

Recommendations of the SEC (Endocrinology & Metabolism) made in its 04th/26 meeting held on 25.02.2026 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1. | CT/189/25 Online Submission (53900) Somatrogen | M/s. Fortrea Development India Private Limited | <p>The firm presented phase III clinical study protocol no. RCRC000035, version no. 3 dated 08 Oct 2025.</p> <p>After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee.</p> <ol style="list-style-type: none"> 1. Scientific justification and rationale for the selected dose of 0.85 mg/kg/week of Somatrogen for the proposed indications. 2. Detailed data with references on adjustments to IGF-I SDS measured in Somatrogen patients over the course of the dosing interval, along with details of IGF-I monitoring time in the proposed trial. 3. IGF 1 is mentioned as a value below -2 standard deviation score (SDS), the absolute values/mean value of IGF 1 should be submitted. 4. For the proposed indication of Small for Gestational Age (SGA), the inclusion criteria regarding children's age in India shall be reviewed in the context of the Indian population. |
| 2. | CT/01/26 Online Submission (54003) LY3841136 | M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd | <p>The firm presented phase III clinical study protocol no. J3R-MC-YDAF, version no. a dated 13 November 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that both functioning and non-functioning pituitary tumors should be included in exclusion criteria for the said study.</p> <p>Dr. Beatrice Anne didn't participate in the discussion.</p> |

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| 3. | CT/04/26 Online Submission (53997) LY3841136 | M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd. | <p>The firm presented phase III clinical study protocol no. J3R-MC-YDAL, version no. a dated 17 November 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that both functioning and non functioning pituitary tumors should be included in exclusion criteria for the said study.</p> <p>Dr. Beatrice Anne didn't participate in the discussion.</p> |
| SND Division | | | |
| 4. | SND/CT21/FF/2025/5 0463 Pioglitazone Tablets 15 mg & 30 mg (additional indication) | M/s. USV Pvt Limited | <p>In light of earlier SEC recommendation dated 26.11.2025 firm presented the published pre-clinical data, clinical literature along with clinical trial protocol for Pioglitazone tablets before the committee.</p> <p>After detailed deliberation, the committee recommended the following:</p> <ol style="list-style-type: none"> 1. Patient population and sample size should be statistically justified. 2. Study to be conducted first in MASH indication in non- diabetes population to further proceed for diabetic population. 3. The design of the study to include test arm as Pioglitazone 15mg tablets in non-diabetic and 30mg tablets for diabetic population with control arm which should clearly define SOC. 4. Primary outcome measures (MRI-DFF/Fibroscan) and method to measure the outcome should be clearly defined and elaborated. 5. Protocol to include interim analysis and primary outcome measures at each 6 month interval which should be assessed by DSMB. Accordingly, as per assessment of DSMB, further intervention i.e., |

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| | | | <p>non-responders of non-diabetic arm can be escalated up to 30 mg dose and late responders can continue in same arm.</p> <p>6. Protocol to include for monitoring of trial subject for bladder cancer.</p> <p>7. Monitoring at the base line and EOT should be done for lipid profile, body weight, SGOT/SGPT, insulin resistant. Index, diastolic dysfunction, hematuria.</p> <p>Accordingly, firm shall submit the revised protocol along with justification for further evaluation by the SEC committee.</p> |
| FDC Division | | | |
| 5. | <p>FDC/CT/25/000014</p> <p>Empagliflozin 5 mg/10 mg/12.5 mg/25 mg + Metformin Hydrochloride IP (ER) 1000 mg/1000 mg/1000mg/1000 mg film coated bilayered tablet</p> | <p>M/s. Zydus Healthcare Limited</p> | <p>In light of earlier SEC recommendation dated 16.10.2025 and as per condition mentioned in permission in Form CT-23 dated 13.12.2024; 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 revise the amended inclusion criteria and provide the justification for use of same strength of medications as FDC in patients with uncontrolled diabetes as mentioned in point number 3 of inclusion criteria.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p> |
| 6. | <p>FDC/CT/25/000062</p> <p>Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin IP + Metformin Hydrochloride (SR) IP + (10 mg + 20 mg + 500 mg & 10 mg + 20 mg + 1000 mg) film coated bilayered tablet</p> | <p>M/s. Mascot Health Series Pvt. Ltd.</p> | <p>In light of the condition mentioned in permission in Form CT-23 dated 27.12.2023; the firm presented the 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 revise the inclusion criteria to include patients with HbA1c between 8% to 10%. 2. Firm should include at least 30% to 40% of female patients. 3. Follow-up HbA1c test should be |

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| | | | <p>done at 12th week.</p> <p>4. Firm should submit the scientific justification for the sample size.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p> |
| 7. | <p>FDC/CT/25/000063</p> <p>Glimepiride IP + Voglibose IP + Metformin HCl IP (ER) (1 mg + 0.2 mg + 500 mg, 2 mg + 0.2 mg + 500 mg, 1 mg + 0.2 mg + 1000 mg & 2 mg + 0.2 mg + 1000 mg) uncoated bilayered tablet</p> | <p>M/s. Mascot Health Series Pvt Ltd</p> | <p>In light of the condition mentioned in permission in Form CT-23 dated 09.01.2023; the firm presented the 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 include upper limit of HbA1c in Inclusion criteria. 2. Firm should also include Chronic Inflammatory Bowel Disease (IBD) and Gastrointestinal ulceration patients in the Exclusion Criteria. 3. Firm should submit the scientific justification for the sample size. <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p> |
| 8. | <p>FDC/CT/25/000066</p> <p>Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10/10mg + Gliclazide IP 60/30 mg (SR) + Metformin Hydrochloride IP 500/500 mg (SR) film coated bilayered tablet</p> | <p>M/s. Eris Lifesciences Ltd.</p> | <p>In light of the condition mentioned in permission in Form CT-23 dated 25.11.2024; the firm presented the 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 include details of randomization of patients in both arms. 2. Firm should include in the exclusion criteria like diabetes foot ulcer, peripheral vascular disease, recurrent UTI patients. 3. Firm should submit the scientific justification for the sample size. <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p> |