

Recommendations of the SEC (Endocrinology & Metabolism) made in its 21st/25 meeting held on 09.10.2025 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/47 125 Somatropin injection (Recombinant human growth hormone injection) 15 IU [5 mg/1.5 ml (3.33 mg/ml)]	M/s Sun Pharmaceutical Industries Limited	In light of the earlier SEC recommendations dated 08.04.2025, the firm was unable to submit and present the PMS report conducted as part of the new drug permission of the already approved 4IU lyophilized powder form in vial presentation. Further, in continuation to the earlier recommendation, the committee also noted that since there is no pharmacovigilance data available for the lyophilized formulation and no comparative safety and efficacy data available for somatropin liquid injection in the Indian population. After detailed deliberation, the committee recommended to conduct the Phase III Clinical Trial to compare the safety and efficacy of the Somatropin liquid injection with that of the innovator's liquid growth hormone injection.
2.	e-Receipt No. 76399 Oral Semaglutide	M/s Novo Nordisk India Pvt. Ltd.	The firm presented the Post Marketing Surveillance (PMS) study report for the study titled "A multicenter, prospective, non-interventional single-arm study investigating clinical parameters associated with the initiation of once-daily oral Semaglutide in a real-world adult population with Type 2 diabetes in India" vide Study ID: NN9924-4960 version 1.0 dated 08.04.2022. After detailed deliberation, the committee noted the adequacy of the results of the Post Marketing Surveillance (PMS) study presented by the firm.
3.	(1). e-Receipt no.: 101677 dated 16.07.2025 (2). e-Receipt No.: 107822 dated 26.08.2025 Xenpozyme® (Olipudasealfa Powder)	M/s Sanofi Healthcare India Pvt. Ltd	The firm presented the proposal of update in Prescribing Information for Xenpozyme® (Olipudasealfa Powder for concentrate for solution for infusion 20 mg vial) in line with Company Core Data Sheet (CCDS) version 04 dated 27th Oct 2022 and version 07 dated 27th June 2024.

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	for concentrate for solution for infusion 20 mg vial)		After detailed deliberation, the committee recommended the proposal of Update of Prescribing Information for Xenpozyme® (Olipudasealfa Powder for concentrate for solution for infusion 20 mg vial) in line with Company Core Data Sheet (CCDS) version 04 dated 27th Oct 2022 and version 07 dated 27th June 2024.
4.	BIO/CT04/FF/2025/50846 Teriparatide injection IP 600 mcg/2.4 mL (250 mcg/mL) (rDNA origin)	M/s. LevimLifetech Pvt. Ltd	<p>The firm presented a proposal to conduct a clinical trial titled, “A Prospective, Randomized, Assessor-blinded, Multicentric, Parallel Group Phase-I/III Clinical Study to Evaluate the Efficacy, Safety, Immunogenicity, Pharmacokinetics and Pharmacodynamics of Biosimilar Teriparatide of Levim Lifetech Pvt. Ltd. with Reference Product (Forteo® of Eli Lilly) in Subjects with Osteoporosis at High Risk of Fracture vide protocol no. ICS/LEV/2025-006 Version: 1.0 dated 09.07.2025.</p> <p>After detailed deliberation, the committee recommended to revise the protocol by incorporating the following changes:</p> <ol style="list-style-type: none"> Outcome parameters of DXA should be clearly defined. The DXA reports should be evaluated by a qualified Endocrinologist. Exclusion and inclusion criteria should be re-evaluated by adding objectivity to the criterias. Safety assessments should be clearly addressed including the antidrug antibodies. Objective definition of protocol violation should be stated. <p>Accordingly, firm should submit the revised protocol for further evaluation before the committee.</p>
New Drugs Division			
5.	ND-12011(13)/32/2025-eoffice Liothyronine 5 mcg & 20 mcg tablets	M/s ACME GENERICS PVT. LTD	The proposal could not be deliberated due to paucity of time.
SNDDivision			

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6.	SND/MA/24/000211 Semaglutide Injection 2 mg {(8 mg/3 ml) (2.68 mg/ml)} (Synthetic Origin)	M/s. Alkem Laboratories Ltd.	In the light of earlier SEC recommendations dated 13.01.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/1.5mL (1.34 mg/mL), 4 mg/3mL (1.34 mg/mL) & 8mg/3ml (2.68 mg/ml) (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise <ul style="list-style-type: none"> • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
7.	SND/MA/24/000005 Semaglutide Injection 2 mg/1.5 ml (1.34 mg/ml) & 4 mg/3 ml (1.34 mg/ml) (Synthetic Origin)	M/s. Alkem Laboratories Ltd.	In the light of earlier SEC recommendations dated 13.01.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/1.5 mL (1.34 mg/mL), 4 mg/3 mL (1.34 mg/mL) & 8 mg/3 mL (2.68 mg/mL) (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise <ul style="list-style-type: none"> • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
8.	SND/MA/24/000077 Semaglutide Injection 2 mg/1.5 mL (1.34 mg/mL), 4 mg/3 mL (1.34 mg/mL) & 8 mg/3 ml (2.68 mg/ml) (Synthetic Origin)	M/s Sun Pharmaceutical Industries Limited	In the light of earlier SEC recommendations dated 13.01.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/1.5 mL (1.34 mg/mL), 4 mg/3 mL (1.34 mg/mL) & 8 mg/3 mL (2.68 mg/mL) (Synthetic Origin) for the following indication, with condition for submission of PMS/PSUR data as per the NDCT Rules, 2019. Indication: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to

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			<p>diet and exercise</p> <ul style="list-style-type: none"> • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
9.	SND/MA/25/000044 Nitisinone Dispersible Tablets 2 mg/5 mg/10 mg	M/s. Akums Drugs and Pharmaceutical Limited	<p>Firm presented their proposal for marketing and manufacturing of Nitisinone Dispersible Tablets 2mg/5mg/10mg along with justification for BE and CT waiver.</p> <p>The committee noted that hereditary tyrosinemia type 1 (HT-1) is a rare disease and the applied strengths are approved as Tablets.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Nitisinone Dispersible Tablets 2mg/5mg/10mg for the proposed indication.</p>
FDC Division			
10.	FDC/CT/25/000014 Empagliflozin 5 mg/10 mg/12.5 mg/25 mg + Metformin Hydrochloride IP (ER) 1000 mg/1000 mg/ 1000 mg/ 1000 mg film coated bilayered tablet	M/s Zydus Healthcare Limited	The proposal could not be deliberated due to paucity of time.