

Recommendations of the SEC (Endocrinology & Metabolism) made in its 18th/26 meeting held on 06.08.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/25/26 Online Submission (55028) CagriSema	M/s. Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated 23.03.2026, the firm presented phase IIIa clinical study protocol no. NN9838-4968, version no. 4.0 dated 08 September 2025, along with data/information requested by earlier SEC. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that Sponsor shall include the Indian Academy of Paediatric (IAP) growth chart, in addition to the CDC growth charts, for assessment and monitoring of growth parameters of Indian pediatric participants throughout the study. Dr. Rajesh Khadgawat didn't participate in the discussion.
2.	CT/24/26 Online Submission (55085) CagriSema	M/s. Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated 23.03.2026, the firm presented phase IIIa clinical study protocol no. NN9388-7988, version no. 2.0 dated 22 October 2025, along with data/information requested by earlier SEC. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the Sponsor shall include the Indian Academy of Paediatric (IAP) growth chart, in addition to the CDC growth charts, for assessment and monitoring of growth parameters of Indian pediatric participants throughout the study. Dr. Rajesh Khadgawat didn't participate in the discussion.
3.	CT/50/26 Online Submission (55812) Paltusotine	M/s. Allucent (India) Private Limited.	In light of earlier SEC recommendation dated 05.05.2026, the firm presented Post Trial Access clinical study protocol no.: CRN00808- 411 version no. 1.0 dated 23-DEC-2025, along with data/information requested by earlier SEC.

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			After detailed deliberation, the committee recommended for grant of permission for the Post Trial Access as presented by the firm. Dr. Rajesh Khadgawat didn't participate in the discussion.
Biological Division			
4.	BIO/CT04/FF/2025/477 73 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 22.05.2026, the firm presented the results of phase I (PK/PD study) along with proposal to conduct Phase III clinical trial titled "A Multi-Centre Randomised, Open Label, Parallel Group, Active Controlled Phase III study to establish the Non-inferiority of Biosimilar Insulin Degludec Injection (rDNA origin) 100 IU/mL to Reference Insulin Degludec Injection (Tresiba) in the Treatment of Type 2 Diabetes Mellitus" vide Protocol No. ECTS/24/010 Version No. 00 dated 17.10.2024. After detailed deliberation, the Committee recommended the firm to incorporate following changes in the protocol: 1. The duration of treatment should be extended to 24 weeks. 2. The rescue therapy criteria should be clearly defined. 3. Ophthalmological assessments/ investigations should be included in the study protocol. 4. The protocol should clearly specify the permitted concomitant anti-diabetic medications to be used during the trial. 5. The protocol should clearly define the schedule and time points for anti-drug antibody (ADA) sample collection, the validated methodology for antibody testing, the criteria for repeat testing, and the assessment of neutralizing antibodies. 6. The protocol should clearly specify the exclusion of subjects with conditions predisposing to hypoglycaemia, including, but not limited to, adrenal insufficiency, hypopituitarism, other endocrine disorders associated with hypoglycaemia, and recent or ongoing

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			glucocorticoid therapy or withdrawal, as applicable. Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation by the committee.
SND Division			
5.	SND/MA/25/000066 Semaglutide Injection (Synthetic Origin) 2 mg/ 1.5ml (1.34 mg/ml), 4 mg/ 3ml (1.34 mg/ml) & 8 mg/ 3 ml (2.68 mg/ml)	M/s. Emcure Pharmaceuticals Limited.	In the light of earlier SEC recommendation dated 17.07.2025, the firm presented Phase III CT report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide Injection (Synthetic Origin) 2mg/1.5mL, 4mg/3mL & 8mg/3mL prefilled pens for the following indication, with condition to submission of PMS/PSUR data as per the NDCT Rules, 2019. <u>Indication</u> Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: - as monotherapy, when metformin-based therapy is considered inappropriate due to intolerance or contraindications. - in addition to other medicinal products for the treatment of diabetes.
FDC Division			
6.	FDC/MA/24/000041 Alogliptin Benzoate eq. to Alogliptin 25mg/25mg + Metformin Hydrochloride IP 500mg/1000mg ER tablet	M/s. Indoco Remedies Limited.	In light of earlier SEC recommendation dated 09.01.2025, the firm presented their proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the condition that measurement of HbA1C at 12 th week should be included. Accordingly, the revised Phase III clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III clinical trial report to

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			CDSCO for further review by the committee.
7.	FDC/CT/25/000014 Empagliflozin 5mg/10mg/12.5mg/25mg + Metformin Hydrochloride IP (ER) 1000mg/1000mg/1000mg/1000mg film coated bilayered tablet	M/s. Zydus Healthcare Limited.	In light of earlier SEC recommendation dated 25.02.2026 and as per condition mentioned in permission in Form CT-23 dated 13.12.2024; the firm presented the revised 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/25/000077 Dapagliflozin propanediol Monohydrate eq. to Dapagliflozin + Metformin Hydrochloride IP (as sustained release) + Vildagliptin IP (as sustained release) (5mg + 500mg + 100mg, 10mg + 500mg + 100mg & 5mg + 1000mg + 100mg) uncoated bilayered tablets	M/s. Mascot Health Series Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 06.03.2023; 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.