

Recommendations of the SEC (Neurology & Psychiatry) made in its 96th meeting held on 13.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000125 Lisdexamfetamine Dimesylate Capsules 70mg	M/s. Ind-Swift Ltd.	<p>The firm presented their proposal for the grant of permission for the amendment in Bioequivalence study protocol with drug Lisdexamfetamine Dimesylate capsules 70mg.</p> <p>After detailed deliberation, the committee noted that the firm has been granted BE study permission (protocol No. CLCD-116-20, version-1.0 dated 03-12-2021) on 13-Apr-2023.</p> <p>Accordingly, the committee recommended for the grant of permission for the BE protocol amendment for protocol No. CLCD-116-20, version-2.0 dated 12-May-2023.</p>
SND Division			
2.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25% w/v	M/s. Savi Health Science	<p>In light of earlier SEC recommendations dated 13.06.2023, the firm presented justification/clarification for use of Midazolam nasal spray 0.5% w/v & 1.25% w/v (Multidose nasal spray) before the committee.</p> <p>The committee noted that Midazolam nasal spray 5mg/Spray (Single dose) approved by USFDA on 17.05.2019 for acute treatment of intermittent, stereotype episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.</p> <p>However, the indication proposed for the applied product Midazolam nasal spray 0.5% w/v & 1.25% w/v (Multidose nasal spray) for preoperative sedation for conscious sedation prior to short diagnostic or endoscopic procedure and for indication of general anaesthesia prior to administration of another anaesthetic agent is entirely different indication of USFDA product. The firm has not presented any clinical data in support of</p>

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			<p>their multidose nasal spray for the proposed indication.</p> <p>After detailed deliberation, the committee recommended to conduct phase III clinical trial.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the Committee.</p> <p>In addition to above, the firm should fulfill CMC data requirement as per New Drugs and Clinical trial Rules, 2019.</p>
3.	<p>SND/MA/20/000368</p> <p>Midazolam Nasal Spray 0.5% w/v & 1.25% w/v</p>	M/s. Biodeal Pharma	<p>In light of earlier SEC recommendations dated 13.06.2023, the firm presented justification/clarification for use of Midazolam nasal spray 0.5% w/v & 1.25% w/v (Multidose nasal spray) before the committee.</p> <p>It was informed by the firm that the indication has been changed to - epilepsy instead of anaesthetic / sedation purpose.</p> <p>The committee noted that Midazolam nasal spray 5mg/Spray (Single dose) approved by USFDA on 17.05.2019 and midazolam nasal spray 2.5mg, 3.75 mg & 5mg is approved as a single dose on 20.01.2023 by Netherlands authority for acute treatment of intermittent, stereotype episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.</p> <p>After detailed deliberation, the committee recommended that the firm should present clinical data in Indian population or conduct of Phase III clinical trial for the proposed indication. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee. In addition to above, firm should fulfill CMC data requirements as per New Drugs and Clinical trial Rules, 2019 along with revised legal document in Form CT-21 for proposed new indication.</p>

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FDC Division			
4.	FDC/MA/23/000256 Pregabalin + Duloxetine Hydrochloride eq. to Duloxetine (as delayed release pellets) + Mecobalmin (75mg+30mg + 1500mcg/75mg+20mg + 1500mcg/75mg+10mg+ 1500mcg/50mg+10mg + 1500mcg/50mg+20mg+ 1500mcg) Hard gelatin capsules	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm presented its proposal along with BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study and Phase III clinical trial study with the condition that BE study report should be presented before the SEC prior to initiation of the Phase III clinical trial study.
GCT Division			
5.	CT/30/23 Online Submission (36752) Olanzapine (TV-44749)	M/s. Lotus Labs	The firm had withdrawn proposal.
6.	CT/67/23 Online Submission (37904) Lumateperone	M/s. IQVIA	The firm presented Phase III clinical study protocol No. ITI-007-505 amendment 1, dated 18 April 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to condition that more government and geographically distributed sites shall be included in the study.
7.	CT/130/20 Online Submission (27129) Fenebrutinib	M/s. Roche Products	The firm presented protocol amendment version 6.0 dated 8th Feb 2023 for protocol No. GN42272. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by firm.
8.	CT/174/21 Online Submission (25177) SAR442168	M/s. Sanofi	The firm presented protocol 08, version No. 1 dated 12 December 2023 for protocol No. EFC16034. After detailed deliberation, the committee recommended for approval of the

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			proposed amendment as presented by firm.
9.	CT/12/23 Online Submission (36044) Basimglurant	M/s. CliniRx Research Pvt. Ltd.	In light of earlier recommendation dated 18.04.2023, the firm presented Phase II/III clinical study protocol No. NOE-TGN-201, version 2.0, dated 26 December 2022 along with the justification for the quires raised in SEC Meeting dated 18.04.2023 for re-consideration of the proposal. After detailed deliberation, the committee accepted the justifications presented by the firm and recommended for grant of permission to conduct the clinical trial.
10.	CT/58/20 Online Submission (26784) Evobrutinib	M/s. IQVIA	The firm presented protocol amendment version No. 6.0 dated 26 Apr 2023 for protocol No. MS200527_0080. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by firm.