Recommendations of the SEC (Neurology & Psychiatry) made in its 13th/25 meeting held on 23.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/33/24 Online Submission (40102) SAR441344/ Frexalimab	M/s.SANOFI HEALTHCARE INDIA PRIVATE LIMITED	The firm presented protocol amendment 03 version 03 dated 19 November 2024 and protocol amendment 04 version 02 dated 22 January 2025 protocol no. EFC17504. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/162/24 Online Submission (47101) BHV-7000	M/s.PPD Pharmaceutical Development India Private Limited	In light of earlier SEC recommendation dated 23.04.2025, now the firm presented phase II clinical trial protocol no. BHV7000-201 version V1.1 CAMSASI dated 12 December 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with subject to condition that DSMB shall closely monitor safety specifically SAEs and discoloration of skin, cutaneous tissue, lips etc. and submit quarterly report to the Ethics Committee and CDSCO.
3.	CT/154/24 Online Submission (46917) BHV-7000	M/s.PPD Pharmaceutical Development India Private Limited	In light of earlier SEC Recommendation dated 23.04.2025, now the firm presented phase II/III clinical trial protocol no. BHV7000-303 version V3.1 APAC dated 15 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with subject to condition that DSMB shall closely monitor safety specifically SAEs and discoloration of skin, cutaneous tissue, lips etc. and submit quarterly report to the Ethics Committee and CDSCO.
BA/BE Division			
4.	BABE/CT05/FF/2025/49635 Gabapentin Extended Release + Nortriptyline Tablets (600 mg +10mg)	M/s Sun Pharma Laboratories Limited,	The firm did not turn up for the presentation.

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SND Division			
5.	SND/CT/25/000042 Cariprazine Hydrochloride Capsules 1.5 mg/3 mg/4.5 mg/6 mg	M/s. Mascot Health Series Private Limited	The firm has presented the Phase-IV clinical trial protocol of Cariprazine Hydrochloride Capsules 1.5 mg/3 mg/4.5 mg/6 mg vide protocol number MCR/CT/0225/02 Version 00 dated 20.02.2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-IV clinical trial as per the protocol presented by the firm
New Drugs Division			
6.	ND/MA/25/000036 Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg	M/s Eris Lifesciences Limited	The firm presented the proposal for the grant of permission to manufacture and market of Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg along with the BE protocol for Cenobamate Tablets 12.5 mg and Phase III clinical trial protocol of Cenobamate Tablets (12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg & 200 mg) before the committee. After detailed deliberation, the recommended for grant of permission to conduct BE study and to conduct Phase III clinical trial as per the protocol presented by the firm Further, the committee opined that the firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III clinical trial.
7.	ND-12011/5/2025-e-office Perampanel vs Clobazam as first add on in children receiving valproate	Dr. Ayush Gupta and Dr. Anju Aggarwal, department of paediatrics, UCMS, GTB Hospital, New Delhi	The study investigator, Department of Pediatrics, UCMS, GTB Hospital, New Delhi presented protocol titled "Perampanel vs clobazam as first add on in children receiving valproate - open labelled randomized trial" for the conduct of clinical trial before the Committee. After detailed deliberation, the committee recommended for conduct of academic trial as per protocol presented by the applicant
8.	12-1/25-DC(Pt-83) Cannabidiol Adjunctive	Dr. YC Janardhan Reddy,	The study investigator presented protocol titled "Cannabidiol Adjunctive Therapy for Acute Bipolar Depression: A

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	Therapy	NIMHANS, Bengaluru	Randomized Double-Blind, Placebo Controlled Trial" for the conduct of clinical trial with the drug Cannabidiol, before the Committee. After detailed deliberation the committee recommended that proposed research study may be allowed as per proposal presented by the applicant
9.	ND/MA/24/000115 Remimazolam Besylate 20 mg lyophilized powder for injection	M/s ENALTEC LABS PVT. LTD	The firm did not turn up for presentation.