Meeting of Subject Experts Committee 47th SEC (Neurology and Psychiatry) held on 15.05.2019 to review proposals and advice Drugs Controller General (India) {DCG (I)} in matters for New Drugs & Clinical Trials

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1	SND/MA/19/000040 Tofisopam tablet 50mg/100mg (Add. Indication)	M/s Acme Pharmaceuticals Pvt. Ltd	Firm presented the proposal for additional indication of Tofisopam tablet 50mg/100mg. After detailed deliberation committee noted that scientific evidence presented was not sufficient. The firm should submit adequate clinical trial data in support of their proposal for review by the committee.
GCT Division			
2	CT/14/18 Paliperidone	J&J	Firm presented their proposal for approval of Protocol amendment 3 dated 11-Feb-19. After detailed deliberation committee recommended for approval of the proposed amendment.
3	CT/31/19 Evenamide (NW-3509	CliniRx	Applicant presented their proposal along with study protocol before the committee. **Assessment of risk versus benefit to the patients-** The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** Efficacy, Safety, and Tolerability of add-on Treatment with Evenamide or Placebo in patients with Treatment-Resistant Schizophrenia (TRS) not Responding Adequately to Stable Therapeutic Plasma Levels of Clozapine. **Unmet medical need in the country-** To develop alternative, safe and efficacious treatment in treatment-resistant schizophrenia (TRS). After detailed deliberation the committee recommended for grant of permission to conduct the study.
4	CT/32/19 Evenamide (NW-3509	CliniRx	Applicant presented their proposal along with study protocol 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 of three fixed doses (7.5, 15 and 30 mg bid) of evenamide, compared to placebo, based on improvement

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			in symptoms of schizophrenia, as assessed by the change from baseline to endpoint (Day 43 or early discontinuation) on the total score on the Positive and Negative Syndrome Scale (PANSS). **Unmet medical need in the country-** The test drug used for treatment established schizophrenia not responding adequately to a stable therapeutic dose of their current single atypical antipsychotic medication. After detailed deliberation the committee recommended for grant of permission to conduct the study.
Medical Device Division			
5	29/Misc/0 3/2018-DC (366) Nuprep and Ten20	M/s Kardiosurgicare	The firm presented details about the product which is mild abrasive gel used during measurement of electrical activity by putting an array of electrodes during ECG, EEG etc. The product doesn't have any pharmacological action and may be considered as a medical device.
BABE Division			
6	12-09/2019/BA-BE/Misc-21/DC Paliperidone Palmitate Extended Release -Injectable Suspension 156 mg	M/s. Wockhardt Limited	The firm presented their proposal along with protocol for clinical trial of Paliperidone Palmitate Extended Release -Injectable Suspension 156 mg as equivalence study. After detailed deliberation, committee recommended for grant of permission to conduct the trial.
7	12-09/2019/BA-BE/Misc-27/DC Carbidopa+Levodopa 60 mg/ 240 mg Tablets and Carbidopa+Levodopa 80 mg/320 mg Tablets	M/s. EcronAcunova	Firm didn't turn up for presentation.
New Drug Division			
8	Phenobarbital-SRP Recommendation	NCC-PvPI	The committee deliberated the recommendation of NCC-PvPI & recommended that CDSCO should request all the State Drug Controllers to direct the manufacturers of Phenobarbital formulations to incorporate Phenobarbital associated drug Rash with Eosinophilia & Systemic Symptoms (DRESS) Syndrome in the package insert of their products.