Recommendations of the SEC (Neurology & Psychiatry) made in its 01st/26 meeting held on 20.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024/ 46605 Levodopa + Benserazide + Entacapone 100/25/200 mg tablets	M/s. AXIS Clinicals Limited.	In light of the earlier SEC recommendation dated 18.06.2025, the firm has presented the amended protocol No. 281-24 Version No. 01 dated 23.10.2025 along with Risk Evaluation Mitigation Strategies for the proposed FDC before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with amended protocol for export purpose only subject to the condition that the firm shall conduct an additional safety monitoring and follow up of the participants up to 30 days post checkout of Period IV.
Biological Division			
2.	E-108243 Ocrelizumab 300 mg concentrate for solution for infusion	M/s. Roche Products (India) Pvt. Ltd.	In light of the earlier SEC recommendation dated 15.05.2025, the firm presented additional data to the Committee. The Committee noted that the proposed updates in the Package Insert related to Pregnancy (Section 4.6.2) and Peripartum Disease Activity (Section 5.2.1 Clinical/Efficacy Studies) have not yet been approved by EMA and USFDA. After detailed deliberation, the Committee recommended that the firm shall submit the following for further evaluation by the SEC: 1. Approvals from EMA and USFDA for the aforementioned proposed updates; and 2. Safety data from Phase IV study of the proposed drug product.
New Drugs Division			
3.	ND/CT/25/000104 Lasmiditan Tablets 50 mg/100 mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	In line with the condition of permission for manufacturing and marketing of drug Lasmiditan Tablets 50 mg/100 mg, the firm presented comparative placebo

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			controlled Phase-IV study protocol (Protocol no. BRPL/CT/LASMI/32/23, Version No.: 1.0 and Date 23.12.2023), before the committee. After detailed deliberation, the committee recommended that firm should conduct non-comparative study of applied drug instead of comparative placebo controlled study. Accordingly, firm should submit revised phase-IV CT protocol to CDSCO within one month, for further review by the committee.
SND Division			
4.	SND/CT21/FF/2023/37451 & SND/MA/23/000136 Vigabatrin Tablets 500 mg	M/s. MSN Laboratories Private Limited.	The Firm has presented their proposal for Manufacturing and Marketing of Vigabatrin tablet 500 mg for treatment of Refectory complex Partial Seizures In patients 2 years of age and older, In light of earlier recommendations dated 17.08.2023. After detailed deliberation, the committee recommended to conduct BE study for Vigabatrin tablet 500 mg. Accordingly, firm should submit the BE protocol to CDSCO for further review by the committee.
5.	SND/CT18/FF/2025/50956 Cladribine Tablets 10 mg (MAVENCLAD)	M/s. Merck Specialties Private Limited.	In light of earlier SEC recommendation dated 26.11.2025 firm presented proposal to import and market the Cladribine Tablets 10 mg for the treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging feature. The Committee also noted that the product is approved in India since 2003. The committee noted that the drug is approved in various countries including US, Europe in applied indication of relapsing multiple sclerosis. After detailed deliberation, the Committee recommended for the grant of permission for the Import and Marketing of the drug Cladribine Tablets 10 mg for the treatment of adult patients with highly

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			active relapsing multiple sclerosis (MS) as defined by clinical or imaging features subject to the condition that, firm should conduct Phase IV clinical trial. Accordingly, firm should submit Phase IV CT protocol to CDSCO for further deliberation by the committee
6.	SND/MA/25/000176 Sovateltide for Injection 30 mcg	M/s. Gufic Biosciences Limited.	The firm presented the proposal for grant of permission to manufacture and market of Sovateltide for Injection 30 mcg along with BE study protocol before the committee. The firm has informed that Sovateltide for Injection 30mcg for Cerebral Ischemic Stroke was approved in India on 31.05.2023. After detailed deliberation, the committee recommended for grant of permission to conduct BE study of Sovateltide for Injection 30 mcg after inclusion of staggered intervention plan in the protocol. Further, the firm should submit BE Study report to CDSCO for review by the committee.
FDC Division			
7.	FDC/MA/25/000157 Naproxen IP 500mg/500mg + Rizatriptan Benzoate IP eq. to Rizatriptan 5mg/10mg film coated tablet	M/s. Tirupati Medicare Limited.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that the firm has not presented the following: 1. Essentiality and desirability of the proposed FDC as individual drugs are already approved for the same indication. 2. Published Clinical trial/ scientific literature in peer reviewed journal on synergistic action of the FDC. Accordingly, the firm should submit the above data to CDSCO for further review by the committee.

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8.	FDC/IMP/25/000001 Carbidopa USP (anhydrous) 35mg/ 52.5mg/70mg/87.5mg + Levodopa USP (ER) 140mg/210mg/ 280mg/350mg capsule	M/s. Amneal Healthcare Pvt. Ltd.	In light of the SEC recommendation dated 29.10.2025, the firm presented the proposal along with justification before the committee. After detailed deliberation, the committee opined that: 1. Firm needs to justify the essentiality and desirability of the proposed FDC as same FDC in different strengths are already approved for the same indication. 2. Firm needs to provide safety and efficacy data compared to the standard approved combination for Parkinson's disease. Accordingly, the firm should submit the above data to CDSCO for further review by the committee.