Recommendations of the SEC (Endocrinology & Metabolism) made in its 14th/24 meeting held on 24.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-39269 Somatrogon 24mg/1.2ml and 60mg/1.2 ml	M/s. Pfizer	In light of earlier SEC recommendations dated 21.03.2024, the firm has presented the revised protocol to conduct the active surveillance study titled "A multicenter, non interventional prospective active surveillance study among participants receiving Somatrogon under routine clinical care in India" vide protocol number C0311026, version :V 2.0 dated 29.05.2024. After detailed deliberation, the committee recommended the firm to conduct the active post marketing surveillance study as per revised protocol presented by the firm. Dr. Rajesh Khadgawat did not participate in this proposal.
2.	4-48/Takeda/PAC-R-Agalsidasealfa/2023-BD & r-DNA-11011(18)/95/2024-eoffice Algalsidase Alfa (REPLAGAL®)	M/s. Takeda Biopharmaceuticals India Pvt. Ltd.	The firm did not turn up for the presentation.
3.	BIO/CT04/FF/2024/42174 Liraglutide solution for Injection 6.0 mg/ml	M/s. Levim Biotech LLP	The firm presented the proposal for the conduct of Phase IV study titled "A Phase IV, Open Label, Prospective, Multi-Center Study to Evaluate the Safety and Efficacy of Liraglutide Biosimilar in Patients with Type 2 Diabetes Mellitus" vide Protocol No. NV-05-1575-2023 Version 2.0 dated 27.02.2024. After detailed deliberation, the committee recommended for the conduct of the proposed Phase IV study subject to the following changes in the protocol- 1. The study should exclude the exploratory objective to evaluate the efficacy of Liraglutide Biosimilar in T2DM patients with NAFLD (Non-

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			Alcoholic Fatty Liver Disease). Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation.
4.	BIO/CT18/FF/2024/42478 Semaglutide Injection 0.25mg/0.5mg/1mg/ 1.7mg/2.4mg [Wegovy] & Semaglutide Injection 0.25mg/0.5mg/1mg/1.7mg/2.4mg (Wegovy FlexTouch)	M/s. Novo Nordisk	The firm presented the proposal for grant of permission for additional indication of the drug product Semaglutide Injection 0.25mg/0.5mg/1mg/1.7mg/2.4mg [Wegovy] & Semaglutide Injection 0.25mg/0.5mg/1mg/1.7mg/2.4mg [Wegovy (Flextouch)] i.e Indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents aged 12years and above with obesity and body weight above 60 kg. The committee noted that the drug product is not yet marketed in India. After detailed deliberation, the committee recommended the firm to submit PSUR data to establish the safety in Indian population for further review of the present proposal by the committee in the presence of pediatrician. Dr. Rajesh Khadgawat did not participate in this proposal.
Medical Devices Division			
5.	CI/MD/2024/116901 iSage Rx version 2.8	M/s. Pharma Leaf India Private Limited	The firm presented their proposal before the expert committee for grant of permission for conduct of Pivotal Clinical investigation of standalone Software iSage Rx App intended to help adult patients understand and follow their healthcare professional's titration plan for its extended Intended purpose/Indication for use i.e. Titration of the basal component of premix insulin, in the country. After detailed deliberation, the committee opined that the clinical study protocol presented before the committee is inadequate. The applicant may revise clinical study protocol by incorporating the following points:

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			1. The proposed single arm study may be redesigned as comparative arm study. 2. Submit proper rationale/justification for proposing the sample size (subjects) for the study. 3. To include the rescue criteria for the subjects enrolled and withdrawal criteria in case if patients fasting blood sugar level is not controlled. 4. Provide clear plan of how the patient will use the device, features of the software app and elaborate on the principle of operation The firm may submit the revised clinical investigation plan accordingly for review by the SEC.
SND Division			
6.	SND/MA/22/000254 Semaglutide Injection 2mg/1.5ml(1.34mg/ml) & 4mg/3ml (1.34mg/ml) (Synthetic Origin)	M/s. Dr. Reddy's Labs Limited	In light of earlier SEC recommendation dated 27.09.2023 & 29.09.2023, the firm presented Bioequivalence study report alongwith the Phase-III clinical trial protocol before the committee. After detailed deliberation, the committee considered the bioequivalence report and recommended for grant of permission to conduct Phase III clinical trial study as per the protocol presented and submit the results for further deliberation.