Recommendations of the SEC (Endocrinology & Metabolism) made in its 14th/26 meeting held on 10.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/25/000098 Miglustat Capsules 100 mg	M/s. Apothecon Pharmaceuticals	In light of earlier recommendation dated 07.08.2025, firm has presented the proposal for grant of permission to manufacture and market drug, Miglustat Capsules 100 mg along with Phase IV CT protocol (Protocol No.: CLI/PRO/220925; Version-1.0 dated 16th Oct 2025) before the committee. Firm presented detailed analysis of intra-individual variability and published literature demonstrating response of the drug in various ethnic population along with side-effects profile. The committee noted that type 1 Gaucher disease is a rare disease. The committee also noted that the drug is already approved in US, EU, Australia and Canada. After detailed deliberation, the committee recommended for the grant of permission for manufacture and marketing of the drug, Miglustat Capsules 100 mg for proposed indication with waiver of Phase III clinical trial subject to the condition that the drug should be prescribed by Endocrinologist/clinical Geneticists only. The firm should provide details regarding the thyroid status of subjects proposed to be enrolled in the Phase IV clinical study and explain the management plan for subjects with hypothyroidism. Accordingly, the firm should submit a revised Phase IV clinical trial protocol to CDSCO before grant of marketing authorization.
SND Division			
2.	SND/MA/25/000070 SND/CT21/FF/2025/48644 Carbimazole Tablets	M/s. Abbott Healthcare Pvt. Ltd	In light of earlier SEC recommendation dated 24.07.2025, the firm presented BE study report of Carbimazole Tablets I.P. 15 mg indicated in already approved indication.

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	I.P. 2.5 mg and 15 mg		Carbimazole tablets 5 mg and 20 mg are already approved in India as well as globally. As per SmPC, the initial dose range for adults is 20-60 mg per day and for pediatric population - children and adolescents (3-17 years of age) is 0.5 mg/kg per day given in two or three divided doses. The proposed strength of 2.5 mg is for dose titration. After detailed deliberation, the committee accepted the BE study report and recommended for the grant of permission for manufacture and marketing of Carbimazole Tablets I.P. 2.5 mg and 15 mg.
3.	SND/MA/24/000215 Semaglutide (Synthetic Origin) Injection 2 mg/3 ml (0.68 mg/ml), 4 mg/3 ml (1.34 mg/ml) & 8 mg/3 ml (2.68 mg/ml) pre-filled pens	M/s. Precise Biopharma Pvt. Ltd.	In the light of earlier SEC recommendations dated 17.07.2025, the firm presented Phase III CT report for Type 2 Diabetes Mellitus before the Committee. After detailed deliberation, the committee accepted the Phase III CT report and recommended to grant permission for manufacture and marketing of Semaglutide (Synthetic Origin) Injection 2mg/3ml (0.68 mg/ml), 4mg/3ml (1.34 mg/ml) & 8mg/3ml (2.68 mg/ml) pre-filled pens 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-based therapy is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes
4.	SND/MA/24/000166 Semaglutide Tablets 3 mg, 7 mg & 14 mg (Synthetic origin)	M/s. Alkem Laboratories Limited.	In the light of earlier SEC recommendations dated 11.09.2025, the firm presented Phase III CT report for Type 2 Diabetes Mellitus before the Committee.

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			After detailed deliberation, the committee accepted the Phase III CT report and recommended to grant permission for manufacture and marketing of Semaglutide Tablets 3mg, 7 mg & 14 mg (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-based therapy is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes.
5.	SND/CT21/FF/2023/36098 SND/MA/23/000047 Cholecalciferol Chewable tablets IP 8000 IU	M/s. Quality Pharma Products Private Limited.	In continuation to earlier SEC deliberations dated 20.04.2023 & 21.04.2023 and 09.12.2025, firm presented justification for BE & CT waiver the proposed strength. Experts noted that various formulations of 60,000 IU are already approved in the country and globally. The committee also noted that Cholecalciferol upto 4000 IU/day is allowed by EU and Cholecalciferol formulation containing 8000 IU/day is not approved anywhere in the world. The proposed posology, i.e., 8000 IU x 7 days, is not supported with clinical data and firm did not present Clinical trial data/ approved Prescribing information, justification for benefits over existing therapeutic option. Therefore, the committee opined that firm should submit Clinical trial data/ globally approved Prescribing information, justification for benefits over existing therapeutic option supporting the efficacy.
6.	SND/MA/25/000229 Hydroxychloroquine Sulfate tablets IP 200	M/s. IPCA Laboratories Private Limited.	The firm presented the proposal for grant of permission for manufacture and marketing of Hydroxychloroquine Sulfate tablets IP 200 mg & 300 mg, for indication

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	mg & 300 mg		as an adjunct to diet and exercise to improve glycemic control of patients on metformin, sulfonylurea combination in patients with Type II Diabetes, along with Phase III clinical trial report, before the committee. Firm presented that, Hydroxychloroquine Sulfate tablets 400 mg was approved in India on 28.07.2014 for applied indication. After detailed deliberation, the committee accepted the Phase III CT report and recommended to grant permission for manufacture and marketing of Hydroxychloroquine Sulfate tablets IP 200 mg & 300 mg for applied indication.
FDC Division			
7.	FDC/MA/25/000014 Empagliflozin 12.5mg/25mg + Metformin Hydrochloride (ER) 500/500 mg Tablets	M/s. Torrent Pharmaceuticals Ltd.	The firm presented their proposal along with justification for essentiality and desirability of the proposed FDC before the committee. After detailed deliberation, committee opined that the proposed FDC do not add any therapeutic value for dose titration beyond the strengths already approved. Hence, the committee did not recommend for approval of the proposed FDC.
8.	FDC/CT/25/000066 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10/10 mg + Gliclazide IP 60/30 mg (SR) + Metformin Hydrochloride IP 500/500 mg (SR) film coated bilayered tablet	M/s. Eris Lifesciences Ltd.	In light of earlier SEC recommendation dated 25.02.2026 and as per condition mentioned in permission in Form CT-23 dated 25.11.2024; the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.