

Recommendations of the SEC (Endocrinology & Metabolism) made in its 13th meeting held on 17.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/51/25 Online Submission (49349) Orforglipron (LY3502970)	Clinical Trials Eli Lilly and Company India Pvt. Ltd	The firm presented phase III clinical study protocol no. J2A-MC-GZPO version no. initial dated 21 March 2025. After detailed deliberation, the committee opined that the firm shall submit comparative PK study for proposed IMP tablet and capsule for further review by committee.
2.	CT/03/24 Online Submission (39298) CagriSema 1.0 (1,0) mg/ ml + 0.5 (0,5) mg/ ml (0.25 mg/ 0.25 mg) / cagrilintide 1.0 (1,0) mg/ ml (0.25 mg) /semaglutide 0.5 (0,5) mg/ ml (0.25 mg) / placebo	M/s Novo Nordisk India Private Limited	The firm presented protocol amendment version 3.0 dated 17 December 2024 and protocol amendment 4.0 dated 17 February 2025 protocol no. NN9388-7700. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/66/25 Online Submission (49764) Baxdrostat Tablets 1 mg or 2 mg or placebo	M/s AstraZeneca Pharma India Limited	The firm presented phase III clinical study Protocol No.: D6974C00001 version no. 1.0 dated 07-APR-2025 Local CSP Addendum IND-1: Version 1.0 dated 17 Apr 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm,
Biological Division			
4.	r-DNA- 11011(18)/163/2024- eoffice (E-80349) Olipudase alfa powder for concentrate for solution for infusion 20 mg vial	M/s. Sanofi Healthcare India Pvt. Ltd	In light of earlier SEC recommendation dated 15.10.2024, the firm presented the safety data of Indian patients w.r.t. SAE's & AE's of all patients treated with the drug product. After detailed deliberation, the committee recommended for the approval of updated Package insert (Version May 2024) based on the CCDS Versions 5 and 6 for the changes proposed in the Sections of posology, use in special population, overdose & patient counselling information section.

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New Drugs Division			
5.	P-29010/26/2025-DMCell Oral Metformin (for prevention of Paclitaxel induced Peripheral Neuropathy)	Dr. Akash Kumar, AIIMS	The study investigator presented the protocol titled “Oral Metformin for prevention of Paclitaxel induced Peripheral Neuropathy - a Double Blind Placebo Controlled Phase 3 Randomised Controlled Trial (Neuro MET trial)” for the conduct of academic clinical trial with the drug Oral Metformin before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct clinical trial with the condition that applicant should revise the protocol to include biochemical screening with inclusion of vitamin B12 measurement at baseline & at the end of study and periodic blood glucose monitoring and at baseline & based on the symptoms during the study.
BA/BE Division			
6.	BABE/CT05/FF/2025/47810 Tiopronin ER Pellets 500 mg	M/s Azidus Laboratories Limited	The firm presented the Protocol No. AZBE012504, Version 1.0 Protocol Date 06-FEB-2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
SND Division			
7.	SND/CT/25/000013 Semaglutide Injection (synthetic origin) 1 mg/1.5 mL (0.68 mg/mL), 2 mg/ 1.5 mL (1.34 mg/ mL), 4 mg/ 3 mL (1.34 mg/ mL), 6.8 mg/ 3 mL (2.27 mg/ mL), 9.6 mg/ 3 mL (3.2 mg/ mL)	M/s Hetero Labs Limited	Firm presented BE study report along with Phase III CT study Protocol (Protocol no. HCR/ III/ SEMAOBE/ 01/2025, ver. 1.0 dated 16.01.2025 for overweight/ obesity before the Committee. After detailed deliberation, the committee accepted the BE study report and recommended to conduct the Phase III clinical trial as per protocol presented by the firm.
FDC Division			
8.	FDC/CT/25/000040 Vildagliptin IP (SR) 100 mg/ 100 mg + Dapagliflozin Propanediol	M/s Eris Lifesciences Limited	As per the condition mentioned in Form CT-23 dated 01.10.2024, the firm presented Phase IV CT protocol in only one strength of the FDC, before the committee.

SEC (Endocrinology & Metabolism) meeting dated 17.06.2025

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	Monohydrate eq. to Dapagliflozin 10 mg/ 10 mg + Metformin Hydrochloride IP (SR) 500 mg/ 1000 mg film coated bilayered tablet		<p>After detailed deliberation, the committee opined that the firm should revise the study design and include both the approved strengths in the study protocol.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p>