm to submit the following: 1. The validation data of the ELISA method proposed to be used for the estimation of C-peptide and Insulin. 2. Revised protocol to include the provision for the prospective evaluation of hypersensitivity of proposed test product Insulin Degludec and Insulin Aspart (70/30) Injection 100 Units/mL; during the subject screening. 3. Justification for the maximum sampling duration for estimation of PD parameters as the duration of activity of the proposed drug is more than 24 hrs.

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			Accordingly, the firm should submit the revised protocol along with the data to CDSCO for further evaluation by the committee.
SND Division			
7.	SND/MA/24/000214 Semaglutide Tablets 3mg/7mg/14mg	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier recommendation dated 05.02.2026, firm presented theclinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III Clinical trial as per protocol presented by the firm and submit the report for further deliberation in SEC.
8.	SND/CT/25/000013 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)	M/s. Hetero Labs Limited	In the light of earlier SEC recommendation dated 17.06.2025, 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 (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) prefilled pen 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.