**Recommendations of the SEC (Urology) made in its 05th/24 meeting held on 25.07.2024 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **Medical Device Division** | | | |
| 1. | CI/MD/2023/108593<br><br>Robotic Surgery System (Brand Name: BMR-5000) | M/s. Crosslay Remedies Limited | In light of earlier SEC recommendations dated 27.03.2024, the firm presented the proposal for grant of permission to conduct Pivotal clinical investigation on proposed device i.e. Robotic Surgery System (Brand Name: BMR-5000) in the country on Indian population, before the committee.<br><br>After detailed deliberation, the committee recommended for the grant of permission to conduct Pivotal clinical investigation of the proposed product in the country. |
| 2. | CI/MD/2023/107687<br><br>Urine leak and flow capture device | M/s.Abhaya-3CD Private Limited | In light of earlier SEC recommendations dated 25.04.2024, the firm presented revised clinical investigation plan for grant of permission to conduct clinical investigation on proposed device i.e. Urine leak and flow capture device in the country on Indian population, before the committee.<br><br>After detailed deliberation, the committee recommended for the grant of permission to conduct Pivotal clinical investigation on proposed device in the country subject to the following condition:<br><br>1. The firm shall include more study centers, preferably two, for the conduct of said study and proportionately the number of patients should also be increased. |
| **FDC Division** | | | |
| 3. | FDC/MA/23/000020<br><br>Tamsulosin Hydrochloride IP (MR) 0.4mg/0.4mg + Mirabegron (ER) 25mg/50mg tablets | M/s. Windlas Biotech Limited | In light of the earlier SEC recommendation dated 28.02.2023, the firm presented the proposal along with BE study report and Phase III CT study protocol before the committee.<br><br>After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol, the |

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| | | | committee opined that:<br><br>1. The protocol is not scientifically justified and need to be revised for better justification.<br>2. BPH patient inclusion criteria should be revised for their confirmed diagnosis.<br>3. Firm should change the comparator arm.<br><br>Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee. |