

Recommendations of the SEC (Neurology & Psychiatry) made in its 04th/24 meeting held on 12.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/36/23 Online Submission (28621) Milvexian	M/s. IQVIA	The firm presented for waive off the condition in the CT NOC, as 50% sites to be included from Govt. hospitals for study protocol No. 70033093STR3001. After detailed deliberation, committee opined that firm did not made effective efforts to include the Govt. hospitals for study protocol No. 70033093STR3001, therefore the condition mentioned in the CT NOC to include 50% sites from Govt. hospitals as recommended by earlier SEC stands valid. Accordingly, the firm includes 50% sites from Govt. hospitals.
2.	CT/116/22 Online Submission (31474) Basimglurant	M/s. CliniRx	The firm presented protocol amendment version 6.1 dated 13 November 2023 protocol No.: NOE-TSC-201. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	4-38/Roche/PAC-R-Ocrelizumab/2023-BD(Diary no 5537) Ocrelizumab 300mg concentrate for solution for infusion	M/s. Roche	The firm presented the post marketing safety data generated globally including Asian and Indian population along with PSUR data generated for the period 28 March 2022 to 27 March 2023 as part of the condition in the MA permission. After detailed deliberation, the committee noted the results presented by the firm. (Dr. Sunil Narayan didn't participate in the deliberation)
4.	BIO/CT18/FF/2024/41384 Lecanemab concentrate solution for Infusion 100 mg/ml	M/s. Eisai Pharmaceuticals Pvt. Ltd.	The firm presented the proposal to import and market Lecanemab concentrate solution for Infusion 100 mg/ml indicated for treatment slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer disease with waiver of local clinical trial based on the clinical data generated from global clinical trials.

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			<p>After detailed deliberation, the committee did not consider the request of the firm for waiver of local clinical trial and recommended the firm to conduct Phase III clinical trial in India.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol in Indian subjects for further consideration of the application submitted by the firm.</p>
BA/BE Division			
5.	<p>12-09/2024/BA-BE/MISC-14/DC BABE/CT05/FF/2023/40881</p> <p>Amifampridine Extended-Release Tablets 10mg (T1 & T2) and Amifampridine Extended-Release Capsules, 10mg (T3)</p>	<p>M/s. Veeda Clinical Research Limited, Ahmedabad - 380015</p>	<p>The firm presented protocol No. 23-VIN-0533, version No.01 dated 21-NOV-2023.</p> <p>After detailed deliberation, the committee recommended for approval of protocol as presented by the firm.</p>
SND Division			
6.	<p>SND/MA/22/000163</p> <p>Buprenorphine Sublingual Films 4 mg/ 6 mg / 8 mg (New Dosage form, additional strength)</p>	<p>M/s. Zim Laboratories Ltd.</p>	<p>In light of earlier SEC recommendations dated 21.06.2022, the firm presented the justification for the waiver of clinical trial before the committee.</p> <p>The firm has informed that the Buprenorphine sublingual tablets 2mg, 8mg are approved in UK, the Netherlands & USA. However, Buprenorphine sublingual films 4mg, 6mg, and 8mg are not yet approved anywhere.</p> <p>After detailed deliberation, the committee reiterated with earlier recommendation to conduct Phase III clinical trial.</p> <p>Accordingly, the firm should submit clinical trial protocol to CDSCO for further review by the committee.</p>
7.	<p>SND/MA/23/000312</p> <p>Nicotine Polacrilex pouches 2 mg & 4mg</p>	<p>M/s. Lyrus Lifesciences Private Limited</p>	<p>The firm presented the proposal for manufacture and marketing of Nicotine Polacrilex pouches 2 mg & 4mg (Additional Dosage form) along with comparative bioavailability study results</p>

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			<p>of Nicotine Polacrilex pouches 4 mg and justification for waiver of Phase III clinical trial before the committee.</p> <p>The firm has informed that the Nicotine Polacrilex lozenges 2mg and 4mg already approved in the country on 18.02.2009 and included in NRT programme.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Nicotine Polacrilex pouches 2 mg & 4mg (Additional Dosage form) subject to condition that the firm should conduct Phase IV clinical trial. In addition to above, the firm should fulfill the requirement of CMC data.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial protocol within 3 months from date of approval to CDSCO for further review by the committee.</p>
New Drugs Division			
8.	ND/MA/22/000139 Cannabidiol Oral Solution 150mg/ml	M/s. Zenera	<p>In light with earlier SEC recommendation dated 18.11.2022, the firm has presented Phase III CT results before the committee.</p> <p>After detailed deliberation, the committee observed that the trial is placebo control and the indication applied for approval is not approved in anywhere else in the world. Hence, in order to verify the results of the safety and efficacy, it has been unanimously suggested by the committee to audit the trial and conduct GCP inspection along with the subject expert. The committee also felt that the sample size for the first time approval based on GCP inspection.</p> <p>The firm is also requested to provide the published data on proposed indication.</p>
9.	ND/CT/23/000074 Cannabidiol Oral Solution 100mg/mL	M/s. Zenera Pharma	<p>In line with the condition of the permission for the manufacturing and marketing of the drug Cannabidiol oral solution, 100mg/ml, the firm presented</p>

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			<p>Phase IV clinical trial protocol for drug Cannabidiol oral solution, 100mg/ml before the committee.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial as per protocol presented.</p> <p>The result of the Phase IV CT study should be presented before SEC for further review by the committee.</p>
FDC Division			
10.	<p>FDC/MA/22/000417</p> <p>Bupropion Hydrochloride (ER) IP 105mg + Dextromethorphan Hydrobromide IP 45mg tablets</p>	M/s. Exemed Pharmaceutical	<p>In light of earlier SEC recommendation dated 18.01.2024 & 19.01.2024, the firm presented the raw data for pharmacokinetic of each subject and detail safety data with causality assessment before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition that the firm should conduct Active PMS study.</p> <p>Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months from the approval for review by the committee.</p>
11.	<p>FDC/MA/24/000032</p> <p>Gabapentin IP (as granules) 200mg/300mg + Duloxetine Hydrochloride IP eq. to Duloxetine (As enteric coated pellets) 20mg/30mg hard gelatin capsule</p>	M/s. Mascot Health Series Pvt. Ltd.	<p>The firm presented the proposal before the committee along with BE protocol.</p> <p>After detailed deliberation, the committee observed that the firm has taken Duloxetine Hydrochloride (delayed release) as reference product in BE protocol. However, the test product is Duloxetine Hydrochloride (IR).</p> <p>Accordingly, the revised BE study protocol should be submitted to CDSCO for further review by the committee.</p>
12.	<p>FDC/MA/23/000287</p> <p>Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline</p>	M/s. Ravenbhel Healthcare Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 12.10.2023, the firm presented the proposal along with BE study report before the committee.</p>

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	Hydrochloride eq. to Nortriptyline IP (600mg+1500mcg+10 mg/ 300mg+ 1500mcg+ 10mg) film coated bilayered tablet		<p>After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission has already been granted by CDSCO.</p> <p>The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.</p>