

Recommendations of the SEC (Neurology & Psychiatry) made in its 94th meeting held on 12.07.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000/232 Nicotine Pouch 4mg and 6 mg	M/s. Leaf Fibre Pvt. Ltd.	The proposal was deferred for next SEC meeting.
2.	SND/MA/23/000136 Vigabatrin tablets 250/500 mg	M/s. MSN Laboratories Pvt. Ltd	The proposal was deferred for next SEC meeting.
3.	SND/MA/21/000489 Zolpidem Sublingual Spray 3.85 % w/v	M/s. Troikaa Pharmaceuticals Ltd.	The proposal was deferred for next SEC meeting.
4.	12-61/2023-DC (Pt-Misc-SND) Brivaracetam 25mg, 50mg,75mg & 100mg	M/s Optimus Pharma	The proposal was deferred for next SEC meeting.
FDC Division			
5.	04-1827/2015-DC (PSC-Synokem) Gabapentine 300mg/400mg + Nortriptyline 5mg/10mg	M/s. Synokem Pharmaceuticals Ltd.	<p>The firm presented Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that following points should be included in exclusion criteria:</p> <ol style="list-style-type: none"> 1. Patient should not be taking any analgesic, opioids, alcohol, INH or any other drug which could lead to neuropathy. 2. To include all types (mild, moderate and severe) of psychiatric illness. <p>The committee recommended that the firm should submit revised Phase IV clinical trial protocol by incorporating above points for further review by the committee.</p>
6.	FDC/MA/23/000131 Pregabalin ER	M/s. Hetero Labs Limited	The firm presented their proposal along with BE study and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	82.5mg I.P. + Polmacoxib 2mg Tablet		recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of BE study should be presented for review by SEC, before initiation of the Phase III clinical trial.
7.	FDC/MA/23/000174 Paroxetine HCL Hemihydrate 12.5mg + Clonazepam 0.25mg Capsules	M/s. Windlas Biotech Ltd.	The proposal was deferred for next SEC meeting.
8.	FDC/MA/23/000108 Gabapentin 200mg/300mg + Duloxetine HCl 20mg/30mg Hard Gelatin Capsules	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next SEC meeting.
9.	FDC/MA/23/000187 Pregabalin 75mg/75mg + Duloxetine 20mg/30mg + Mecobalmin 1500mg/1500mg Hard gelatin capsules	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next SEC meeting.
GCT Division			
10.	CT/26/23 Online Submission (36640) Divozilimab	M/s. Invitro Research Pvt. Ltd.	The firm has presented the proposal for grant of permission to conduct Phase III clinical trial with protocol no. BCD-132-6/AQUARRELLE, version 02 dated 09-Jan-2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial subject to the following condition: 1. The existing proposed 11 clinical trial sites (07 Private sites + 04 Government) sites are not considered and applicant is required to submit clinical trial sites based on data published by National Registry of Multiple Sclerosis and allied

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Demyelinating Disorders by ICMR to CDSCO for approval of clinical trial sites.
11.	CT/03/20 Online Submission (22774) Evenamide	M/s. CliniRx	In light of recommendations of SEC dated 18.04.2023, the firm presented the consolidated interim analysis report along with DSMB recommendation with respect to proposed protocol amendment no. 4.2 dated 08.07.2022 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment.
12.	CT/57/20 Online Submission (24126) Evobrutinib	M/s. IQVIA	The firm presented the proposed amendment to protocol version 5.0 dated 06-December-2022 for Study Protocol no. S200527_0082 before the committee. After detailed deliberation the committee recommended for approval of the protocol amendment.
13.	CT/116/21 Online Submission (24608) OAV101	M/s. Novartis	The firm presented the proposed amendment to protocol version 2.0 dated 08Aug. 2022 for Study Protocol no. COAV101B12301 and request to increase number of patients before the committee. After detailed deliberation the committee recommended for approval of the protocol amendment and increase of No of subjects patients from 14 to 30 numbers in the study from India.
14.	CT/120/22 Online Submission (34243) CUD-1905	M/s. Clianza	In light of earlier SEC dated 17-01-2023, the applicant presented justification for trial design & selection of dose and presented safety data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.
15.	CT/179/21 Online Submission (21248) SAR442168	M/s. Sanofi	In light of recommendations of SEC dated 18.04.2023, the firm presented the proposal of protocol amendment no. 06 version 01 dated 23-May-2022 and protocol amendment no. 07 version 01 dated 13-Sep-2022 to protocol no. EFC16645 before the committee.

SEC (Neurology & Psychiatry) meeting dated 12.07.2023

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for approval of the protocol amendment.
16.	CT/169/22 Online Submission (35261) LY315920 & LY333013	M/s. Inventive International	The firm presented Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.
17.	CT/122/20 Online Submission (25131) Galcanzumab	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
18.	CT/123/20 Online Submission (25133) Galcanzumab	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
19.	CT/36/23 Online Submission (36935) Milvexian an Oral Factor XIa Inhibitor	M/s. IQVIA	The proposal was deferred for next SEC meeting.
20.	CT/176/21 Online Submission (25975) Remibrutinib versus Teriflunomide	M/s. Novartis	The proposal was deferred for next SEC meeting.
21.	CT/65/22 Online Submission (26646) Brilaroxazine (RP5063)	M/s. PRA	The proposal was deferred for next SEC meeting.