Recommendations of the SEC (Neurology & Psychiatry) made in its 18th/25 meeting held on 11.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/120/25 Online Submission (51475) CYB704 (Ocrelizumab) 300 mg/ 10 mL concentrate for solution for infusion	M/s. Veeda Clinical Research Limited	The firm presented phase of PK similarity study protocol no.: CCYB704A12301 version no. 3.0 dated 18-JUL- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Medical Devices Division			
2.	MED-14/20/2025-eoffice Mental health self-assessment software application	Dr. Renu Sharma Child Psychologist Department of Psychiatry, AIIMS, New Delhi, India	The applicant presented their proposal for conducting feasibility studies on the "InterRAI mental health self-assessment software application" indicated for use in children and youth (4-21 years of age) for their mental health screening. After detailed deliberation, the committee recommended for consideration of the proposed study vides Protocol No. ALL3453202 subject to the condition that in the study protocol title shall be rephrased in line with the study objectives, and all the psychometric tools used in validation of the said device shall also be added in the study protocol.
3.	MED-14/20/2025-eoffice Avatar therapy system (AI-based)	Dr. Mamta Sood, Professor (Psychiatry), Department of Psychiatry, AIIMS, New Delhi, India	The applicant presented their proposal for conducting feasibility studies on the "AVATAR therapy system software tool" indicated for use in psychiatric patients under the supervision of trained healthcare professionals. After detailed deliberation, the committee recommended for conduct of the proposed study vides Protocol No. ALL36172025.
Biological Division			
4.	BIO/CT18/FF/2025/49633 Erenumab solution for injection in prefilled pen 70mg/mL	M/s. Novartis Healthcare Private Limited	The firm presented a proposal for the grant of permission for an additional pack presentation, i.e., a prefilled pen for the drug product "Erenumab solution for injection in prefilled pen 70 mg/mL" in addition to the already approved pack presentation i.e. "Erenumab solution for injection in prefilled syringe 70 mg/mL." The Committee noted that the proposed pack presentation, "Erenumab solution

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			for injection in prefilled pen 70 mg/mL," is approved in 69 countries, including the USA, EU, UK, Japan and Canada. After detailed deliberation, the Committee recommended the grant of permission for the proposed additional pack presentation, i.e., prefilled pen.
BA/BE Division			
5.	BABE/CT05/FF/2025/ 51768 Brivaracetam Extended-Release Tablets [T1FA: 250 mg and [T2FA: 62.5 mg*4=250 mg)]	M/s. Veeda Clinical Research Limited,	The firm presented BA/BE study Protocol No. 25-VIN-0453, Version No. 01 Dated: 04Aug.2025 (For Export purpose only), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for export purpose only.
New Drugs Division			
6.	ND/CT/25/000064 Rimegipant Oral Disintegrating tablets (ODT) 75 mg	M/s. Pfizer Limited	In line with the condition of permission for import and marketing of the drug, Rimegepant 75 mg ODT tablet, the firm presented Phase IV clinical trial protocol titled "An Open-Label Multicenter Study to Evaluate the Safety and Tolerability of Rimegepant 75 mg ODT for Acute Treatment of Migraine in Adult Participants in India with Previous Insufficient Response to Triptans" (Protocol number C4951088 dated 26.08.2025) before the committee. After detailed deliberation, the committee opined that: 1) There were no government sites in the clinical trial protocol presented by the firm. Accordingly, firm should include government sites in CT protocol. 2) Firm should include TSQM (Treatment Satisfaction Questionnaire) Index as one of the efficacy parameter and other relevant efficacy parameters in protocol as secondary endpoint. 3) Cost of study drug/rescue/other treatment during study shall be borne by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			4) Firm need to revise Prescribing Information w.r.t. maximum number of doses in a month for which safety is established inline with International prescribing information. Accordingly, firm should submit revised protocol and prescribing information to CDSCO within one month for further review by the committee
SND Division			
7.	SND/MA/24/000087 Lacosamide Injection 1mg/ml and 2mg/ml 100 ml bottle	M/s. Intas Pharmaceuticals Limited	In continuation to the earlier SEC recommendation dated 26/09/2024. Firm has presented additional data in support of equivalence of proposed formulation with existing approved formulation. The committee noted that, Lacosamide Injection 10 mg/ml is approved in India since 2012 which is to be diluted before the administration. The concentration of proposed ready to used formulation is equivalent to the approved formulation after dilution. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Lacosamide Injection 1 mg/ml 100 ml bottle and Lacosamide Injection 2 mg/ml 100 ml Bottle for the applied indication.
FDC Division			
8.	FDC/MA/25/000200 Gabapentin IP 300 mg/600 mg (as extended release) + Nortriptyline Hydrochloride IP equivalent to Nortriptyline 10 mg/10 mg film coated tablet	M/s. Sun Pharma Laboratories Limited	The firm presented their proposal with rationality of the proposed FDC along with BE study protocol under fasting & fed condition and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the rationality of the proposed FDC and recommended for grant of permission to conduct the BE study under fasting & fed condition and Phase III clinical trial. The result of the BE study should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.