Recommendations of the SEC (Neurology & Psychiatry) made in its 93rd meeting held on 13.06.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/ 000086 Lumateperone Capsules 42mg	M/s. Sun Pharma Laboratories Limited	The firm presented the proposal of manufacturing and marketing of Lumateperone capsule 42mg along with the results of bioequivalence studies and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial as per the protocol presented by the firm subject to the condition that the firm should revise the protocol with respect to the inclusion criteria to enroll patients with upper age limit up to 65 years instead of 75 years.
SND Division			
2.	SND/MA/23/ 000126 Vigabatrin Powder for oral solution USP 250mg/Sachet	M/s. MSN Laboratories Pvt. Ltd.	The firm presented the proposal for manufacturing and marketing of Vigabatrin powder for oral solution USP- 250mg/sachet for already approved indication along with therapeutic rationale and BE study/clinical trial waiver justifications, before the committee. The committee noted that the higher strength of Vigabatrin powder for oral solution USP 500mg/sachet is already approved in India for following indication: 1. "For the treatment of refractory complex partial seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; Vigabatrin powder for oral Solution, USP, 500 mg is not indicated as a first line agent". 2. "Infantile spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss" The committee considered BE study/clinical trial waiver based on justification presented by the firm. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Vigabatrin powder for oral solution USP 250mg/sachet for already approved indication.

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3.	SND/MA/22/ 000232 Nicotine Pouch 4mg and 6 mg	M/s. Leaf Fibre Pvt. Ltd.	The firm didn`t turn up for presentation.
4.	SND/MA/20/ 000368 Midazolam Nasal Spray 0.5 %w/v & 1.25% w/v	M/s. Biodeal Pharmaceuticals	In light of earlier SEC recommendation dated 16.12.2022, the firm presented the proposal for manufacturing and marketing permission of Midazolam nasal spray 0.5%w/v & 1.25%w/v for already approved indication along with comparative in-vitro study data with innovator's product, before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Midazolam nasal spray 0.5%w/v & 1.25%w/v for already approved indication subject to condition that the firm should conduct Phase IV clinical trial with minimum 500 patients. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of manufacturing and marketing permission.
5.	SND/MA/22/ 000052 Midazolam Nasal Spray 0.5%w/v & 1.25% w/v	M/s. Savi Health Science	In light of earlier SEC recommendation dated 16.12.2022, the firm presented the proposal for manufacturing and marketing permission of Midazolam nasal spray 0.5%w/v & 1.25%w/v for already approved indication along with comparative in-vitro study data with innovator product, before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Midazolam nasal spray 0.5%w/v & 1.25%w/v for already approved indication subject to condition that the firm should conduct Phase IV clinical trial with minimum 500 patients. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of manufacturing and marketing permission.
6.	SND/MA/22/ 000068 Ketamine Hydrochloride	M/s. Themis Medicare Ltd.	In light of earlier SEC recommendation dated 18.04.2023, the firm presented the modified protocol for Phase III clinical trial with the relevant publication for proposed indication, before the committee.

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	Injection 50 mg/ml		After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm.
7.	SND/MA/22/ 000052 Gabapentin ER tablets 300mg/600mg	M/s. Sun Pharma Laboratories	The firm presented the proposal for grant of manufacturing and marketing permission of Gabapentin ER tablets 300mg/600mg for the treatment of neuropathic pain as an additional indication along with the clinical trial waiver justification and clinical trial data of other countries, before the committee. The committee noted that the product is already approved in India and USA and firm is also holding manufacturing and marketing permission of Gabapentin ER tablets 300mg/600mg for the management of post-herpetic neuralgia. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Gabapentin ER tablets 300mg/600mg for the treatment of neuropathic pain as an additional Indication.
8.	SND/MA/23/ 000136 Vigabatrin tablets 250/500 mg	M/s. MSN Laboratories Pvt. Ltd.	The firm didn`t turn up for presentation.
9.	SND/CT/22/ 000052 Pregabalin Gel 8% w/w	M/s. Lyka Labs Limited	In light of earlier SEC recommendation dated 18.04.2023, the firm presented the revised protocol for Phase III clinical trial w.r.t study design, primary end point and sample size, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm.
10.	SND/MA/22/ 000227 Edaravone Powder for oral Suspension 105 mg in sachet	M/s BDR Pharmaceuticals International Pvt. Ltd.	The firm presented the proposal for grant of manufacturing and marketing permission of Edaravone powder for oral suspension 105mg in sachet (1.5gm) for the indication as “For the treatment of amyotrophic lateral sclerosis (ALS)” along with BE study report, before the committee. The committee noted that Edaravone oral suspension 105mg/5ml in a multidose amber glass bottle is already approved by USFDA on

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			12.05.2022 for the proposed indication. After detailed deliberation, the committee recommended for grant of manufacturing and marketing permission of Edaravone powder for oral suspension 105mg in sachet (1.5gm) for the proposed indication subject to condition that the firm should conduct PMS study. Accordingly, firm should submit PMS study protocol to CDSCO within 3 months of manufacture and marketing permission of the drug.
FDC Division			
11.	4-91/2017(Pt. 01) Gabapentin 6.0%w/w USP + Lidocaine HCl 5.0%w/w IP eq. to Lidocaine cream	M/s. Akums drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 16.12.2022, the firm presented the revised Phase III clinical trial protocol w.r.t changes made in exclusion criteria, sample size, rescue medication etc. before the committee. After detailed deliberation, the committee recommended that firm should present the comparative chart before the committee for review after incorporating the said points in the revised protocol.
12.	04-1827/2015-DC (PSC-Synokem) Gabapentine 300mg/400mg + Nortriptyline 5mg/10mg Tablet	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
13.	FDC/MA/23/ 000131 Pregabalin ER 82.5mg I.P. + Polmacoxib 2mg Tablet	M/s. Hetero Labs Limited.	The proposal was deferred for next meeting.
GCT Division			
14.	CT/26/23 Online Submission (36640) Divozilimab	M/s. Invitro Research Solution Pvt. Ltd.	The proposal was deferred for next meeting.
15.	CT/03/20 Online Submission (22774) Evenamide	M/s. CliniRx	The proposal was deferred for next meeting.

SEC (Neurology & Psychiatry) meeting dated 13.06.2023

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16.	CT/57/20 Online Submission (24126) Evobrutinib	M/s. IQVIA	The proposal was deferred for next meeting.
17.	CT/116/21 Online Submission (24608) OAV101	M/s. Novartis Healthcare Private Limited	The proposal was deferred for next meeting.
18.	CT/120/22 Online Submission (34243) CUD-1905	M/s. Cliantha	The proposal was deferred for next meeting.