Recommendations of the SEC (Endocrinology & Metabolism) made in its 02nd/25 meeting held on 13.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/19/000074 Vildagliptin SR Tablets 100mg	M/s. Synokem Pharmaceuticals Limited	Firm presented PMS Study Protocol vide protocol no. CT/2023/15 dated: 28.03.2023 of Vidagliptin SR Tablet 100 mg before the Committee. After detailed deliberation, the Committee recommended for grant of approval for PMS Study as per protocol presented by the Firm.
2.	SND/MA/22/000262 Vildagliptin SR Tablets 100mg	M/s Eris Life Sciences Limited	Firm presented PMS Study Report as per their approved Protocol no. CT/2023/16, Version No. 00 dated 29.03.2023 of Vidagliptin SR Tablet 100mg before the Committee. After Detailed deliberation, the Committee considered the of PMS Study report presented by firm.
3.	SND/MA/24/000209 Semaglutide Solution for Injection Multi-dose Prefilled Pens 1mg/1.5ml, 2mg/1.5ml, 4mg/3ml, 6.8mg/3ml, 9.6mg/3ml (Synthetic Origin)	M/s. Natco Pharma Limited	Firm presented the BE study report and CT Protocol no. ICS/NAT/2024-007, Version No. 1 dated 18.10.2024 for weight management before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the Phase III CT Study with following change in the CT protocol: • Retinal examination (fundoscopy) should be done at each visit.
4.	SND/MA/24/000077 Semaglutide solution for injection (Synthetic origin) 2mg/1.5ml, 4mg/3ml, 8mg/3ml	M/s. Sun Pharma Labs Limited	Firm presented the BE study report and revised Phase-III clinical trial protocol for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase-III Clinical Trial with following change in the study protocol: • Retinal examination (fundoscopy) should be done at each visit.

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5.	SND/MA/24/000062 Semaglutide solution for injection (Synthetic origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7 mg/0.75ml and 2.4mg/0.75ml	M/s. Sun Pharma Labs Limited	In light of earlier SEC recommendation dated 23.04.2024, the firm presented the amended Phase III CT protocol for Weight Management before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct Phase III CT study with following changes in the CT protocol: • Treatment with glucose lowering agents (s) within 90 days before screening should be removed from the exclusion criteria for non-diabetic patients. • Retinal examination (fundoscopy) should be done at each visit. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
6.	SND/MA/24/000211 Semaglutide Injection 2 mg {(8mg/3ml) (2.68mg/ml)}	M/s Alkem Laboratories Ltd	Firm presented the Bioequivalence study report and Phase III CT study Protocol ALK37-SEM1,Version No. 03, dated 08.10.2024 in Type 2 Diabetes Mellitus for additional strength of Semaglutide Injection 2 mg {(8mg/3ml) (2.68mg/ml)} before the Committee. After detailed deliberation, the committee considered the bioequivalence report and recommended for grant of permission for Phase III CT study with following change in the CT protocol. • Retinal examination (fundoscopy) should be done at each visit.
7.	SND/MA/24/000215 Semaglutide (Synthetic Origin) Injection 2mg/3ml (0.680 mg/ml, 0.25 mg & 0.5 mg dose), 4mg/3ml (1.34	M/s Precise Biopharma Pvt. Ltd	Firm presented BE study protocol vide no. BN24-023, Version No. 01, Dated 29.10.2024 and Phase III CT study protocol vide no. CT/2024/33 Version No. 00, dated 03.06.2024 for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the

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	mg/ml, 1 mg dose) & 8mg/3ml (2.68 mg/ml, 2 mg dose)		Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following change in the CT protocol: • Retinal examination (fundoscopy) should be done at each visit. • List of prohibited medications should be mentioned in the protocol. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
8.	SND/MA/24/000005 Semaglutide solution for injection (Synthetic origin) 2mg/1.5ml, 4mg/3ml	M/s. Alkem Laboratories Ltd	In light of earlier SEC recommendation dated 23.04.2024, the firm presented Bioequivalence study report along with the revised Phase-III clinical trial protocol for Type 2 Diabetes Mellitus before the committee. After detailed deliberation, the committee considered the bioequivalence report and recommended for grant of permission to conduct Phase III CT study with following change in the CT protocol. • Retinal examination (fundoscopy) should be done at each visit.
9.	SND/MA/24/000172 Semaglutide Injection 2mg/3ml (0.68mg/ml), 4mg/3ml (1.34mg/ml) & 8mg/3ml (2.68mg/ml)	M/s.MSN Laboratories Private Limited	The firm presented BE study protocol vide no. AZBE112410 Version No. 1.0, Dated 05.12.2024 and Phase-III clinical trial protocol vide no. MSN/SEMA/Phase-III/2024-2025, Version No. 1.0, Dated 12.07.2024 forType 2 Diabetes Mellitus before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following changes in the CT protocol. • Retinal examination (fundoscopy) should be done at each visit. • Serum calcitonin level should be mentioned in the protocol • Secondary endpoint: Neutralizing

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			Antibody study should be included in the protocol • Firm should include the more CT sites which are geographically distributed and atleast 50% should be from Government Hospitals. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.