Recommendations of the SEC (Endocrinology & Metabolism) made in its 10th/24 meeting held on 16.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/14/22 Online Submission (32514) Paltusotine	M/s. Pharm Olam/ Allucent	The firm presented protocol amendment version 4.0 dated 22.11.2023 protocol no. CRN00808-08. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
2.	SND/MA/24/000077 Semaglutide solution for injection (Synthetic origin) 2mg/1.5ml, 4mg/3ml, 8mg/3ml	M/s. Sun Pharma Labs Limited	The firm has presented their proposal for grant of permission to manufacture and marketing of Semaglutide solution for injection (Synthetic origin) (2mg/1.5ml) 1.34mg/ml, (4mg/3ml)1.34mg/ml, (8mg/3ml) 2.68mg/ml) for the indication: 1. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type to diabetes mellitus. 2. 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 and established cardiovascular disease, along with Phase-III clinical trial and Bioequivalence study protocol before the Committee. The firm has informed that Semaglutide solution for injection (rDNA origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml and 2.4mg/0.75ml is already approved by the CDSCO on 20.04.2022. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial. Further, the firm should submit Bioequivalence report for review by the SEC committee before initiating the Phase III clinical trial.
3.	SND/MA/24/000288 Semaglutide pre-filled pen 4mg/3ml	M/s. NATCO Pharma Limited	The firm has presented their proposal for grant of permission to manufacture and marketing of Semaglutide solution for injection (Synthetic origin), 2mg/1.5ml

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	& 2mg/1.5 ml		(1.34mg/ml) & 4mg/3ml (1.34mg/ml) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, 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 and established cardiovascular disease, along with justification for Phase III clinical trial waiver and Bioequivalence study protocol, which was submitted to BABE Export division before the Committee. The firm has informed that Semaglutide solution for injection (rDNA origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml and 2.4mg/0.75ml already approved by the CDSCO on 20.04.2022. After detailed deliberation, the committee opined that firm is required to submit Phase-III clinical trial protocol along with Bioequivalence study report for further review by the committee.
4.	SND/MA/23/000295 Eliglustat Sublingual Film 16mg	M/s. Kashiv Biosciences Private Limited	In light of earlier SEC recommendations dated 22.02.2024, the firm presented Phase III Clinical trial protocol (Protocol No. CE-24-03, Version: 1.0, Dated: 19.04.2024) before the committee. After detailed deliberation, the Committee recommended for grant of permission to conduct Phase III Clinical trial as per protocol presented by the firm with the condition that more number of geographically distributed sites shall be included in the proposed clinical trial subject to the condition that firm needs to fulfill the CMC requirement for both 8mg & 16mg strength.
New Drugs Division			
5.	ND/MA/22/000063 Sodium Phenylbutyrate Powder	M/s. Laurus Labs Ltd.	In light of the recommendations of SEC (Endocrinology & Metabolism) dated 03.06.2022, the firm presented their BE study report for grant of permission to manufacture and market Sodium Phenyl

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			butyrate powder. The committee noted that the Urea Cycle Disorder is very rare disease and there is unmet medical need in the country. The committee also noted that the drug is already approved in US, Europe and Canada. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the applied drug for proposed indication subject to the condition that the firm shall conduct Phase IV clinical trial for which Phase IV CT protocol to be submitted to CDSCO within 3 months of approval for further evaluation by the committee.
FDC Division			
6.	FDC/IMP/18/000012 Saxagliptin Hydrochloride 5.95mg eq. to Saxagliptin 5mg + Dapagliflozin Propanediol Monohydrate 12.3mg eq. to Dapagliflozin 10mg film coated tablet	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 15.10.2020 and as per condition of Form CT-23 dated 24.09.2019, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.