

**Recommendations of the SEC (Neurology & Psychiatry) made in its 85<sup>th</sup> meeting held on 14.10.2022 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/MA/22/000139  Cannabidiol Oral Solution 150mg/ml	M/s. Zenara Pharma Pvt. Ltd.	<p>The firm presented their proposal to manufacture and market Cannabidiol Oral Solution 150mg/ml along with Phase III CT protocol before the committee.</p> <p>During presentation by the firm, the committee provided various specific comments on Phase III clinical trial protocol.</p> <p>Accordingly, the committee recommended that the firm should submit revised Phase III clinical trial Protocol to CDSCO for further review by the committee.</p>
2.	ND/MA/22/000140  Cannabidiol Oral Solution 100mg/ml	M/s. Zenara Pharma Pvt. Ltd.	<p>The firm presented their proposal to manufacture and market Cannabidiol Oral Solution 100mg/ml alongwith justification for waiver of CT and BE study before the committee.</p> <p>The proposed drug is already approved in USA, Australia and Netherland.</p> <p>The committee noted that the indication for which the proposal has been submitted is for a difficult to treat condition and thus can be decided differently.</p> <p>After detailed deliberation, the committee recommended to take expert opinion from two Pediatric Neurologists who are treating epilepsy.</p> <p>Opinion of the experts would be further discussed in next SEC meeting.</p>
3.	ND/MA/22/00079  Etifoxine Hydrochloride capsules 50mg	M/s. Sun Pharma	<p>In light of earlier SEC recommendation dated 21.07.2022, the firm presented their revised protocol of Etifoxine Hydrochloride capsule 50mg for Phase III Clinical trial study before the committee.</p> <p>After detailed deliberation, the committee recommended grant of permission to conduct Phase III CT for Etifoxine Hydrochloride capsule 50mg with revised protocol.</p>

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<b>SND Division</b>			
4.	SND/CT/21/000081  Nortriptyline 10mg+Mecobalamin 1500mcg + Pregabalin 75mg	M/s. BDR Pharma	The firm did not turn up for presentation.
<b>FDC Division</b>			
5.	FDC/MA/21/000060  Nortriptyline 10mg+Mecobalamin 1500mcg + Pregabalin 75mg	M/s. Synokem Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 16.04.2021, the firm presented BE study report before the committee.  The committee noted that the same FDC with Pregabalin in PR (Prolonged Release) form is already approved by CDSCO (for the treatment of patients with diabetic peripheral neuropathic pain with coexistent Vitamin B12 deficiency), based on the Clinical Trial Study data on 17.03.2022.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
<b>Medical Device Division</b>			
6.	IMP/MD/2022/58425  NAV PAK Needle, Trocar and NIM NAV PAK Needle, Trocar International	M/s. India Medtronic Pvt. Ltd	The firm did not turn up for presentation.
7.	CI/MD/2021/40587  Sensor Evaluation of Neurologic Status in Emergencies (SENSE Device) (SDx3)	M/s. Pat Pharma Consultants India Private Ltd	The firm presented their proposal for amendment of clinical investigation Protocol SENSE-003, version 2.3 dated 27.06.2022 before the committee.  After detailed deliberation, the committee recommended for grant of permission for amendment of clinical investigation protocol SENSE-003, Version 2.3 dated 27.06.2022.
<b>SND Division</b>			
8.	SND/MA/20/000368  Midazolam Nasal Spray 0.055w/v & 1.25% w/v	M/s. Biodeal Pharmaceuticals	In light of earlier SEC recommendation dated 15.09.2022, the firm presented their proposal of Midazolam Nasal Spray 0.055w/v & 1.25% w/v with request of BA/BE study waiver based on BCS Class I classification.

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			However, the firm did not produce any documental evidence and justification for the same. Hence the committee opined that the firm should come with proper documental evidence of proposed BCS Class-I based BA/BE waiver.
9.	SND/MA/22/000271 Gabapentin ER Tablet 300mg & 600mg	M/s. Sun Pharma	The firm did not turn up for presentation.
<b>GCT Division</b>			
10.	CT/57/20 Online Submission (17881)  Evobrutinib	M/s. IQVIA	<p>The firm has presented their proposal for protocol amendment version 4.0 (03 April 2022) before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit the following-</p> <ol style="list-style-type: none"> <li>1. Rationale for increase of treatment duration from initial 96 weeks to 156 weeks.</li> <li>2. Reason for not completing enrollment of initial target of 16 subjects from India with applicant having informed CDSCO that as per previous version of protocol, enrollment is completed.</li> <li>3. The applicant informed that the increase of duration of trial and increase of sample size will compensate the analysis part (modified FAS), however there is no proposal for increase in number of subjects in proposed protocol amendment mentioned.</li> </ol>