Recommendations of the SEC (Urology) made in its 03rd/24meeting held on 25.04.2024 at CDSCO HQ, New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
1.	CI/MD/2023/107687 Urine leak and flow capture device	M/s.Abhaya-3CD Private Limited	The firm presented the revised clinical investigation plan before the experts. After detailed deliberation, the expert committee suggested that the firm should come up with more sites and patients by including Government institutions for conduct of the clinical study. Accordingly, the firm need to submit revised clinical investigation plan for further deliberation before committee.
FDC Division			
2.	FDC/MA/23/000003 Mirabegron (As prolonged Release) + Tamsulosin Hydrochloride (As Prolonged Release) 25mg/50mg/25mg/50 mg + 0.2mg/0.2mg/0.4mg/0 .4mg	M/s. Ravenbhel Healthcare	In light of earlier SEC recommendation dated 28.02.2023, the firm presented the proposal along with BE study report and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol, the committee opined that the control arm should have active control in Phase III CT protocol. Accordingly, the firm should submit revised Phase III clinical trial protocol for further review by the committee.