

Recommendations of the SEC (Neurology & Psychiatry) made in its 02nd/26 meeting held on 12.02.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/10/26 Online Submission (54374) Buprenorphine	M/s ALZASYNO LIFE SCIENCES PRIVATE LIMITED	The firm presented phase III clinical study protocol no. 0004181, version no. 0.5 dated 29 January 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Atul Ambekar didn't participate in discussion.
2.	CT/172/25 Online Submission (53291) Salanersen	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. 277SM302 (STELLAR-1) version no. 2.0 dated 19 September 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm, subject to the condition that the proposed number of participants to be screened and the number of clinical trial sites in India be increased. Dr. Sheffali Gulati didn't participate in discussion.
Biological Division			
3.	E- 114620 Ofatumumab 20 mg/0.4 mL solution for injection in pre-filled syringe	M/s. Novartis Healthcare Private Limited	The firm presented the proposal for update in the Package Insert of Ofatumumab 20 mg/0.4 mL solution for injection in pre-filled syringe. The proposed update includes revisions to Section 2.1- Assessments Prior To First Dose of Ofatumumab, Section 6-Adverse Reactions and Section 17-Patient Counseling Information, in line with USFDA-approved Prescribing information. After detailed deliberation, the committee recommended approval of the updated Package Insert version dated 01 Oct 2025 incorporating the proposed changes.
4.	E-119371 Donanemab Injection (350 mg/20 mL solution in vial)	M/s. Eli Lilly & Company (India) Pvt Ltd	The firm presented the proposal for update in the Package Insert of Donanemab Injection 350 mg/20 mL (17.5 mg/mL) Solution for IV Infusion in a single-dose vial (r-DNA origin). The proposed update includes revisions to Section 4.2- Posology and method of administration, Section 4.4 - Special Warnings & Precautions for use, Section 4.5-

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			<p>Adverse Reactions, Section 4.6– Use in special populations, Section 5.0– Pharmacological properties and Section 7.0 – Clinical Studies, based on the results of the Phase 3b clinical trial-TRAILBAZER-ALZ6 (Study 15T-MC-AACQ) and in line with the USFDA-approved Prescribing information.</p> <p>After detailed deliberation, the committee recommended approval of the updated Package Insert Version dated 27 October 2025 incorporating the proposed changes.</p>
New Drugs Division			
5.	ND/CT/23/000074 Cannabidiol 100 mg/ml oral solution	M/s Zenara Pharma Private Limited	<p>The firm presented their proposal for Amendment in Phase-IV CT Protocol of Cannabidiol 100 mg/ml oral solution, before the committee.</p> <p>The committee noted that the firm’s proposal is regarding the change in study design (from Phase-IV clinical trial to observational data collection study) along with administrative (Addition/ deletion of study investigators) and editorial changes (typographical corrections).</p> <p>After detailed deliberation, the committee did not recommended the proposed amendments w.r.t. Study design (from Phase-IV clinical trial to observational data collection study). However, the committee considered the administrative and editorial changes, as presented by the firm.</p> <p>The committee recommended that the firm should conduct the Phase-IV study as per the permission issued vide no. CT/ND/06/2024 dated 21.05.2024.</p> <p>Further, the Committee noted that the firm has proposed an additional data collection study. The Committee opined that the firm should submit a separate protocol/proposal for the same to CDSCO for further review by the Committee.</p>
6.	ND/CT/21/000083 Lemborexant Tablets 5 mg /10 mg,	M/s Eisai Pharmaceuticals India Private Limited	<p>In light of earlier SEC recommendations dated 18.11.2021, the firm presented Phase IV clinical trial report (Study Protocol Number: E2006-M091-503, Report dated: 23.04.2024) of Lemborexant Tablets 5mg and 10mg before the committee.</p>

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			After detailed deliberation, the Committee considered Phase IV clinical trial results for Lemborexant Tablets 5 mg and 10 mg, as presented by the firm.
SND Division			
7.	SND/CT/25/000143 Amantadine Extended Release 129 mg/ 193 mg Tablets	M/s Pure & Cure Healthcare Pvt. Ltd.	<p>The firm presented Phase IV Clinical Trial protocol for grant of permission to conduct study of Amantadine Extended Release Tablets 129 mg /193 mg for approved indication before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct phase IV clinical trial with following conditions:</p> <ol style="list-style-type: none"> 1. The stratification of percentage of patients to be recruited for each indication with different age group. 2. Out of clinical trial sites selected 50% shall be Government sites and should be geographically distributed. <p>Accordingly, firm should submit the revised protocol to CDSCO within 15 days.</p>
FDC Division			
8.	FDC/MA/24/000202 Pregabalin + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed released pellets) + Methylcobalamin (75 mg + 30 mg + 1500 mcg/75 mg + 20 mg + 1500 mcg/ 75 mg+10 mg + 1500 mcg/ 50 mg +10 mg +1500 mcg/ 50 mg +20 mg+1500 mcg) hard gelatin capsules	M/s. Pure and Cure Healthcare Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 16.10.2024, the firm presented the proposal along with BE study report under fasting condition before the committee.</p> <p>Committee noted that the proposed FDC is already approved in two strengths i.e., Pregabalin + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed released pellets) + Methylcobalamin (75 mg + 30 mg + 1500 mcg and 75 mg + 20 mg + 1500 mcg) hard gelatin capsules.</p> <p>Further, the firm stated that they have already withdrawn three unapproved strengths i.e. Pregabalin + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed released pellets) + Methylcobalamin (75 mg + 10 mg + 1500 mcg/ 50 mg + 10 mg + 1500 mcg/ 50 mg + 20 mg+1500 mcg) hard gelatin capsules.</p> <p>After detailed deliberation, the committee considered the BE study report and</p>

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			recommended for grant of permission to manufacture and market the product in two strengths i.e., Pregabalin + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed released pellets) + Methylcobalamin (75 mg + 30 mg + 1500 mcg and 75 mg + 20 mg + 1500 mcg) hard gelatin capsules.