

Recommendations of the SEC (Reproductive & Urology) made in its 81st meeting held on 26.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/0000060 Lacticaseibacillus rhamnosus regenerans LCR35 vaginal capsules	M/s. Sundyota Numandis probioceuticals Pvt. Ltd.	The firm presented the proposal to import and marketing the drug Lacticasaibacillus rhamnosus regenerans LCR35 vaginal capsules 341.0mg along with request for local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should submit Phase-III clinical trial protocol with sample size of 200 - 300 subjects of non-pregnant women for further consideration of the committee.
2.	ND/MA/23/000057 Elagolix film coated tablets 150mg & 200mg	M/s. Alkem Laboratories Ltd	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Elagolix Tablets 150mg and 200mg along with protocol for BE study and protocol for Phase-III clinical trial before the committee. After detailed deliberation, the committee recommended to conduct the BE study and Phase-III clinical trial subject to following conditions: I. The clinical trial sites should be equally distributed amongst government and private institutions. II. The clinical trial sites should be geographically distributed in the country.
SND Division			
3.	SND/MA/22/000317 Dydrogesterone film coated sustained release tablets 20mg	M/s. Synokem Pharmaceuticals	The firm presented the application for manufacturing and marketing of Dydrogesterone film coated sustained release tablets 20mg for the indication “for the treatment of endometriosis in women” along with Phase III clinical trial protocol and BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial and BE study as per the protocol presented by the firm.

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			The committee also suggested to monitor the size of the endometrioma of participating subjects during the clinical trial.
4.	SND/MA/23/000051 Dydrogesterone Extended release tablets 30mg	M/s. Zydus Healthcare Limited	The firm presented the application for manufacturing and marketing of Dydrogesterone film coated sustained release tablets 30mg for the indication “For the management of various conditions where the progesterone supplement is needed”. The firm presented the Phase III clinical trial protocol to assess the efficacy and safety of Dydrogesterone film coated sustained release tablets 30mg for the treatment of endometriosis in women and BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial and BE study as per the protocol presented. The committee also suggested to monitor the size of the endometrioma in the participating subjects during the clinical trial and more clinical trial sites should be included in the study.
5.	SND/MA/22/000203 Estradiol Vaginal Inserts USP 4mcg and 10mcg	M/s. West-Cost Pharmaceutical Works Ltd.	The firm requested to defer the proposal for next meeting.
6.	SND/MA/23/000069 Dydrogesterone film coated sustained release tablets 30mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the application for manufacturing and marketing of Dydrogesterone film coated sustained release tablets 30mg for the indication “Treatment of Women Patients diagnosed with confirmed Endometriosis” along with Phase III clinical trial protocol and BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial and BE study as per the protocol presented. The committee also suggested to monitor the size of the endometrioma of trial participants during the study.

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FDC Division			
7.	FDC/MA/18/000074 L-Methylfolate 1mg + Dehydroepiandrosterone SR 75 mg + Vitamin D3 2000IU tablets	M/s. Synokem Pharmaceuticals	Inlight of earlier SEC recommendation dated 15.10.2019, the firm presented its proposal before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 15.10.2019. Accordingly, the firm should submit the detailed justification for the FDC with supportive literature for review by the SEC.
8.	FDC/MA/22/000068 Silodosin 8mg + Solifenacin Succinate 5mg tablets	M/s. Savi Health	In light of earlier SEC recommendation dated 27.04.2022, the firm presented its proposal before the committee along with justification for Phase III CT waiver. After detailed deliberation, the committee recommended that the firm should submit the Phase-III CT study report for which CT permission was already granted to the firm. The result of the study should be presented before the committee for further review.
9.	FDC/MA/22/000418 Estradiol (as hemihydrate) USP eq. to Anhydrous Estradiol 0.5mg/1.0mg + Drospirenone IP 0.25mg/0.5mg tablets	M/s. Akums	In light of the earlier SEC recommendation dated 30.01.2023, the firm presented its proposal before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 30.01.2023. The committee also recommended that the firm should present the Phase IV CT protocol along with justification for Phase III CT waiver to CDSCO for further consideration of the committee.
Medical Device Division			
10.	MFG/MD/2023/85265 Uroflowmeter (AccuflowUro)	M/s. VTitan Corporation Private Limited	The firm presented the proposal for the product Uroflowmeter (AccuflowUro) for grant of permission to manufacture for sale or distribution in India before the committee. After detailed deliberation, the committee observed that the clinical data presented by the firm was inadequate for establishing safety and performance of the proposed device. Further, the committee recommended that the firm should submit a clinical investigation protocol to conduct clinical

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			investigation in India for generating sufficient clinical data for establishing quality, safety and performance of the proposed device.