Recommendations of the SEC (Neurology & Psychiatry) made in its 99th meeting held on 12.12.2023 & 13.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000078 Aripiprazole Oral Solution 1 mg/ml	M/s. Pulse Pharma Limited	The firm presented their proposal for grant of permission for manufacturing and marketing of Aripiprazole Oral Solution 1mg/ml indicated for Schizophrenia with a request for Bio-waiver. After detailed deliberation, the committee opined that the firm's request for bio-waiver can not be considered and firm shall conduct Bioequivalence study with the innovator product approved in EU / USA. Accordingly, firm needs to submit BE study protocol for further review and deliberation.
2.	SND/MA/23/000216 Cariprazine Capsules 0.75 mg	M/s. Mascot Healthseries Private Limited	The firm presented their proposal for grant of permission for manufacturing and marketing Cariprazine Capsules 0.75mg indicated for the treatment of Schizophrenia in adults and acute treatment of manic or mixed episodes associated with Bipolar I disorder in adults with a request for BE & CT waiver. It is informed by the firm that they had already been granted approval for higher strength of Cariprazine Capsules – 1.5mg/3mg/4.5mg/6mg) and the proposed lower strength of 0.75mg is not approved anywhere in the world. After detailed deliberation, the committee opined that a scientific rationale of proposed lower strength to achieve the efficacy is required to be submitted along with the PMS data of already approved strength of 1.5mg, 3mg, 4.5mg & 6mg of Cariprazine capsules. Accordingly, firm needs to submit the requisite information for further review and deliberation.

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3.	SND/MA/20/000368 Midazolam Nasal Spray 0.5% w/v & 1.25% w/v	M/s. Biodeal Pharma	In light of earlier SEC recommendation dated 13/09/2023, the firm presented published clinical trials data on Indian population and stated that intra-nasal preparations are effective in proposed indication. Firm stated that the said formulation – Midazolam Nasal Spray with different concentrations 2.5mg, 3.75mg & 5mg are approved by Ministry of Health, Netherlands and the concentration of 5mg/spray is approved by US-FDA as a single dose formulation. Therefore, considering the pharmacokinetics, posology and method of administration of the drug product, they have designed and formulated their product in multi dose with low concentration (the dose may be optimized from 0.5mg to any higher concentration) for optimum use and benefit to Indian population. After detailed deliberation, the committee opined that the firm needs to submit comparative physicochemical data which shall be certified by an accredited lab for the proposed formulation of Midazolam nasal spray 0.5%w/v & 1.25%w/v (multidose nasal spray), for further review by the committee.
4.	SND/MA/22/000238 Caroverine Capsules 40 mg (Additional strength)	M/s. Lincoln Pharmaceuticals Ltd.	In light of earlier recommendation of SEC dated 15/02/2023, the firm presented the BE study report of Caroverine Capsules 40mg (additional strength) with a request for CT waiver. After detailed deliberation, the committee observed that the proposed higher strength is not approved anywhere in the world and opined that the firm is required to submit a therapeutic justification and clinical relevance of higher strength Caroverine Capsules 40mg alongwith Phase-III clinical trials protocol for further review of committee.

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FDC Division			
5.	FDC/MA/23/000328 Gabapentin (as Sustained release) IP + Methycobalamin IP + Nortriptyline Hydrochloride IP eq. to Nortriptyline (300mg+1.5mg+10mg , 400mg+1.5mg+10mg, 600mg+1.5mg+10mg) Film coated Tablet	M/s. Theon Pharmaceuticals Ltd.	The firm presented the proposal for FDC in three strengths i.e. Gabapentin IP (SR) +Methylcobalamin IP + Nortriptyline Hydrochloride IP eq. to Nortriptyline (300mg+1.5mg+10mg,400mg+1.5mg+10 mg, 600mg+1.5mg+10mg)film coated tablet along with BE study protocol before the committee. After detailed deliberation, the committee considered the FDC in two strengths i.e. Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (300mg+1.5mg+10mg,600mg+1.5mg+10 mg)film coated tablet and recommended for grant of permission to conduct BE study as per presented BE protocol. Accordingly, the result of BE study should be presented for review by the SEC along with Phase III CT protocol. Further regarding FDC of Gabapentin IP (SR) +Methylcobalamin IP + Nortriptyline Hydrochloride IP eq. to Nortriptyline (400mg+1.5mg+10mg) film coated tablet, committee noted the following: 1. The firm did not present any published literature in support of significant clinical need for the proposed strengths of the FDC. 2. The firm did not present the justification on dose titration with recent supporting document/ literature. 3. Dosing schedule of the proposed strength of FDC is not matching. In view of above, the firm should submit above data to CDSCO for further review by the committee.
6.	FDC/MA/23/000347 Gabapentin IP 300mg/400mg +	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal before the committee.

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	Mecobalamin IP 500mcg/500mcg + Nortriptyline Hydrochloride IP eq. to Nortriptyline 10mg/10mg film coated tablet		After detailed deliberation, the committee opined the following: 1. The firm should present the justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature in support of significant clinical need for the proposed strengths of the FDC in immediate release form. 3. The firm did not present the justification on dose titration with recent supporting document/ literature. 4. Dosing schedule of the proposed strength of FDC is not matching. Accordingly, the firm should submit above data for further review by the committee.
GCT Division			
7.	CT/122/20 Online Submission (25131) LY2951742 (Galcanezumab)	M/s. Eli Lilly	The firm presented increase in number of patients in India from 30 to 50, Protocol no. 15Q-MC-CGAS. After detailed deliberation, the committee recommended for approval to increase in number of patients in the trial in India from 30 to 50 as presented by the firm.
8.	CT/123/20 Online Submission (25133)Galcanezumab	M/s. Eli Lilly	The firm presented Increase in number of patients in India from 40 to 55, Protocol no. 15Q-MC-CGAT. After detailed deliberation, the committee recommended for approval to Increase in number of patients in the trial in India from 40 to 55 as presented by the firm.
9.	CT/175/21 Online Submission (26712) LOU064 (Remibrutinib)	M/s. Novartis	The firm did not turn up for presentation.
10.	CT/58/20 Online Submission(28265)	M/s. IQVIA RDS	The firm presented protocol amendment version 6.0 dated 27 April 2023, the protocol no. MS200527_0082.

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	Evobrutinib		After detailed deliberation, the committee recommended for approval of Protocol amendment as Presented by the firm
11.	CT/121/23 Online Submission (39791) Vidofludimus Calcium	M/s. Worldwide Clinical Trials	The firm didn't turn up for presentation.
12.	CT/117/23 Online Submission (39645) IMU-838-RC Tablets (Vidofludimus Calcium Tablets)	M/s. Worldwide Clinical Trials	The firm didn't turn up for presentation.
13.	CT/92/23 Online Submission (38775) BAY 2433334 (Asundexian) 50mg tablets	M/s. Bayer Pharmaceuticals	The firm presented Phase III Clinical study protocol no. 20604. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that clarity on PFO and arterial episodes findings in Echo as embolic or non embolic shall be mentioned in inclusion criteria.
14.	CT/89/18 Online Submission (26249) Ofatumumab	M/s. Novartis	The firm presented protocol amendment version 03 dated 13 April 2023, Protocol no. COMB157G2399. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
15.	CT/182/22 Online Submission (28008) Ocrelizumab (RO4964913)	M/s. PPD	The firm presented protocol amendment version 04 dated 28 March 2023, Protocol no. WN42086. After detailed deliberation, the committee recommended for approval of the protocol amendment as Presented by the firm.
16.	CT/116/21 Online Submission (28551) OAV101	M/s. Novartis	The firm did not turn up for presentation.
17.	CT/116/22 Online Submission (28267) NOE 101	M/s. Clinirx Research Pvt. Ltd	The firm presented DSMB Interim Report dated 21 August 2023, Protocol no. NOE-TSC-201.

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			After detailed deliberation, the committee accepted DSMB Interim Safety Report as presented by the firm.
BA/BE Division			
18.	File No. 12-09/ 2023 /BA-BE/MISC-32/DC (BABE/CT05/FF/2023/38794) Carbidopa + Levodopa Extended-Release Capsules 87.5 mg/350 mg	M/s. Alembic Pharmaceuticals Limited Vadodara.	The firm presented their proposal along with the BE Study protocol for export purpose only. After deliberation, the committee recommended for BA/BE study for export purpose only.
19.	File No. 12-09/ 2023 /BA-BE/ MISC-23/DC (BABE/CT05/FF/2023/37922) Carbidopa and Levodopa Controlled Release Tablets 62.5mg/250mg	M/s. Cliantha Research Limited, Ahmedabad.	The firm presented their proposal along with the BE Study protocol for export purpose only. After deliberation, the committee noted that already Carbidopa and Levodopa Sustained Release Tablets (Sinemet) 50 mg/200 mg is available in market hence reasonable scientific justification submitted by the firm is not adequate and further it does not help unmet need of immediate release in the early morning. Therefore, the committee did not recommend for approval of the proposed study protocol.
20.	File No. 12-09/2023/ BA-BE/MISC-29/DC (BABE/CT05/FF/2023/38728) Lithium Carbonate Extended Release Tablets 900 mg	M/s. Veeda Clinical Research Limited Ahmedabad-380015	The firm presented their proposal along with the BE Study protocol for export purpose only. After deliberation, the committee recommended for permission to conduct the BA/BE study (for export purpose only) with a condition to submit safety and tolerability data to the DCG(I) office after completion of the study, as the IP, Lithium Carbonate Extended Release Tablets 900 mg is not approved globally.
New Drugs Division			
21.	ND/MA/22/000079 Etifoxine hydrochloride capsules 50 mg	M/s Sun Pharmaceutical Industries Limited	The firm presented Phase-III Clinical Trial Report of drug Etifoxine HCl Capsule 50 mg for the purpose of grant of manufacture & market permission in the country. After detailed deliberation the committee recommended for grant of permission to manufacture & market Etifoxine HCl

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			Capsule 50 mg for generalized anxiety disorder with somatic symptoms. The firm should conduct the PMS study with primary objective of evaluating the drug dependence on Indian subjects.