**Recommendations of the SEC (Cardiovascular & Renal) made in its 113th meeting held on 10.11.2022 at CDSCO (HQ), New Delhi:**

| S.No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **SND Division** | | | |
| 1. | SND/MA/22/000083<br><br>Polystyrene Sulphonate Jelly 20% w/w | M/s. Pharose Remedies | The firm did not turn up for presentation. |
| **FDC Division** | | | |
| 2. | FDC/MA/21/000007<br><br>Ivabradine HCl eq. to Ivabradine 5mg/5mg+Metoprolol Tartrate 50mg/25mg tablets | M/s. Pure & Cure | The firm did not turn up for presentation. |
| 3. | FDC/MA/22/000241<br><br>Chlorthalidone IP 6.25mg/12.5mg + Cilnidipine 5mg/10mg + Bisoprolol Fumarate 5mg/10mg tablets | M/s. Windlas Biotech Ltd. | In light of earlier SEC recommendation dated 11.10.2022 the firm presented the revised Phase III CT Protocol before the committee.<br><br>After detailed deliberation, the committee noted that the firm presented the three arm design which is not appropriate as Arm 1 is not comparable and two dose escalation is not advisable.<br>The committee recommended that the firm should revise the Phase III protocol for further deliberation by the committee. |
| 4. | FDC/MA/22/000259<br><br>Cilnidipine IP 20mg +Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (As ER) 50mg Tablets | M/s. Ajanta Pharma Ltd. | The firm did not turn up for presentation. |
| 5. | FDC/MA/22/000299<br><br>Metoprolol Tartrate 50mg/100mg + Sacubitril & Valsartan tri sodium salt hemi Pentahydrate 100mg/200mg tablets | M/s. Windlas Biotech Ltd. | The firm presented their proposal alongwith CT protocol as well as BE study protocol for the proposed FDC before the committee.<br><br>After detailed deliberation, the committee recommended that the firm should present adequate rational, justification as well as clinical proof of concept for the |

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| | | | proposed FDC for further review by the committee. |
| 6. | FDC/MA/22/000302<br><br>Rosuvastatin + Bempedoic acid (5mg+180mg, 10mg + 180mg, 20mg + 180mg) tablet | M/s. Exemed | The firm presented their proposal before the committee. The committee noted that the firm did not present adequate literature/justification of the applied lower strengths.<br><br>After detailed deliberation, the committee did not recommend the proposed lower strengths of the FDC. |
| 7. | FDC/MA/22/000313<br><br>Ezetimibe 10mg + Rosuvastatin Calcium 40mg tablets | M/s. Windlas Biotech Ltd. | The firm presented their proposal before the committee. The committee noted that the proposed FDC is already approved in various strengths and the proposed strength is also approved by USFDA. The committee also noted that the firm has already conducted BE study on one of the strengths of the FDC earlier.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed additional strength of the FDC with the condition that Phase IV clinical trial should be conducted. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months from the date of approval. |
| 8. | 04-03/2017-DC (Pt. Akums)<br><br>Cilnidipine 20mg +Telmisartan IP 40mg Tablets | M/s. Akums Drugs & Pharmaceuticals | In light of earlier SEC recommendation dated 27.04.2022, the firm presented the results of the BE study report before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that Phase IV clinical trial should be conducted. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months from the date of approval. |
| 9. | FDC/MA/22/000234<br><br>Bisoprolol Fumarate IP 5mg/2.5mg+ Cilnidipine IP 10mg/10mg tablets | M/s. Windlas Biotech | In light of earlier SEC recommendation dated 07.09.2022, the firm presented the BE and CT protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for conducting the proposed BE study.<br>As regard to the Phase III clinical trial, |

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| | | | the committee recommended that patients with essential hypertension associated with CAD should be included in the study. Accordingly, the firm should revise the indication and submit the revised Phase III clinical trial protocol for further review by the committee. |
| **GCT Division** | | | |
| 10. | CT/26/21<br>Online Submission (18083)<br><br>Itolizumab (EQ000) | M/s. Bioinnovat | The proposal for protocol amendment 5 was deferred for deliberation in the next meeting in presence of Nephrologists. |
| 11. | CT/109/20<br>Online Submission (20748)<br><br>Finerenone BAY 94-8862 | M/s. Bayer Pharmaceuticals | The firm has presented protocol amendment version 3.0, dated 16 May 2022 before the committee.<br><br>After detailed deliberation, the committee recommended for grant permission for approval of the protocol amendment. |
| **Medical Device Division** | | | |
| 12. | CI/MD/2022/62891<br><br>Transcatheter Heart Valve(THA) Model 3 | M/s. Meril Life sciences Pvt. Ltd | The firm has presented their protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for the post marketing clinical investigation with the condition that atleast 50 percent of the investigation site should be from government hospitals. |
| 13. | MD/PostAppr/2019/ 936<br><br>Biodegradable polymer based sirolimus eluting coronary stent system | M/s. Meril Life sciences Pvt. Ltd | In light of earlier SEC recommendations dated 09.06.2022 & 10.06.2022, the firm presented their proposal before the committee.<br><br>After detailed deliberation, the committee recommended for the approval of modified indication for global market/export purpose. |
| **GCT Division** | | | |
| 14. | CT/91/22 Online Submission (33690)<br><br>Macitentan 75mg versus Macitentan 10mg | M/s. J&J | The proposal for fresh application was deferred for deliberation in the next meeting in presence of Nephrologists. |