

**Recommendations of the SEC (Neurology & Psychiatry) made in its 18<sup>th</sup> meeting held on 26.11.2024 27.11.2024 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	GCT/PostAppr/2024/35413 Online Submission (35413) OMB157 (Ofatumumab)	M/s Novartis	The firm presented protocol amendment version 4.0 dated 02 July 2024 protocol no. COMB157G2399.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/PostAppr/2024/35643 Online Submission (35643) Ocrelizumab	M/s PPD	The firm presented protocol amendment version 6 dated 06 May 2024 protocol no. WN42086.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/PostAppr/2024/35823 Online Submission (35823) Lumateperone	M/s IQVIA	The firm presented protocol amendment 2 dated 26 August 2024 protocol no. ITI-007-505.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>BA/BE Division</b>			
4.	BABE/CT05/FF/2024/44931  B2227 (Cariprazine) Extended-Release (ER) injectable suspension 90 mg	M/s CBCC Global Research	The firm presented the protocol No. Protocol No: MW240010, Version 2.0 dated 29/Jul/2024.  After detailed deliberation, the committee recommended for grant of permission for the conduct of the study for export purpose only.
<b>SND Division</b>			
5.	SND/CT/24/000041  Clostridium Botulinum neurotoxin type A 50 Unit /100 units	M/s Cliniexpert services Pvt. Ltd.	The firm did not turn up for the presentation.
6.	SND/CT/24/000042  Clostridium Botulinum neurotoxin type A 50 Unit /100 units	M/s CliniExperts services Pvt. Ltd.	The firm did not turn up for the presentation.

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7.	SND/CT/24/00043  Clostridium Botulinum Neurotoxin Type A 50 Units & 100 Units	M/s Cliniexperts Services Private Limited	The firm did not turn up for the presentation.
8.	SND/MA/24/000090  Ketorolac Tromethamine Sublingual Tablets 30mg	M/s. Troikaa Pharmaceuticals Limited	<p>In light of earlier SEC recommendations dated 07.08.2024, the firm presented data of the adverse events occurred in the initial one week of the Phase III clinical trial especially in the group administered with placebo and effect of the drug product on kidney before the committee.</p> <p>After detailed deliberation, the Committee recommended for grant of permission for manufacture and marketing of Ketorolac Tromethamine Sublingual Tablets 30mg indicated for the treatment of migraine headache pain subject to condition that the firm should conduct Post Marketing Surveillance (PMS) study.</p> <p>Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.</p>
9.	SND/CT/24/000076  Zolpidem Sublingual Spray 3.85% w/v	M/s. Troikaa Pharmaceuticals Limited	<p>In light of earlier SEC (Neurology &amp; Psychiatry) recommendation dated 17.08.2023, the firm presented the Phase IV clinical study protocol no. CT/57/01/24 ver. 01 dated 01.06.2024 before the committee.</p> <p>After detailed deliberation, the committee opined that the presented Phase IV Clinical Study Protocol shall be revised to include:</p> <ol style="list-style-type: none"> <li>1. Dosage treatment period shall be revised to two weeks and follow up period upto four weeks.</li> <li>2. To evaluate dependence validated Questionnaire is to be submitted.</li> </ol> <p>Accordingly, firm is required to submit the revised Phase IV Clinical study protocol to CDSCO for further review by the committee.</p>
10.	SND/MA/19/000106  Aripiprazole Tablets	M/s Torrent Pharmaceuticals Limited	Firm presented the Post Marketing Surveillance study report of Aripiprazole Tablets 2mg for the treatment of

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	2mg		<p>Schizophrenia in adolescent patients (13 to 17 years of age).</p> <p>After detailed deliberation, committee opined that firm should submit the following-</p> <ul style="list-style-type: none"> <li>• Clarity on methodology followed for data collection during the study.</li> <li>• Management of Adverse Effects like Extrapramidal disorder, bradykinesia.</li> <li>• Details of unreported/ uncaptured Adverse Effects like Insomnia, Anxiety &amp; Restlessness etc.</li> </ul> <p>Accordingly, the firm should submit the above additional data to CDSCO for further review by the committee.</p>
11.	12-03/2009-DC(Pt-Injection) Lacosamide Injection 10mg/ml	M/s Torrent Pharmaceuticals Limited	<p>Firm presented the report of Phase IV clinical trial of the product Lacosamide Injection 10mg/ml in Patients with Partial Onset Seizures.</p> <p>After detailed deliberation, committee accepted the safety and tolerability study as per the condition of marketing authorization granted for the product Lacosamide Injection 10mg/ml in Patients with Partial Onset Seizures.</p>
<b>New Drugs Division</b>			
12.	ND/CT/21/000085 Cariprazine Capsules 1.5 mg, 3 mg, 4.5 mg and 6 mg	M/s Sun Pharmaceutical Industries Limited	<p>The firm presented Phase IV clinical trial report of drug Cariprazine Capsules 1.5 mg, 3 mg, 4.5 mg and 6 mg before the committee.</p> <p>After detailed deliberation, the committee noted and agreed the results of the report</p>
13.	ND/MA/24/000135 Lumateperone Capsules (10.5 mg, 21 mg & 42 mg)	M/s Exemed Pharmaceuticals	<p>The firm presented proposal for grant of permission to manufacture and market Lumateperone Capsules (10.5 mg, 21 mg &amp; 42 mg) along with Bioequivalence study protocol and Phase III clinical trial protocol before the Committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented.</p> <p>The committee also recommend for the grant permission for the conduct of phase III clinical trial study as per the protocol presented subject to the condition that:</p>

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			<ol style="list-style-type: none"> <li>The Phase III clinical trial should be initiated only after satisfactory evaluation of bioequivalence study results by SEC.</li> <li>The firm should include more trial site from the Govt. hospital.</li> </ol>
14.	ND/MA/22/000139 Cannabidiol Oral Solution, 150 mg/m	M/s Zenara Pharma Private Limited	<p>In light with earlier SEC recommendation dated 12.03.2024, the firm has presented Phase III CT results along with the published data before the committee. CDSCO has presented the GCP inspection report from the six clinical trial sites before the committee. After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> <li>Looking at the incidences of the mild to moderate anxiety disorder, the present clinical trial on the 178 subject may not be sufficient for first time approval in world for the proposed indication. Hence, the firm should submit comparative phase III CT protocol with statistically significant number of subjects for further review by the committee</li> <li>The firm should submit the raw data from the all the trial sites for the further review by the committee.</li> <li>Firm should submit justification/clarification for no placebo response in proposed clinical trial across all the subject in placebo treatment group.</li> <li>Firm should submit the data on the addiction potential of the proposed drug.</li> </ol>
<b>FDC Division</b>			
15.	FDC/CT/21/000001 Pregabalin IP (as prolonged release) + Etoricoxib IP	M/s. Sun Pharma Laboratories Ltd.	In light of earlier SEC recommendation dated 23.10.2019 and as per condition of Form CT-23 dated 07.11.2019, the firm presented Phase IV clinical trial report before the committee.

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	75mg+60mg tablet		<p>After detailed deliberation, the committee noted and agreed to the result of the clinical trial report. Further, the committee also recommended that the treatment duration should be 2-3 weeks since etoricoxib is also included in the combination.</p> <p>Accordingly, firm should submit updated labels and package insert/prescribing information to CDSCO.</p>