

**Recommendations of the SEC (Neurology & Psychiatry) made in its 72<sup>nd</sup> meeting held on 15.09.2021 at CDSCO HQ New Delhi:**

<b>Agenda No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendation</b>
<b>New Drugs Division</b>			
1.	12-04/19-DC  2'O-Methyl Phosphothioate antisense OligoRibonucleotide	Dystrophy Anihilation Research Trust	The firm presented their proposal for amendment in the protocol.  The committee after detailed deliberation recommended for approval of the proposed amendment.
<b>SND Division</b>			
2.	SND/MA/20/000351  Naltrexone Decanaote Sustained Release Injection 190mg/ml	M/s. Rusan Pharma	The firm has presented the proposal of manufacture and marketing of Naltrexone Decanaote Sustained Release Injection 190mg/ml requesting local clinical trial and BE study waiver.  The committee noted that the proposed injectable dosage form is different from the dosage form which is approved internationally.  After detailed deliberation the committee recommended that the firm should conduct Phase III clinical trial for assessing the safety and efficacy and also assess the pharmacokinetics of the drug product as part of the Phase II clinical trial. Accordingly, the firm should submit the study protocol for review by the committee.
3.	SND/MA/20/000368  Midazolam Nasal Spray 0.5% w/v & 1.25% w/v	M/s Biodeal Pharmaceuticals	In light of recommendations of the earlier committee meeting held on 16.04.2021, the firm presented their justification along with published literature.  After detailed deliberation the committee recommended that the firm should conduct BE study in comparison with the reference product approved internationally. Accordingly, the firm should submit the BE study protocol for review by the committee.
<b>FDC Division</b>			

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4.	FDC/MA/21/0000191  Pyridoxine HCl 3mg+ Folic acid 5mg +Vitamin D3 1000IU IP + Methylcobalamin 1500 mcg mouth dissolving tablets.	M/s. Unison	<p>The firm presented their proposal before the committee. After detailed deliberation, the committee noted that;</p> <ol style="list-style-type: none"> <li>1. The firm did not present any rationale/ published literature on proposed FDC for diabetic neuropathy.</li> <li>2. Standard treatment guidelines do not recommend the proposed FDC for use in diabetic neuropathy.</li> <li>3. The firm did not present any evidence w.r.t role of each of the ingredients for proposed indication.</li> </ol> <p>In view of above, the committee recommended that the firm should initially submit justification above points for further review by the committee.</p>
<b>GCT Division</b>			
5.	CT/59/21 (12286) Online Submission (25820) Dated 27/05/21  BAF312	M/s. Novartis	<p>The firm presented their justification for waiver of condition for already approved protocol.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation dated 22.06.2021 with conditions as specified in the CTNOC.</p>
6.	CT/62/21 Online Submission (26129) dated 02/06/21  Varespladib Methyl	M/s. Premier Research	<p>The firm presented their proposal for conducting Phase-II clinical trial.</p> <p><b>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 of a multiple-dose regimen of oral Varespladib-Methyl with standard of care (SOC) in subjects after venomous snakebite.</p> <p><b>Unmet medical need in the country-</b> The test drug used for treatment of snakebite envenoming in conjunction with standard of care. After detailed deliberation the committee recommended for grant of</p>

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			<p>permission to conduct the proposed study with following conditions-</p> <ol style="list-style-type: none"> <li>1. In the Clinical trial title “ placebo controlled” should be Changed to “ Placebo-Controlled Add-On therapy.”</li> <li>2. Composite outcome in respiratory paralysis, acute renal failure major thrombotic events, and death should also be part of the primary end point.</li> </ol>
<b>Medical Device Division</b>			
7.	CI/MD/2021/40587  Sensor Evaluation of Neurologic Status in Emergencies	M/s. Pat Pharma Consultants India Private Ltd	<p>The firm presented their proposal for pivotal clinical investigation before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the pivotal clinical investigation of the proposed product in the country.</p>

