

**Recommendations of the SEC (Neurology & Psychiatry) made in its 01<sup>st</sup>/25 meeting held on 28.01.25. at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/58/24 Online Submission (36608)  Rimegepant	M/s. Pfizer Limited	The firm presented protocol amendment 3 dated 19 November 2024 protocol No.C4951013.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT154/24 Online Submission (46917)  BHV-7000	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase II/III clinical trial protocol no. BHV7000-303 version V3.1 APAC dated 15 November 2024.  After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee:  <ol style="list-style-type: none"> <li>1. A qualified Neurologist having specialization on treatment of epilepsy shall be included as PI in the study. Accordingly, sites and PI shall be selected.</li> <li>2. Details of possible AE's and their management to be mentioned in the protocol.</li> <li>3. More government sites shall be included in the study.</li> </ol>
3.	CT/84/24 Online Submission (36652)  Inebilizumab	M/s Medspace Clinical Research India Private Limited	The firm didn't turn up for the presentation.
4.	CT/162/24 Online Submission (47101)  BHV-7000	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase II clinical trial protocol no. BHV7000-201 version V1.1 CAMSASI dated 12 December 2024.  After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<ol style="list-style-type: none"> <li>1. A qualified Neurologist having specialization on treatment of epilepsy shall be included as PI in the study. Accordingly, sites and PI shall be selected.</li> <li>2. Details of possible AE's and their management to be mentioned in the protocol.</li> <li>3. More government sites shall be included in the study.</li> </ol>
5.	CT/163/24 Online Submission (47104)  Evenamide	M/s Clinirx Research Pvt Ltd	<p>The firm presented phase III clinical trial protocol no. NW-3509/023/III/2024 Amendment 1, version 2.0 dated 12 November 2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm</p>
<b>Biological Division</b>			
6.	E-49509  Ofatumumab solution for injection in pre filled syringe 20mg/0.4mL	M/s. Novartis Healthcare Pvt. Ltd.	<p>The firm presented the proposal for update in Package insert for the drug product Ofatumumab solution for injection in pre-filled syringe 20mg/0.4mL based on the U.S pack insert dated 12 April 2024 with changes in Sections of Contraindications, Warning and Precaution, Patient Counseling Information and Instructions for use.</p> <p>After detailed deliberation, the committee recommended for the approval of updated package insert dated 26 July 2024 of the drug product for the proposed changes.</p>
<b>New Drugs Division</b>			
7.	ND/MA/24/000023  Cenobamate Tablets 12.5mg, 25 mg, 50mg, 100mg, 150mg & 200mg	M/s MSN Laboratories Ltd.	The firm did not turn up for the presentation.
8.	ND/MA/23/000121  Brexipiprazole Tablets 0.25/0.5	M/s Hetero Labs Limited	The firm presented their proposal for grant of permission to conduct the BE study (Protocol No BIOS/2023/204, Version-01, dated: 29.03.2024) and Phase III Clinical Trial study (protocol no.:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg/1mg/2mg/3mg/4mg		<p>HCR/III/BRXSP/06/2023, Version 1.0, dated:11.07.2023) for Brexpiprazole Tablets before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented and Phase III Clinical Trial with the following changes:</p> <ol style="list-style-type: none"> <li>1. Firm should revise the title of the study w.r.t. Newly diagnosed patients of schizophrenia to adults with acute schizophrenia.</li> <li>2. Firm should include a qualified Psychiatrist by training and experience as the Principal Investigator as the drug (Brexiprazole) will be evaluated in Psychiatric patients.</li> <li>3. Firm should enrol more number of government sites.</li> </ol> <p>Accordingly, the firm should submit the revised protocol to CDSCO.</p> <p>Further, the firm should submit BE study report to CDSCO for review by the SEC committee before initiating the Phase III Clinical Trial.</p>
<b>FDC Division</b>			
9.	FDC/MA/24/000267  Ascorbic Acid 150 (mg) + Methylcobalamin 1000 (µg) + Nicotinamide 100 (mg) + Pyridoxine Hydrochloride 100 (mg) + D-Panthenol 50 (mg) + Benzyl Alcohol 0.9000 % v/v Injection	M/s Aristo Pharmaceuticals Private Limited	The firm did not turn up for the presentation.