Recommendations of the SEC (Neurology & Psychiatry) made in its 06th/26 meeting held on 17.06.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/25 Online Submission (51715) Phenytoin Cream 20 %	M/s. Cliantha Research Limited	The firm presented phase II clinical study protocol no.: C2A05319 version 01 dated 18 Jul 2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee: 1. Detailed justification for conducting the proposed trial along with scientific rationale/evidence. 2. The design of the study should include an active comparator arm along with placebo control proof of concept arm with standard of care treatments. 3. All ethical parameters shall be considered in the design of protocol.
2.	CT/72/26 Online Submission (56856) Nizubaglustat	M/s. Worldwide Clinical Trials India Private Limited	The firm presented phase II clinical study protocol no.: AZA-001-202-GD3, version 1.0 dated 26 February 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the rescue criteria and exit criteria to be included in the study protocol. Accordingly, revised protocol shall be submitted to CDSCO.
3.	CT/74/26 Online Submission (56912) Evenamide	M/s.Clinirx Research Pvt. Ltd	The firm presented phase III clinical study protocol no.:NW-3509/025/III/2025 version 1.1 dated 11 MAY 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drug Division			
4.	ND/MA/24/000013 Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg and 200 mg	M/s. Bajaj Healthcare Ltd.	In light of earlier SEC recommendation dated 07.08.2024, firm presented Phase III Clinical trial report (Clinical trial report no.: LCT-04/23/CTR/1, Version No: 1.0, Date of report: 24-Apr-26) for manufacture and marketing of new drug Cenobamate Tablets before the committee.

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			After detailed deliberation, committee considered the Phase III Clinical Trial result as presented by the firm and recommended for the grant of permission to manufacture and market drug Cenobamate Tablets 12.5 mg, 25 mg, 50mg, 100 mg, 150 mg & 200 mg. The Committee also recommended that the drug should be sold by retail under the prescription of Neurologist. Further, the committee reviewed the prescribing information (PI) and opined that firm shall update the PI in-line with innovator PI. Accordingly, the firm should submit revised PI to CDSCO.
5.	ND/MA/26/000056 Vamorolone Oral Suspension, 40 mg/ml	M/s. DMT Healthcare Private Limited	The firm presented its proposal for grant of permission to manufacture and market drug, Vamorolone Oral Suspension 40 mg/ml along with request for BE study waiver and Phase-III Clinical Trial waiver before the committee. The committee noted that drug has been approved in countries such as US, EU, Canada etc. The firm presented global Phase IIb clinical study data, however, firm did not present data on Indian population. Further, the committee did not agree for waiver of BE study. Accordingly, the firm should submit BE study protocol to CDSCO for further evaluation by the committee. Further, the committee recommended that the firm need to submit the long-term efficacy and safety data for the patients enrolled in pivotal-trial especially regarding the slowing in progression of disease.
SND Division			
6.	SND/MA/22/000238 Caroverine HCL 40 mg Capsules	M/s. Lincoln Pharmaceuticals Ltd.	Proposal was deferred to next meeting for deliberation in presence of at-least two ENT experts.

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FDC Division			
7.	FDC/IMP/26/000001 Foslevodopa 240 mg + Foscarbidopa 12 mg per ml solution for injection	M/s. AbbVie Healthcare India Private Limited	The firm presented their proposal along with request for complete clinical trial waiver before the committee. The committee noted that: • The said FDC is already approved in the USA, Japan, and Canada etc. • Dosage form of the FDC solution for infusion will be injected by medical device which is not yet approved by CDSCO and firm stated that they have already submitted application for the approval of the said device. Further, the firm presented Global clinical data, however no Indian patients participated in the said Global clinical trial and the firm didn't present any safety and efficacy data generated in Indian Population. After detailed deliberation, the committee did not consider CT waiver and recommended to conduct Phase III CT study. Accordingly, the firm should submit Phase III CT protocol to CDSCO for further review by the committee.
8.	FDC/MA/26/000070 Gabapentin IP (as ER) 600 mg/300 mg + Duloxetine Hydrochloride (as DR) 20 mg/20 mg film coated bilayered tablets	M/s.Alkem Laboratories Ltd.	The firm presented their proposal along with BE study protocol under both Fasting and Fed condition & Phase III clinical trial protocol before the committee. Committee noted that the BE and Phase III CT NOC has already been issued to other firm for the same FDC. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study (Fasting and Fed condition) & Phase III clinical trial. Accordingly, the result of the BE study (Fasting and Fed condition) should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.