**Recommendations of the SEC (Gastroenterology & Hepatology) made in its 14th/25 meeting held on 08.10.2025 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| | CT/115/25<br>Online Submission (51359)<br><br>Icotrokinra (JNJ-77242113) | M/s Johnson & Johnson Pvt. Ltd. | The firm presented phase III clinical trial protocol no. 77242113UCO3001 Amendment 1 dated 24 July 2025.<br><br>After detailed deliberation, the committee opined that the proposed trial is aimed at studying the safety and efficacy of icotrokinra, an IL-23-receptor antagonist, in patients with moderate to severe ulcerative colitis. The proposal consists of two sub-studies: (i) an induction study (12-week duration) - to evaluate efficacy in inducing disease remission, and (ii) a maintenance study (40 weeks -- after the initial induction phase) - to assess the efficacy of the drug in maintaining remission. It is planned to enroll 822 patients, and randomize them to active treatment or placebo (in 2:1 ratio).<br><br>(A) On completion of the induction study, all the subjects who received icotrokinra will enter the maintenance study, and continue to receive this drug irrespective of whether they had a beneficial response to the study drug during the induction phase or not.<br><br>(B) During the presentation, the company presented a sample size calculation to show that the sample size needed for the induction study (assuming 11% response rate in the placebo group and a difference of 12% in the treated group) is much smaller (of the order of 250).<br><br>(C) It may not be justifiable to expose a nearly 3-fold larger number of subjects to this treatment and for a prolonged duration (of 52 weeks) -- in particular those who do not improve following the induction therapy -- especially when determination of safety is one of the objectives of the protocol. |

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| | | | The above points need to be justified, or the trial needs to be modified to include fewer patients. Also, only those with clinical response during the induction phase (and not those without clinical response) should be continued to the maintenance phase.<br><br>Accordingly, firm need to submit a response for further review by the committee. |
| | CT/125/25<br>Online Submission (51512)<br><br>SPY001-001; SPY002-091 | M/s PSI CRO Pharma Pvt. Ltd. | The firm presented phase II clinical trial protocol no. SPY123-201 version no. 1.2 dated 04-JUN-2025.<br><br>After detailed deliberation, the committee recommended grant of permission to conduct the trial as presented by the firm |
| | CT/91/25<br>Online Submission (50281)<br><br>TAK-242 | M/s Klinera Global Services | The firm did not turn up for presentation. |
| | CT/97/25<br>Online Submission (50716)<br><br>MT-501 | M/s PSI CRO Pharma Pvt. Ltd. | The firm presented phase II clinical study protocol no.: MT-100-201 version no. 2.0 dated 12-JUN-2025.<br><br>After detailed deliberation, the committee recommended grant of permission to conduct the trial as presented by the firm |
| **New Drug Division** | | | |
| | ND/MA/24/000085<br><br>Fexuprazan hydrochloride tablets 40 mg | M/s Sun Pharma Laboratories Limited | The firm did not turn up for presentation. |
| | ND/CT/25/000070<br><br>Plecanatide Tablets 3 mg | M/s MSN Laboratories Private Limited | The firm did not turn up for presentation. |
| | ND/CT/25/000067<br><br>Vonoprazan tablets 10 mg/20 mg | M/s Dr. Reddy's Laboratories Limited | In line with the condition of permission for manufacturing and marketing of drug Vonoprazan Tablets 10 mg/20 mg, the firm presented Phase IV clinical trial protocol titled "A Phase-IV Study to Assess the Safety and Effectiveness of Vonoprazan 10/20mg in Adult Patients with Acid Peptic Disorders." (Protocol no. DRL/VONO/2025-01, Version no.: 0, Dated: 24-06-2025), before the |

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| | | | committee.<br><br>After detailed deliberation, the committee opined that the proposed sample size is too small considering that this is Phase IV trial.<br><br>Also, there is no sample size specified for the higher (20 mg) dose, which is a more important target for this phase IV study.<br><br>Accordingly, committee opined that the firm should submit a justification for the proposed sample size and define the number of patients to be enrolled for each (10 mg and 20 mg) strength and submit a revised protocol within 15 days to CDSCO for further review by the committee. |
| **SND Division** | | | |
| | SND/MA/25/000108<br><br>Ursodeoxycholic Acid Tablets I.P 450 mg & 600 mg | M/s. Abott India Limited | In light of the earlier SEC recommendation dated 24.07.2025, the firm presented a revised protocol for Phase III CT along with proof of concept (Published retrospective observational Study) in support of the new indication applied for.<br><br>After detailed deliberation, the committee opined that:<br><br>1. The proposed effect size for primary endpoint (difference in mean ALT levels between the treated and the placebo group of 25 IU/L) is not clinically relevant, particularly because the range of ALT level at enrolment is very broad (~120 to 1000 IU/L).<br><br>2. The need for and rationale of treating liver injury observed with dengue virus infection in the form of liver enzyme elevation (without any clinical manifestation or increase in bilirubin) is unclear. Such injury is well known to improve spontaneously and quickly over a few days. Also, there is no |

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| | | | rationale provided for why ursodeoxycholic acid would be expected to ameliorate 'liver injury' in patients with dengue virus infection.<br><br>Accordingly, committee did not recommend the proposed phase III clinical study and opined that firm should conduct the proof of concept study in the indication applied for. |
| **FDC Division** | | | |
| | FDC/MA/24/000180, FDC-/07/2025-eoffice<br><br>Sodium Alginate IP 250 mg + Sodium Bicarbonate IP 106.5 mg + Calcium Carbonate IP 187.5 mg uncoated chewable tablet | M/s Sun Pharma Laboratories Limited | As per the condition mentioned in Form CT-23 dated 09.04.2025; the firm presented an active post-marketing surveillance protocol.<br><br>After detailed deliberation, the committee recommended for conduct of the proposed study.<br><br>Results of the study, when available, should be submitted to CDSCO for review by the committee. |