Recommendations of the SEC (Endocrinology & Metabolism) made in its 22nd/25 meeting held on 06.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2025/51518 Semaglutide Tablets (r-DNA origin) 3 mg, 7 mg, and 14 mg	M/s. Novo Nordisk India Pvt Ltd.	The firm presented the proposal for grant of approval of additional indication of the drug Semaglutide (r-DNA origin) Tablets 3 mg, 7 mg, 14 mg - "to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events", based on the data generated from Global Clinical Trials where India was part of the study. The committee noted that the drug Semaglutide Tablets 3 mg, 7 mg and 14 mg is approved in India since Jul, 2020 and the proposed indication is approved in USA & EU. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication. Note: Dr. Rajesh Khadgawat did not participate in the deliberation.
2.	BIO/CT04/FF/2025/50975 Insulin Degludec (r-DNA origin) Injection 100 IU/mL in 3 mL cartridge and 3 mL prefilled pen	M/s. Lupin Limited	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "An open label, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover pharmacokinetic and pharmacodynamic bioequivalence study of Insulin Degludec Injection 100 Units/mL manufactured by Jilin Huisheng Biopharmaceutical Co., Ltd. for Lupin Ltd, India comparing with Insulin Degludec Injection (TRESIBA) of Novo Nordisk in healthy, adult, human participants using Euglycaemic clamp technique under fasting conditions"; vide Protocol Number: 25-138, Version No..: 01, Dated:18 Jul 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm with

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			the condition that the firm shall provide the sensitivity and specificity data of the ELISA method proposed to be used for the estimation of C-peptide and insulin. Accordingly, the firm shall submit the above data to CDSCO for evaluation.
3.	E-109914 Romosozumab (rDNA origin) Injection 90 mg/mL	M/s. Amgen Technology Pvt Ltd	The firm did not turn up for the meeting.
New Drugs Division			
4.	ND-12011(11)/2/2025-eoffice Trelagliptin Tablets 25 mg and 50 mg	M/s. Zuventus Healthcare Limited	In light of earlier recommendations dated 24.07.2025, the firm has submitted revised active PMS study protocol for the drug Trelagliptin Tablets 25 mg and 50 mg (Protocol No. ZUV/ Trelaglip/ 01/ 2025, Version No. 3.0, dated 26 August 2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct active PMS study as per the protocol presented with condition that firm should continue study for follow up period of 24 weeks after the end of the treatment for which firm should submit the revised protocol to CDSCO. Accordingly, report of active PMS study should be submitted to CDSCO for further review by the committee
SND Division			
5.	SND/MA/25/000139 Eliglustat Sublingual Film 8 mg and 16 mg	M/s. Amneal Pharmaceuticals Pvt. Ltd	In light of earlier SEC recommendation dated 07.08.2025, firm has presented interim report for the clinical study CE-24-03 dated 09.10.2025 for grant of marketing authorization. After detailed deliberation, the committee recommended that firm shall submit final results of Cohort 1 and 2 for the clinical study CE-24-03 for further review by the committee.
6.	SND/MA/24/000104 Semaglutide injection 15 mg/3 ml (Synthetic Origin)	M/s. Zydus Lifesciences Limited	In the light of earlier SEC recommendations dated 06.02.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee.

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			After detailed deliberation, the committee opined that firm shall submit and present the clinical data of each clinical trial site before the committee for further review by the committee.
FDC Division			
7.	FDC/CT/25/000101 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (as extended release) (10 mg+1 mg+1000 mg & 10 mg+2 mg+1000 mg) film coated bilayered tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 07.12.2023; 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/25/000103 Empagliflozin 10 mg/25mg + Linagliptin 5mg/5mg + Metformin Hydrochloride (ER) IP 1000 mg/1000 mg film coated tablets	M/s. Pure and Cure Healthcare Pvt. Ltd	In light of the condition mentioned in permission in Form CT-23 dated 14.01.2025; 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.