Recommendations of the SEC (Neurology & Psychiatry) made in its 19th/25 meeting held on 26.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/133/25 Online Submission (51735) Trospium chloride + Xanomeline	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study protocol no. CN0120023 version no. original dated 21 February 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/137/25 Online Submission (51840) Trospium Chloride + Xanomeline	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study protocol no. CN0120037, version no. amendment 01 dated 14 April 2025 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/142/25 Online Submission (51915) Trospium Chloride + Xanomeline	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no. CN0120038, Protocol Amendment 01 dated 14 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	E-91102 Erenumab Solution for injection in prefilled syringe 70 mg/ml	M/s Sandoz Private Limited	The firm presented the proposal for update in Package Insert dated 19 May 2025 based on USPI dated 21 March 2025 for the drug product Erenumab Solution for injection in prefilled syringe 70 mg/ml to include safety updates in the sections of adverse reactions, clinical pharmacology and patient counseling information based on the human data collected across clinical trials, pregnancy exposure registry and post-marketing experience. After detailed deliberation, the committee recommended for approval of updated package insert 19 May 2025 of the said drug product for the proposed changes.
New Drugs Division			
5.	ND/CT/25/000088 Siponimod Tablets 0.25 mg, 1 mg and 2 mg	Dr. Reddy's Laboratories Limited	In line with the condition of permission for import and marketing of the drug, Siponimod Tablets 0.25 mg/1 mg/2 mg, the firm presented Phase IV clinical trial protocol titled " A Prospective Open Label, Multicenter, Non-Comparative, Phase-IV study of Siponimod to

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			Characterize its safety, and Effectiveness in Indian Patients with Secondary Progressive Multiple Sclerosis (SPMS) with active disease" for permission to manufacture and market of the new drug Siponimod Tablets in India (Protocol ID. DRL-IND-NDA35-SIP/2025, Version No.: 1.0 Dated 05-AUG- 2025) before the committee. After detailed deliberation, the committee opined that the firm should include more clinical trial sites that are geographically distributed throughout the country. Further, the committee recommended that firm should also carry out cyp2c9 gene polymorphism test in all the patients. Accordingly, firm should submit revised protocol to CDSCO.
6.	ND/MA/25/000141 Suvorexant Tablets 5 mg, 10 mg, 15 mg and 20 mg	M/s Sun Pharmaceutical Industries Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Suvorexant Tablets 5 mg, 10 mg, 15 mg and 20 mg along with Phase III clinical trial protocol (Protocol No.: ICR/25/017 Protocol Version No: 1.0, dated 22-Aug-2025) and BE study report (Project No. 25-ENEM-006) before the committee. After detailed deliberation, the committee considered the BE study result as presented by the firm. The committee also recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented. The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee.
SND Division			
7.	SND/IMP/25/000079 Cladribine Tablets 10 mg (MAVENCLAD)	M/s Merck Specialties Private Limited	The firm presented their proposal to import and market the Cladribine Tablets 10 mg (MAVENCLAD) for the treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging feature along with the justification for local clinical trial waiver and clinical studies data generated for other countries.

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			After detailed deliberation, committee recommended that oncology experts shall be invited for deliberation of proposal in SEC meeting.
FDC Division			
8.	FDC/CT/25/000100 Etizolam IP 0.5 mg/0.5 mg + Propranolol Hydrochloride IP 20 mg/40 mg film coated tablet	M/s Windlas Biotech Limited	In light of DTAB subcommittee report dated 28.12.2021 where in expert committee recommended "To conduct Phase IV Clinical Trial evaluate efficacy and safety of the FDC in comparison with Etizolam, with efficacy as the primary objective in statistically significant number of patients for the indication as approved by SEC. The Clinical Trial protocol must receive approval of the SEC and the study must be completed within one year." Accordingly, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial with the condition to modify the efficacy as primary objective and the safety as secondary objective. Accordingly, revised Phase IV clinical trial protocol should be submitted to CDSCO for review, after approval from CDSCO, the firm should submit Phase IV CT study report to CDSCO for further review by the committee.