

Recommendations of the SEC (Neurology & Psychiatry) made in its 86th meeting held on 18.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000146 Pimavanserin Tartrate 40 mg Capsule	M/s. Pure & Cure	<p>The firm presented their proposal for manufacture and market of Pimavanserin Tartrate 40 mg Capsule along with Phase III CT protocol and waiver of BE study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial and also approved the BE study waiver request submitted by the firm.</p>
2.	ND/MA/22/000125 Lisdexamfetmaine Dimesylate capsules 10/20/30/40/50/60/70 mg	M/s. Ind Swift Ltd.	<p>The firm presented their proposal for manufacture and market of Lisdexamfetmaine Dimesylate capsules 10/20/30/40/50/60/70mg along with justification for Phase III CT waiver and BE protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should conduct BE study as per the protocol presented and submit the BE study results before the committee for further consideration.</p>
3.	ND/MA/22/000151 Lasmiditan Tablets 50mg/100mg/200mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	<p>The firm presented their proposal for manufacture and market of Lasmiditan Tablets 50mg/100mg/200mg along with Phase III CT protocol and waiver of BE study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial and also approved the BE study waiver request submitted by the firm.</p>
4.	ND/MA/22/000139 Cannabidiol Oral Solution 150mg/ml	M/s. Zenara Pharma Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 14.10.2022, the firm presented revised Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberations, the committee recommended for grant of permission to conduct the Phase III clinical trial as per revised CT protocol (Protocol No. CP-CBD001-22, Version No. 4.0 Date: 01 Nov 2022).</p>

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SND Division			
5.	SND/CT/21/000081 Edaravone Oral Suspension 150 mg 930 mg/ml)	M/s. BDR Pharma	The firm did not turn up for the presentation.
6.	SND/MA/22/000271 Gabapentin ER Tablet 300 mg & 600 mg	M/s. Sun Pharma	<p>The firm presented the proposal for manufacturing and marketing of Gabapentin ER Tablet 300 mg & 600 mg (once daily) for the management of postherpetic neuralgia.</p> <p>The firm presented the advantage of Gabapentin ER Tablet (once daily) over immediate release formulation.</p> <p>The firm also presented the results of the BE study conducted on Gabapentin ER Tablet 600 mg against Gralise (Gabapentine) tablets 600 mg USA.</p> <p>The committee noted the results of the BE study where the test product is bioequivalent to reference product. Gralise (Gabapentine) tablets 300mg, 600 mg is approved in USA since 2011.</p> <p>After detailed deliberations, the committee recommended for permission for manufacturing and marketing of Gabapentin ER Tablet 300 mg & 600 mg (once daily) for the management of postherpetic neuralgia subject to the condition that the firm should conduct Phase IV clinical trial. The protocol for Phase IV clinical trial should be submitted within 3 months of the approval to CDSCO.</p>
7.	SND/CT/22/000052 Pregabalin Gel 8 % w/w	M/s. Lyka Labs	<p>In light of earlier SEC recommendation dated 23.08.2022,the firm presented the justification as below-</p> <ol style="list-style-type: none"> 1. Rationale for proposed new dosage form. 2. Justification from peer-reviewed journals. 3. Pharmacokinetic PK-PD data from experimental study in animal model to suggest that Pregabalin has peripheral mode of action. <p>The firm also presented the Phase III clinical trial protocol.</p>

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			<p>After detailed deliberation, the committee recommended the following:</p> <ol style="list-style-type: none"> 1. Design of clinical trial should be add-on design along with best oral medications, with active comparator approved drug product for neuropathic pain. 2. Sample size should be recalculated. 3. The firm should include more sites. <p>Accordingly, revised Phase III clinical trial protocol should be submitted for further review by the committee.</p>
8.	<p>SND/MA/21/000489</p> <p>Zolpidem Sublingual Spray 3.85% w/v</p>	<p>M/s. Troikaa Pharmaceuticals Ltd.</p>	<p>The firm presented their proposal of grant of manufacture and market of Zolpidem sublingual Spray 3.85% w/v alongwith BE report of the drug product (in fasting condition) and BE protocol of the applied drug product in fed condition before the committee.</p> <p>The firm has submitted study report of bioavailability study of Zolpidem Sublingual Spray vs Zolpidem Tartrate Tablets 10mg under fasting condition. The results of said study indicate that Zolpidem Sublingual Spray is bioequivalent to Zolpidem Tartrate Tablets 10mg and is well tolerated and the therapeutic concentration from Zolpidem Sublingual Spray reaches faster as compared to Zolpidem Tartrate Tablets 10mg. Pharmacodynamic assessment also shows statistically significant better scores at 06 minutes and 13 minutes for Zolpidem Sublingual Spray in comparison to oral tablets indicating faster onset of action Further it is reported that food decreases the rate and extent of absorption and prolongs the T_{max} of Zolpidem tablets. Thus, Zolpidem tablets should not be administered with or immediately after a meal, for faster sleep onset. In order to assess the effects of food on the rate and extent of absorption of this novel formulation the firm intended to conduct comparative bioavailability study of Zolpidem Sublingual Spray (a dose of two sprays equivalent to 10 mg) of Troikaa Pharmaceuticals Ltd., India with Zolfresh 10 mg Zolpidem Tartrate tablets I.P. 10</p>

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			mg of Abbott India Limited, India in healthy, adult human subjects under fed condition. After detailed deliberation, the committee recommended for grant of permission for conduct of the bioavailability study as per the protocol presented by the firm.
FDC Division			
9.	4-91/2017-DC Gabapentin USP6.0% w/w + Lidocaine HCl IP eq. to Lidocaine 5.0% w/w Gel	M/s. Akums Drugs & Pharmaceuticals	The firm did not turn up for the presentation.
10.	FDC/MA/19/000086 Pregabalin IP + Duloxetine Hydrochloride IP eq. to Doloxetine (as gastro resistant pellets) (50mg + 10mg & 75mg + 20mg) hard gelatin capsules	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 14.07.2020, the firm presented their proposal along with justification for Phase III CT study waiver in lower strength i.e 50mg + 10mg. The committee noted that the product is already approved in higher strength i.e 75mg + 20mg on 25.10.2021. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.
Medical Device Division			
11.	CI/MD/2021/000022 Sensor Evaluation of Neurologic Status in Emergencies (SENSE Device) (SDx3)	M/s. Pat Pharma Consultants India Private Ltd	The firm presented their proposal for amendment of clinical investigation protocol of the proposed device from SENSE-003, version 2.3 dated 27.06.2022 to SENSE-003, version 4.0 dated 05.07.2022 before the committee. After detailed deliberation, the committee recommended for grant of permission for amendment of clinical investigation protocol of the proposed device from SENSE-003, Version 2.3 dated 27.06.2022 to SENSE-003, Version 4.0 dated 05.07.2022.
12.	IMP/MD/2022/58425 NAV PAK Needle, Trocar and NIM NAV PAK Needle, Trocar International	M/s. India Medtronic Pvt. Ltd	The firm presented their proposal for grant of permission to import and market the proposed products before the committee. After detailed deliberation, the committee recommended for grant of permission to

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			import and market the proposed products in the country.
GCT Division			
13.	CT/57/20 Online Submission (17881) Evobrutinib	M/s. IQVIA	In light of earlier SEC recommendation dated 14.10.2022, the firm presented their justification for protocol amendment version 4.0 (03-April-2022). After detailed deliberation, the committee opined that the applicant should submit the following for further review by the committee: 1. Published safety data of investigational drug. 2. Specific data on AEs and SAEs of this investigational drug from pre-extension phase of this MS study and from any long term immunosuppressive therapy for MS or non-MS.
SND Division			
14.	SND/MA/22/000091 Brivaracetam Sustained Release Tablet 200mg	M/s. Ravenbhel Healthcare Pvt. Ltd	The firm presented their proposal of Manufacture and market of Brivaracetam sustained release tablets 200mg (additional dosage form) for already approved indication alongwith BE study report before the committee. Therapeutic justification for this proposed SR dosage form of Brivaracetam has been given by the firm as below: The recommended starting dose of Brivaracetam is either 50mg/day or 100mg/day based on physician's assessment of required seizure reduction versus potential side effects. The dose should be administered in two equally divided doses, once in the morning and once in the evening. Based on individual patient response and tolerability, the dose might be adjusted in the dose range of 50 mg/day to 200mg/day. The sustained release formulation has aim of patient convenience to take one tablet of SR formulation of Brivaracetam 200mg once a day instead of twice a day for IR formulation where patient needs 200mg of Brivaracetam daily. Brivaracetam has short half-life and high

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			<p>water solubility. These characteristics are ideal to develop controlled release pharmaceutical compositions which invariably would offer various advantages over conventional immediate release drug products such as constant therapeutic plasma concentration of Brivaracetam over prolonged periods, reduced number of doses per day or week, reduced adverse effects and improved patient compliance and convenience.</p> <p>Approved BE protocol and BE NOC No. is as below: BE NOC No. BE/SND/20/2022 dated 02.05.2022. Protocol No. S-22-699, Version: 01, Dated 15.06.2022. Amendment in Form CT-07 has been granted on 30.06.2022.</p> <p>After detailed deliberation, the committee recommended for grant of permission of manufacture and marketing of Brivaracetam sustained release tablets 200mg (modified dosage form) for already approved indications subject to condition that the firm should conduct active PMS study after marketing of the drug product.</p>