

**Recommendations of the SEC (Neurology & Psychiatry) made in its 13<sup>th</sup>/24 meeting held on 26.09.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/94/24 Online Submission (44439)  Trospiumchloride + Xanomeline tartrate	M/s. IQVIA RDS (India) Private Limited	The firm presented phase 3 clinical study protocol no. KAR-012 version 5.0 dated 02 November 2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that the protocol title shall be amended as “A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Adjunctive KarXT in Subjects with Inadequately Controlled Symptoms of Schizophrenia”.
2.	CT/175/21 Online Submission (34550)  LOU064 (Remibrutinib)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 29 May 2024 protocol no. CLOU064C12301.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/176/21 Online Submission (34552)  LOU064 (Remibrutinib)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 29 May 2024 protocol no. CLOU064C12302.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>Biological Division</b>			
4.	BIO/CT04/FF/2023/3 8428  Ocrelizumab 300 mg concentrate for solution for infusion	M/s. Roche Products (India) Private Limited	In light of earlier SEC recommendation dated 18.01.2024 & 19.01.2024, the firm presented revised Phase IV study protocol titled “A Multi-Center, Open -Label, Single Arm Phase IV Study to assess the safety and effectiveness of Ocrelizumab in Multiple Sclerosis (RMS and PPMS) patients in India (Overture) vide protocol No. ML45008 Version 2.0 dated 24.06.2024 before the committee.  After detailed deliberation, the committee recommended for approval of the revised protocol presented by the firm for conduct of Phase IV clinical study.

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<b>BA/BE Division</b>			
5.	BABE/CT05/FF/2024 /42165  FDC of Duloxetine and Pregabalin Extended-release Tablets 60mg and 330 mg	M/s ZenRise Clinical Research Pvt. Ltd.	The firm presented the Protocol No. MR-137A-01-TMR-1002 (128-23), Version No. 01, Protocol Date 08-JAN-2024 and Protocol No. MR-137A-01-TMR-1003 (129-23), Version No. 01, Protocol Date 08-JAN-2024 for BA/BE study for export purpose only.  After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
6.	BABE/CT05/FF/2023 /40552  Vinpocetine 30mg Extended-Release tablets	M/s. Admerus Biosciences Private Limited	In light of the earlier SEC recommendation dated 18.04.2024, the firm re-deliberated the proposal.  After detailed deliberation, the committee examine the response and recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
<b>SND Division</b>			
7.	SND/MA/24/000087  Lacosamide Injection 1mg/ml and 2mg/ml 100 ml bottle	M/s Intas Pharmaceuticals Limited	Firm presented the proposal for grant of permission to manufacture and market of Lacosamide Injection 1mg/ml 100 ml Bottle and Lacosamide Injection 2mg/ml 100 ml Bottle along with justification for waiver of Clinical Trial study before the committee.  After detailed deliberation, the committee opined that firm should submit following data to CDSCO for further review by the committee:  i. Adequate data/ justification regarding equivalence of proposed formulation with existing approved formulation along with therapeutic concentration for applied indication in proposed formulation.  ii. Benefit / rational of the proposed formulation over the existing approved formulations.
<b>FDC Division</b>			
8.	FDC/MA/23/000131  Pregabalin ER	M/s Hetero Labs Limited	In light of the earlier SEC recommendation dated 12.07.2023, the firm presented the proposal along with

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	82.5mg I.P. + Polmacoxib 2mg Tablet		<p>BE study report and Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol, the committee opined that “The firm should change the comparator to established approved medication for chronic back pain.”</p> <p>Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.</p>
9.	FDC/MA/23/000256  Pregabalin + Duloxetine Hydrochloride eq. to Duloxetine (delayed release pellets) + Mecobalamin (75mg+30mg+1500mcg/ 75mg+20mg+1500mcg/ 75mg+10mg+ 1500mcg/ 50mg+ 10mg+ 1500mcg/50mg+ 20mg+ 1500mcg) Hard gelatin capsules	M/s Ravenbhel Healthcare Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 23.02.2024, the firm presented the proposal along with Phase III clinical trial report for two strengths i.e. Pregabalin + Duloxetine Hydrochloride eq. to Duloxetine (as delayed release pellets) + Methylcobalamin(75mg+30mg+1500mcg / 75mg+20mg+1500mcg) hard gelatin capsules before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product in above two strengths.</p>
10.	FDC/MA/24/000003  Gabapentin IP (ER) tablet 600mg/300mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release) tablets 20mg/20mg film coated tablet	M/s Ravenbhel Healthcare Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 13.06.2024, the firm presented the proposal along with source data of BE study report and Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee opined that following should be defined in the CT protocol:</p> <ul style="list-style-type: none"> <li>• Titration of medication in case of break through pain/ non-response of pain.</li> <li>• Procedure for dose up-titration.</li> </ul> <p>Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.</p>