**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 205nd meeting held on 21-01-2022 at CDSCO, HQ New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
|---|---|---|---|
| **New Drug Division** | | | |
| 1. | ND/MA/22/000013<br><br>Combi pack of Nirmatrelvir Tablets 150/300 mg + Ritonavir Tablets 100/100 mg tablet in India | Ms Hetero lab limited | The firm presented their proposal of clinical trial waiver for grant of permission to manufacture and market the drug Combi pack of Nirmatrelvir Tablets 150/300 mg + Ritonavir Tablets 100/100 mg in India.<br><br>After detailed deliberation, the committee opined that firm should submit detailed pharmacokinetics, dose finding study and clinical trial study data along with justification and plan for addressing the issues related to comparative Pharmaceutical/PK evaluation of the proposed product with internationally approved original drug. |
| 2. | ND/CT21/FF/2022/30074<br><br>Combi pack of Nirmatrelvir Tablets 150 mg + Ritonavir Tablets 100 mg in India | M/s Optimus Pharma Private limited | The firm presented their proposal of clinical trial waiver for grant of permission to manufacture and market the drug Combi pack of Nirmatrelvir Tablets 150/300 mg + Ritonavir Tablets 100/100 mg in India.<br><br>After detailed deliberation, the committee opined that firm should submit detailed pharmacokinetics, dose finding study and clinical trial study data along with justification and plan for addressing the issues related to comparative Pharmaceutical/PK evaluation of the proposed product with internationally approved original drug. |
| 3. | ND/CT21/20/23164<br><br>Aviptadil Injection 150µg/ml (FF) | M/s Zuventus Healthcare | In light of the earlier recommendation of the SEC (COVID) meeting held on 29.07.2021, the firm presented the results of Clinical Trial and requested for emergency approval of Aviptadil Injection 150 ug/ML before the committee.<br><br>After detailed deliberation, the committee recommended that the firm should submit following additional data for further consideration.<br><br>1. Safety and efficacy data of the drug in ARDS patients including Non COVID patients along with its benefits in Mortality at various time points.<br>2. Serial Lung Images of the trial patients.<br>3. Data on RT-PCR negativity of the trial patients. |

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| **SND Division** | | | |
| 4. | SND/MA/21/000577<br><br>Molnupiravir Tablets 800 mg | M/s Mylan Laboratories | The firm did not turn up for presentation. |
| 5. | SND/CT/21/000029<br><br>Remdesivir Injectin 100mg/20ml 95mg/mL (Solution Form) | M/s Dr. Reddy 's Labs | The firm did not turn up for presentation. |
| 6. | SND/CT/21/000033<br><br>Doxazosin Tablets 2mg | M/s Stand Life Sciences | The firm presented the amended protocol for the Clinical Trial of Doxazosin to prevent COVID-19, study number SLS-JHM-02, Version no. 3.0 dated 20.12.2021.<br><br>After detailed deliberation, the committee recommended for approved of the protocol amendment as presented. |
| **FDC Division** | | | |
| 7. | FDC/MA/22/000005<br><br>Combikit of Aspirin GR tablets IP 150mg & Promethazine HCL tablets 5mg & Multivitamin-minerals tablets. | M/s Meyer Vitabiotics | The firm presented their proposal before the committee.<br>After detailed deliberation the committee opined that :-<br>1. The firm did not present any scientific rational for the proposed combipack<br>2. The proposed combipack is not recommended in any standard guideline<br>3. Dosage of promethazine is sub therapeutic.<br>4. The firm did not present any published study w.r.t. proposed combipack.<br><br>In view of above, committee did not recommend the proposed combipack. |
| **BA/BE Division** | | | |
| 8. | 12-09/2021/BA-BE/MISC-30/DC<br><br>Molnupiravir Tablets 800 mg | M/s Emcure Pharmaceuticals Limited | The firm presented their proposal to conduct BA-BE study of Molnupiravir Tablets 800 mg for export purpose<br>After detail deliberation, the committee recommended for grant of permission to conduct BA/BE study with following condition- |

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| | | | 1) Male subjects should not donate semen for atleast 3 months<br>2) Female subjects should be tested negative for pregnancy with beta HCG before each dosing<br>3) All subjects should be tested negative for RTPCR for Covid 19 before each dosing. |