

**Recommendations of the SEC (Neurology & Psychiatry) made in its 16<sup>th</sup>/25 meeting held on 24.09.2025 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/113/25 Online Submission (51271)  KarXT/BMS-986510 Xanomeline+ Tropium Chloride	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no.: KAR-033 version no. 4.0 dated 14-OCT-2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/122/25 Online Submission (51343)  LOU064 (Remibrutinib)	M/s Novartis Healthcare Private Limited	The firm presented phase III clinical study protocol no.: CLOU064P12301 version no. 00 dated 26-JUN- 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/123/25 Online Submission (51520)  BIIB141 or RTA-408 (Omaveloxolone)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no.: 296FA301 version no. 1 dated 07-FEB-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Biological Division</b>			
4.	E-91102  Erenumab Solution for injection in prefilled syringe 70 mg/ml	M/s. Sandoz Private Limited	The firm didn't turn up for presentation.
<b>New Drugs Division</b>			
5.	ND/MA/25/000096  Suvorexant 5/10/15/20 mg tablets	M/s Bajaj Health care Ltd.	The firm presented the proposal for grant of permission for manufacture and market of the drug Suvorexant Tablets 5/10/15/20 mg along with BE study protocol and Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented with the condition that firm should include equal number of men and women in the study and exclude assessment of depression.  The committee also recommended for grant of permission to conduct Phase III

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			<p>clinical trial, as per the protocol presented with the condition that subjects with alcohol and tobacco consumption should be excluded &amp; the inclusion criteria should be clearly defined and firm should submit the revised protocol to CDSCO.</p> <p>Further, the committee opined that the firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating Phase III Clinical trial.</p>
6.	ND/23/2025-eoffice  Methylphenidate Hydrochloride Extended-Release Tablets 18mg/36mg/54mg - CONCERTA	M/s Johnsons and Johnsons	<p>The firm presented proposal for updating the prescribing information dated 06.12.2023 for drug product, Methylphenidate Hydrochloride Extended-Release Tablets 18mg/36mg/54mg before the committee.</p> <p>The key changes in the proposed prescribing information are related to editorial changes in the drug interactions and undesirable effects.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed updates in prescribing information as presented by the firm.</p>
<b>SND Division</b>			
7.	SND/CT/25/ 000091  Cariprazine Capsules 1.5 mg/ 3 mg/4.5mg /6mg	M/s. Optimus Pharma Private Limited	<p>Firm presented their proposal for grant of permission to conduct Phase-IV clinical trial vide protocol No. CARI/OPT/Phase-IV/2025-2026 before the Committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol presented by the firm with following condition:</p> <p>1) For dose titration, flow diagram for change of medication based on severity of disease and AE/SAE should be available to Principal Investigator at each CT site.</p> <p>2) List of AE &amp; TEAE as primary endpoint to be provided to Principal</p>

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			<p>Investigator at each CT site as per Investigator's Brochure.</p> <p>Accordingly, firm should submit the revised Phase IV CT protocol to CDSCO.</p>
8.	<p>SND/CT04/FF/2025/49854</p> <p>Vortioxetine Tablets 5mg/10mg/20mg</p>	<p>M/s MSN Laboratories Private Limited</p>	<p>Firm presented their proposal for grant of permission to conduct Phase-IV clinical trial vide protocol No. 012/VRTXE/MSX/2025 before the Committee.</p> <p>After detailed deliberation, the committee opined that firm should revise their protocol to include following points.</p> <ol style="list-style-type: none"> <li>1) For dose titration, flow diagram for change of medication based on severity of disease and AE/SAE should be available to Principal Investigator at each CT site.</li> <li>2) List of AE &amp; TEAE as primary endpoint to be provided to Principal Investigator at each CT site as per Investigator's Brochure.</li> <li>3) For point no.3 of inclusion criteria, washout period should be provided between two drugs.</li> </ol> <p>Accordingly, firm should submit the revised Phase IV CT protocol to CDSCO for further review by the committee within 15 days.</p>