Recommendations of the SEC (Endocrinology & Metabolism) made in its 01st/25 meeting held on 09.01.25 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 700U/mL, 1050U/1.5mL, 2100U/3mL	M/s. Novo Nordisk	In light of earlier SEC meetings dated 11.01.2024, 10.04.2024 and 19.06.2024, the firm updated the regulatory status of the drug. The committee noted the updates and reiterated the earlier committee recommendations. Further, the committee recommended the firm to include equal number of subjects from Type 1D and Type 2D in active PMS study.
2.	BIO/CT04/FF/2024/43907 Biphasic Isophane Insulin Injection IP 100 IU/mL cartridges	M/s Virchow Biotech Private Limited	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single-dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of Insulin 30/70 suspension for injection 100IU/mL (Biphasic isophane insulin injection-30% soluble insulin/ 70% isophane insulin) of Virchow Biotech, Hyderabad, India and HUMINSULIN®30/70 100 IU/mL suspension for injection in cartridge (Biphasic isophane insulin injection-30% soluble insulin/ 70% isophane insulin) of Lilly France S.A.S, Centre de Production 2, Rue Du Colonel Lilly, Zone Industrielle, F-67640 Fegersheim France, in healthy, adult, human male subjects using Euglycemic clamp technique under fasting conditions" vide Protocol No. AR105-24 Version No. 02 dated 24.09.2024. After detailed deliberation, the committee recommended for approval to conduct the study as per protocol presented by the firm with following condition: 1. Investigator who is having experience in performing Clamp study should be the part of the

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			study as Co-investigator. Accordingly, revised protocol should be submitted to CDSCO for further evaluation.
3.	E-43564 BIO/CT/21/000086(r-DNA-11015(13)/46/2024-eoffice) Insulin Regular/neutral 30/70 (Wosulin R, Wosulin N and Wosulin 30/70)	M/s. Wockhardt Limited	The firm presented the amendment in protocol for Phase IV clinical trial titled "A Prospective, Open-Label, Randomized, Parallel Group, Comparative, Multi-center, Phase IV Trial to Evaluate the Immunogenicity and Safety of Wockhardt's Basal or Bolus human insulin (Wosulin R, Wosulin N and Wosulin 30/70) with Eli Lilly's Basal or Bolus human insulin (Huminsulin R, Huminsulin N and Huminsulin 30/70) in Subjects with Diabetes Mellitus" as per protocol no WOC/WOS/CT-37/14 version 02 dated 08 Jan 2021-amendment no 02 date 07 Jun 2024" After detailed deliberation, the committee recommended for the approval of amended protocol vide Amendment no 02 dated 07 Jun 2024.
4.	E. 45672 USVCAP capsules (Human Insulin IP 75 IU/150 IU/300IU)	M/s USV Pvt Ltd.	The Firm did not turn up for the presentation .
New Drugs Division			
5.	ND-12011/10/2024-eoffice Eliglustat	Department of Pediatrics, AIIMS (Dr. Neerja)	The study investigator, Department of Pediatrics, AIIMS presented protocol titled "Pharmacokinetics, Pharmacodynamics and efficacy assessment of Eliglustat monotherapy in Paediatric Patients with Gaucher Disease Type 1 and Type 3 : A single-arm interventional trial (ELEGANT)" for the conduct of clinical trial with the drug Eliglustat. After detailed deliberation, the committee recommended for the grant of permission to conduct the clinical trial as per the protocol presented.
FDC Division			

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6.	FDC/MA/24/000041 Alogliptin Benzoate eq. to Alogliptin 25mg/25mg + Metformin Hydrochloride IP 500mg/1000mg ER tablet	M/s Indoco Remedies Limited	In light of the earlier SEC recommendation dated 07.03.2024, the firm presented BE study report before the committee. After detailed deliberation, the committee considered the BE study report and did not consider the justification for CT waiver and recommended to conduct Phase-III CT study with proposed FDC. Accordingly, the firm should submit Phase III CT Protocol to CDSCO for further review by the committee.
7.	FDC/MA/24/000108 Glimepiride (1mg + 2mg) + Linagliptin (5mg + 5mg) Tablets	M/s Pure and Cure Healthcare Pvt. Ltd	The firm presented the proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. As regard to Phase III clinical trial protocol, the committee opined that- 1. Exclusion criteria should be adequately modified w.r.t patients with Fasting Plasma Glucose (FPG) should be 200 mg/dL. 2. Duration of study should be 24 weeks. Accordingly, the firm should submit revised Phase III clinical trial protocol along with BE study report to CDSCO for further review by the committee.