Recommendations of the SEC (Endocrinology & Metabolism) made in its 19th/24 meeting held on 13.11.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2023/39333 Insulin Icodec	M/s. Novo Nordisk	The firm did not turn up for the presentation.
2.	r-DNA-11013(12)/19/2024-eoffice Insulin Lispro Ultrarapid Injection 100 IU & 200 IU	M/s. Eli Lilly and Company (India) Pvt.Ltd.	The firm presented the proposal for amendment in the warning statement for already approved drug products Insulin Lispro Ultrarapid (UR) 100 U/ml & 200 U/ml from: "WARNING: To be sold by retail on the prescription of a Registered Endocrinologist only" to "Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only". After detailed deliberation, the committee recommended that warning statement may be amended as WARNING: To be sold by retail on the prescription of a Registered Endocrinologist and/or MD (Medicine)" The committee further recommended the firm to submit Phase-IV study data for expanding the prescription warning for Registered Medical Practitioner.
3.	BIO/CT04/FF/2024/45156 Recombinant Insulin Aspart IP 100U/mL solution for injection in 3mL cartridge and 10 mL vial	M/s. Bio Genomics Limited	The firm presented the proposal for permission to conduct Phase-IV Clinical Trial titled as "A multicenter, open-label, single-arm, Phase IV study to assess the safety and efficacy of InsuQuick® (Insulin Aspart) in adult patients with Type 2 Diabetes Mellitus" vide protocol No. BGL-IA-CTP-401-V2, Version 2.0 dated 12 Jul 2024. After detailed deliberation, the committee recommended for approval to conduct the study with following changes in the protocol: 1. Safety management plan shall be included in the protocol. 2. Sample size should be increased to 150 evaluable subjects considering the subjects enrolled in the Phase III study & Similar Biologics guidelines requirements.

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			Accordingly, firm shall submit the revised protocol to CDSCO for further evaluation.
New Drugs Division			
4.	ND/MA/22/000152 Trelagliptin Tablets 25 mg, 50 mg and 100 mg	M/s. Zuventus Healthcare Limited	The firm presented BE study report and Phase-III local clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of the drug Trelagliptin Tablets 25 mg, 50 mg and 100 mg with the condition that firm should conduct Active PMS study on Trelagliptin Tablets 25 mg and 50 mg. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.
FDC Division			
5.	FDC/MA/24/000238 Acarbose IP 25mg/25mg/50mg/50 mg + Sitagliptin Phosphate Monohydrate 50mg/50mg/50mg/50 mg + Metformin Hydrochloride IP 500mg/1000mg/500mg/1000mg film coated tablet	M/s Hetero Labs Limited	The firm presented the proposal before the committee. After detailed deliberation, the committee opined the following: 1. The firm did not present adequate justification/rationale for the proposed triple drug combination in the specified strengths/dose. 2. More published scientific literature in peer reviewed journal in support of rationality and desirability of triple drug combination is to be presented. 3. The committee noted that the proposed FDC is not approved internationally. 4.The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. Accordingly, the firm should submit above data for further review by the committee.