Recommendations of the SEC (Neurology & Psychiatry) made in its 92nd meeting held on 17.05.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000087 Sumatriptan Nasal Spray 10 mg/0.1 ml	M/s. Dr. Reddy's Labs Limited.	The firm presented the proposal for manufacturing and marketing of Sumatriptan Nasal Spray 10 mg/0.1 ml for the indication "for the acute treatment of migraine attacks with or without aura along with results of BE Study and multicentric efficacy study conducted in USA. The firm also requested for local clinical trial waiver. The committee noted that the Sumatriptan Nasal Spray 5mg and 20mg per actuation are already approved in India by CDSCO. Also, the Sumatriptan Nasal Spray 10mg/0.1ml of Dr. Reddy's Lab is approved in USFDA. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Sumatriptan Nasal Spray 10mg/0.1ml for the indication "for the acute treatment of migraine attacks with or without aura".
2.	SND/MA/22/000232 Nicotine Pouch 4mg and 6mg	M/s. Leaf FiberPvt. Ltd.	The firm didn`t turn up for presentation.
FDC Division			
3.	FDC/MA/23/000108 Gabapentin 200mg/300mg+ Duloxetine HCl 20mg/30mg Hard Gelatin Capsules	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the proposal along with BE study protocol and also requested for deliberation of Phase III clinical trial study protocol before the committee. After detailed deliberation, the committee recommended that firm should justify following points before presenting the protocol: 1. The firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration along with dosing schedule. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support of combining the two drugs in this FDC.

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			In view of above, firm should submit the said justification/documents to CDSCO for review by the committee.
GCT Division			
4.	CT/115/22 Online Submission (34193) Fenebrutinib Compared with Ocrelizumab	M/s. Roche	The firm has withdrawn the proposal.
5.	CT/178/21 Online Submission (21177) SAR442168	M/s. Sanofi	The firm presented protocol amendments for protocol number- EFC16035, version -04, 06, 07, 08, 09 & 10 before the committee. After detailed deliberation, the committee recommended protocol amendments as presented.
6.	CT/58/20 Online Submission (24007) Evobrutinib	M/s. IQVIA	The firm presented protocol amendment-MS200527_0080 Version- 5.0 dated 06-Dec-2022 before the committee. After detailed deliberation, the committee recommended to approve the presented protocol amendment.
7.	CT/83/20 Online Submission (24648) Inebilizumab	M/s. Medpace	The firm presented current update on study and protocol amendment-VIB0551.P3.S1 version- 6.1 dated 07-Jan-2023 before the committee. After detailed deliberation, the committee recommended to approve the protocol amendment as presented. (Dr. Sunil Narayan didn't participate in the deliberation.)
Medical Device Division			
8.	IMP/MD/2023/79104 DuraSeal Dural Sealant System & DuraSealXact Sealant System	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal for grant of permission to import and market the proposed products DuraSeal Dural Sealant System & DuraSeal Xact Sealant System in the country before the committee. During the presentation, the committee noted the published clinical data, post marketing surveillance data & regulatory

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			status of the proposed products worldwide (approved in more than 70 countries). After detailed deliberation, the committee recommended for grant of permission for import and market of the proposed products DuraSeal Dural Sealant System & DuraSeal Xact Sealant System in the country with the condition that comments should be obtained from neurosurgeon before issuing of permission. Further, the firm should conduct post marketing clinical investigation of the proposed product in the country on Indian population. Accordingly, the firm should submit post marketing clinical investigation protocol to CDSCO for further review by the committee.
9.	CI/MD/2023/87197 Nerivio	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal for grant of permission for conduct of pivotal clinical investigation of the proposed product Nerivio in the country before the committee. The committee observed that proposed study protocol is single arm study to be conducted on 60 patients at 5 private institutes in India. After detailed deliberation, the committee recommended that the study should be under a scientifically robust, well-designed protocol with statistically validated sample size. Accordingly, the firm should submit revised protocol for further review by the committee.