Recommendations of the SEC (Endocrinology & Metabolism) made in its 08th/25 meeting held on 22.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/50/23 Online Submission (38191) LY3437943	M/s Eli Lilly And Company	The firm presented protocol amendment (b) dated 24 January 2025 protocol no. J1I-MC- GZBK. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	r-DNA-11011(18)/31/2025-eoffice Agalsidase Beta Powder for concentrate for solution for infusion, 35 mg and 5 mg	M/s Sanofi Healthcare India Pvt. Ltd.	The firm presented the proposal for update in prescribing information for the drug product Fabrazyme® (Agalsidase Beta Powder for concentrate for solution for infusion, 35 mg and 5 mg) in line with Company Core Data Sheet (CCDS) version 5 dated 06 May 2021, version 6 dated 18 Nov 2021 and version 7 dated 20 Jul 2023. After detailed deliberation, the committee recommended for the approval of updated prescribing information (Version dated Oct 2024) of the drug product. Further, the firm is required to submit EMA approval of the updated prescribing information to CDSCO for further evaluation.
3.	E-67418 Aldurazyme® (Laronidase for Solution for Injection 2.9 mg/5 ml)	M/s. Sanofi Healthcare India Pvt Ltd	The firm presented the proposal for update in prescribing information for the drug product Aldurazyme ® (Laronidase for solution for injection 2.9mg/5mL) in line with USPI dated December 2023. After detailed deliberation, the committee recommended for the approval of updated prescribing information (Version dated Dec 2024) of the drug product.
BA/BE Division			
4.	BABE/CT05/FF/2025/47484 Empagliflozin / Pioglitazone Film-Coated Tablets 25mg /	M/s. AXIS Clinicals Limited	Firm presented the BA/BE study Protocol No. 369-24 (Fasting), Version 01, dated 18th January 2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to

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	30 mg		conduct the BABE study for export purpose only.
SND Division			
5.	SND/MA/25/000014 Semaglutide Injection 0.25mg/0.5mg/1mg Pre-filled pen (4mg/3ml) Semaglutide Injection 1.7mg/2.4mg Pre-filled pen (9.6mg/3ml)	M/s Macleods Pharmaceuticals Ltd	Firm presented BE study protocol vide protocol no. BEQ-3990-SEMA-2025, Version no. 01 and Phase III CT protocol vide protocol no. CT-065-SEMA-2025, Version no. 01 for weight management before the Committee. Firm has informed that preclinical subacute toxicity study of Semaglutide Injection in two species is ongoing. After detailed deliberation, the Committee in principle agreed with presented BE protocol and Phase III CT protocol and recommended that firm should submit and present preclinical subacute toxicity study report before initiation of BE study.
6.	SND/CT/24/000096 Hydroxy chloroquine Sulphate Tablets IP 300 mg	M/s IPCA Laboratories Limited	The firm presented the proposal for grant of permission to conduct Phase III clinical trial vide protocol No. Ipca/HYDR/PIII-24, Version: 01, dated 29.07.2024 before the committee for Evaluation of Efficacy and Safety of Hydroxychloroquine in uncontrolled type 2 diabetes patients with Dyslipidemia and Stable Atherosclerotic Cardiovascular Disease. The committee noted that single primary objective and multiple secondary objectives are mentioned in the Phase III protocol presented by firm. After detailed deliberation, the committee opined to revise the protocol as below- 1) Primary objectives and secondary objectives to be redefined based on terminology available in Scientific literature and therapeutic rationale. 2) Atherosclerotic Cardiovascular Disease to be defined in the protocol. Accordingly, the firm should submit revised protocol to CDSCO.

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FDC Division			
7.	FDC/CT/25/000010 Empagliflozin + Metformin Hydrochloride (SustainedRelease) 25mg/10mg +1000mg/1000mg tablets	M/s Abbott Healthcare Pvt. Ltd	In light of the condition mentioned in permission in Form CT-23 dated 01.10.2024, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase-IV clinical trial with the condition that more sites should be added and geographically distributed. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee