Recommendations of the SEC (Endocrinology & Metabolism) made in its 02nd/26 meeting held on 13.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2025/52117 Semaglutide Tablets 3 mg, 7 mg and 14 mg	M/s Dr. Reddy's Laboratories Limited	The firm presented the proposal to manufacture and market the drug product Semaglutide Tablets 3 mg, 7 mg and 14 mg based on the results of Phase-III clinical trial conducted by the firm for the following indication: Oral Semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Also, in combination with other medicinal products for the treatment of Type 2 diabetes Limitations of Use • Has not been studied in patients with a history of pancreatitis. • Not indicated for use in patients with type 1 diabetes mellitus The Committee noted that the firm has conducted a non-inferiority Phase III clinical trial to evaluate the efficacy, safety, and tolerability of oral Semaglutide tablets manufactured by Dr. Reddy's Laboratories Ltd., in comparison with Rybelsus® (Semaglutide) tablets, in adult patients with inadequately controlled Type 2 diabetes mellitus. The Committee further observed that the drug is to be prescribed only by registered Endocrinologists. After detailed deliberations, the Committee recommended for on-site verification of the above-mentioned Phase III clinical trial data generated at least 02 clinical trial sites, selected based on risk-based criteria, prior to consideration of marketing authorization for the firm.
2.	E-31426 Semaglutide Injection 0.25 mg/0.5 mg/1 mg	M/s Novo Nordisk India Pvt Ltd.	The firm presented the proposal to conduct India specific PMS study for the approved drug product Semaglutide Injection 0.25 mg/0.5 mg/1 mg (r-DNA Origin), solution

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	(Ozempic)		for injection in pre-filled pen [Ozempic®] with protocol title as: "A multicenter, prospective, open-label, observational, post marketing surveillance study to evaluate the safety and effectiveness of Ozempic® (s.c. Semaglutide 1.0 mg) in adults with type 2 diabetes mellitus in Indian real-world clinical practice (EPIC-India)" vide Protocol/study ID No. NN9535-8761, v 1.0 dated 11 Dec 2025." After detailed deliberation, the committee recommended for approval to conduct the proposed PMS study as per protocol presented by the firm subject to following conditions: 1. Subjects with diabetic retinopathy shall be excluded from the study. 2. Study subjects shall be assessed at Week 12 and Week 24 for ophthalmological disorders, and renal & hepatic function. 3. Study sites shall be geographically distributed across the country. Accordingly, the revised protocol shall be submitted to CDSCO.
3.	E-88602 Insulin Icodec Solution for injection 700 U/1 mL, 1050 U/1.5 mL & 2100 U/3 mL in prefilled pen	M/s Novo Nordisk India Pvt Ltd.	The firm presented a proposal to conduct a PMS study titled, "A multi-centre, prospective, open-label, non-interventional, single-arm, 26-week post-marketing study to investigate safety and clinical parameters of once-weekly Awiqli® (insulin icodec) in adults with diabetes mellitus under a real-world clinical practice setting in India" (ICONIC)", vide protocol no. NN1436-8338 Version 1.0 dated 28 March 2025. After detailed deliberation, the Committee recommended grant of permission to conduct the PMS study as per the protocol presented by the firm. However, the Committee advised that an equal number of subjects with Type 1D and Type 2D should be included in the study.

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BABE Division			
4.	BABE/CT05/FF/2025/ 48803 Fludrocortisone Tablets USP 0.2 mg	M/s Advity Research Private Limited,	The firm has withdrawn the application.
SND Division			
5.	SND-11011/57/2025-eoffice Tirzepatide 2.5 mg/0.6 ml, 5 mg/0.6 ml, 7.5 mg/0.6 ml, 10 mg/0.6 ml, 12.5 mg/0.6 ml and 15 mg/0.6 ml solution for injection in a multiple-dose prefilled pen	M/s.Eli Lilly	The firm presented the proposal for update version of Package insert dated 07-Oct-2025 along with summary of changes before the Committee. After detailed deliberation, the Committee opined that section 4.6 for "Fertility, pregnancy and lactation" to have statement with more clarity under separate heading for planned and unplanned pregnancy/failure of contraception. Accordingly, firm should submit the revised package insert to CDSCO.