Recommendations of the SEC (Endocrinology & Metabolism) made in its 15th/25 meeting held on 17.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/62/24 Online Submission (39644) CagriSema 1.0 (1,0) mg/ml + 0.5 (0,5) mg/ml (0.25 mg/ 0.25) CagriSema 2.0 (2,0) mg/ml + 1.0 (1,0) mg/ml (0.5 mg/ 0.5 mg) CagriSema 4.0 (4,0) mg/ml + 2.0 (2,0) mg/ml (1.0 mg/ 1.0 mg)	M/s Novo Nordisk India Private Limited	The firm presented protocol amendment version 3.0 dated 17 January 2025 protocol no. NN9388-7741. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	BIO/CT04/FF/2025/48765 Semaglutide Tablets 3 mg, 7 mg, and 14 mg	M/s Sun Pharma Laboratories Limited	The firm presented the proposal to conduct Phase III clinical trial titled "A Multicenter, Randomized, Double-Blind, Double-Dummy, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Oral Semaglutide Tablets of Sun Pharma Laboratories Limited in Comparison to Rybelsus (Semaglutide) Tablets in Type 2 Diabetes Mellitus" as per Protocol Number-ICR/23/009, Version 2.0 dated 18.06.2025 along with the results of Bioavailability Study (SEM10524) conducted in India by the firm in India. After detailed deliberation, the committee recommended grant of permission to conduct the Phase III clinical trial as per the presented protocol with the following changes: 1. Inclusion of Optical Coherence Tomography (OCT) as part of the eye examination.

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			2. Subjects with proliferative/ unstable retinopathy and maculopathy to be excluded from the trial. 3. Fasting and postprandial blood glucose monitoring should be used for dose titration. HbA1c levels should be assessed after completion of 08-12 weeks of study treatment. Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation**.**
3.	BIO/CT18/FF/2025/48879 Semaglutide injection 0.25 mg/ 0.5 mg/ 1 mg	M/s Novo Nordisk India Pvt. Ltd.	The firm presented the proposal for grant of approval of following additional indication of the drug Semaglutide Injection 0.25 mg, 0.5 mg, and 1 mg based on the data generated from Phase III Global Clinical Trials where India was part of the study: Semaglutide injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease • To reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.” The committee noted that the proposed indication is approved in USA & EU. After detailed deliberation, the committee recommended for grant of approval

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			for the proposed additional indication with a condition to conduct post marketing surveillance (PMS) study in India. Accordingly, the firm shall submit the India specific PMS protocol to CDSCO within 03 months of the grant of permission for this additional indication.
BA/BE Division			
4.	BABE/CT05/FF/2025/47823 Tiopronin ER Pellets 1000 mg	M/s Azidus Laboratories Limited.	Firm presented the BA/BE study Protocol No. AZBE012505, version No. 01, dated 06.02.2025 for export purposes, before the committee. After detailed deliberation, the committee opined that the firm shall provide recent published literatures with respect to the safety and tolerability of the applied drug product. Accordingly, the firm should submit the published literature/data to CDSCO, for further review by the committee
New Drugs Division			
5.	ND/CT/25/000001 Eliglustat 84 mg	All India Institute Of Medical Sciences (Department Of Pediatrics)	In light of earlier SEC recommendation dated 09.01.2025 wherein the committee recommended for the grant of permission to conduct the clinical trial as per the protocol presented by the applicant, the study investigator, Department of Pediatrics, AIIMS presented revised protocol titled "Pharmacokinetics, Pharmacodynamic and efficacy assessment of Eliglustat Monotherapy in Paediatric Patients with Gaucher Disease Type 1 and type 3: A single-arm interventional trial (ELEGANT)" for conduct of clinical trial with the drug Eliglustat before the committee. Committee reviewed the proposed dose & age group related changes in the revised protocol presented by the applicant.

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			After detailed deliberation, committee recommended for the grant of permission to conduct the clinical trial as per the revised protocol
SND Division			
6.	SND/MA/24/000215 Semaglutide (Synthetic Origin) Injection 2 mg/ 3 ml (0.68 mg/ml, 0.25 mg & 0.5 mg dose), 4 mg/ 3 ml (1.34 mg/ml, 1 mg dose) & 8 mg/ 3 ml (2.68 mg/ml, 2 mg dose)	M/s Precise Biopharma Pvt. Ltd.	In light of earlier SEC recommendation dated 13.01.2025, the firm presented Bioequivalence study report alongwith the revised Phase-III clinical trial protocol (protocol vide no. CT/2024/33 Version No. 01, dated 24.01.2025) for Type 2 Diabetes Mellitus before the committee. After detail deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase III clinical trial as per the revised protocol presented by the firm.
7.	SND/MA/25/000052 Semaglutide Injection (Synthetic Origin) 1 mg/ 1.5 ml (0.68 mg/ml), 2 mg/ 1.5 ml (1.34 mg/ml), 4 mg/ 3 ml (1 .34 mg/ml), 6.8 mg/ 3 ml (2.27 mg/ml) & 9.6 mg/ 3 ml (3.2 mg/ml)	M/s Emcure Pharmaceuticals Limited	Firm presented Bioequivalence study report along with the Phase-III clinical trial protocol (Protocol No. ECTS/25/002, Version No. 00, Dated 13.02.2025) for chronic weight management before the committee. After detail deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase III clinical trial as per protocol presented by the firm with following changes/conditions: 1. Detailed rescue medication, withdrawal criteria and Hypoglycemia management should be mentioned in the protocol. 2. 50% Govt. CT sites geographically distributed shall be included in Clinical trial study.
8.	SND/MA/25/000066 Semaglutide Injection (Synthetic Origin) 2 mg/ 1.5ml (1.34	M/s Emcure Pharmaceuticals Limited	Firm presented Bioequivalence study report along with the Phase-III clinical trial protocol (Protocol No. ECTS/25/001, Version No. 00, Dated 28.02.2025) for type 2 diabetes mellitus

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	mg/ml), 4 mg/ 3ml (1.34 mg/ml) & 8 mg/ 3 ml (2.68 mg/ml)		before the committee. After detail deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase III clinical trial as per protocol presented by the firm with following changes/conditions: 1. Detailed rescue medication, withdrawal criteria and Hypoglycemia management should be mentioned in the protocol. 2. Fasting and postprandial blood sugar levels should be used for dose titration. 3. 50% Govt. CT sites geographically distributed shall be included in Clinical trial study.
FDC Division			
9.	FDC/MA/25/000022 Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg + Metformin Hydrochloride IP (SR) 1000 mg film coated bilayered tablet	M/s Eris Lifesciences Limited	The firm presented the proposal along with BE study protocol and justification for CT waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee. Further, decision on the Phase III clinical trial may be taken after review of BE study results