

Recommendations of the SEC (Neurology & Psychiatry) made in its 82nd meeting held on 21.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25 % w/v	M/s Savi Health	The firm didn't turn up for presentation.
2.	SND/MA/21/000490 Rizatriptan Benzoate Orally Disintegrating Tablets 5mg	M/s. Cipla Limited	The firm presented the proposal for manufacturing and marketing of Rizatriptan Benzoate Orally Disintegrating Tablets 5mg along with BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study However the committee recommended to reduce sampling time points and blood volume during the study. The firm should submit the revised protocol to CDSCO.
FDC Division			
3.	FDC/MA/21/000277 Alpha Lipoic acid USP 200mg + Mecobalamin IP 1500mcg + Myo-inositol 100mg + Folic acid IP 1.5mg + Pyridoxine Hydrochloride IP 3mg	M/s. Pure & Cure Healthcare Pvt.Ltd.	The proposal was deferred for next SEC meeting.
GCT Division			
4.	CT/44/22 Online Submission (31996) Casimersen (SRP-4045) & Golodirsen (SRP-4053)	M/s. PPD	The firm presented the proposed phase 3 trial protocol no. 4045-301, version 12 (amendment 11) dated 14May2021 (ESSENCE) before the committee. Risk versus benefit- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. Innovation vis-a-vis existing therapeutic- The primary objective of this study is to evaluate the effect of SRP-

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			<p>4045 and SRP-4053 (Combined-active group) compared with placebo on ambulation, endurance and muscle function as measured by the 6-minute walk test (6MWT).</p> <p>Unmet medical need-The Investigational drugs may be useful in the treatment of patients with specific Duchenne Muscular Dystrophy genotypes.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions:</p> <ol style="list-style-type: none"> 1) Trial subjects number to be up to 20 from India. 2) Post trial access should be provided to the trial subjects as per the provisions of New Drugs and Clinical Trial Rules, 2019.
5.	<p>CT/45/22 Online Submission (31977)</p> <p>Eteplirsen</p>	M/s. PPD	<p>The firm presented the proposed Phase 3b trial protocol no. 4658-402, version 08 dated 18 Jun 2021 (MIS51ON) before the committee.</p> <p>Risk versus benefit- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-a-vis existing therapeutic-The objective of this study is evaluate the safety and efficacy of a high dose of Eteplirsen in Duchenne Muscular Dystrophy with Deletion Mutations Amenable to Exon 51 Skipping.</p> <p>Unmet medical need-The investigational drugs may be useful in the treatment of patients with Duchenne Muscular Dystrophy with Deletion Mutations Amenable to Exon 51 Skipping.</p> <p>The committee noted that the Part 2 of the proposed Phase 3b trial will be conducted in India with proposed 46 subjects as part of global trial.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions:</p> <ol style="list-style-type: none"> 1) The applicant should develop safety

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			management plan and implement it across all the sites. 2) Post trial access should be provided to the trial subjects as per the provisions of New Drugs and Clinical Trial Rules, 2019.
6.	CT/62/21 Online Submission (17611) Dated 05/05/2022 Varespladib Methyl	M/s. Premier Research Group	The firm presented the proposed amendment in the Phase II trial protocol no.: OPX-PR-01 (BRAVO Study) vide Amendment Version 3.1, dated 03-May-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with condition that the applicant should submit application for the increase in recruitment number of Indian subjects from 50 to 73, as initial CTNOC was granted with 50 subjects from India.
7.	CT/179/21 Online Submission (16918) Dated 01/04/22 SAR442168 Tolibrutinib	M/s. Sanofi Healthcare	The proposal was deferred for next SEC meeting.
Additional Proposal –New Drug Division			
8.	ND/MA/22/000079 Etifoxine hydrochloride capsules 50 mg	M/s. Sun Pharma	The firm presented their proposal of manufacturing and marketing of Etifoxine hydrochloride capsules 50 mg along with BE study results and Phase III clinical trial protocol. After detailed deliberation, the committee recommended that the protocol should be amended with respect to the following: 1. Inclusion and exclusion criteria should be amended. Only patients with generalized anxiety disorder are included. All other anxiety disorders are excluded. 2. Detailed assessment for cognitive effects to be included. Accordingly, the firm should submit a revised protocol to CDSCO for further review by the committee.