Recommendations of the SEC (Endocrinology & Metabolism) made in its 16th/26 meeting held on 07.07.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/24/26 Online Submission (55085) CagriSema	M/s. Novo Nordisk India Pvt. Ltd	The firm did not attend the meeting.
2.	CT/25/26 Online Submission (55028) CagriSema	M/s. Novo Nordisk India Pvt. Ltd	The firm did not attend the meeting.
BA/BE Division			
3.	BABE/CT05/FF/2025/49439 Thyrod Tablets, USP (low, medium, high) (Contains Levothyroxine (T4) and Liothyronine (T3)+Thyroid Tablets)	M/s. Veeda Clinical Research Limited	In light of the earlier SEC recommendation dated 05-02-2026, the firm presented the study Protocol No.: 25-VIN-0096, Version No.:02 Date: 07-Nov-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
Biological Division			
4.	BIO/CT18/FF/2026/54845 Semaglutide 9.6 mg/ml solution for injection, prefilled syringe 0.75ml Single dose pen-injector for Semaglutide (7.2 mg)	M/s. Novo Nordisk India Pvt. Ltd	The firm presented the proposal for addition of a new strength as once weekly maintenance dose of Semaglutide Injection 7.2 mg (9.6 mg/ml) solution for injection in pre-filled Pen. The committee noted that 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg strengths are already approved in India since April-2022 with 2.4 mg once-weekly as a maintenance dose for weight management as an adjunct to reduced-calorie diet and increased physical activity. The committee further noted that the proposed 7.2 mg dose has not demonstrated any additional clinically meaningful benefit over the already approved 2.4 mg dose. Therefore, it does not meet the requirements of Rule 101 of the NDCT Rules, 2019, for a waiver of the local clinical trial.

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			After detailed deliberation, the committee recommended the firm to submit the following: 1. Data of Indian subjects for dose escalation to justify the use of a 7.2 mg maintenance dose instead of the already approved 2.4 mg dose. 2. Comparability data between semaglutide tablet doses and Semaglutide subcutaneous injection doses to justify clinically the omission of intermediate doses between 2.4 mg and 7.2 mg for the proposed once-weekly maintenance dose. Accordingly, the firm shall submit the respective data to the CDSCO for further evaluation by the committee. (Dr. Rajesh Khadgawat did not participate in the deliberation.)
SND Division			
5.	SND/MA/26/000007 Magnesium Sulfate in 5% Dextrose Injection USP (10 mg/ ml)	M/s. Otsuka Pharmaceutical India Pvt. Ltd.	In light of the earlier SEC recommendation dated 23.03.2026, the firm presented the proposal of PMS study waiver for Magnesium Sulfate in 5% Dextrose Injection USP (10 mg/ml) before the Committee. After detailed deliberation, the Committee did not agree for PMS study waiver and reiterated its earlier recommendation that the firm should conduct a Post-Marketing Surveillance (PMS) study for Magnesium Sulfate in 5% Dextrose Injection USP (10 mg/mL).
FDC Division			
6.	FDC/MA/23/000367 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg/10 mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 10 mg/20 mg film coated tablet	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 07.08.2025, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee. Committee noted that the firm did not present raw data of BE study report as per earlier SEC recommendation. After detailed deliberation, the committee opined that the comparison

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			should be done with the same reference drug i.e. Rosuvastatin and Dapagliflozin using separately in Phase III CT Protocol. Accordingly, Raw data of BE study report for pharmacokinetic of each subject along with revised Phase III clinical trial protocol should be presented for further review by the committee.
7.	FDC/CT/25/000074 Vildagliptin (SR) 100 mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (SR) 1000 mg uncoated bilayered tablets	M/s. Mascot Health Series Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 13.01.2023; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
8.	FDC/CT/25/000107 Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (As ER) (5 mg + 50 mg + 500 mg & 5 mg + 50 mg + 1000 mg) film coated tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 13.07.2023; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.