Recommendations of the SEC (Urology) made in its 2nd/24 meeting held on 27.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2023/90001 Feto Safe (Cervical) Cerclage Pessary	M/s.Ziller Medical Inc.	The firm presented proposal for grant of permission under MD-23 for conduct of Pilot clinical investigation on "Feto Safe (Cervical) Cerclage Pessary device" in the country. before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of pilot clinical investigation of the proposed product in the country.
2.	CI/MD/2023/108593 Robotic Surgery System (Brand Name: BMR-5000)	M/s.Crosslay Remedies Limited	The firm presented the proposal for grant of permission for conduct of Pivotal Clinical Investigation on proposed medical device Robotic Surgery System (Brand Name: BMR-5000) in the country on Indian population, before the committee. After detailed deliberation, committee recommended the following: 1. The Sponsor and Investigator of the study should not be from the same/subsidiary institution. 2. Include additional study centers which are not the part/unit/subsidiary of the Sponsor (i.e. M/s. Crosslay Remedies Limited) Accordingly, firm should submit above said documents as asked by the committee to CDSCO for taking further necessary action in the matter.
3.	MD/PostAppr/2023/14522 HepaSphere Embolization MicroSpheres, Embosphere Microspheres in vial	M/s.Merit Medical Systems India Pvt. Ltd.	In light of earlier SEC recommendations dated 30.08.2023, the firm presented proposal for extension of intended use of the proposed products (1) HepaSphere Embolization MicroSpheres and (2) Embosphere Microspheres in vial before the committee for allowing import of devices for commercial sale.

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			After detailed deliberation, the Committee observed that Safety and performance data of the product HepaSphere Embolization MicroSpheres for extended indication is adequate. However, the committee observed that Safety and performance data of the product Embosphere Microspheres in vial for extended indication in the embolization of Prostatic arteries for symptomatic Benign Propstatic Hyperplasia (BPH) is inadequate. In this regard, the committee recommended that the firm should submit following details of the product Embosphere Microspheres in vial for extended indication in the embolization of Prostatic arteries for symptomatic Benign Propstatic Hyperplasia (BPH) for further consideration: 1. Clinical data generated on Indian population in the country. 2. Post Marketing Surveillance data of the product Embosphere Microspheres in vial (for extended indication in the embolization of Prostatic arteries for symptomatic Benign Propstatic Hyperplasia (BPH)) from the countries where the extended indication is approved and marketed. 3. Details of current / revised guidelines available in USA & Europe for embolization procedures and recommended clinical study on proposed products for extending the indication as per the said guidelines. 4. Clarification for the delay in submission of application for said extended indication for the product Embosphere Microspheres in vial for commercialization in India, as it is observed that the said product was already approved in USA since 2018.

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SND Division			
4.	SND/MA/23/000234 Flavoxate HCl SR Tablets 600mg	M/s. Ravenbhel Healthcare Private Limited	This proposal is for correction in minutes of meeting held on 19.12.2023. In the said minutes of meeting in item no.03 for Flavoxate HCL SR tablet 600mg of M/s Ravenbhel Healthcare Pvt. Ltd. In the recommendation column, the second para may be corrected as **"**The Committee noted that the Flavoxate HCl Tablets 100mg already approved by the CDSCO in year 1981" instead of "The Committee noted that the Flavoxate HCl SR Tablets 100mg already approved by the CDSCO in year 1981." The committee recommended for correction in the minutes of meeting held on 19.12.2023.
FDC Division			
5.	FDC/MA/22/000081 Dutasteride IP + Silodosin 0.5mg/0.5mg + 4mg/8mg uncoated bilayered tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 09.12.2022, the firm presented the Active PMS protocol before the committee. After detailed deliberation, the committee opined the following modification: 1. Inclusion criteria should be modified by reducing the PSA level to less than 4. 2. PSA should be done at baseline and at the end of the study after 3 months. 3. More sites to be included which should be geographically distributed so that there should be 50% each from Government and Private sites. Accordingly, revised Active PMS protocol should be submitted to CDSCO for further review by the committee.