Recommendations of the SEC (Endocrinology & Metabolism) made in its 25th/25 meeting held on 17.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/159/25 Online Submission (51406) LUM-201 (Ibutamoren Mesylate)	M/s. Pharmaceutical Research Associates India Private Limited.	The firm presented phase III clinical study protocol no. LUM-201-10, Version 2.0 dated 01 Jul 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that Independent DSMB (country specific) shall be organized to closely monitor the safety related issues and side effects like effect on appetite, weight gain, insulin resistance, blood glucose alteration & changes in hepatic function tests and quarterly report submitted to the Ethics Committee and CDSCO. (Dr. Sanjay Saran and Dr. Rajesh Khadgawat didn't participate in the discussion)
Biological Division			
2.	E-109914 Romosozumab (r-DNA origin) Injection 90 mg/mL	M/s. Amgen Technology Pvt Ltd.	The firm presented the proposal to amend the warning statement of Romosozumab (r-DNA origin) Injection 90 mg/mL, approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture, from "To be sold by retail on the prescription of a Registered Orthopaedics only" to "To be sold by retail on the prescription of Registered Orthopaedicians, Endocrinologists and Rheumatologists experienced in treating the disease(s) as per the approved label." After detailed deliberation, the Committee recommended approval of the proposed addition of Registered Endocrinologists and Rheumatologists in the warning statement of the drug product for the approved indication of treatment of osteoporosis
3.	BIO/CT21/FF/2025/50379 1. Biphasic Isophane Insulin Injection IP 100 IU/mL	M/s. Regenix Biosciences Ltd.	The firm presented the proposal for grant of permission to manufacture and market the drug product Biphasic Isophane Insulin Injection IP 100 IU/ml (30/70) in three presentations: 10 ml vial, 3 ml cartridge and 3 ml cartridge in disposable pen for

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	(30/70), 10mL Vial 2. Biphasic Isophane Insulin Injection IP 100IU/mL (30/70), 3mL Cartridge 3. Biphasic Isophane Insulin Injection IP 100IU/mL (30/70), 3mL Cartridge in Disposable Pen		the treatment of Diabetes Type I and Type II, based upon the results of Phase III clinical trial study conducted in India. After detailed deliberation, the committee recommended the firm to submit the following additional data pertaining to the Phase III clinical study: • Data specific to Type I diabetes subjects including Mean age group, Baseline HbA1c levels, dose administered. • Gender-wise subgroup analysis of efficacy and safety outcomes of the study. Accordingly, the firm should submit the additional data to CDSCO for further evaluation by the committee
4.	BIO/CT04/FF/2025/50846 Teriparatide injection IP 600 mcg/2.4 mL (250 mcg/mL) (rDNA origin)	M/s. Levim Lifetech Private Limited.	In light of earlier recommendation of SEC (Endocrinology & Metabolism) dated 09.10.2025, firm has presented a revised protocol to conduct a Phase I/III 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: 2.0 dated 27.10.2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per the protocol presented by the firm
SND Division			
5.	SND/MA/25/000020 Semaglutide Injection 0.25 mg/0.5 mg/1 mg Pre-filled pen (4 mg/3 ml) & Semaglutide Injection 2.0mg Pre-	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 22.04.2025 & 18.11.2025, the firm presented the raw data (pathological & biochemical) on studied animals along with revised common BE study protocol [vide Protocol ID: BEQ-4074-SEMA-2025 before the committee

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	filled pen (8 mg/3 ml) (Synthetic origin)		After detailed deliberation, the committee recommended to accept the presented toxicity data and recommended to grant permission for conduct of the BE study as per the protocol presented by the firm. The BE report shall be submitted to CDSCO for further review by committee and consideration on the CT study.
6.	SND/MA/25/000014 Semaglutide Injection 0.25 mg/0.5 mg/1 mg Pre-filled pen (4 mg/3 ml) & Semaglutide Injection 1.7 mg/2.4 mg Pre-filled pen (9.6 mg/3 ml)	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 22.04.2025 & 18.11.2025, the firm presented the raw data (pathological & biochemical) on studied animals along with revised common BE study protocol [vide Protocol ID: BEQ-4074-SEMA-2025 before the committee After detailed deliberation, the committee recommended to accept the presented toxicity data and recommended to grant permission for conduct of the BE study as per the protocol presented by the firm. The BE report shall be submitted to CDSCO for further review by committee and consideration on the CT study.