**Recommendations of the SEC (Neurology & Psychiatry) made in its 03rd/25 meeting held on 28.02.2025. at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/84/20<br>Online Submission (36652)<br><br>Inebilizumab | M/s Medpace Clinical Research India Pvt. Ltd. | The firm presented protocol Amendment 7 Version 8.0 dated 17-Sep-2024 Protocol no.: VIB0551.P3. S1.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 2. | CT/09/25<br>Online Submission (47634)<br>Cariprazine Depot | M/s CBCC Global Research LLP | The firm presented phase I/IIa clinical study protocol no. Mapi Cariprazine Depot Phase I/IIa–001 version 2 dated 22 October 2024.<br><br>After detailed deliberation, the committee opined that the firm should submit phase I data for further review by the committee. |
| 3. | CT/178/21 37173<br>Online Submission (37173)<br>SAR442168 (Tolebrutinib) | M/s Sanofi Healthcare India Private Limited. | The firm presented protocol amendment 14, version 01 dated 31-Oct-2024 protocol no. EFC16035.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 4. | CT/135/24 46277<br>Online Submission (46277)<br>Cladribine | M/s IQVIA RDS (India) Private Limited | In light of earlier SEC Recommendation on 12.12.2024, now the firm presented phase 3 clinical study protocol no. MS700568_0183 version 2.0 dated 14 March 2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm should submit quarterly safety data to CDSCO for further review by the committee. |
| **SND Division** | | | |
| 5. | **SND/MA/24/000091**<br><br>Dexmedetomidine Hydrochloride 0.9% sodium chloride | M/s Amneal Pharmaceuticals Pvt.Ltd. | The firm presented the proposal for grant of permission to manufacture and market of Dexmedetomidine Hydrochloride 0.9% sodium chloride injection 4mcg/ml (200mcg/ 50ml) and (400mcg/100ml) along with justification for waiver of |

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| | injection 4mcg/ml (200mcg/ 50ml) and (400mcg/100ml) | | Phase-III clinical trial and bioequivalence study before the Committee.<br><br>The firm has informed that they are holding product approval of proposed formulation from USFDA with AND number A216604 with applied indication.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Dexmedetomidine Hydrochloride 0.9% sodium chloride injection 4mcg/ml (200mcg/ 50ml) and (400mcg/100ml) for applied indication subject to condition that the firm should conduct Phase-IV clinical trial.<br><br>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within three months from date of approval of the drug for further review by the Committee. |
| 6. | **SND/MA/22/000163**<br><br>Buprenorphine Hydrochloride sublingual films (8/6/4 mg) | M/s Zim Laboratories Limited | In light of earlier SEC recommendation dated 12.03.2024, the firm presented Phase III Clinical trial study Protocol AIIMSA3364 ver. no.01 dated 30.12.2024 before the Committee.<br><br>The firm has informed that Buprenorphine Hydrochloride sublingual film 8/6/4 mg (Buprenorphine Neuraxpharm) approved by EMA in Jan, 2025 for applied indication.<br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial study as per protocol presented by the firm with subject to following conditions:<br>(i) To conduct pilot study for validation of questionnaire scale for the subjects<br>(ii) Urine test to be performed for every visit<br>(iii) Sample size and power of the study shall be increased upto 90%. |

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| **New Drug Division** | | | |
| 7. | ND/MA/24/000013<br><br>Cenobamate Tablets 12.5mg, 25 mg, 50mg,100mg, 150mg & 200mg | M/s Bajaj Healthcare Ltd | In light of earlier SEC recommendations dated 07.08.2024, the firm presented the revised Phase III clinical trial protocol of Cenobamate Tablets 12.5mg, 25 mg, 50mg,100mg, 150mg & 200mg, before the committee.<br><br>After detailed deliberation, the committee recommended for the grant of permission to conduct Phase III clinical trial, as per the protocol presented. |