

Recommendations of the SEC (Endocrinology & Metabolism) made in its 08th/26 meeting held on 08.04.2026 at CDSCO HQ New Delhi:

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1. | CT/180/25 Online Submission (53425) Dapagliflozin and Metformin Hydrochloride + gliclazide | M/s. Cliantha Research Limited | The firm presented phase III clinical study protocol No.: C2A06189 version No. 01 Dated 25-NOV-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that management of hypoglycemia protocol shall be prepared and followed during the conduct of clinical trial to ensure the safety of participants. |
| 2. | CT/189/25 Online Submission (53900) Somatrogen | M/s. Fortrea Development India Private Limited | In light of earlier SEC recommendation dated 25-02-2026, the firm presented phase III clinical study protocol no.: RCRC000035 version no. 3 dated 08-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Rajesh Khadgawat did not participate in the discussion. |
| Biological Division | | | |
| 3. | BIO/CT21/FF/2025/50379 i. Biphasic Isophane Insulin Injection IP 100 IU/mL (30/70), 10mL Vial ii. Biphasic Isophane Insulin Injection IP | M/s. Regenix Biosciences Ltd. | In light of the earlier recommendation of the SEC (Endocrinology & Metabolism) dated 17.12.2025, the firm presented the following data: <ul style="list-style-type: none"> • Data specific to Type I diabetes subjects, including mean age, baseline HbA1c levels, and dose administered. • Gender-wise subgroup analysis |

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| | <p>100IU/mL (30/70), 3mL Cartridge</p> <p>iii. Biphasic Isophane Insulin Injection IP 100IU/mL (30/70), 3mL Cartridge in Disposable Pen</p> | | <p>of efficacy and safety outcomes of the study.</p> <p>After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Biphasic Isophane Insulin Injection IP 100 IU/ml (30/70) in 03 presentations: 10 ml vial, 3 ml cartridge, and 3 ml cartridge in a disposable pen, for the indication: "to improve glycemic control in adults with diabetes mellitus", with the condition that a post-marketing surveillance (PMS) study shall be conducted in India.</p> <p>Accordingly, the firm shall submit the India-specific PMS protocol to CDSCO within three months of the grant of this permission.</p> |
| SND Division | | | |
| 4. | <p>SND/MA/24/000209</p> <p>Semaglutide Solution for Injection, Multi-dose Prefilled Pens 1 mg/1.5 ml (0.68 mg/ml), 2 mg/1.5 ml (1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), 6.8 mg/3ml (2.27 mg/ml), 9.6 mg/3 ml(3.2 mg/ml) (Synthetic Origin)</p> | M/s. Natco Pharma Limited | <p>In the light of earlier SEC recommendation dated 13.01.2025, the firm presented Phase III CT report for chronic weight management before the Committee.</p> <p>After detailed deliberation, the committee accepted the Phase III CT report and recommended for grant of permission for manufacture and market of Semaglutide Solution for Injection, Multi-dose Prefilled Pens 1mg/1.5ml (0.68mg/ml), 2mg/1.5ml (1.34mg/ml), 4mg/3ml (1.34mg/ml), 6.8mg/3ml (2.27mg/ml), 9.6mg/3ml (3.2mg/ml) (Synthetic Origin) for the following indication with subject to condition that the firm should conduct PMS study;</p> <p><u>Indication</u></p> <p>It is indicated as an adjunct to a</p> |

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| | | | <p>reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of</p> <ul style="list-style-type: none"> • 30 kg/m² or greater (obesity) or • 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). <p>Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.</p> |
| 5. | <p>SND/MA/25/000014</p> <p>Semaglutide Injection Pre-filled pen (4 mg/3 ml) & Semaglutide Injection Pre-filled pen (9.6 mg/3 ml)</p> | <p>M/s. Macleods Pharmaceuticals Ltd.</p> | <p>In light of earlier SEC recommendation dated 22.04.2025, 11.06.2025, 18.11.2025 & 17.12.2025, firm presented the BE study report for Semaglutide Injection before the Committee.</p> <p>After detailed deliberation, the Committee accepted the presented BE study report and recommended to grant of permission for conduct of Phase-III Clinical Trial studies as per earlier presented CT study protocols for Chronic Weight Management and Type 2 Diabetes Mellitus with following change in the study protocols:</p> <ul style="list-style-type: none"> • DEXA scan (for fat mass & lean muscle mass) should be monitored during the clinical trial studies. <p>Further, the firm should submit Clinical Trial studies reports for review by the committee.</p> |
| FDC Division | | | |

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| 6. | <p>FDC/CT/25/000037</p> <p>Gliclazide SR 30mg/60 mg + Sitagliptin 100mg/100mg film coated bilayered tablet</p> | <p>M/s. Eris Lifesciences Limited</p> | <p>In light of earlier SEC recommendation dated 14.05.2025 & 05.03.2026 and as per condition mentioned in permission in Form CT-23 dated 07.12.2023; the firm presented the revised Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. Firm should modify secondary endpoints as “Proportion of patients achieving a therapeutic glycemic response, i.e., defined as HbA1c≤7% at the end of the study visit.” 2. The firm should increase the sample size to have appropriate statistical power to detect the expected primary outcome of the study and accordingly the sample size to be re-calculated. <p>Accordingly, the revised Phase IV clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase IV clinical trial report for further review by the committee.</p> |
| 7. | <p>FDC/CT/25/000040</p> <p>Vildagliptin IP (SR) 100 mg/100 mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg/10 mg + Metformin Hydrochloride IP (SR) 500 mg/1000</p> | <p>M/s. Eris Lifesciences Limited</p> | <p>In light of earlier SEC recommendation dated 17.06.2025 and as per condition mentioned in permission in Form CT-23 dated 01.10.2024; the firm presented the revised Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should increase the sample size to have appropriate statistical power to detect the expected primary outcome of the study and accordingly the sample size</p> |

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| | mg film coated bilayered tablet | | <p>to be re-calculated.</p> <p>Accordingly, the revised Phase IV clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase IV clinical trial report for further review by the committee.</p> |