

**Recommendations of the SEC (Cardiovascular) made in its 21<sup>st</sup> meeting held on 06.11.2024 at CDSCO HQ New Delhi:**

| S. No               | File Name & Drug Name, Strength  | Firm Name  | Recommendations  |
|---------------------|--|--|--|
| <b>GCT Division</b> |  |  |  |
| 1.                  | GCT/CT04/FF/2024/43223<br>Online Submission (43223)<br><br>AZD5462                       | M/s. Parexel International Clinical Research Private Limited | In light of earlier SEC recommendation dated 17.09.2024, the firm presented Phase Iib clinical study protocol No. D9090C00008, version No.: 1.0 / Local CSP India-1, dated 16-October-2024.<br><br>The firm presented that protocol has been revised to remove NYHA FC Class IV patients as per SEC recommendation.<br><br>After detailed deliberation, the committee, recommended for grant of permission to conduct the trial as presented by the firm.  |
| 2.                  | GCT/Post Appr/2024/35629<br>M/S Eli Lily<br><br>Online Submission (35629)<br>Retatrutide | M/s. Eli Lily  | The firm didn't turn up for presentation.  |
| <b>SND Division</b> |  |  |  |
| 3.                  | SND/MA/24/000034<br><br>Enzalutamide 80mg tablet   | M/s Intas Pharma   | The firm did not turn up for the presentation  |
| 4.                  | SND/MA/22/000110<br><br>PrazosinHydrochlorid e Sustained Release tablets 2.5mg and 5mg   | M/s Pfizer Limited   | Firm presented the BE Study report for protocol no. version 1,study code 018/22 dated 16.03.2022 and committee noted that the BE results are not meeting the acceptance criteria for BE parameters such as Cmax AUC0-t, AUC0-info.Therefore , the said results and respective application for Prazosin HCL SR tablets 2.5 mg & 5 mg may not be considered.<br><br>Further, the firm presented the revised BE Protocol version no.3; study code: 084-23 with proposed reformulated test product. The committee in principle agreed with the BE protocol which firm should submit with the fresh application for |

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|                           |   |   | proposed reformulated test product to CDSCO.  |
| <b>New Drugs Division</b> |   |   |   |
| 5.                        | ND-11011(15)/10/2024-e office<br>Vericiguat 2.5 mg, 5 mg and 10 mg film coated tablets      | M/s Bayer Pharmaceuticals Pvt. Ltd.       | <p>The firm presented the proposal for amendment in the warning statement of permission granted to import and market Vericiguat 2.5 mg, 5 mg and 10 mg film coated tablets before the committee.</p> <p>After detailed deliberation, the committee agreed for the amendment in warning statement from 'To be sold by retail under the prescription of a cardiologist only' to 'To be sold by retailer under the prescription of consultant cardiologist and physician with post graduate qualification in medicine only'.</p> <p>The committee recommended that the firm should submit PSUR every year for next 4 years from the date of amendment to the warning statement to be reviewed by SEC cardiology.</p> |
| 6.                        | ND/IMP/21/000062<br>Inclisiran Solution for injection in pre-filled syringe<br>284mg/1.5 ml | M/s Novartis Healthcare Ltd.              | <p>The firm presented the proposal for amendment in the warning statement of permission granted to import and market Inclisiran Solution for injection before the committee.</p> <p>After detailed deliberation, the committee did not recommend for the amendment in warning statement.</p> <p>The drug Inclisiran solution for injection should be prescribed with warning statement as follows: 'To be sold by retail under the prescription of cardiologist only'.</p>  |
| 7.                        | ND/MA/24/000125<br>Esaxerenone tablets<br>2.5mg and 5 mg                                    | M/s Sun Pharmaceutical Industries Limited | <p>The firm presented the proposal to manufacture and market Esaxerenone Tablets along with request for grant of permission to conduct phase –III Clinical trial and deliberation of comparative bioavailability before the committee.</p> <p>The committee deliberated in detail that Esaxerenone tablets 2.5mg and 5 mg is not indicated for essential hypertension as per the guidelines.</p>  |

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|                     |  |                                  | <p>The committee noted that another applicant has been recommended for grant of permission to conduct Phase-III Clinical trial of same drug with the indication resistant hypertension.</p> <p>The committee reviewed and requested the firm that the BE study conducted for export purpose should be submitted along with BE study protocol for further review.</p> <p>The firm also presented the phase III protocol on essential hypertension which was reviewed by the committee. The committee opined that the firm needs to conduct a phase III clinical study on resistant hypertension and submit the protocol accordingly to the committee.</p>   |
| <b>FDC Division</b> |  |                                  |  |
| 8.                  | <p>FDC/MA/24/000232</p> <p>Bisoprolol Fumarate IP 2.5mg/5mg + Cilnidipine IP 10mg/10mg + Telmisartan IP 40mg/40mg film coated tablet</p> | M/s Ravenbhel Healthcare Pvt Ltd | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee recommended as under:</p> <ol style="list-style-type: none"> <li>1. The firm should present the justification on rationality for combining this FDC and its significant benefit along with recent supporting document/ literature.</li> <li>2. Justification on dose titration with recent supporting document/ literature.</li> <li>3. International approval status.</li> <li>4. Recent scientific literature available from peer reviewed journal in support of combining the 3 drugs in this FDC.</li> </ol> <p>Accordingly, the firm should submit above data for further review by the committee.</p> |