**Recommendations of the SEC (Cardiovascular & Renal) made in its 130th meeting held on 19.07.2023 at CDSCO (HQ), New Delhi:**

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **SND Division** | | | |
| 1. | SND/MA/22/000169<br><br>Desidustat Tablets 100mg | M/s. Zydus Life Sciences | In light of earlier SEC recommendation dated 19.04.2023, the firm presented their proposal for package insert approval of Desidustat tablets 100mg along with safety data before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the package insert with condition that, the firm should update the PSUR data periodically on the quarterly basis along with strength wise patient utilization data and adverse events. |
| 2. | SND/IMP/23/000037<br><br>Empagliflozin Tablets 10 mg & 25 mg | M/s. Boehringer Ingelheim | The firm did not turn up for presentation. |
| 3. | SND/MA/23/000010<br><br>Bisoprolol Fumarate Tablets 1.25 mg/ 3.75 mg/7.5 mg | M/s. Windlas Biotech Ltd. | The firm did not turn up for presentation. |
| 4. | SND/MA/23/000055<br><br>Bisoprolol Fumarate Tablets 3.75mg/7.5mg | M/s. Akums Drugs & Pharmaceuticals | In light of earlier SEC recommendation dated 29.03.2023, the firm has presented their proposal for manufacturing and marketing of Bisoprolol Fumarate tablets 3.75mg/7.5mg along with approval status of the product in key countries, facts for BE and clinical trial study waiver with justification, supporting data/ literature etc. before the committee.<br><br>After detailed deliberation, the committee considered the request of the firm for Bioequivalence study and clinical trial waiver and recommended for grant of permission for manufacturing and market of the applied product Bisoprolol Fumarate tablets 3.75mg/7.5mg for already approved indication. |

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **FDC Division** | | | |
| 5. | FDC/MA/22/000108<br><br>Metoprolol Succinate 25mg (as extended release tablet) + Telmisartan 40mg + Amlodipine 5 mg tablets | M/s. Ajanta Pharma Ltd. | The firm did not turn up for presentation. |
| 6. | 04-11/2017-DC (Pt.Akums)<br><br>Cilnidipine + Chlorthalidone + Telmisartan (20mg+12.5mg+ 40mg) Film Coated Tablets | M/s. Akums Drugs & Pharmaceuticals | In light of the earlier SEC recommendation dated 12.01.2018, the firm presented its proposal before the committee along with Phase III clinical trial study protocol.<br><br>After detailed deliberation, the committee recommended that the firm should include the following points in the protocol:<br>1. The firm should revise inclusion criteria i.e. chronic disease patients and patients with severe essential hypertension should also be included.<br>2. Modification in Lab investigation like investigation for secondary cause of hypertension, Renal Doppler test and Ultrasonography, etc. need to be added. Repeat test should be done at visit 1, 2 and 3.<br><br>Accordingly, the firm should submit the revised Phase III clinical trial protocol to CDSCO for further review by the committee. |
| 7. | FDC/MA/23/000164<br><br>Metoprolol Succinate eq. to Metoprolol Tartrate 25mg/50mg + Telmisartan 40mg/40mg + Amlodipine Besilate eq. to Amlodipine5mg/5mg Tablets | M/s. Akums Drugs & Pharmaceuticals | The firm presented its proposal before the committee along with BE study protocol and Phase III clinical trial waiver.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study.<br>Phase III clinical trial waiver was not considered at this stage.<br><br>The result of the BE study should be presented before the committee for review and further consideration of the clinical trial waiver. |

**SEC (Cardiovascular & Renal) meeting dated 19.07.2023**