Recommendations of the SEC (Neurology & Psychiatry) made in its 73rd meeting held on 14.10.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1	12-01/18-DC (Pt.337) Lamotrigine induced TEN/SJS	PvPI, IPC	The recommendation of the PvPI was discussed. After detailed deliberation the committee recommended that CDSCO may request the State Drugs Controllers to direct the manufacturers of the drug to incorporate lamotrigine induced TEN/SJS in the PIL of the drug.
SND Division			
2	SND/CT/21/0000081 Edaravone Oral Suspension 150mg (30mg/ml)	M/s BDR Pharma	Earlier the proposal was deliberated in SEC (Cardiovascular & Renal) meeting dated 08.10.2021. After detailed deliberation the committee recommended that the proposal to be deliberate in SEC (Neurology & Psychiatry). The firm has presented their proposal for permission to conduct Bioavailability Study of Edaravone oral suspension 150 mg (30 mg/ml) under fasting conditions. After detailed deliberation the committee recommended for the grant of permission to conduct the bioavailability study for Edaravone oral suspension 150 mg (30 mg/ml) under fasting conditions as per the protocol presented.
3	SND/MA/21/000078 Clobazam Mouth Dissolving Tablet 2.5 mg	M/s. Pure & Cure Healthcare	Earlier the proposal of the firm was deliberated in 69th SEC (Neurology & Psychiatry) meeting held on 22.06.2021 and the committee recommended for grant of permission for conduct of the BE study. The firm presented the BE study report before the committee for approval of Clobazam Mouth Dissolving Tablet 2.5 mg. After detailed deliberation the committee recommended for grant of permission for manufacturing and marketing of Clobazam Mouth Dissolving Tablet 2.5 mg indicated as an adjunctive therapy in patients with refractory epilepsy.
FDC Division			
4	FDC/MA/21/000107 Pregabalin + Duloxetine (75 mg +	M/s. Torrent Pharmaceuticals	Inlight of earlier SEC recommendation dated 17.08.2021, the firm presented their proposal alongwith the detailed safety

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	20 mg, 50 mg + 20 mg & 75 mg + 30 mg) capsules		data. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
GCT Division			
5	CT/57/20 Online Submission (11333) Evobrutinib	M/s. IQVIA	The firm presented the proposed protocol amendment Version 2.0 dated 09-Dec-2020 before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the study as per the amended protocol presented.
6	CT/83/20 Online Submission (11990) Inebilizumab	M/s. Medpace	The firm presented the proposed protocol amendment Version 5.0 dated 23-Apr-2021 before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the study as per the amended protocol presented.
7	CT/116/21 Online Submission (28116) OAV101	M/s. Novartis	The firm presented their Phase III clinical trial proposal before the committee. **Assessment of Risk versus benefit to the patients-**The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** To evaluate the efficacy and safety of intrathecal (IT) OAV101 in patients with later onset Type 2 spinal muscular atrophy (SMA) who are ≥ 2 to < 18 years of age, treatment naive, sitting, and never ambulatory **Unmet medical need in the country-** The test drug used for treatment of later onset Type 2 spinal muscular atrophy (SMA) who are ≥ 2 to < 18 years of age, treatment naive, sitting, and never ambulatory. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the firm need to submit six month DSMB interim safety report.
8	CT/03/19 Online Submission (12327) Phenobarbital Sodium	M/s. CBCC	The firm presented the proposed protocol amendment to protocol no. CBCC/2018/006, Version 8.0 dated 29-Jul-2021 before the Committee. After detailed deliberation, the Committee recommended for grant of

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			permission to conduct the study as per the amended protocol presented.
Medical Device Division			
9	MD/Post Appr/2021/5555 Neurovascular Stent (Credo Stent)	M/s. Morulaa Health Tech Pvt Ltd	The firm did not turn up for the presentation