Meeting of Subject Experts Committee 50th SEC (Neurology and Psychiatry) held on 28.08.2019 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
New Drug Division			
1	12-03/2009-DC(Pt IV injection) Lacosamide Injection 10mg/ml	M/s Torrent	Firm presented their proposal before the committee. After detailed deliberation, committee noted gross errors in amendment presented in the phase IV protocol. Committee opined the following suggestions for further review by the committee. : 1. Firm should include Investigators from appropriate epilepsy monitoring units. 2. Firm should provide adequate justification for amendment in the protocol along with inclusion /exclusion criteria.
2	12-01/16-DC (Pt-9 –Torrent/ Paliperidone) Paliperidone ER Tablet 3mg/6mg/9mg	PSC Case	Committee desired that the set of literature prepared by CDSCO should be circulated to the members as well as a summary of the same should be prepared for further deliberation in the next meeting.
3	12-01/12-DC (Pt-9 Sun/Zotepir Zotepine 25mg/50mg/100mg tablets	PSC Case	Committee desired that the set of literature prepared by CDSCO should be circulated to the members as well as a summary of the same should be prepared for further deliberation in the next meeting.
FDC Division			
4	File No. 04-02/2019 (PSC-Theon FDC of Gabapentin 400 mg + Nortriptyline HCL eq. to Nortriptyline 10 mg film coated tablet	M/s Theon Pharmaceuticals	Firm presented their proposal before the committee. After detailed deliberation the committee opined that the firm should make a detailed presentation on the product for further consideration.
5	File no-.4-1962/2015-DC (PSC-Akums FDC of Gabapentin 300mg and Amitriptyline Hydrochloride 10mg tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	Firm did not turn up for presentation.
6	File No.04-54/2019-DC (Pt.1) Sun Pharma FDC of Domperidone Maleate eq to Domperidone IP 10mg/10mg + Naproxen sodium USP 500mg/250mg	M/s Sun Pharma	The committee noted that this FDC is already considered as rational by Sub-committee of DTAB. After detailed deliberation the committee recommended for continued manufacturing and marketing of Proposed FDC.

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	film coated tablet		
7	File No.04-146/2007-DC (Pt.1)-54/2019 (Abbott) Domperidone Maleate eq to Domperidone IP 10mg/10mg + Naproxen sodium USP 500mg/250mg film coated tablet	M/s Abbott	The committee noted that this FDC is already considered as rational by Sub-committee of DTAB. After detailed deliberation the committee recommended for continued manufacturing and marketing of Proposed FDC
8	File No.04-74/2017-DC (Akums) FDC of Domperidone Maleate eq to DomperidoneIP 10mg/10mg + Naproxen sodium USP 500mg/250mg film coated tablet	M/s Akums	The committee noted that this FDC is already considered as rational by Sub-committee of DTAB. After detailed deliberation the committee recommended for continued manufacturing and marketing of Proposed FDC
9	File No.04-146/2007-DC (Pt.1)-46/2019 (Micro) FDC of Pregabalin IP 75mg + Methylcobalamin IP 1500mcg (in tablet form) + (Thioctic acid) Alpha Lipoic acid USP 200mg + Folic acid IP 1.5mg + Pyridoxine HCl IP 3mg capsules	M/s Micro	The committee opined that the concerned manufacturer/firm should make presentation before the committee for further consideration.
10	File No. 04-18/2019-DC(PSC-SUN), 28.08.2019 FDC of Gabapentin + Nortriptyline (300 mg + 10 mg, 400 mg + 10 mg) film coated tablets-	M/s Sun Pharma	Firm presented their proposal before the committee. After detailed deliberation the committee opined that the firm should make a detailed presentation on the product for further consideration.
GCT Division			
11	CT/33/19 Evenamide (NW-3509)	CliniRx	Applicant has presented the proposal along with protocol before the committee. **Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** To evaluate the long-term safety and tolerability of evenamide (7.5, 15 and 30 mg bid), compared to placebo, in patients with schizophrenia on a stable dose of their current atypical antipsychotic medication. **Unmet Medical Need in the country:** The test drug may potentially provide alternate

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			treatment option in patients with 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.
12	CT/34/19 Evenamide (NW-3509)	CliniRx	Applicant has presented the proposal along with protocol before the committee. **Assessment of risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including Single-Dose Toxicity, repeat dose toxicity, Female Reproduction and Development Toxicity Studies, Genotoxicity Phase I & II clinical study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is to determine the long-term efficacy, safety, and tolerability of add-on treatment with evenamide in patients with treatment-resistant schizophrenia (TRS) not responding adequately to clozapine." **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with treatment-resistant schizophrenia (TRS) not responding adequately to clozapine. After detailed deliberation the committee recommended for grant of permission to conduct the study.
SND Division			
13	SND/MA/19/000078 Pregabalin ER Tablet 82.5mg & 165mg (add. Strength)	M/s Intas Pharma Ltd.	Firm presented the proposal for Pregabalin ER Tablet 82.5mg & 165mg (add. Strength) before the committee. After detailed deliberation the committee opined that proposed strength 82.5 and 165mg have shown bioequivalence to the innovator product, committee recommended for grant of permission to manufacture and market of Pregabalin ER Tablet 82.5mg & 165mg (add. lower strength) in adults.
14	SND/MA/19/000085 Clobazam Oral suspension 5mg/5ml & 10mg/5ml (add. Strength)	M/s Tanmed Pharmaceuticals Ltd.	Firm presented the proposal for Clobazam Oral suspension 5mg/5ml & 10mg/5ml (add. Strength) before the committee. After detailed deliberation the committee recommended for the grant of bioequivalence study as per the protocol presented with the condition to assess solmonance using Epworth sleepiness scale and cognition Mini Mental status

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			examination.
15	SND/IMP/19/000065 Perampanel tablets 2mg /4mg/6mg/8mg/10mg/12mg (additional indication)–	M/s Eisai Pharmaceuticals India Pvt ltd	Firm presented their proposal for Perampanel tablets 2mg /4mg/6mg/8mg/10mg/12mg (additional indication) before the committee. After detailed deliberation, committee recommended for grant of permission for additional indication for the adjunctive treatment of primary generalized tonic-clonic seizures in patients with epilepsy aged 12 years and older.
16	SND/MA/19/000040 Tofisopam Tablet 50mg/100mg (Add. Indication)	M/s. Acme Pharmaceuticals Pvt Ltd	Firm presented the proposal for Tofisopam Tablet 50mg/100mg (Add. Indication) before the committee. After detailed deliberation the committee recommended that there is no adequate clinical trial data in support of their proposal. The committee rejected the proposal for clinical trial waiver for additional indication.
17	12-38/2018-DC (Pt-Dyspo-SND Trihexyphenidyl Hydrochloride IP 1mg Tablet (Additional Strength)	M/s. D.D. Pharmaceutical Pvt Ltd	Firm presented their proposal for Trihexyphenidyl Hydrochloride IP 1mg Tablet before the committee. After detailed deliberation, committee recommended for the grant of permission to conduct Bio-equivalence study with Trihexyphenidyl Hydrochloride subject to inclusion of ECG during screening & final assessment.
Biological Division			
18	BIO/Form 44/FF/2019/13464 BIO/CT-19/000016 Peg interferon beta 1 a injection	Reliance Life Sciences Pvt. Ltd	The firm presented their revised Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per revised protocol except that the primary end point should be based on proportion of patients with MRI active lesions rather than the no. of lesions.

S.No	SEC –Experts Name & Designation	Signature
1.	Dr. Debashish Chowdhury, Director-Professor & HOD of Neurology, GB Pant, New Delhi	
2.	Dr. ManjariTripathi, Professor, Dept. Of Neurology, AIIMS, New Delhi	
3.	Dr. K. S. Anand, Professor & Head, Dept. of Neurology, RML, New Delhi	
4.	Dr. Shruti Srivastava, Professor. Dept. of Psychiatry, UCMS, New Delhi	
5.	Dr. M. S. Bhatia, Professor & Head, Dept. of Psychiatry, University College of Medical Sciences, New Delhi	
6.	AtulAmbekar, Professor, Dept. of Psychiatry, AIIMS, New Delhi	
7.	Dr. Kameshwar Prasad, Prof. & Head, Dept. of Neurology, AIIMS, New Delhi	
8.	Dr. H. S. Rehan, Prof. & Head, Department of Pharmacology LHMC, New Delhi	