

**Recommendations of the SEC (Neurology & Psychiatry) made in its 09<sup>th</sup>/24 meeting held on 18.07.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/73/24 Online Submission (43367)  GZ402671/ Venglustat	M/s. Sanofi Healthcare India Private Limited	The firm presented Phase III clinical study protocol no. EFC17045, Amended protocol 04, version number 01, dated 06 Oct 2023.  After detailed deliberation, the committee opined that the firm shall provide the details as below: (i) Details of SAE occurred globally including Italy & China. (ii) Fabry Diagnostic kit should be provided to clinical study sites and subject should be tested before enrolment in the study. Accordingly, protocol should be revised and submitted for further review by the committee.
2.	CT/121/23 Online Submission (32781) IMU-838 (Vidofludimus Calcium)	M/s. Worldwide Clinical Trials India Private Limited	The firm presented amendment protocol Version 4.0, 18 March 2024, protocol No. P3-IMU-838-RMS-02 (ENSURE-2)  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/117/23 Online Submission (32780) IMU-838 (Vidofludimus Calcium)	M/s. Worldwide Clinical Trials India Private Limited	The firm presented amendment protocol Version 4.0, 18 March 2024, protocol No. P3-IMU-838-RMS-01 (ENSURE-1).  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/130/20 Online Submission (32645)  Fenebrutinib	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 7, dated 15 Feb 2024, protocol No. GN42272.  After detailed deliberation, the committee opined that there was extreme concern about death in a very young patient, which was related to the study protocol and medication. CDSCO need to review the documents which were filed by the study sponsor and action taken thereof. Accordingly, data shall be submitted for further review by the committee.

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5.	CT/143/23 Online Submission (40495)  OAV101	M/s. Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 18.01.2024 & 19.01.2024, the firm presented Phase 3b clinical study protocol no. COAV101A12308, version number: 03; Release date: 04-May-2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Medical Devices Division</b>			
6.	CI/MD/2024/116301  Nerve Electrical Stimulator (Brand Name: Nerivio) (Model No.:FGD0000 75 - 18 treatments)	M/s. Dr. Reddy's Laboratories Limited	The firm presented the Clinical study protocol for conduct of Post Marketing Clinical Investigation on the product "Nerve Electrical Stimulator", as a fulfilment of one of the condition of the permission granted to import the product in Form MD-26, before commercialization.  After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Post Marketing Clinical Investigation study in the Indian population.
<b>BA/BE Division</b>			
7.	File No. BABE/ CT05/FF/2024/41854  Brexpiprazole 15.3 mg for Extended Release Injection	M/s. CBCC Global Research LLP	The firm presented the Protocol No.: MW230026 ver. 4.0 dated 07.02.2024 for BA/BE study for export purpose only.  After detailed deliberation, the committee recommended to revise the protocol with PANSS score in inclusion criteria.  Accordingly, the firm should submit the revised protocol for re-deliberation by the SEC.
<b>SND Division</b>			
8.	SND/MA/24/000102  Chlordiazepoxide Tablets I.P.15mg & 20mg	M/s. Abbott Healthcare Private Limited	The firm presented the proposal for grant of permission to manufacture and marketing of Chlordiazepoxide Tablets I.P.15mg & 20mg (Intermediate strength) along with bioequivalence study protocol (Protocol no: BE/24/089 version no.:00 dated: 16.05.2024) and justification for waiver of Phase III clinical trial before the committee.  The firm has informed that the Chlordiazepoxide Tablets 5mg, 10mg, and 25mg already marketed in the India.

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			<p>However, proposed strength 15mg and 20mg are not approved anywhere in the world.</p> <p>After detailed deliberation, the committee opined to take opinion of experts from Ministry of Health &amp; Family Welfare involved in management of alcohol dependence.</p>
<b>New Drugs Division</b>			
9.	ND/IMP/24/000032  Rimegepant ODT 75 mg (Nurtec)	M/s. Pfizer Ltd.	<p>The firm presented the proposal for grant of permission to import and market of Rimegepant ODT 75 mg (Nurtec) with Phase III local Clinical Trial wavier for the indication 'Acute treatment of Migraine in Adults with a previous insufficient response to Triptans'.</p> <p>After detailed deliberation, the committee has opined that the Triptan resistant migraine is an unmet medical need and addition of another drug may be useful for the patients suffering from Triptan resistant Migraine. The committee recommended Phase III Clinical Trial Wavier with the condition that the drug should be sold on the prescription of Neurologist and Psychiatrist only.</p> <p>Also, the committee recommended that the product package insert should contain sufficient information/ data on Clinical trials with Triptan resistant Migraine. The Package insert should include caution for patients with cardiovascular disorder and pregnant women.</p> <p>The firm should submit above information to CDSCO for further review.</p>
10.	ND/CT/24/000028  Rimegepant 75 mg ODT tablets	M/s. Pfizer Ltd.	<p>The firm presented the proposal for grant of permission to conduct Phase III Clinical of Rimegepant 75 mg ODT tablets for the indication 'Acute Treatment of Migraine with or without Aura'.</p> <p>After detailed deliberation, the committee recommended that the firm need to submit revised Clinical trial protocol to CDSCO by incorporating efficacy as primary study objective instead of secondary study objective. Also,</p>

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			proposed study should include at least 50% Govt. sites.
<b>FDC Division</b>			
11.	FDC/MA/24/000007 Gabapentin IP (as SR) 300mg/400mg/600mg + Nortriptyline Hydrochloride IP eq.to Nortriptyline 10mg/10mg/10mg + Methylcobalamin IP 1500mcg/1500mcg/1500mcg Film Coated Tablets	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 23.02.2024, the firm presented the proposal along with revised BE study protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per proposed protocol.  Accordingly, the result of the BE study should be presented along with Phase III clinical trial protocol to CDSCO for review by the committee.