**Recommendations of SEC (Cardiovascular & Renal) made in its 104th meeting held on 09.06.2022 & 10.06.2022 at CDSCO (HQ), New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **New Drug Division** | | | |
| 1. | ND/MA/22/000078<br><br>FDC of Bempedoic acid and Ezetimibe tablets 180mg/10mg | M/s. MSN Laboratories Pvt. Ltd. | The firm didn't turn up for presentation. |
| 2. | ND/CT/22/000033<br><br>Vericiguat2.5/5/10 mg | M/s. Bayer | In light of the condition of permission to import and market Vericiguat 2.5/5/10 mg film coated tablets granted to the firm on 25th Feb 2022, the firm presented Phase IV clinical trial protocol for Vericiguat 2.5/5/10 mg before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the condition that patients with Hb-11.5 g/dL should be investigated for anemia and treated before initiation of intervention. |
| 3. | ND/MA/20/000097<br><br>Bempedoic Acid 180 mg and Ezetimibe 10 mg tablet | M/s. Akums | In light of earlier SEC recommendation dated 19.05.2022, the firm presented the progress in respect of conduct of trial.<br><br>After detailed deliberation, the committee recommended that the firm should initiate Phase III clinical trial and submit the interim report before the committee for further consideration. |
| **SND Division** | | | |
| 4. | SND/MA/22/000132<br><br>BisoprololFumarate Tablets 7.5mg | M/s Merck Specialities | The firm presented the proposal for manufacturing and marketing of Bisoprolol Fumarate Tablets 7.5mg along with justification for BE study and clinical trial waiver before the committee.<br><br>The committee noted that the proposed strength of the drug is approved in UK since 2010.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Bisoprolol Fumarate Tablets 7.5mg for already approved indications. |

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| 5. | SND/MA/22/000152<br><br>Sacubitril/Valsartan 200mg tablets | M/s Aet Laboratories | The firm presented the proposal for manufacturing and marketing of Sacubitril/Valsartan 200 (97/103) mg film coated tablets along with the results of BE studies.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Sacubitril/Valsartan 200 (97/103) mg tablets for already approved indication. |
| **FDC Division** | | | |
| 6. | FDC/MA/19/000104<br><br>Efonidipine Hydrochloride Ethanolate 20mg/20mg/40mg/40mg+Chlorthalidone6.25 mg/12.5mg/6.25mg/12.50mg tablets | M/s. Zuventus Healthcare Ltd. | The firm presented BE study and Phase III CT reports for higher strength for FDC of Efonidipine Hydrochloride Ethanolate 40mg+Chlorthalidone 12.5mg tablets before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Efonidipine Hydrochloride Ethanolate 40mg+Chlorthalidone 12.5mg tablets in higher strength. |
| 7. | FDC/MA/22/000132<br><br>Bempedoic acid 180mg + Ezetimibe 10mg tablets | M/s. Optimus Pharma Pvt. Ltd. | The firm presented BE study protocol along with the request for Phase III CT waiver before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. With respect to Phase III CT waiver, the firm should initially present BE study results before the committee for further consideration of Phase III clinical trial waiver at that point of time. |
| 8. | FDC/MA/22/000108<br><br>Metoprolol Succinate IP 23.75mg/47.50mgeq to Metoprolol Tartrate (as extended release tablet) 25mg/50mg + Telmisartan IP 40mg/40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg/5mg Tablets | M/s. Ajanta Pharma Ltd. | The firm presented the Phase III CT protocol and BE study protocol before the committee.<br><br>The committee opined that the firm should include following points in Phase III CT protocol:<br>1. Arm 1 should be removed.<br>2. 2D echo, Ultrasound Renal doppler should be included in the screening and 2D echo should be redone at the last visit.<br>3. Renal function test should be included at visit3. |

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| | | | After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with above changes. The revised Phase III CT protocol should be submitted to CDSCO for approval. As regard to BE study, the committee recommended for grant of permission to conduct the BE study. |
| 9. | FDC/MA/22/000149<br><br>Rosuvastatin Calcium eq. to Rosuvastatin 5mg/10mg/20mg/40mg +Bempedoic acid 180mg/180mg/180mg/ 180mg tablets | M/s. Exemed Pharmaceuticals | The firm presented the proposed BE study protocol for higher strength along with the request for Phase III CT waiver for all proposed strengths before the committee.<br><br>Based on the presentation made, the committee did not recommend the proposed lower strengths i.e Rosuvastatin Calcium eq. to Rosuvastatin 5mg/10mg/20mg +Bempedoic acid 180mg/180mg/180mg tablets.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. As regard to clinical trial waiver for higher strength, the committee recommended that the firm should initially present the BE study results before the committee for further consideration of Phase III clinical trial waiver at that point of time. |
| 10. | FDC/MA/22/000094<br><br>Bempedoic Acid 180 mg/180mg/180mg/180 mg +Atorvastatin Calcium eq. to Atorvastatin 10 mg/20 mg/40 mg/80mg tablets | M/s. Exemed Pharmaceuticals | The firm presented the proposed BE study protocol for higher strength along with the request for Phase III CT waiver for all proposed strengths before the committee.<br><br>Based on the presentation made, the committee did not recommend the proposed lower strengths i.e FDC of Bempedoic Acid 180mg/180mg/180mg + Atorvastatin Calcium eq. to Atorvastatin 10mg/20 mg/40 mg tablets.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. As regard to clinical trial waiver for higher strength, the committee recommended that the firm should initially present the BE study results before the committee for further |

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| | | | consideration of Phase III clinical trial waiver at that point of time. |
| **GCTDivision** | | | |
| 11. | CT/20/22 Online Submission (30523)<br><br>Selexipag | M/s Parexel | The firm did not turn up for presentation. |
| 12. | CT/35/22 Online Submission (31533)<br><br>Sibeprenlimab | M/s. George Clinical India | The firm did not turn up for presentation. |
| 13. | CT/43/21 Online Submission (17251)<br><br>Atacicept | M/s. Medpace Clinical Research | The firm presented the proposed protocol no. VT-001-0050, amendment 4 dated 10-Mar-2022 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. |
| **Medical Device Division** | | | |
| 14. | MD/Post Appr/2019/936<br><br>Sirolimus Eluting Coronary Stent System. | M/s Meril Life Sciences India Pvt. Ltd. | The firm presented their proposal for new indication before the committee.<br><br>The committee noted that the proposed indication is new and the firm submitted only pool data.<br><br>After detailed deliberation, the committee recommended that the firm should submit rationale and justification for the new indication with randomized control clinical investigation data. |