Recommendations of the SEC (Reproductive & Urology) made in its 85th meeting held on 30.08.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000109 Dydrogesterone Film Coated Sustained Release tablets 20mg/30mg	M/s. Macmillon Pharmaceuticals Pvt. Ltd.	The firm presented two separate BE study protocols for Dydrogesterone Film Coated Sustained Release tablets 20mg and 30mg respectively. Firm has mentioned that they will submit CT protocol later on as there clinical team is currently unwell and not available for presentation. After detailed deliberation, the committee recommended to conduct the BE Study for Dydrogesterone Film Coated Sustained Release tablets 20mg and 30mg separately and asked the firm to submit the CT protocol along with BE study reports of Dydrogesterone Film Coated Sustained Release tablets 20mg/30mg.
FDC Division			
2.	FDC/MA/21/000254 Silodosin + Mirabegron (8mg/8mg+ 25mg/50mg) Tablets	M/s. Windlas Biotech Ltd.	In light of earlier SEC recommendation dated 28.07.2022, the firm presented the Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
3.	FDC/IMP/20/000045 Dydrogesterone + Estradiol (2.5 mg + 0.5mg) Tablets	M/s. Abbott India Ltd.	The firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended to revise the following in Phase IV CT protocol: 1. In Inclusion criteria-seven or more hot flushes over the past 7 days during the 2 week screening period should be replaced by “having an impact on quality of life”.

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			2. Primary end point - Change in quality of life (QOL) scoring. 3. Secondary end point-Change in the frequency of hot flushes from baseline. 4. Objective criteria needs to be defined for mild, moderate and severe hot flushes depending on QOL scale scoring. Accordingly, the firm should submit revised Phase IV CT protocol for review by DCGI.
4.	FDC/MA/22/000421 Norethindrone acetate USP + Estradiol (as hemihydrate) eq. to Estradiol + Relugolix (0.5mg+1.0mg+40mg) Tablets	M/s. Akums Drugs & Pharmaceuticals	In light of earlier SEC recommendation dated 31.01.2023, the firm presented the BE report along with justification for Phase III CT waiver before the committee. The committee noted that one of the drug Relugolix in the proposed FDC is recommended by the committee but not yet approved by CDSCO. After detailed deliberation, the committee considered and accepted the BE report and opined that further decision on manufacturing and marketing of the proposed FDC may be taken, once the approval of the drug Relugolix is released.
5.	FDC/MA/22/000319 Estradiol USP (as hemihydrate) eq. to anhydrous Estradiol + Progesterone IP (1mg+100mg) soft gelatin Capsule	M/s. Akums Drugs & Pharmaceuticals	In light of earlier SEC recommendation dated 30.11.2022, the firm presented the BE report along with justification for Phase III CT waiver before the committee. The committee noted that the said FDC is already approved in US, Australia, UK, Canada, EU etc. After detailed deliberation, the committee considered the Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
6.	FDC/MA/23/000014 Combikit of Silodosin Capsules 8mg/8mg + Mirabegron ER	M/s. MSN Laboratories Pvt. Ltd.	The firm did not turn up for presentation.

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	Tablets 25mg/50mg Tablets		
7.	FDC/MA/23/000184 Levonorgestrel IP 0.15mg+ Ethinyloestradiol IP 0.03 mg Tablet	M/s. Pfizer Limited	The firm presented their proposal for additional indication for the proposed FDC before the committee. After detailed deliberation, the committee recommended for grant of approval for the additional indication of the proposed FDC, subject to condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
Medical Device Division			
8.	MD/PostAppr/2023/14522 HepaSphere Embolization MicroSpheres, Embosphere Microspheres in vial	M/s. Merit Medical System India Pvt. Ltd.	The firm presented proposal for extension of intended use of the proposed products HepaSphere Embolization MicroSpheres andEmbosphere Microspheres in vial before the committee for allowing import of devices for commercial sale. Committee observed that Safety and performance data of thetwo proposed products for extending indication are inadequate. After detailed deliberation,the committee recommended that the firm should submit following details for further consideration: 1. Robust clinical investigational study data such as Randomized control trials with multi-arm generated from the bothproposed products for extended indication. 2. 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. 3. Details of clinical data submitted forregulatory approvals of the proposed products for extending indication in countries such as USA & EU along with

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			their approvals certificate. 4. Also details of year wise units sold in countries where the extended indication is approved along with post market surveillance data.
SND Division			
9.	SND/MA/23/000140 Dydrogesterone Sustained Release Tablets 20mg	M/s. Abbott India Limited	In light of earlier SEC recommendation dated 25.05.2023, the firm presented the BE report before the committee. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial as per the earlier SEC recommendation dated 25.05.2023
10.	SND/MA/23/000196 Dydrogesterone Tablets Kit (Each kit contains; Part (A) 1 Dydrogesterone Tablets 40mg + Part (B) 14 Dydrogesterone Tablets 10mg)	M/s. Mankind Pharma Ltd.	The firm presented the Phase III clinical trial waiver justification and BE Study protocol before the committee. After detailed deliberation, the committee is of the opinion that the Dydrogesterone Tablets Kit (Each kit contains; Part (A) 1 Dydrogesterone Tablets 40mg + Part (B) 14 Dydrogesterone Tablets 10mg) is not approved anywhere in the world. The proposed dose is very high and may lead to intolerance, ADR, SAEs. Further, patients with threatened abortion may develop absent cardiac activity or may get aborted anytime. Clinicians may want to change/titrate the dose regimen based on the patient response/condition. As 10 mg tablets of dydrogesterone are available, clinician should have the discretion for change or titration of dose. Therefore, the committee did not recommend for approval of the subject kit at this stage without any safety and supporting data.
11.	SND/MA/23/000207 Dydrogesterone Sustained Release Tablets 20mg	M/s. Mankind Pharma Ltd.	The firm presented the BE Study protocol and revised 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 20mg. Further, the Phase III clinical trial permission may be

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			granted after submission and review of the BE study report by the committee.