Recommendations of the SEC (Endocrinology & Metabolism) made in its 23rd/25 meeting held on 18.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/50846 Teriparatide Injection IP 600mcg/2.4ml (250mcg/ml)(rDNA origin)	M/s. Levim Lifetech Private Limited	The firm did not turn up for the presentation.
SND Division			
2.	SND/CT04/FF/2025/51138 Liraglutide 6 mg/mL solution for Injection in Pre-Filled Pen (Synthetic Origin)	M/s. Biocon Pharma Limited	The firm presented the Phase IV Clinical study protocol for Liraglutide 6 mg/ml solution for Injection in Pre-Filled Pen (Synthetic Origin) before the Committee. After detailed deliberation, the Committee recommended conduct of the Phase IV clinical trial, subject to the condition that patients admitted in emergency or surgical settings are appropriately followed up to ensure comprehensive safety monitoring and outcome assessment.
3.	SND/MA/25/000020 Semaglutide Injection 0.25 mg/0.5 mg/1 mg Pre-filled pen (4 mg/3 ml) & Semaglutide Injection 2.0 mg Pre-filled pen (8 mg/3 ml) (Synthetic Origin)	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 23.09.2025, firm presented the histopathological data, organ section data and statistical report on biochemical parameters and parameters related to regulatory toxicity observed during subacute toxicity study. After detailed deliberation, committee raised the concern on preclinical study data and recommended that all original raw data (pathological & biochemical) on studied animals should be submitted to CDSCO for further examination.
4.	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 23.09.2025, firm presented the histopathological data, organ section data and statistical report on biochemical parameters and parameters related to regulatory toxicity observed during subacute toxicity study. After detailed deliberation, committee raised the concern on preclinical study data and recommended that all original raw data (pathological & biochemical) on studied animals should be submitted to CDSCO for further examination.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	SND/CT/25/000002 Semaglutide Solution for injection in pre-filled pen 2 mg/1.5 mL, 4 mg/3 mL, & 8 mg/3mL(Synthetic Origin)	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 23.09.2025, firm presented daily monitoring data for physiological parameters of animals, cause of mortality in the animals, causality assessment and data/ information on SAE reported subject. Firm also presented the Phase III Clinical Trial Protocol for Type 2 Diabetes Mellitus. After detailed deliberation committee recommended for grant of permission to conduct the Phase III Clinical Trial as per the protocol presented before the committee with condition 50% Clinical Trial Sites should be Government sites
6.	SND/CT/25/000086 Semaglutide Solution for injection in pre-filled pen 2mg/1.5mL, 4 mg/3 mL, 6.8mg/3mL, 9.6mg/3mL (Synthetic Origin)	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 23.09.2025, firm presented daily monitoring data for physiological parameters of animals, cause of mortality in the animals, causality assessment and data/ information on SAE reported subject. Firm also presented the Phase III Clinical Trial Protocol for obese or overweight adult patient. After detailed deliberation committee recommended for grant of permission to conduct the Phase III Clinical Trial as per the protocol presented before the committee.
7.	File no. ND-12011/4/2025-eoffice E-86708/25 for SND file • Tirzepatide 2.5 mg / 0.5 ml, 5 mg/0.5 ml, 7.5 mg/0.5 ml,10 mg/0.5 ml,12.5 mg/0.5 ml,15 mg/0.5 ml solution for injection in a single dose prefilled pen (SDP (ND/IMP/23/000017) • Tirzepatide 2.5 mg/ 0.5 ml, 5 mg /0.5 ml, 7.5 mg/0.5 ml, 10 mg/0.5 ml, 2.5 mg/0.5 ml & 15 mg/0.5 ml Single dose Vials (IMP/SND/24/000076) • Tirzepatide 2.5 mg/0.5 ml, 5 mg/0.5 ml, 7.5	M/s Eli Lilly And Company	The firm presented a justification for waiver to conduct the Phase IV study on single-dose presentation pens/vials of Tirzepatide before the Committee. The Committee noted that, SEC (Endocrinology & Metabolism) meeting held on 23-09-2025, recommended to conduct Phase IV clinical trial with Tirzepatide Multiple doses pens. After detailed deliberation, the Committee recommended for grant of waiver for the single-dose presentation, considering the earlier recommendation to conduct the Phase IV trial for Tirzepatide multiple-dose pens and said Phase IV Clinical study suffice the purpose for all pack presentations.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg/0.5ml 10 mg/0.5 ml, 12.5 mg/0.5 ml, 15 mg/0.5 ml solution for injection in a single dose prefilled pen (SND/IMP/24/000032)		