Recommendations of the SEC (Neurology & Psychiatry) made in its 09th/25 meeting held on 30.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/36/23 Online Submission (38650) Milvexian	M/s IQVIA RDS (India) Private Limited	The firm presented India Specific protocol amendment 2 (PA2/ind-1) dated 19 March 2025 protocol no. 70033093STR3001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/40/25 Online Submission (49093) PF-07899801 (Rimegepant)	M/s Pfizer Limited	The firm presented phase IIIb clinical study protocol no. C4951063 amendment 1 dated 05 December 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the prior medications shall be allowed to the high Menstrual Migraine attack to the subject during the clinical trial.
3.	CT/41/25 Online Submission (49110) Nizubaglustat	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. AZA-001-301 Version No. 3.0 dated 16-JAN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/111/24 Online Submission (38957) Lumateperone	M/s IQVIA RDS (India) Private Limited	The firm didn't turn up for presentation.
5.	CT/93/20 Online Submission (38408) Edoxaban	M/s CBCI Society For Medical Education	The firm presented protocol amendment version 3.0 dated 22.07.2024 protocol no. NCT03950076. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/49/25 Online Submission (49321) BMS-986510 (KarXT) (Xanomeline +Trospium Chloride)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. CN0120056 version no. 02 dated 24-FEB-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			distributed government sites shall be included in the study.