Recommendations of the SEC (Endocrinology & Metabolism) made in its 17th/26 meeting held on 16.07.2026 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/82/26 OnlineSubmission (57290) LY3502970	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical study protocol no. J2A-MC-GZGY amendment a dated 08 May2026. After detailed deliberation, the committee opined that firm shall submit the following for further review by the committee: 1) Adequate justification for using Dulaglutide as a comparator product which is not approved in India for the proposed trial in Paediatric population. 2) Effects of the investigational product on Paediatric population with respect to growth, pubertal development, reproductive health (reproductive axis) and the hypothalamic-pituitary-adrenal (cortisol) axis, with supportive data from pre-clinical and pivotal studies conducted. 3) Clinical data on changes in lean muscle mass/body composition. 4) Dose-escalation regimen, particularly for the rationale from 12 mg to 36 mg is not properly justified in the absence of intermediate dose levels (e.g., 24 mg), and the justification for selection of the maximum dose of IMP for proposed study population. 5) Procedure for Dose Escalation in case of the maximum dose is not tolerated.
2.	CT/93/26 Online Submission (57686) LY3841136	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical study protocol no. J3R-MC-YDAS amendment a dated 22-MAY-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2026/55222	M/s. Novo Nordisk India Pvt. Ltd	The firm presented the proposal for addition of a new strength of Semaglutide Injection 2 mg (2.68 mg/ml) solution for

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	Semaglutide Injection 2 mg (r-DNA Origin) (2.68 mg/mL), solution for injection in pre-filled pen.		injection in pre-filled pen. The committee noted that 0.25mg, 0.5mg & 1mg strengths are already approved in India since Sep-2025 for improving glycemic control in adults with Type-2 diabetes mellitus. The Committee further noted that, in support of the proposed strength, the firm conducted a global Phase 3b clinical trial (SUSTAIN FORTE) to evaluate the efficacy and safety of semaglutide 2.0 mg administered subcutaneously once weekly compared with semaglutide 1.0 mg administered subcutaneously once weekly in subjects with type 2 diabetes mellitus, and that India was not a participating country in the study. After detailed deliberation, the committee considered the local Phase-III clinical trial waiver and recommended the grant of approval for the proposed strength, considering the significant therapeutic advancement where additional glycemic control is required in T2D patients, in line with the USFDA; subject to the condition that firm shall conduct the Phase-IV clinical trial in India. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of the grant of marketing authorization permission.
4.	BIO/CT21/BO/2026/55351 Insulin Glargine Injection I.P. 100IU/mL-3mL Cartridge and 10mL Vial	M/s. Virchow Biotech Private Limited	The firm presented the proposal for the grant of permission to manufacture and market the drug product Insulin Glargine I.P (r-DNA Origin) Injection 100 IU/ml. The Committee noted that firm has conducted a phase-3 study to compare the efficacy and safety of VB70G (Insulin Glargine Injection 100 Units/mL) with LANTUS® in Type 2 Diabetes Mellitus patients with Uncontrolled Oral Antidiabetic therapy. After detailed deliberation, the committee recommended for the grant of permission to the firm to manufacture and market

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			Insulin Glargine I.P (r-DNA Origin) Injection 100 IU/ml for the "Treatment of Type II Diabetes Mellitus in Adults only" with a condition to conduct a Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of marketing authorization permission to manufacture and market the drug product.