

**Recommendations of the SEC (Urology) made in its 04<sup>th</sup>/25 meeting held on 17.04.2025 at CDSCO HQ New Delhi:**

| S. No                     | File Name & Drug Name, Strength             | Firm Name                                  | Recommendations   |
|---------------------------|---|--|---|
| <b>New Drugs Division</b> |   |  |   |
| 1.                        | ND/MA/24/000147<br>Vibegron Tablets<br>75mg | M/s MSN<br>Laboratories<br>Private Limited | <p>The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vibegron Tablets 75 mg along with Phase III clinical trial protocol and BE study report before the committee.</p> <p>The committee noted the BE study result as presented by the firm.</p> <p>After detailed deliberation, the committee noted that Tolterodine is not an appropriate comparator as proposed by the firm for Phase III Clinical Trial to study safety &amp; efficacy of the drug Vibegron Tablets 75mg. The committee recommended the drug Mirabegron as comparator arm.</p> <p>Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.</p> |