

Recommendations of the SEC (Neurology & Psychiatry) made in its 04th/26 meeting held on 23.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/45/26 Online Submission (55673) TAK-755 (rADAMTS13)	M/s. IQVIA RDS (India) Private Limited	The firm presented phase II clinical study protocol no.: TAK-755-2002, amendment 1 dated 01 December 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government sites and with geographical distribution shall be included in the study.
Biological Division			
2.	BIO/CT04/FF/2025/52727 Lecanemab concentrate for solution for infusion 100 mg/mL	M/s. Eisai Pharmaceuticals India Private Limited	The firm presented the proposal to conduct Phase IV clinical trial titled “A Prospective, Multicentre, Postmarketing Phase 4 Trial to Assess the Safety and Use of LEQEMBI in Routine Clinical Practice in India”. Protocol No.: BAN2401-M091-512 Version V1.0 Dated 24-Oct-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the presented protocol, subject to the following conditions: 1. Term “observational” shall be removed from the subject Phase-IV study protocol. 2. Day care facilities shall not be used as a clinical trial site. 3. Clinical trial sites shall be geographically distributed. 4. Number of patients shall be proportionate between government and private clinical trial sites.
New Drugs Division			
3.	ND/MA/22/000125 Lisdexamfetamine Dimesylate Capsules 10mg/20mg/30mg/40 mg/50mg/60mg/70mg	M/s. IND- SWIFT LTD.	In light of earlier SEC recommendation dated 24.07.2024, firm redeliberated their proposal for grant of permission to import and marketing of the Lisdexamfetamine Dimesylate Capsules 10 mg/20 mg/30 mg/40 mg/50 mg/60 mg/70 mg along with additional published safety and efficacy data and justification for local Phase III Clinical Trial waiver before the committee. The committee reviewed the safety and

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			<p>efficacy data submitted by the firm and noted the drug is indicated for pediatric population with ADHD.</p> <p>After detailed deliberation, the committee noted that the drug has serious adverse events which required evaluation in Indian patients.</p> <p>The committee did not consider Phase III waiver. Hence, the committee recommended that the firm should conduct comparative randomized Phase III Clinical Trial on Indian population.</p> <p>Accordingly, the firm should submit the Phase III CT Protocol to CDSCO for further review by the committee.</p>
SND Division			
4.	SND/MA/24/000229 Lacosamide Sustained Release Tablets 200MG, 150mg, 100mg	M/s. Eris Lifesciences Limited	<p>The firm presented the proposal for grant of permission to manufacture and marketing of Lacosamide Sustained Release Tablets 100mg/150mg/200mg with Bioequivalence study fasting and fed report for Lacosamide SR Tablets 200mg.</p> <p>After detailed deliberation, committee recommended to accept the BE study report and recommended for grant of permission for the marketing and Marketing of Lacosamide Sustained Release Tablets for as an adjunctive treatment of partial onset seizures in patients > 17 years of age.</p>
5.	SND/MA/25/000170 Ketamine Subcutaneous Injection 50mg/ml	M/s. Themis Medicare Ltd	<p>The firm presented the proposal for grant of permission for manufacturing and marketing of Ketamine subcutaneous Injection 50mg/ml for the indication as an adjunct treatment to ongoing antidepressant therapy in patients with Treatment-Resistant Depression (TRD) in adults along with Phase-III clinical trial report and proposed package insert.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Ketamine Subcutaneous Injection 50mg/ml in the below mentioned indication to be used in</p>

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			<p>hospital settings upon prescription by Neurologist/ Psychiatrist and subject to condition that the firm should conduct Phase-IV study;</p> <p>“As an adjunct treatment to ongoing antidepressant therapy in patients with Treatment-Resistant Depression (TRD) in adults who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode”.</p> <p>Accordingly, the firm should submit Phase-IV clinical study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.</p>
6.	SND/MA/26/000018 Atomoxetine Oral Solution 4mg/ml	M/s. Akums Drugs & Pharmaceuticals Limited	<p>The firm presented the proposal for grant of permission for manufacturing and marketing of Atomoxetine Oral Solution 4mg/ml for the indication for the treatment of Attention-Deficit/ Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults along with the request for BE and Clinical trial study waiver.</p> <p>The committee noted that the Atomoxetine Oral Solution 4mg/ml was already approved in Europe and Japan. Atomoxetine Hydrochloride capsules - 10mg, 18mg, 25mg, 40mg and 60mg and Atomoxetine (as HCl) Sachet (10/18 /25/40mg) approved in India for the indication for the treatment of attention deficit hyperactivity disorders.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug Atomoxetine Oral Solution 4mg/ml.</p>
FDC Division			
7.	FDC/MA/24/000014 Gabapentin IP 100mg/200mg/300mg/ 400mg/400mg + Duloxetine Hydrochloride IP eq. to Duloxetine (As	M/s. Torrent Pharmaceuticals Ltd.	<p>In light of the earlier SEC recommendation dated 29.10.2024, the firm presented the proposal along with BE study report wherein BE study under fasting condition did not meet the bioequivalence criteria.</p> <p>In view of above, the firm presented the fresh BE study protocol under both fasting</p>

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	enteric coated pellets) 20mg/20mg/20mg/20 mg/30mg hard gelatin capsule		<p>and fed condition and Phase III CT Protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the fresh BE study protocol under both fasting and Fed condition & Phase III clinical trial.</p> <p>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.</p>
8.	FDC/MA/24/000220 Rizatriptan Benzoate IP eq. to Rizatriptan + Naproxen Sodium USP (5mg + 550mg & 10mg + 550mg) film coated tablets	M/s. Akums Drugs and Pharmaceutical Limited	<p>In light of the SEC recommendation dated 19.03.2025, the firm presented the proposal along with justification before the committee.</p> <p>After detailed deliberation, the committee reiterated the earlier recommendation dated 19.03.2025 and opined that the combination of Migraine abortification drug i.e., Rizatriptan with analgesic & anti-inflammatory drug i.e., Naproxen is not rational combination because triptans are given only in acute and hyper acute migraine condition whereas Naproxen used as symptomatic therapy for 2-3 days.</p> <p>Accordingly, the committee did not approve the rationality of the proposed FDC at present.</p>