Recommendations of the SEC (Endocrinology & Metabolism) made in its 02nd/25 meeting held on 29.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-56357 Dulaglutide 0.75 mg and 1.5mg	M/s. Eli Lilly and Company India Pvt Ltd	The firm presented the proposal for update in package insert of the drug product Dulaglutide 0.75 mg and 1.5 mg solution for injection in prefilled pen in the Section 4.4 along with other administrative changes. After detailed deliberation, the committee recommended for the approval of updated package insert dated 16 September 2024 for the proposed changes.
2.	E-59254 Dulaglutide 0.75 mg and 1.5mg	M/s. Eli Lilly and Company India Pvt Ltd	The firm presented the final CSR of Phase IV clinical trial titled "A 24-week multicenter, open-label, single-arm study to evaluate safety in patients with type 2 Diabetes mellitus in India treated with Dulaglutide" conducted vide protocol no. H9X-IN-GBGR(b). After detailed deliberation, the committee noted the results of the study.
3.	E-59264 Semaglutide tablets 3mg, 7mg, 14mg	M/s. Novo Nordisk	In light of earlier recommendation dated 25.08.2022 & 26.08.2022, the firm presented the additional safety data in Indian population for the proposed change in warning statement of the drug product Semaglutide tablets 3mg, 7mg, 14mg from "To be sold by retail on the prescription of a Registered Endocrinologist or Physician with Post graduate qualification in medicine" to "To be sold by retail on the prescription of Registered Medical Practitioner". The committee noted that real world long term safety data is not available with the firm. After detailed deliberation, the committee did not consider the firm' request for the proposed amendment in the warning statement.
4.	BIO/CT21/FF/2024/45669	M/s Wockhardt Limited	The firm presented the proposal to manufacture and market Recombinant Insulin Aspart Injection 100 IU/mL based on the results of Phase I clinical trial

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	Insulin Aspart Injection 100 IU/mL ,10ml multidose vial, 3 mL Multi-dose Cartridge		conducted by the firm in India with the request for waiver of Phase III clinical trial. After detailed deliberation, the committee did not consider the firm's proposal to manufacture and market the drug product Recombinant Insulin Aspart Injection 100 IU/mL with Phase III clinical trial waiver.
5.	BIO/CT04/FF/2024/46109 Semaglutide Tablets 3 mg, 7 mg and 14 mg	M/s DrReddys Laboratories Limited	The firm presented the proposal to conduct Phase III clinical trial titled "A Randomized, Multicentric, Double-Blind, Active-Controlled, Parallel Group, Phase III Non-Inferiority Clinical Trial to Evaluate the Efficacy, Safety and Tolerability of Oral Semaglutide Tablets of Dr. Reddy's Laboratories Pvt. Ltd Compared with RYBELSUS (Semaglutide) Tablets in Adult Patients with Inadequately Con-trolled Type 2 Diabetes Mellitus" vide Protocol no. DRL-IND-NDA28-SEM/2024,Version 1.0 dated 15 Oct 2024 along with the results of BE study conducted by the firm in India. After detailed deliberation, the committee recommended for approval to conduct the study with the following changes in the protocol- 1. Calcitonin limit in the inclusion criteria should be less than 100 2. BMI lower cutoff in inclusion criteria should be ≥23 kg/m2 at screening 3. Diabetes insipidus should be removed in exclusion criteria. 4. Unstable retinopathy or maculopathy should be clearly defined in the exclusion criteria 5. Urine albumin and creatinine ratio should be part of follow-up assessment. 6. Clinical trial sites should be geographically distributed and should include Government sites. Accordingly, the revised protocol should be submitted to CDSCO for further

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			evaluation.
6.	BIO/CT21/FF/2024/46102 Insulin Glargine injection IP 100IU/mL	M/s. Regenix Biosciences Ltd	The firm presented the proposal to manufacture and market the drug product Recombinant Insulin Glargine Injection 100IU/ml based on the results of Phase III clinical trial conducted by the firm. The committee noted that the firm is using the approved drug substance for manufacturing of their formulation. After detailed deliberation, the committee recommended for the grant of permission to the firm to manufacture and market Recombinant Insulin Glargine Injection 100IU/ml
SND Division			
7.	SND/MA/23/000235 Dapagliflozin 2,3-butanediol Monohydrate Tablet 5mg & 10mg	M/s. Biocon Limited	In light of earlier SEC recommendations dated 24.01.2024, the firm presented Bioequivalence study reports conducted under Fasting and Fed condition and justification for waiver of Phase-III clinical trial including API sameness, tentative ANDA approval from USFDA for proposed formulation, comparative physicochemical study data and pre-clinical toxicity data before the committee. The firm has informed that the Dapagliflozin propanediol Tablets 5mg & 10mg already approved in the country on 25.02.2015. The firm has also informed that they have received tentative ANDA approval from USFDA on 15.01.2020 for proposed formulation (Dapagliflozin 2,3-butanediol Monohydrate). Further, firm presented results of BE studies under Fasting and Fed condition to evaluate the PK and safety of Dapagliflozin 2,3-butanediol Monohydrate tablet 10mg compared with Dapagliflozin propanediol Monohydrate tablet 10mg in healthy subjects. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Dapagliflozin

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			2,3-butanediol Monohydrate tablet 5mg & 10mg with Phase-III clinical trial waiver for proposed indication.
FDC Division			
8.	FDC/MA/24/000266 Dapagliflozin propanediol monohydrate (10mg + 10mg) + Pioglitazonehydrochloride (15mg + 15mg) + Metformin hydrochloride ER (500mg + 1000mg) Tablets	M/s Alkem Laboratories Ltd	The firm presented the proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined the following: 1. Firm should submit the data/published literature on effect of addition of Pioglitazone to Dapagliflozin on bone loss. 2. Firm should submit more scientific literature on safety data of combining Pioglitazone with Dapagliflozin propanediol and Metformin hydrochloride as triple combination. Accordingly, the firm should submit above data for further review by the committee.