Recommendations of the SEC (Neurology & Psychiatry) made in its 14th/24 meeting held on 16.10.2024 at CDSCO HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/44718 Online Submission (44718) Levetiracetam	M/s Ergomed Clinical Research India Private Limited	The firm presented Phase III clinical study protocol no. NXPLEVE/24/P3-6 version 2.0 dated 03 July 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions: (I) Adult subject shall be enrolled in the study. (II) More government sites shall be included.
2.	GCT/CT04/FF/2024/44697 Online Submission (44697) Leriglitazone	M/s Global Regulatory & Consumer Insights	The firm presented phase III clinical study protocol no. MT-3-01, final version 4.0 dated 08 April 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	GCT/PostAppr/2024/34689 Online Submission (34689) Cemdisiran 200mg/ml liquid formulation for subcutaneous administration + Pozelima b 200 mg/ml liquid formulation for SC administration	M/s Parexel International Clinical Research Private Limited	The firm presented protocol amendment 3 dated 17 May 2024 protocol no. R3918-MG-2018. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	GCT/CT04/FF/2024/45063 Online Submission (45063) KarXT (A Combination of Xanomeline Tartrate and Trospium Chloride)	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. KAR-013 version 5.0 dated 02 Nov 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that protocol no. KAR-012 shall be approved by CDSCO.
5.	GCT/CT04/FF/2024/45122	M/s IQVIA RDS (India) Private	The firm presented phase III clinical study protocol no. ITI-007-451,

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	Online Submission (45122) Lumateperone	Limited	Amendment 2 dated 03July 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
6.	GCT/CT04/FF/2024/31999 Online Submission (31999) SAR44216	M/s Sanofi Healthcare India Private Limited	In light of earlier SEC recommendation dated 15.05. 2024 and 16.05.2024, now the firm presented protocol amendment 12 version 1 dated 28 September 2023 and protocol amendment 13 version 1 dated 20 November 2023, protocol no. EFC16035. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
New Drugs Division			
7.	ND/MA/23/000086 Lumateperone capsules 42 mg	M/s. Sun Pharma Laboratories Limited	The firm has presented Phase III CT report of Lumateperone capsules 42 mg before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of drug Lumateperone capsules 42 mg for the proposed indication subject to the condition that- (a)The firm should conduct Phase IV CT on Lumateperone capsules 42 mg for which Phase IV CT protocol should be submitted to CDSCO within 3 months of approval for further evaluation by the committee. (b)The drug should be sold by retail under the prescription of Neurologist or Psychiatrist only.
FDC Division			
8.	FDC/MA/24/000202 Pregabalin (as granules) + Duloxetine Hydrochloride eq. to Duloxetine (as delayed release pellets) + Methylcobalamin (as granules) (75mg+30mg+1500m	M/s Pure and Cure Healthcare Pvt. Ltd.	The firm presented the proposal along with BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct of proposed BE study and Phase III clinical trial study with the condition that BE study report should be presented in the SEC meeting before initiating the Phase III clinical trial.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	cg/75mg+20mg+1500 mcg/ 75mg+10mg+ 1500mcg/50mg+10m g+1500mcg/50mg+20 mg +1500mcg) hard gelatin capsules		