Recommendations of the SEC (Endocrinology & Metabolism) made in its 19th/25 meeting held on 11.09.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/116/25 Online Submission (51340) IcoSema 700 U/ml + 2 mg/ml Insulin Icodec 700U/ml + Semaglutide 2.0 mg/ml	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase IIIb clinical study protocol no. NN1535 -8377 Version No. 1.0 dated 30 – Apr - 2025. After detailed deliberation, the committee opined that the firm should submit the following for further review by the committee: 1. Scientific justification for use of Insulin in Type II diabetes patients who were not in prior OAD drugs. 2. Clarification for inclusion criteria for HbA1c 7.0% (limit 7.0-10%) in study protocol. 3. Phase-II study data for use of Insulin in Type II diabetes with patients (HbA1c 7.0-10.0%).
BA/BE Division			
2.	BABE/CT05/FF/2025 /48803 Fludrocortisone Tablets USP 0.2 mg	M/s. Advity Research Private Limited	In light of the earlier SEC recommendation dated 07.08.25, the firm presented the protocol along with published literature of Fludrocortisone Tablet USP 0.2 mg. After detailed deliberation, the committee did not recommend the study due to the possible risk of expected adverse effects of Fludrocortisone Tablet USP 0.2 mg in healthy subjects.
3.	BABE/CT05/FF/2025 /47823 Tiopronin ER Pellets1000 mg	M/s. Azidus Laboratories Limited	In light of the earlier SEC recommendation dated 17.07.2025, firm presented the recent published literature with respect to safety and tolerability of applied product. After detailed deliberation, the committee referred the proposal for further opinion of SEC (Renal).
SND Division			
4.	SND/MA/24/000166	M/s. Alkem Laboratories Ltd.	In light of earlier SEC recommendation dated 06.02.2025, the firm presented

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	Semaglutide Tablets 3mg, 7mg & 14mg (Synthetic origin)		Bioequivalence study report along with the revised Phase-III clinical trial protocol (protocol vide no. ALK40/SEM3 Version No. 1.1, dated 19.02.2025 for Type 2 Diabetes Mellitus before the Committee. After detail deliberation, the Committee recommended to accept the BE study report and recommended to conduct the Phase III clinical trial as per the revised protocol presented by the firm.
5.	SND/MA/22/000254 & SND/CT/25/000029 Semaglutide Injection 2 mg/1.5mL (1.34 mg/mL), 4 mg/3mL (1.34 mg/mL) & 8mg/3ml (2.68 mg/ml) (Synthetic Origin)	M/s. Dr. Reddy's Labs Limited	In light of earlier SEC recommendation dated 14.05.2025, the firm presented Phase III CT study report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT study report and recommended for grant of permission for manufacture and market of Semaglutide Injection 2 mg/1.5mL (1.34 mg/mL), 4 mg/3mL (1.34 mg/mL) & 8mg/3ml (2.68 mg/ml) (Synthetic Origin) for the following indication, with condition to submission of PMS/PSUR data as per the NDCT Rules, 2019. <u>Indication:</u> Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy, when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
FDC Division			
6.	FDC/MA/22/000411 Metformin HCl IP (As extended release) 500mg/1000mg/500mg/1000mg + Glimepiride IP 1mg/1mg/2mg/2mg + Empagliflozin	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 16.02.2023 & 17.02.2023, the firm presented the proposal along with BE study report and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee did not consider the BE study report as the report is inconclusive and flawed

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	10mg10mg/10mg/10 mg tablets		regarding adverse events reported. As regard to Phase III clinical trial protocol, the committee opined that there is a concern of the risk of genital mycosis and UTI with Empagliflozin. The clinical utility of this combination is questionable especially in cases of stable diabetes. In view of above, the committee did not consider the proposed FDC.
7.	FDC/MA/23/000362 Empagliflozin 10mg/25mg + Vildagliptin IP (SR) 100mg/100mg tablet	M/s. Exemed Pharmaceuticals	Under Discussion.
8.	FDC/MA/25/000001 Alogliptin benzoate 17mg eq. to Alogliptin 12.5mg + Metformin hydrochloride IP 850 mg eq. to Metformin 663mg film coated tablet	M/s. Torrent Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 20.02.2025, the firm presented justification and rationality for the proposed strength of the FDC before the committee. The committee noted that the proposed FDC is already approved in UK, EU, Canada and Australia. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition to conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.