

**Recommendations of the SEC (Neurology & Psychiatry) made in its 07<sup>th</sup>/25 meeting held on 23.04.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/162/24 Online Submission (47101)  BHV-7000	M/s PPD Pharmaceutical Development India Private Limited	<p>In light of earlier SEC recommendation dated 28.01.2025, now the firm presented phase II clinical trial protocol no. BHV7000-201 version V1.1 CAMSASI dated 12 December 2024.</p> <p>After detailed deliberation, the committee noted the following:</p> <ol style="list-style-type: none"> <li>(1) The present study is lesser duration and follow-up duration also less instead of 24 months.</li> <li>(2) Reason for black box warning for the similar molecule by USFDA is not provided.</li> <li>(3) Data regarding Asian descent is not provided.</li> </ol> <p>The committee has expressed reservation on the possibility of the ethnic difference on the adverse effects particularly with Asian descent on the present study.</p> <p>Therefore, the committee did not recommend the present study protocol in the present form presented by the firm.</p>