Recommendations of the SEC (Neurology and Psychiatry) made in its 8th/26 meeting held on 28.07.2026 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/96/26 Online Submission (57659) Venglustat (GZ402671)	M/s. Sanofi Healthcare India Private Limited	The firm presented phase III clinical study protocol no.: EFC18362 version 2 dated 12 Feb 2026. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee: 1. Safety data generated from the study conducted in paediatric participants aged 2 to 5 years. 2. Scientific justification for comparing Venglustat (a glucosylceramide synthase inhibitor) with Cerezyme (enzyme replacement therapy).
BA/BE Division			
2.	BABE/CT05/FF/2026/ 54262 B2227 LAI (B2227 Extended-Release Injectable Suspension)	M/s. Lambda Therapeutic Research Limited.	Firm presented the BA/BE study Protocol No. 0513-25 Version No. 1.0 Protocol Date 06-JAN-2026 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Pharmacokinetics, Safety, and Tolerability study for export purpose only.
New Drugs Division			
3.	ND/MA/22/000125 Lisdexamfetamine Dimesylate Capsules 10mg/20mg/30mg/40 mg/50mg/60mg/70mg	M/s. Ind-Swift Laboratories Limited.	In light earlier SEC recommendation dated 23.04.2026, the firm presented phase III Clinical Trial Protocol for manufacturing and marketing permission of new drug, Lisdexamfetamine Dimesylate Capsules 10mg/20mg/30mg/40mg/50mg/60mg/70mg before the committee. After detailed deliberation, the committee noted that firm should justify following: 1. Use of placebo as a comparator. 2. Rational for assumed treatment different from baseline. 3. Calculation of sample size and its assumption. 4. The firm should clarify the number of patients in pediatric and adult age group. Accordingly, firm should submit revised

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			Phase III clinical trial protocol to CDSCO for further review by the committee.
4.	ND/MA/25/000088 FDC of Olanzapine/Samidorphan (5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, and 20 mg/10 mg)	M/s. Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 26.08.2025, the firm presented BE study report of Olanzapine 20mg and Samidorphan 10mg Film Coated bilayered tablet (Protocol No. 085-24, Version No.01, report dated 20Jun2026) and Phase III Clinical Trial Protocol (Protocol No. VRL-CT- 25-045, Version no. 1.0 dated 31-Mar-2026) before the committee. After detailed deliberation, the committee considered the BE study results of FDC Olanzapine 20mg and Samidorphan 10mg Film Coated bilayered tablet. Further, the committee opined that the firm should revise the Phase III Clinical Trial protocol and following information: 1. Data on efficacy of metabolic parameter of Samidorphan at the end of 6 months. 2. The firm should clearly specify the comparator drug formulation, dose titration regimen and the use of matching placebo during the titration period. 3. Clarification of sample size calculation. Accordingly, the firm should submit revised protocol to CDSCO for further review by the committee.
5.	ND/MA/25/000158 Brexpiprazole Tablets 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg	M/s. Zenara Pharma Private Limited.	The firm presented proposal for grant of permission to manufacture and market of Brexpiprazole Tablets 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg, along with BE study report, before the committee. The committee noted that drug Brexpiprazole tablets 0.25 mg/0.5 mg/1 mg/2 mg/3 mg/4 mg is already approved in the country for manufacture and market on 16.02.2026. The committee also reviewed India specific package insert. After detailed deliberation, the committee considered the BE study result and recommended for grant of permission to manufacture and market of drug

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			Brexpiprazole tablets 0.25mg/ 0.5mg/ 1mg/ 2mg/3 mg/ 4mg for the proposed indication.
6.	ND/MA/26/000046 Valbenazine Capsules 40 mg, 60 mg, 80 mg	M/s. Sun Pharma Laboratories Limited.	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Valbenazine Capsules 40 mg, 60 mg, 80 mg with Phase III clinical trial protocol (Protocol no ICR/26/003, Version No. 1.0 dated 14/JAN/2026) and justification for BE study waiver before the committee. After detailed deliberation, the committee did not agree for waiver of BE study and asked the firm to conduct Single-dose, two-treatment, two-period, crossover in-vivo study with Pharmacokinetic endpoints. Further, the committee reviewed in detailed the Phase III protocol presented and recommended for the grant of Phase III clinical trial study. Accordingly, the firm should submit results of BE study before the initiation of phase III clinical trial to CDSCO for further review by the committee.
7.	ND/MA/26/000062 MirogabalinBesylate 2.5mg, 5mg,10mg and 15 mg Tablets	M/s. Exemed Pharmaceuticals	The firm presented the proposal for grant of permission to manufacture and market Mirogabalin Besylate Tablets 2.5 mg, 5 mg, 10 mg and 15 mg along with BE waiver justification and Phase III Clinical Trial Protocol (Protocol No: CT/2026/09, Protocol Version No: 00, dated 30 April 26) before the committee. After detailed deliberation, the committee considered the request for bio waiver and recommended for grant of permission to conduct Phase III clinical trial of Mirogabalin Besylate Tablets 2.5 mg, 5 mg, 10 mg and 15 mg as per the protocol presented by the firm with the condition that firm should include patients with other severe painful neuropathic conditions like trigeminal neuralgia and neuropathic pain associated with carcinomatosis in the study. Accordingly, firm should submit the revised protocol to CDSCO.