

Recommendations of the SEC (Endocrinology & Metabolism) made in its 23rd/26 meeting held on 07.10.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/82/26 Online Submission (57290) LY3502970	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd	In light of earlier SEC recommendation dated 16.07.2026, the firm presented phase III clinical study protocol no. J2A-MC-GZGY amendment a dated 08 May 2026 along with justification/information requested by SEC Committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
2.	BIO/CT04/FF/2025/47773 Insulin Degludec (r-DNA origin) injection 100 IU/mL in 3 mL cartridge and pre filled pen	M/s. Lupin Limited	In light of earlier SEC recommendation dated 06.08.2026 wherein the firm presented the results of phase I (PK/PD study) and Phase III clinical trial protocol, the firm presented the revised protocol bearing no .ECTS/24/010 Version No.: 01, Dated: 26 AUG 2026 incorporating the changes recommended by SEC. After detailed deliberation, the Committee recommended for grant of permission to conduct clinical trial as per the revised protocol presented by the firm.
3.	BIO/CT04/FF/2025/53996 Insulin Degludec and Insulin Aspart (70/30) Injection 100 Units/mL	M/s. Alkem Laboratories Ltd	In light of earlier SEC recommendation dated 25.08.2026, the firm presented the revised protocol bearing no. AR262-25, Version No. 02, Amendment No. 01 dated 23.09.2026 incorporating the changes recommended by SEC. After detailed deliberation, the Committee recommended for grant of permission to conduct clinical trial as per the revised protocol presented by the firm with the condition that commercially available IVD ELISA Kit duly approved by CDSCO may be used for C-Peptide estimation.
4.	E- 136775 Lyumjev® (Insulin Lispro Ultra-Rapid Injection 100 U/mL)	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm did not attend the meeting.
5.	BIO/CT04/FF/2025/53907 Semaglutide Tablets	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal to conduct Phase I/III Clinical Trial of Semaglutide Tablets 1.5 mg, 4 mg and 9 mg (r-DNA origin) titled as "A Multicentric,

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	1.5 mg, 4 mg and 9 mg (r-DNA origin)		Prospective, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase I/III Clinical Trial to Evaluate the Efficacy, Pharmacokinetics, Safety and Tolerability of Oral Semaglutide Tablets of Dr. Reddy's Laboratories Ltd Compared with RYBELSUS® of Novo Nordisk (Semaglutide) Tablets in Adult Patients with Inadequately Controlled Type 2 Diabetes Mellitus." vide Protocol ID: IND-NDA38-SEM/2025, Version 4.0; 02-Sep-2026 After detailed deliberation, the Committee recommended for grant of permission to conduct clinical trial as per the protocol presented by the firm.
6.	E-receipt No.:150193/2026/CRU Insulin Icodec	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented the proposal for waiver of condition to include equal number of subjects with Type 1D and Type 2D in the approved PMS study titled "A multi-Centre, prospective, open label, non-interventional, single arm, 26 -week post marketing study to investigate safety and clinical parameters of once weekly Awikli® (insulin icodec) in adults with diabetes mellitus under a real world clinical practice setting in India (ICONIC)" vide protocol no. NN1436-8338 version 1.0 dated 28 March 2025. After detailed deliberation, the committee did not consider firm's proposal for waiver of condition prescribed in MA and PMS study protocol approved by CDSCO. Note: Dr. Rajesh Khadgawat did not participate in the discussion.
SND Division			
7.	SND/CT21/FF/2025/5 0463 (SND/MA/25/000156) Pioglitazone Tablets 15 mg & 30mg	M/s. USV Pvt. Limited.	In light of earlier SEC recommendation dated 25.02.2026 firm presented the revised Phase III clinical trial protocol for Pioglitazone tablets before the committee. After detailed deliberation, the committee recommended the following: 1. Patients with CHF, Severe Anaemia, Osteoporosis, Risk of fracture Retinopathy, fluid overload and hypogonadism shall be excluded from the

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			study. 2. Monitoring of Hb1Ac should be done at every 12 weeks, Dexa scan should be performed at baseline and 28, 42 and 72 weeks (EOT) and other critical parameters like Anaemia should be done throughout the study. 3. The statistical power should be increased to 85% 4. Protocol to include interim analysis and primary outcome measures at every 6 month Accordingly, firm shall submit the revised protocol for further evaluation by the SEC committee.
FDC Division			
8.	FDC/MA/26/000054 Imeglimin Hydrochloride (ER) + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (1000mg + 50mg & 1000mg + 100mg) film coated bilayer tablet	M/s. Exemed Pharmaceutical.	In the light of earlier SEC recommendation dated 05.05.2026, the firm presented BE study reports (under fasting and fed condition) before the committee. After detailed deliberation, the committee considered the BE study reports (under fasting and fed condition) and recommended to initiate Phase III clinical study for which permission is already issued by CDSCO. Accordingly, Phase III clinical trial report should be submitted to CDSCO for further review by the committee.