Recommendations of the SEC (Endocrinology & Metabolism) made in its 07th/26meeting held on 24.03.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/51855 Insulin Aspart Injection I.P.	M/s. G.C.CHEMIE PHARMIE LTD.	In light of earlier recommendation of SEC (Endocrinology & 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 pharmacodynamics bioequivalence research of Insulin Aspart Injection I. P. 100 units/mL of G. C ChemiePharmie Limited, India comparing with NovoRapid 100 units/ml solution for injection 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 156-24, Version No.: 02, Date.: 21 Aug 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the presented protocol**.**
2.	E-115187 Thyrotropin Alfa lyophilized powder for solution for injection 0.9mg/mL	M/s. Sanofi Healthcare India Pvt Ltd	The firm presented the proposal for amendment in warning statement of drug product Thyrotropin Alfa lyophilized powder for solution for injection 0.9mg/ml from "To be sold by retail on the prescription of a registered Oncologist only" to "To be prescribed by Oncologist, Nuclear Medicine Physicians, Endocrinologists and ENT/Endocrine surgeons". After detailed deliberation, the committee recommended approval for the following warning statement; **"**To be sold by retail on the prescription of Oncologist, Nuclear Medicine Physician and Endocrinologist Only"
3.	BIO/CT18/FF/2025/52834 Idursulfase Beta 6mg/3mL Concentrate for solution for infusion	M/s. Cliniexperts Services Private Limited	The firm did not attend the meeting.

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4.	E-126609 Somapacitan Solution for Injection 5 mg/1.5 ml; 10 mg/1.5 ml; 15 mg/1.5 ml (r-DNA origin)	M/s. Novo Nordisk India Private Limited	The firm presented the proposed revised package insert dated 23 Dec 2025 for the Drug Product Somapacitan Solution for Injection 5 mg/1.5 ml; 10 mg/1.5 ml; 15 mg/1.5 ml to include the safety update with respect to "Slipped capital femoral epiphysis (SCFE)" under section 4.4 “Special warnings and precautions for use” and other changes; in-line with EU SmPC. After detailed deliberation, the committee recommended approval of the updated Package Insert dated 23 Dec 2025 incorporating the proposed changes in line with EU SmPC.
SND Division			
5.	SND/MA/25/000236 Semaglutide Injection (Synthetic Origin) 0.68 mg/mL (1 mg/1.5 mL Prefilled Pen), 1.34 mg/mL (2 mg/1.5 mL Prefilled Pen), 1.34 mg/mL (4 mg/3 mL Prefilled Pen) & 2.68 mg/mL (8 mg/3 mL Prefilled Pen)	M/s. Intas Pharmaceuticals Ltd	In the light of earlier SEC recommendations dated 14.05.2025, the firm presented Phase III CT report for Type 2 Diabetes Mellitus 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) 0.68 mg/mL (1 mg/ 1.5 mL Prefilled Pen), 1.34 mg/mL (2 mg/ 1.5 mL Prefilled Pen), 1.34 mg/mL (4 mg/3 mL Prefilled Pen) & 2.68 mg/mL (8 mg/3 mL Prefilled Pen) for the following indication, with condition to submission of PMS/PSUR data as per the NDCT Rules, 2019. <u>Indication</u> Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: • as monotherapy, when metformin-based therapy is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
6.	SND/MA/25/000237 Semaglutide Injection (Synthetic Origin) 0.68	M/s. Intas Pharmaceuticals Ltd	In the light of earlier SEC recommendation dated 08.05.2025, the firm presented Phase III CT report for chronic weight management before the Committee.

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	mg/mL (1 mg/1.5 mL Prefilled Pen), 1.34 mg/mL (2 mg/1.5 mL Prefilled Pen), 1.34 mg/mL (4 mg/3 mL Prefilled Pen), 2.27 mg/mL (6.8 mg/3 mL Prefilled Pen) and 3.2 mg/mL (9.6 mg/3 mL Prefilled Pen)		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) 0.68 mg/mL (1 mg / 1.5 mL Prefilled Pen), 1.34 mg/mL (2 mg/1.5 mL Prefilled Pen), 1.34 mg/mL (4 mg/3 mL Prefilled Pen), 2.27 mg/mL (6.8 mg/3 mL Prefilled Pen) and 3.2 mg/mL (9.6 mg/3 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/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) 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.
7.	SND/MA/25/000228 Semaglutide Injection 2 mg/1.5 mL, 4 mg/3 mL & 8 mg/3 mL Prefilled Pens (Synthetic Origin)	M/s. Hetero Labs Limited	In the light of earlier SEC recommendations dated 11.06.2025, the firm presented Phase III CT report for Type 2 Diabetes Mellitus 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 2 mg/1.5 mL, 4 mg/3 mL & 8 mg/3 mL Prefilled Pens (Synthetic Origin) for the following indication, with condition to submission of PMS/PSUR data as per the NDCT Rules, 2019. <u>Indication</u> Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: • as monotherapy, when metformin-

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			based therapy is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
8.	SND/MA/22/000363 Cholecalciferol Aqueous Injection 600,000 IU	M/s. Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 22.05.2025 firm presented the revised PK/PD Protocol vide no: BIOS/2025/082 Ver 02 before the committee. After detailed deliberation, the committee recommended to conduct the PK/PD study with additional 20 study subjects as per presented protocol with condition to monitor the adverse effect shall be monitored during the study.