**Recommendations of the SEC (Neurology & Psychiatry) made in its 97th meeting held on 12.10.2023 at CDSCO (HQ), New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **BiologicalDivision** | | | |
| 1. | BIO/CT21/BO/2022/34374<br><br>Tenecteplase | M/s. Gennova | As per the recommendation of earlier SEC dated 15.09.2022, firm presented clinical study results of active PMS study of Tenecteplase (0.2 mg/kg of body weight) in adult patients within 3.0 hrs and within 4.5 hrs of onset of Acute Ischemic Stroke symptoms as per approved Protocol No IRIS-TNK Registry, version no 2.1 dated 29.10.2022.<br><br>After detailed deliberation, the committee noted the results of the study and recommended that the administration time of the drug in Acute Ischemic Stroke may be extended from 3.0 hrs to upto 4.5 hrs of stroke onset. |
| **SND Division** | | | |
| 2. | SND/CT/23/000045<br><br>Gabapentin ER Tablets 300mg & 600mg (Additional Indication) | M/s. Sun Pharma Laboratories Limited | The firm presented proposal for grant of permission to conduct Phase IV clinical trial of Gabapentin ER Tablets 300mg & 600mg along with Phase IV clinical trial protocol before the committee.<br><br>After detailed deliberation, the Committee recommended for grant of permission to conduct the Phase IV clinical trial study as per protocol presented by the firm subject to the following conditions:<br><br>1. Specific diagnostic criteria for PHN & neuropathic pain as per international guideline should be included in the study protocol.<br>2. Psychological problem/disorder patient should be mentioned in the excluding criteria. |
| **FDC Division** | | | |
| 3. | 04-1827/2015-DC (PSC-Synokem)<br><br>Gabapentin + Nortriptyline 300mg/400mg + 10mg/10mg tablets | M/s. Synokem Pharmaceuticals Ltd. | In light of earlier SEC recommendation dated 12.07.2023, the firm presented their proposal along with Phase IV clinical trial protocolbefore the committee.<br><br>The firm informed that they have revised the Phase IV clinical trial protocolby |

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| | | | changing the FDC of Gabapentin + Nortriptyline (300mg/400mg + 5mg/10mg) capsule to FDC of Gabapentin + Nortriptyline(300mg/400mg + 10mg/10mg) tablets.<br><br>The committee noted that the FDC of Gabapentin + Nortriptyline(300mg/400mg + 10mg/10mg) tabletsfalls under category 'd' as per Prof. Kokate Committee report.<br><br>Accordingly, the committee recommended that the Phase IV clinical trial shall be evaluated as perrecommendation of Prof. Kokate Committee. |
| 4. | FDC/MA/23/000267<br><br>VortioxetineHydrobromide eq. to Vortioxetine + Clonazepam IP (5mg+ 0.5mg, 5mg + 0.25mg, 10mg + 0.5mg, 10mg + 0.25mg, 20mg + 0.5mg) film coated tablet | M/s. Torrent Pharmaceutical Ltd. | The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.<br><br>After detailed deliberation, the committee opined the following:<br>1. The firm should present the justification on rationality of the combination and its significant benefits.<br>2. The proposed FDC is not approved anywhere in the world.<br>3. Dosing schedule of the proposedFDC is not matching.<br>4. The firm should present recent scientific literature available from peer reviewed journal in support of combining the drugs in this FDC.<br><br>Accordingly, the firm should submit above data for further review by the committee. |
| 5. | FDC/MA/23/000287<br><br>Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (600mg+1500mcg+10 mg/ | M/s. Ravenbhel Healthcare Pvt. Ltd. | The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. |

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| | 300mg+1500mcg+ 10mg) film coated bilayered tablet | | The result of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial. |
| 6. | FDC/MA/23/000298<br><br>Clonazepam IP (as uncoated tablet) 0.5mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as Gastro-resistant pellets) 20mg capsule | M/s. Akums Drugs & Pharmaceuticals Ltd. | The firm presented their proposal along with BE study protocol before the committee.<br><br>After detailed deliberation, the committee opined the following:<br>1. The firm should present the justification on rationality of the combination and its significant benefits.<br>2. The proposed FDC is not approved anywhere in the world.<br>3. The firm should present recent scientific literature available from peer reviewed journal in support of proposed indication of the FDC.<br>4. Dosing schedule of the proposed FDC is not matching.<br><br>Accordingly, the firm should submit above data for further review by the committee. |
| 7. | FDC/MA/22/000228<br><br>Mecobalamine IP 1500mcg + Nortriptyline 10mg + Pregabalin IP(SR) 75 mg film coated bilayered tablet | M/s. Savi Health Science | The firm presented their proposal along with justification for BE waiver before the committee.<br><br>The committee noted that the proposed FDC is already approved by CDSCO on 17.03.2022.<br>However, after detailed deliberation, the committee did not consider the justification for BE waiver and recommended to conduct BE study with proposed FDC. |
| **Medical Device Division** | | | |
| 8. | CI/MD/2021/40587<br><br>Sensor Evaluation of Neurologic Status in Emergencies (SENSE Device) (SDx3) | M/s. PAT Pharma Consultants India Private Limited | The firm presented proposal for amendment in Clinical Investigation protocol of the proposed product Sensor Evaluation of Neurologic Status in Emergencies (SENSE Device) (SDx3) from Protocol Number SENSE-003, Version 4.0 dated 05.07.2022 to Protocol Number SENSE-003, Version 5.1 dated 25.05.2023 before the committee.<br>After detailed deliberation, the committee recommended for amendment in the |

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| | | | Clinical Investigation protocol as presented by the firm. |
| **BA/BE Division** | | | |
| 9. | File No. 12-09/2023/BA-BE/MISC-17/DC (BABE/CT05/FF/2023/36831)<br><br>Carbidopa and Levodopa Controlled-Release Tablets (50mg/200 mg) | M/s. Cliantha Research Limited | The firm presented proposal for grant of BA/BE permission for clinical development of Carbidopa and Levodopa Controlled-Release Tablets of various strengths to evaluate bioavailability and food effect study before the committee.<br><br>After detailed deliberation, the committee recommended for submission of following documents:<br>1. The firm was not able to provide supporting data of AE's reported during presentation. Hence the firm should provide the previous BE study data with reported AE's.<br>2. Details of various pharmaceutical preparations (test products) with composition including excipients etc.<br>3. Safety and tolerability of the proposed test product.<br><br>Accordingly, the firm should submit the above information for re-deliberation by SEC. |
| 10. | File No. 12-09/2023/BA-BE/MISC-18/DC (BABE/CT05/FF/2023/37229)<br><br>Carbidopa and Levodopa Controlled-Release Tablets (25mg/100mg, 37.5mg/150mg, 50mg/200 mg, 25mg/150mg) | M/s. Cliantha Research Limited | The firm presented proposal for grant of BA/BE permission for clinical development of Carbidopa and Levodopa Controlled-Release Tablets of various strengths to evaluate bioavailability and food effect study before the committee.<br><br>After detailed deliberation, the committee recommended for submission of following documents:<br>1. The firm was not able to provide supporting data of AE's reported during presentation. Hence the firm should provide the previous BE study data with reported AE's.<br>2. Details of various pharmaceutical preparations (test products) with composition including excipients etc.<br>3. Safety and tolerability of the proposed test product.<br><br>Accordingly, the firm should submit the above information for re-deliberation by SEC. |

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| 11. | File No. 12-09/2023/BA-BE/MISC-23/DC (BABE/CT05/FF/2023/37922)<br><br>Carbidopa and Levodopa Controlled Release Tablets 62.5mg/250mg | M/s. Cliantha Research Limited | The firm presented proposal for grant of BA/BE permission for clinical development of Carbidopa and Levodopa Controlled-Release Tablets of various strengths to evaluate bioavailability and food effect study before the committee.<br><br>After detailed deliberation, the committee recommended for submission of following documents:<br>1. The firm was not able to provide supporting data of AE's reported during presentation. Hence the firm should provide the previous BE study data with reported AE's.<br>2. Details of various pharmaceutical preparations (test products) with composition including excipients etc.<br>3. Safety and tolerability of the proposed test product.<br><br>Accordingly, the firm should submit the above information for re-deliberation by SEC. |