

Recommendations of the SEC (Endocrinology & Metabolism) made in its 21st/26 meeting held on 17.09.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/118/26 Online Submission (58541) Survodutide	M/s. IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no.1404-0115 version no. 3.0 dated 26 June 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/125/26 Online Submission (58648) LY3298176 + LY3841136	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical study protocol no. J7C-MC-YQAA amendment b dated 16 June 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	E-133044 & E-163477 Soliqua® SoloStar® (Fixed Ratio Combination of Insulin Glargine and Lixisenatide 100U + 50mcg/33mcg)	M/s. Sanofi Healthcare India Private Limited	The firm presented the proposal for an update in the Package Insert based on CCDS version v8 dated 04 th December 2025 for the drug product Soliqua® SoloStar® (Fixed Ratio Combination of Insulin Glargine and Lixisenatide 100U +50mcg/33mcg); under section posology & method of administration, undesirable effects and clinical Efficacy. After detailed deliberation, the Committee recommended approval of the proposed updates to the Package Insert, subject to the condition that the maximum dose of premixed insulin used/allowed in the clinical study and the corresponding dose-conversion instructions to Soliqua® SoloStar® should be clearly incorporated in the Package Insert Accordingly, firm shall submit the revised package insert to CDSCO for further evaluation.
4.	E- 136775 Lyumjev® (Insulin Lispro Ultra-Rapid Injection 100 U/mL)	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented the clinical study report (CSR) for the Phase IV study titled “A 26-Week, Multicenter, Open-Label, Single-Arm, Phase 4 Study to Assess the Safety of Lyumjev in Adult Patients with Type 2 Diabetes Mellitus in India; Study Number: I8B-MC-ITTA”.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the Committee noted the results of the Phase-IV study presented by the firm.
SND Division			
5.	SND/MA/26/000063 Semaglutide solution for Injection 1mg /1.5ml, 2mg /1.5ml, 4mg /3 ml, 6.8mg /3 ml, 9.600 mg /3 ml cartridge with pen; Semaglutide Solution for Injection 2mg/3 ml, 4 mg/3 ml, 6.8mg/3 ml, 9.6mg/3 ml vials and Semaglutide Solution for Injection 0.25 mg/0.38ml, 0.5mg/0.38ml, 1mg/0.75ml, 1.7mg/0.75ml & 2.4mg/0.75ml pre-filled syringe	M/s. Alkem Laboratories Limited	The firm presented their proposal along with justification for Phase III CT waiver for approval of the additional indication - "In combination with a reduced calorie diet and increased physical activity: To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight" for the already approved drug, Semaglutide Solution for Injection. The firm stated that, reference Semaglutide Injection of r-DNA/ biological origin is approved for the applied indication in India since 25.02.2025, hence, firm has requested for Phase III CT waiver. The Committee noted that proposed product is of synthetic origin and firm did not present any clinical data supporting the efficacy of their product in applied indication. Hence, the Committee did not recommend Phase III clinical trial waiver for the grant of applied drug for the applied indication.
6.	SND/CT21/FF/2022/3 5268 (SND/MA/22/000363) Cholecalciferol Aqueous Injection 600,000 IU/2 mL	M/s. Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 22.05.2025, the firm presented PK/PD study report of Cholecalciferol Aqueous Injection 600,000 IU/2mL indicated in already approved indication along with the request of Phase III clinical trial wavier. The committee noted that the data generated in PK/PD study shows a much higher values of Cmax and AUC of Cholecalciferol and 25(OH)D as compared to reference product which raises safety concern like hypercalcemia, calcification in coronary artery, etc. After detailed deliberation, the committee did not recommend for wavier of Phase III Clinical trial for the applied product.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
7.	FDC/CT/26/000060 Alogliptin benzoate 17mg eq. to Alogliptin 12.5mg + Metformin Hydrochloride IP 850mg eq. to Metformin 663mg film coated tablet	M/s. Torrent Pharmaceuticals Ltd.	The firm presented Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that the approved indication i.e., “as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus” should be mentioned in the title of the protocol. Accordingly, the revised Phase IV CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO, the firm should submit the Phase IV CT report for review by the committee.
8.	FDC/CT/26/000064 Empagliflozin + Metformin Hydrochloride (as ER) (5mg + 1000mg, 10mg + 1000mg, 12.5mg + 1000mg & 25mg + 1000mg) film coated bilayer tablets	M/s. Exemed Pharmaceuticals	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.