

Recommendations of the SEC (Neurology & Psychiatry) made in its 5th/26 meeting held on 06.05.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/0001 39 Cannabidiol Oral Solution, 150 mg/ml	M/s. Zenara Pharma Private Limited	<p>In light of earlier SEC recommendation dated 26.11.2024 & 27.11.2024 discussion was held with the SEC members along with ICMR expert with respect to Phase III clinical trial report/results.</p> <p>After detailed deliberation, the committee reviewed the Phase III CT results of Cannabidiol Oral Solution, 150 mg/ml and noted that efficacy of proposed product is statistically significant as compared to placebo. The results indicate that Cannabidiol Oral Solution has a satisfactory safety profile and is well tolerated. The committee further noted that efficacy and safety of Cannabidiol Oral solution will also be evaluated during the Phase IV active-controlled (standard of care drug as comparator) clinical trial of Cannabidiol Oral Solution, 150 mg/ml”.</p> <p>Further, committee recommended for grant of permission to manufacture and market of Cannabidiol Oral Solution 150 mg/ml subject to the conditions that the firm should conduct and submit results of a Phase IV active-controlled (standard of care drug as comparator) Clinical Trial study, for which the trial protocol should be submitted to CDSCO within 3 months of approval of marketing authorization of the drug for further review by the committee.</p> <p>Additionally, the committee recommended the drug Cannabidiol Oral Solution 150 mg/ml should be prescribed with warning statement as: ‘To be sold by retail under the prescription of Psychiatrist only’</p> <p>Further, the committee opined that firm should submit revised prescribing information (PI) with inclusion of all adverse events and addiction potential sections and submit the updated PI to CDSCO.</p>