**Recommendations of the SEC (Gastroenterology & Hepatology) made in its 02nd/26 meeting held on 11.02.2026 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/09/26<br>Online Submission (54386)<br><br>Pegozafermin | M/s. Medpace Clinical Research India Pvt. Ltd. | The firm presented phase III clinical study protocol no. BIO89-100-132, version no. 3.0 dated 02 June 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial on Pegozafermin in subjects with compensated cirrhosis due to Metabolic dysfunction-associated steatohepatitis (MASH), as presented by the firm. |
| **Biological Division** | | | |
| 2. | BIO/CT18/FF/2025/52755<br><br>Guselkumab Solution for Injection 100 mg/ml (SC) & 200 mg/2 ml (SC) and 200 mg/20 mg for IV Infusion | M/s. Johnson & Johnson Pvt. Ltd. | The firm presented a proposal for grant of approval of Guselkumab Solution for Injection for the following.<br><br>1. New indication of Ulcerative Colitis and Crohn's disease for 100 mg/ml (approved presentation) and 200 mg/2 ml (new presentation) through subcutaneous route in pre-filled syringe and pre-filled pen.<br><br>2. New Indication of Ulcerative Colitis and Crohn's disease, new route of administration (IV infusion), new presentation (vial) and new strength for 200 mg/20 ml.<br><br>The committee noted that Guselkumab solution for injection (100 mg/ml subcutaneous route) is approved in India since Feb 2024 for active psoriatic arthritis. Further, proposed changes as mentioned above with specified dosage regimen are approved in Europe, US and U.K. Indian safety data are being collected in the ongoing psoriatic arthritis trial.<br><br>After detailed deliberation, the committee recommended for grant of approval for the use of Guselkumab for the proposed indications with the proposed doses and presentations, considering the significant therapeutic advancement over the current standard of care, in-line with the EMA |

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| | | | approval for these indications subject to the condition that the firm will conduct Phase IV clinical trial in the proposed indications.<br><br>Accordingly**,** a protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indications. |
| **New Drug Division** | | | |
| 3. | ND/MA/23/000141<br><br>Eluxadoline tablets 75 mg & 100 mg | M/s. Sun Pharmaceutical Industries Limited | Under Discussion. |
| 4. | ND/MA/24/000048<br><br>Teduglutide for Injection 5 mg/Vial | M/s. MSN Laboratories Private Limited | The firm presented proposal for manufacture & marketing of Teduglutide for Injection 5 mg/vial along with a request for BE waiver & local Phase III clinical trial waiver.<br><br>The committee noted that firm has presented clinical data of rDNA product from another source, whereas the product applied for is a synthetic peptide.<br><br>Further, firm has not presented sameness and characterization data of applied Teduglutide synthetic peptide with Reference Listed Drug (RLD).<br><br>After detailed deliberation, the committee did not recommend for either BE or local Phase III clinical trial waiver.<br><br>Further, the committee recommended that firm may be asked to present sameness and characterization data of the applied Teduglutide synthetic peptide to the SEC. |
| 5. | ND/MA/25/000170<br><br>Resmetirom 60 mg, 80 mg and 100 mg Tablets | M/s. BDR Pharmaceuticals International Pvt. Ltd. | The firm presented the proposal for grant of permission to manufacture and market of Resmetirom Tablets 60 mg/ 80 mg/ 100 mg along with BE study report and Phase III Clinical Trial Protocol before the committee.<br><br>The committee considered the BE results presented by the firm.<br><br>Further, it is noted that the Phase-III CT protocol is not fit for purpose. The dose of this drug needs adjustment based on body |

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| | | | weight and other drugs being received. The trial design does not provide for such adjustment. Instead, it proposes 1:1:1:1 randomization into one placebo group and three separate treatment groups each receiving a different dose of Resmetirom (60 mg, 80 mg or 100 mg).<br><br>Thus, the Committee found the study design as inappropriate. Instead, a 2-arm design with dose adjustment in each arm based on weight and other co-administered drugs is needed.<br><br>After detailed deliberation, the committee did not approve the Phase-III CT protocol presented by the firm. |
| 6. | ND/MA/25/000177<br><br>Resmetirom tablet 60 mg, mg, 80 mg & 100 mg | M/s. Cipla Limited | The firm has presented the proposal for grant of permission to manufacture and market of Resmetirom Tablets 60 mg/ 80 mg /100 mg along with BE study report (Protocol No.: 0262-08-24) and Phase III Clinical Trial Protocol (Study Code: CP/08/25, Version no. 1.0 dated 17/Oct/2025), before the committee.<br><br>After detailed deliberation, the committee considered the BE study results of Resmetirom Tablets and recommended for grant of permission to conduct Phase III clinical trial.<br><br>The firm should submit Phase III clinical trial results to CDSCO for further review by the committee. |
| 7. | ND/MA/25/000188<br><br>Tribenoside and Lidocaine Hydrochloride Cream (5 % w/w + 2.12 % w/w | M/s. Sun Pharmaceutical Industries Limited | The firm presented the proposal for grant of permission to manufacture and market the drug Tribenoside and Lidocaine Hydrochloride Cream (5 % w/w + 2.12 % w/w) along with Phase III Clinical Trial protocol before the committee.<br><br>After detailed deliberation, the committee opined that the protocol presented by the firm does not use a suitable comparator, which should also contain a vasoactive or anti-inflammatory drugs and a local anaesthetic.<br><br>Further, the sample size calculation uses efficacy of a treatment other than the |

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| | | | proposed comparator and a very wide non-inferiority margin. These are not acceptable for a non-inferiority design.<br><br>A subjective outcome (encompassing pain, burning and itching) has been proposed the primary outcome and an objective outcome (exudates, bleeding etc.) has been proposed as the secondary outcome. The treatment of haemorrhoids is primarily for treating haemorrhage and hence, the objective score, being more clinically relevant, should be the primary outcome.<br><br>The committee did not approve Phase-III CT protocol presented by the firm. |
| 8. | Dairy no. 123251<br><br>Tofacitinib (ER) Tablets 11 mg-Reg. | M/s. ALKEM LABORATORIES LTD. | The firm did not attend the meeting. |