

Recommendations of the SEC (Neurology & Psychiatry) made in its 76th meeting held on 18.01.2022 at CDSCO HQ New Delhi:

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
|--------------------------|---|-----------------------------|--|
| New Drug Division | | | |
| 1. | ND/MA/20/000124 Vigabatrin Powder for oral solution 500 mg | M/s. MSN Laboratories Ltd | The firm didn't turn up for presentation. |
| 2. | ND/IMP/20/000073 Risdiplam powder for oral solution | M/s. Roche | In light of earlier recommendation of SEC dated 18.11.2021, the firm presented Post Marketing Surveillance (PMS) Study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Post Marketing Surveillance (PMS) Study subject to the following conditions: 1. The Inclusion criteria for recruiting SMA patients should be changed from 02 months to 02 years. |
| 3. | ND/MA/20/000078 Pimavanserin capsules 34 mg | M/s. Sun Pharma Ltd. | In light of earlier recommendation of SEC meeting dated 18.11.2021, the firm presented the revised phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial. |
| SND Division | | | |
| 4. | SND/MA/19/000085 Clobazam Oral Suspension 5mg/5ml & 10mg/5ml | M/s. Tanmed Pharmaceuticals | The firm presented the results of the BE study. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Clobazam Oral Suspension 5mg/5ml & 10mg/5ml for the already approved indication. |
| 5. | SND/MA/20/000351 Naltrexone Sustained Release Injection 190mg/ml | M/s. Rusan Pharma | In light of the earlier recommendation of SEC meeting dated 15/09/2021, the firm presented the protocol for conduct of bioavailability study. After detailed deliberation, the |

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| | | | <p>committee opined that the firm should conduct a three arm comparative PK study with test product, Naltrexone tablets 50 mg and Naltrexone for extended-release injectable suspension which is already available in USA.</p> <p>Accordingly, the firm should submit the revised protocol for review by the committee.</p> |
| FDC Division | | | |
| 6. | <p>FDC/MA/19/000079</p> <p>Pregabalin IP (as prolonged release form) + Nortriptyline Hydrochloride IP eq. to Nortriptyline + Mecobalamin IP (75mg+ 10mg+1500mcg)film coated bilayered tablet</p> | M/s. Synokem Pharmaceuticals Ltd. | <p>The firm didn't turn up for presentation.</p> |
| 7. | <p>FDC/MA/21/000191</p> <p>Pyridoxine HCl + Folic acid +Vitamin D3 IP + Methylcobalamin(3mg+5mg+10 00IU+1500 mcg) mouth dissolving tablets</p> | M/s. Unison | <p>In light of earlier SEC recommendation dated 15.09.2021, the firm presented their proposal before the committee.</p> <p>The committee noted that same FDC is already approved as soft gelatin capsule with Folic acid 1.5 mg.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC for the management of diabetic neuropathy in patients with hyperhomocysteinemia.</p> |
| 8. | <p>FDC/MA/21/000108</p> <p>Nortriptyline Hydrochloride eq. to Nortriptyline + Gabapentin(10mg+200mg) tablet</p> | M/s. Pure & Cure Healthcare Pvt. Ltd. | <p>In light of earlier recommendation dated 16.04.2021, the firm presented their proposal along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conducting the proposed BE study.</p> |
| 9. | <p>FDC/MA/21/000277</p> <p>Alpha Lipoic acid USP 200mg + Mecobalamin IP 1500mcg + Myo-inositol 100mg + Folic acid IP 1.5mg + Pyridoxine Hydrochloride IP 3mg Chromium Picolinate eq. to</p> | M/s. Pure & Cure Healthcare Pvt.Ltd. | <p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial for proving the efficacy and safety of the FDC in the proposed indication.</p> |

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| | Chromium USP 200mg + Benfotiamine 200mg tablets | | Accordingly, the firm should submit the clinical trial protocol for further deliberation by the committee. |
| 10. | FDC/MA/21/000293 Etoricoxib 60mg/90mg/120mg + Pregabalin (As prolonged release form) 75mg/75mg/75mg tablets | M/s. Akums Drugs and Pharmaceutical Ltd. | The firm didn't turn up for presentation. |
| GCT Division | | | |
| 11. | CT/57/20 Online Submission (14348) Evobrutinib | M/s. IQVIA | The firm presented clinical trial protocol-MS200527_0082, amendment 3, dated 19 May 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the amended clinical trial protocol. |
| 12. | CT/130/20 Online Submission (14517) Fenebrutinib & Teriflunomide | M/s. Roche | The firm presented clinical trial protocol-GN42272, amendment 4, dated 14 Sep. 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the amended clinical trial protocol. |
| 13. | CT/86/19 Online Submission (14336) Evenamide | M/s. CliniRx | The firm presented clinical trial protocol-NW-3509/014/II/2019, amendment 6, dated 17 June 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the amended clinical trial protocol. |
| 14. | CT/03/20 Online Submission (14343) Evenamide | M/s. CliniRx | The firm presented clinical trial protocol-NW-3509/015/II/2019, amendment 4.1 (India), dated 30 Nov. 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the amended clinical trial protocol. |
| BA/BE Division | | | |

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| 15. | 12-09/2021/BA-BE/Misc-31/DC Dextromethorphan and Bupropion Extended Release Tablets 45/105 mg | M/s. Alembic Pharmaceuticals Limited. | <p>The firm presented the proposal along with BE study protocol of Dextromethorphan and Bupropion Extended Release Tablets 45/105 mg before the SEC.</p> <p>After detailed deliberation, the committee opined that the FDC of Dextromethorphan and Bupropion Extended Release Tablets 45/105 mg has not yet been approved anywhere and the study is to be conducted for submission to USFDA for Export registration purpose.</p> <p>Hence, the committee recommended that the firm needs to submit regulatory communication from the USFDA for conduct of the BE study as per currently applied study protocol.</p> |