Recommendations of the SEC (Neurology & Psychiatry) made in its 81th meeting held on 21.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18-DC(Pt 337) Olanzapine associated Hyponatraemia	NCC-PvPI, IPC Ghaziabad	The SRP recommendation was appraised before the committee. After detailed deliberation the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include ADR of Olanzapine associated Hyponatraemia in the package insert of the drug marketed in the country.
2.	12-01/18-DC(Pt 337) Haloperidol associated cogwheel rigidity	NCC-PvPI, IPC Ghaziabad	The SRP recommendation was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include ADR of Haloperidol associated cogwheel rigidity in the package insert of the drug marketed in the country.
3.	12-01/20-DC Glutathione Supplement	M/s. National Brain Research Center	The Principal Investigator presented their proposal to conduct academic clinical trial with drug Glutathione Supplement before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the academic clinical trial as presented by the applicant.
SND Division			
4.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25 % w/v	M/s. Savi Health	The firm did not turn up for presentation.
5.	SND/MA/22/000163 Buprenorphine Sublingual film 4 mg/6mg/8mg	M/s. Zim Laboratories Ltd.	The firm presented the proposal for manufacturing and marketing of Buprenorphine Sublingual film 4 mg/6mg/8mg. The firm presented the results of BE study conducted on Buprenorphine Sublingual film 8mg. After detailed deliberation,the committee recommended for conduct of phase III clinical trial accordingly protocol should be submitted to CDSCO for further review by the committee.

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6.	SND/MA/22/000164 Perampanel oral suspension 0.5 mg/ml	M/s. Alkem Laboratories Ltd.	The firm presented the proposal for manufacturing and marketing of Perampanel oral suspension 0.5 mg/ml along with BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct BE study as per proposed protocol. The result of Bioequivalence study should be submitted to CDSCO for further review by the committee.
FDC Division			
7.	FDC/MA/21/000277 Alpha Lipoic acid USP 200mg + Mecobalamin IP 1500mcg + Myo-inositol 100mg + Folic acid IP 1.5mg + Pyridoxine Hydrochloride IP 3mg Chromium Picolinate eq. to Chromium USP 200mg + Benfotiamine 200mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 18.01.2022, the firm presented their proposal before the committee along with justification for Phase III CT waiver. After detailed deliberation, the committee recommended that firm should present BE study protocol before the committee for further consideration.
8.	FDC/MA/20/000190 Nortriptyline HCl eq to Nortriptyline 10mg/10mg + Gabapentin 100mg/200mg	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 16.04.2021, the firm presented their proposal before the committee along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC with the condition that firm should conduct Phase IV CT. Accordingly, the firm should submit the protocol to CDSCO within 03 months from the date of approval of drug for review by the committee.
9.	FDC/MA/21/000108 Nortriptyline HCl eq to Nortriptyline 10mg + Gabapentin 200mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 18.01.2022, the firm presented their proposal before the committee along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC with the condition that firm should conduct Phase IV CT.

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			Accordingly, the firm should submit the protocol to CDSCO within 03 months from the date of approval of drug for review by the committee.
GCT Division			
10.	CT/03/19 Online Submission (16544) Phenobarbital Sodium for Injection	M/s. CBCC Global Research	The applicant presented protocol amendment version 9.0 dated 10/02/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment version 9.0 dated 10/02/2022 with condition that only 140 subjects should be enrolled from India in the study.
Medical Device Division			
11.	CI/MD/2022/57125 MRI Equipment	M/s. Wipro GE Healthcare Private Limited	The firm presented their proposal for pilot clinical investigation of the proposed product before the committee. After detailed deliberation the committee recommended that protocol should be amended with respect to following: 1. Portability word needs to be removed from the protocol. 2. Sample size should be increased to 2000. 3. The firm needs to include government laboratory/hospitals as clinical investigation sites. 4. Study design & analytical plan have to be clearly defined & needs to be included in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.