Recommendations of the SEC (Reproductive & Urology) made in its 88th meeting held on 29.11.2023 & 30.11.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000129 Elagolix 150mg & 200mg Tablets	M/s. Exemed Pharmaceuticals	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Elagolix Tablets 150 mg and 200 mg along with protocol for BE study (Elagolix Tablets 200mg) and protocol for Phase III clinical trial (Elagolix Tablets 150 mg) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Bioequivalence study as per the presented protocol (protocol no. 022-23 version no. 00 dated 29.07.2023) subject to the condition that the firm should submit pre-clinical toxicity study report. The firm should submit Bioequivalence study report for further review of phase 3 clinical trial by committee.
2.	12-01/23-DC (Pt-149) Mitomycin	Lok Manya Tilak Municipal Medical College, Sion, Mumbai	The firm presented the proposal of academic clinical trial to conduct the study on efficacy of intralesional mitomycin as an adjunct to direct visual internal urethromy, a randomized clinical trial of the drug before the committee. After detailed deliberation, the committee opined that- 1. A compiled clinical trial literature/data along with justification for use of subject drug mitomycin in the present study. 2. Stability of the formulation after reconstitution should be submitted to the CDSCO for further review by committee.
SND Division			
3.	SND/MA/23/000164 Azithromycin Tablets 500mg (New Indication)	M/s. Alembic Pharmaceuticals Limited	In light of earlier recommendation of SEC dated 20.07.2023, the firm re-deliberated the proposal for additional indication of Azithromycin tablets 500 mg i.e. "To prevent maternal infection in women undergoing planned vaginal delivery". The firm presented additional published literature and the results of international clinical trials data with subset of Indian patients and requested

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			for local clinical trial waiver along with the justification. After detailed deliberation, the committee opined that there is no justification in using the drug as prophylactic drug in normal/planned vaginal delivery. Therefore, the committee did not recommend for approval of the proposed additional indication of Azithromycin tablets 500 mg of the firm.
4.	SND/MA/23/000234 Flavoxate Hydrochloride IP 600 mg sustained release tablet	M/s. Ravenbhel Healthcare Private Limited	The firm did not turn up for presentation.
5.	SND/MA/23/000259 Dydrogesterone SR Tablet 30mg	M/s. Mankind Pharma Limited	The firm presented the BE Study protocol and Phase III clinical trial protocol for the indication – Endometriosis Associated Pelvic Pain before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol of Dydrogesterone Sustained Release Tablets 30 mg. Further, the Phase III clinical trial permission may be granted after submission and review of the BE study report by the committee.
6.	SND/MA/23/000196 Dydrogesterone Tablets kits (Each Part contains Part (A) 1 Dydrogesterone Tablet 40 mg + Part (B) 06 Dydrogesterone Tablets 10 mg (Earlier 10 Dydrogesterone tablets 10 mg)	M/s. Mankind Pharma Limited	In light of earlier recommendation of SEC dated 30.08.2023,the firm re-deliberated the proposal for Dydrogesterone Tablets kits with Phase-III CT protocol & BE Protocol and reduce Part (B) Dydrogesteone tablets 10 mg pack size from 10 tablets to 06 tablets. The firm presented BE Protocol for generating the safety data in Indian population and also requested for conducting the Phase III clinical trial. After detailed deliberation, the committee opined initially, firm should conduct the Bioequivalence study of Dydrogesterone Tablet 40 mg and submit the data before the committee to conduct the Phase III clinical trial. Accordingly, firm is required to present the BE study report along with clinical trial Protocol for further consideration.

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7.	SND/MA/23/000051 Dydrogesterone Extended Release Tablets 30mg	M/s. Zydus Healthcare Limited	In light of earlier recommendation of SEC dated 26.04.2023, the firm presented their proposal for grant of permission to manufacture and marketing of Dydrogesterone film coated sustained release tablets 30mg for the applied indication alongwith the Bioequivalence study report and Phase III Clinical study report. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Dydrogesterone film coated sustained release tablets 30mg for the indication "For the treatment of Endometriosis" with the condition to conduct a Phase IV Clinical study. However, the firm should fulfil the requirements of CMC data before approval of the product. Accordingly, the firm should submit Phase IV protocol to CDSCO within 3 months of approval for further evaluation by the committee.
8.	SND/MA/22/000353 Dydrogesterone Extended Release Tablets 30mg	M/s. Ravenbhel Healthcare Private Limited	In light of earlier recommendation of SEC dated 31.01.2023, the firm presented their proposal for grant of permission to manufacture and marketing of Dydrogesterone film coated sustained release tablets 30mg for the applied indication alongwith the Phase III Clinical study report. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Dydrogesterone film coated sustained release tablets 30mg for the indication "For the treatment of Endometriosis" with the condition to conduct a Phase IV Clinical study. However, the firm should fulfil the requirements of CMC data before approval of the product. Accordingly, the firm should submit Phase IV protocol to CDSCO within 3 months of approval for further evaluation by the committee.
FDC Division			
9.	FDC/MA/18/000074	M/s. Synokem Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 20.07.2023, the firm presented their proposal along with justification for the proposed FDC.

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	L-Methylfolate + Dehydroepiandrosterone (as sustained release) + Vitamin D3 IP 1mg + 75 mg +2000IU film coated bilayered tablet		After detailed deliberation, the committee noted the following: 1. The firm did not present any published literature, peer review of the FDC for support of use of these drug in female infertility. 2. The product is not approved internationally. 3. DHA 75mg SR is not approved. 4. There is no unmet need for the proposed strengths of the FDC. In view of above, the committee rejected for approval of the FDC.
10	FDC/MA/23/000309 Mirabegron Ph. Eur. (ER tablets) 25mg/50mg + Tamsulosin Hydrochloride IP (ER pellets) 0.4mg/0.4mg in capsule	M/s. Sun Pharma Laboratories Limited	The firm presented its proposal before the committee along with BE study protocol and justification for CT waiver. After detailed deliberation, the committee did not consider the request for CT waiver and recommended for conducting the BE study. The result of the BE study should be presented before the committee along with Phase III clinical trial protocol.
11	FDC/MA/23/000323 Mirabegron Ph. Eur. (ER tablets) 25mg/50mg + Silodosin JP (as granules) 8mg/8mg in capsule	M/s. Sun Pharma Laboratories Limited	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial.
12	FDC/MA/23/000319 Tamsulosin Hydrochloride IP (as extended release tablet) 0.4mg + Dutasteride IP (as film coated tablet) 0.5mg + Tadalafil IP (as film coated tablet) 2.5mg/5mg capsule	M/s. Malik Lifesciences Pvt. Ltd.	The firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for conducting the BE study. Accordingly, the firm should submit BE study report along with Phase III clinical trial protocol to CDSCO for further review by the committee.
Medical Device Division			

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13	CI/MD/2023/90001 Cerclage Pessary (Cervical)	M/s. Ziller Medical INC.	The firm presented the case before the committee. It has been observed that the applicant has not generated the biocompatibility study data, preclinical data and other QC data on the investigational devices after obtaining test license in MD 13 under MDR, 2017. After detailed deliberation, the experts opined that the firm should submit the above data after obtaining MD-13 to the Central Licensing Authority to prove the safety of the devices before it is to be used in the proposed clinical investigation.