

**Recommendations of the SEC (Neurology and Psychiatry) made in its 74<sup>th</sup> meeting held on 18.11.2021 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/IMP/20/000073  Risdiplam Oral solution 0.75 mg.ml	M/s. Roche Product India Pvt. Ltd	The firm presented the PMS study protocol before the committee.  After detailed deliberation, the committee recommended that the firm should submit revised PMS study protocol including as follows: <ul style="list-style-type: none"> <li>a) Sample size recalculation based on effect size etc., and prior publication data that is more relevant to their work and to accommodate multiple doses they were trying.</li> <li>b) To define the study population criteria more specific, clarifying the type and duration and stages of the disease.</li> </ul> Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.
2.	ND/CT04/FF/2021/28536  Cariprazine Capsules 1.5 mg,3 mg & 6 mg	M/s. Sun Pharmaceuticals Industries Pvt. Limited	The firm presented their phase IV clinical trial protocol no. ICR/21/014, version no. 1.0 dated 01.10.2021 before the committee for Cariprazine capsules 1.5/3.0/4.5/6.0 mg.  After detailed deliberation, the committee recommended for grant of permission to conduct the phase IV CT subject to condition that the firm should include the rescue medication in their protocol.
3.	ND/CT/21/000083  Lemborexant tablets 5mg/10mg	M/s. Eisai Pharmaceuticals India Pvt. Ltd	The firm presented their phase IV clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial of the subject to condition that the patients in the age group of 18-65 years should be included in the study.
4.	ND/MA/20/000078	M/s. Sun Pharma Lab Limited	In light of earlier recommendation of SEC dated 06.08.2020 and 16.04.2021, the

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	Pimavenserin capsules 34 mg		<p>firm presented their phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should revised clinical trial protocol including as follows:</p> <ol style="list-style-type: none"> <li>Sample size recalculation based on effect size etc., and prior publication data that is more relevant to their work and to accommodate multiple doses they were trying.</li> <li>To define the study population criteria more specific, clarifying the type and duration and stages of the Parkinsonism.</li> </ol> <p>Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.</p>
<b>SND Division</b>			
5.	SND/MA/21/000476  Betahistine Dihydrochloride Orally Disintegrating Strips 8 mg	M/s. Shilpa Medicare	<p>The firm presented the proposal along with BE study report of Betahistine Dihydrochloride Orally Disintegrating Strips 24 mg.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Betahistine Dihydrochloride Orally Disintegrating Strips 8 mg (Additional strength) for the already approved indication.</p>
<b>GCT Division</b>			
6.	CT/86/19 Online Submission (11254) Evenamide	M/s. CliniRx	<p>The firm presented the proposed protocol amendment 5.0 (Version 6.0) dated 14-Feb-2021 for the protocol no. NW-3509/014/II/2019 before the Committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p>
7.	CT/128/21 Online Submission (28366) IMU-838	M/s. Bioinnovat Research	<p>The firm presented their phase III clinical trial proposal before the committee.</p> <p><b>Assessment of risk versus benefit to the patients-</b>The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p><b>Innovation vis-a-vis existing therapeutic:-</b>To evaluate the efficacy,</p>

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			<p>safety, and tolerability of IMU-838 versus placebo in adults with Relapsing Multiple Sclerosis (ENSURE-1).</p> <p><b>Unmet medical need in the country-</b> The test drug used for Relapsing Multiple Sclerosis.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study.</p>
8.	CT/130/21OnlineSubmission(28472) IMU-838	M/s. Bioinnovat Research	<p>The firm presented their phase III clinical trial proposal before the committee.</p> <p><b>Assessment of risk versus benefit to the patients-</b>The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p><b>Innovation vis-a-vis existing therapeutic:-</b>To evaluate the efficacy, safety, and tolerability of IMU-838 versus Placebo in adults with Relapsing Multiple Sclerosis (ENSURE-2).</p> <p><b>Unmet medical need in the country-</b> The test drug used for Relapsing Multiple Sclerosis.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study. (Dr. Debashish Chowdhury did not participate in the deliberation.)</p>
9.	CT/87/18 OnlineSubmission (12429) Ofatumumab	M/s. Novartis	<p>The firm has presented protocol amendment 02 dated 03-June-2021 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p>
10.	CT/62/21 OnlineSubmission (13121)  Varespladib-methyl (LY333013)	M/s. Premier Research	<p>The firm presented the proposed protocol amendment Version 2.1 dated 12Oct2021 for the phase II protocol no. OPX-PR-01 (BRAVO Study) before the Committee.</p> <p>After detailed deliberation, the committee recommended that the proposed amendment is to incorporate the SEC recommendations made in last meeting, and hence, on deliberation, the committee recommended for approval of the proposed protocol amendment.</p>
<b>Medical Device Division</b>			

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11.	MD/Post Appr/2021/5555  Neurovascular Stent (Credo Stent)	M/s.Morulaa Health Tech Pvt.Ltd	<p>The firm presented their proposal for post approval change in indication before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit following information for review by the committee:</p> <ol style="list-style-type: none"> <li>1. Post market surveillance follow up of the 710 patients who have been implanted in Europe.</li> <li>2. Regulatory approval certificate in United Kingdom (UK) issued by MHRA.</li> <li>3. Post market surveillance study generated by the manufacturer in India for existing approved indication of the proposed product.</li> <li>4. Copy of regulatory and marketing approval for new indication from country of origin.</li> </ol>
<b>BA/BE Division</b>			
12.	12-09/2021/BA- BE/Misc-24/DC  AV104 (Nalmefene) buccal film 2mg	M/s. CBCC Global Research LLP	<p>The firm presented the proposal along with BE study protocol of AV104 (Nalmefene) buccal film 2mg.</p> <p>After detailed deliberation, the committee recommended to refer the proposal to Gastroenterology and Hepatology SEC meeting.</p>