Recommendations of the SEC (Endocrinology & Metabolism) made in its 18th/25 meeting held on 20.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/62/23 Online Submission (40375) LY3502970	M/s. Clinical Trials Eli Lilly and Company (India) Pvt. Ltd.	The firm presented protocol amendment (d) dated 30 April 2025 protocol no. J2A-MC-GZGP. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/106/25 Online Submission (51036) Utreglutide (GL0034)	M/s Sun Pharmaceutical Industries Limited	The firm presented phase II clinical study protocol no. UTRE-24-01 version no. initial dated 12 June 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/51/25 Online Submission (49349) Orforglipron (LY3502970)	M/s Clinical Trials Eli Lilly and Company India Pvt Ltd.	In light of earlier SEC Recommendation dated 17.06.2025, now the firm presented comparative PK study for proposed IMP tablet and capsule for phase III clinical study protocol no. J2A-MC-GZPO version no. initial dated 21 March 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	e-Receipt No.: 72324 e-Receipt No.: 72325 e-Receipt No.: 72326 e-Receipt No.: 72327 e-Receipt No.: 72332 e-Receipt No.: 72337 e-Receipt No.: 72361 Range of Insulin Products (rDNA origin)	M/s Novo Nordisk (India) Private Limited	The firm presented the proposal to discontinue their multiple Insulin drug products (rDNA origin) from Indian market. The committee noted that the firm has proposed for the discontinuation of products based on a business decision and not due to any safety or efficacy concerns and further noted that alternative therapies are available in Indian market. After detailed deliberation, the committee consented for firm's proposal for discontinuation of their multiple Insulin drug products (rDNA origin) from Indian market.
5.	E-83204 and E-76833 Rybelsus 3 mg, 7 mg and 14 mg tablets	M/s Novo Nordisk (India) Private Limited	The firm presented the proposal for update in Package Insert (Version February 2025) for the changes in the Sections of Special Warnings and Precautions for use, Drug Interactions, Use in special populations and

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			Undesirable effects of the drug product Rybelsus 3 mg, 7mg and 14 mg tablets in line with EMA approval. After detailed deliberation, the committee recommended for approval of updated package insert Version February 2025 of the said drug product for the proposed changes.
SND Division			
6.	SND/MA/25/000109 Semaglutide 0.25 mg/0.375 mL (0.68 mg/ml), 2 mg/0.75 mL (2.68 mg/ml) & 8 mg/3 mL (2.68 mg/ml) (Synthetic Origin)	M/s Virchow Biotech Private Limited	Firm presented Pre-clinical studies reports, Bioequivalence study Protocol (Protocol No.: AR089-25, Version No.: 01, Date: 09.05.2025) along with the Phase-III clinical trial protocol (Protocol No.: VBSEMA-DM/2025-CT1, Version No.: 1, Date: 05.05.2025) for type 2 diabetes mellitus before the committee. After detail deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following change in the CT protocol: 1. Fasting and postprandial blood sugar levels should be used for dose titration. 2. Thyroid screening for Medullary carcinoma Thyroid by Ultrasound should be part of screening for subject eligibility. 3. Caution for Medullary Thyroid carcinoma (MTC) should be part of Informed Consent Form. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
7.	SND/MA/25/000110 Semaglutide (Synthetic Origin) 0.25 mg/0.5 mL (0.5 mg/mL), 2.4 mg/0.75mL (3.2 mg/ml) & 1.5 mg/3mL (0.5 mg/mL) (Synthetic Origin)	M/s Virchow Biotech Private Limited	Firm presented Pre-clinical studies reports, Bioequivalence study Protocol (Protocol No.: AR088-25, Version No.: 01, Date: 09.05.2025) along with the Phase-III clinical trial protocol (Protocol No.: VBSEMA-WM/2025-CT1, Version No.: 1, Date: 05.05.2025) for chronic weight management before the committee. After detail deliberation, the Committee recommended for grant of permission to conduct the BE study and Phase III clinical trial with following change in the

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			CT protocol: 1. Thyroid screening for Medullary carcinoma Thyroid by Ultrasound should be part of screening for subject eligibility. 2. Caution for Medullary Thyroid carcinoma (MTC) should be part of Informed Consent Form. 3. After completion of CT study, one-month follow-up period should be included in the protocol. Further, the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
FDC Division			
8.	FDC/MA/25/000055 Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 50 mg/50 mg + Glimepiride IP 0.5 mg/0.5 mg + Metformin hydrochloride IP 500 mg/1000 mg film coated tablet	M/s Sun Pharma Laboratories Limited	The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee. After detailed deliberation, the committee opined the following: 1. Firm did not present any data for the proposed strength of the FDC. 2. Lower dose of Glimepiride adding to Sitagliptin and Metformin hydrochloride once daily is clinically not useful. 3. The product is not approved internationally. Hence, the committee did not recommend for approval of the proposed FDC.
9.	FDC/MA/25/000091 Empagliflozin 10 mg/25 mg + Linagliptin 5 mg/5 mg + Metformin Hydrochloride IP (ER) 500 mg/500 mg film coated bilayer tablet	M/s Theon Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 22.05.2025, the firm presented the justification and rationality for the proposed strength of the FDC before the committee. After detailed deliberation, the committee did not consider the justification and reiterated its earlier recommendation. In view of above, the firm should submit above data for further review by the committee.