

Recommendations of the SEC (Endocrinology & Metabolism) made in its 16th/25 meeting held on 24.07.2025 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1. | <p>CT/147/23 Online Submission (40156)</p> <p>CagriSema 1.0 mg/ml + 0.5 mg/ml (0.25 mg/0.25 mg)</p> <p>CagriSema 2.0 mg/ml + 1.0 mg/ml (0.5 mg/0.5 mg)</p> <p>CagriSema 4.0 mg/ml + 2.0 mg/ml (1.0 mg/1.0 mg)</p> <p>CagriSema 6.8 mg/ml + 3.4 mg/ml (1.7 mg/1.7 mg)</p> <p>CagriSema 9.6 mg/ml + 4.8 mg/ml (2.4 mg/2.4 mg)</p> | M/s Novo Nordisk India Pvt Ltd | <p>The firm presented protocol amendment version 2.0 dated 24 January 2025 protocol no. NN9388-4894.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p> |
| Biological Division | | | |
| 2. | <p>BIO/CT04/FF/2025/48 948</p> <p>Insulin Glargine Injection IP 100 IU/ml, 3 ml Cartridge</p> | M/s.M. J. Biopharm Pvt. Ltd | The firm did not turn up for the presentation |
| 3. | <p>E- 90433</p> <p>Semaglutide Injection 0.25 mg/0.5 mg/ 1 mg/1.7 mg/2.4 mg (r- DNA Origin) [Brand Name: Wegovy® FlexTouch®]</p> | M/s. Novo Nordisk India Pvt Ltd | The firm presented the proposal to conduct PMS study titled "STEP REAL INDIA: A post marketing surveillance study of Wegovy® (s.c. semaglutide 2.4 mg) to evaluate the safety and effectiveness in adults with overweight or obesity in routine clinical practice setting in India" vide protocol study ID: NN9536-8519; Version 1.0 dated 08 May 2025 for the drug product Semaglutide Injection 0.25 mg/ 0.5 mg/ 1 mg/ 1.7 mg/ 2.4 mg (r-DNA Origin) [Brand Name: Wegovy® FlexTouch®] as part of condition of the approval of additional indication ie., Semaglutide injection is indicated to reduce the risk of major |

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| | | | <p>adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight”.</p> <p>After detailed deliberation, the committee recommended for the conduct of proposed study as per the protocol presented by the firm with a condition that firm shall include not less than 30% of patients of proposed sample size (approx. 553 participants) with the risk of cardiovascular disease in the proposed study.</p> |
| 4. | E-79595 Agalsidase Alfa (r-DNA origin) | M/s. Takeda Biopharmaceutica ls India Private Limited | <p>The firm presented the proposal for protocol amendment of Phase IV clinical study titled “A Prospective, Open-label, Multicenter, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Replagal™ (Agalsidase alfa (r-DNA origin)) in Indian Children and Adults with Fabry Disease” vide Study Number: TAK-675-4008, Version 4.0 dated 13 Feb 2025.</p> <p>The proposed changes in the amended protocol (Version 4.0 dated 13 Feb 2025) include increase in the number of subjects (3 new patients) and intimation for the study to be continued with new study CRO partner M/s JSS Medical Research Asia Pacific Pvt. Ltd.</p> <p>After detailed deliberation, the committee recommended for the approval of proposed protocol amendment presented by the firm.</p> |
| SND Division | | | |
| 5. | SND/MA/25/000070 Carbimazole Tablets I.P 2.5 mg & Carbimazole Tablets I.P 15 mg | M/s Abbott Healthcare Pvt. Ltd | Firm presented the proposal for grant of permission to manufacture & market Carbimazole Tablets I.P. 2.5 mg & Carbimazole Tablets I.P 15 mg along with therapeutic rationale and justification for proposed formulation in applied strengths. Also, firm presented the justification for clinical trial wavier and BE study protocol for higher strength i.e. Carbimazole Tablets I.P 15 mg. |

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| | | | After detailed deliberation, firm granted the permission for conduct of BE study along with clinical trial wavier. |
| 6. | SND/MA/25/000119 Semaglutide Tablets 3.0 mg, 7.0 mg and 14 mg (Synthetic) | M/s. LUPIN LIMITED | <p>The firm presented the proposal for grant of permission to manufacture and marketing of the drug Semaglutide Tablets 3 mg, 7 mg and 14 mg for Proposed indication, along with BE study Protocol vide no. 25-VIN-0292, ver. no. 01 dated 16-May-2025 before the Committee.</p> <p>After detailed deliberation, the Committee recommend for grant of permission to conduct BE study as per Protocol presented.</p> <p>Accordingly, firm should submit BE-study report to CDSCO further review by the Committee.</p> |
| New Drugs Division | | | |
| 7. | ND-12011(11)/2/2025-eoffice Trelagliptin Tablets 25 mg, 50 mg, and 100 mg | M/s. Zuventus Healthcare Limited | <p>In light of earlier SEC recommendations dated 13.11.2024 and as per the condition no. 9 of new drug permission for Trelagliptin Tablets 25 mg, 50 mg and 100 mg, firm presented active PMS study protocol for the drug Trelagliptin Tablets 25 mg, 50 mg and 100 mg, before the committee.</p> <p>The committee reviewed the justification of the firm on number of patients with moderate renal impairment to be enrolled in active PMS study for Trelagliptin Tablets 50 mg and patients with severe renal dysfunction/patient with end-stage renal disease to be enrolled in active PMS study for Trelagliptin Tablets 25 mg.</p> <p>The committee noted that Phase-III Clinical trial has been conducted in Trelagliptin Tablets 100 mg and no clinical data has been generated on Trelagliptin Tablets 25mg & 50 mg in Indian patients.</p> <p>The justification regarding total number of patients to be enrolled in proposed active PMS study was not accepted by the committee.</p> |

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| | | | <p>The committee recommended that for the proposed active PMS study, firm should include at least 180 patients with moderate renal impairment for Trelagliptin Tablets 50 mg and at least 60 patients with severe renal dysfunction/ patients with end-stage renal disease for Trelagliptin Tablets 25 mg, in order the generate sufficient data on Indian population.</p> <p>Accordingly, the firm should submit the revised protocol to CDSCO within one month.</p> |