

Recommendations of the SEC (Reproductive and Urology) made in its 64th meeting held on 28.10.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-36/17-DC Film coated tablets of dry extract of AgnusCastus fruit	M/s. G.S. Pharmabutor Pvt. Ltd.	In light of earlier SEC recommendation dated 25.02.2021, the applicant presented the proposal before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 25.02.2021. Accordingly, the firm should present the case with proper addressal of the issue. It should also meet the regulatory requirements.
2.	12-39/17-DC Film coated tablets of dry extract of Cimicifuga rhizome	M/s. G.S. Pharmabutor Pvt. Ltd.	In light of earlier SEC recommendation dated 25.02.2021, applicant presented the proposal before the committee. After detailed deliberation the committee reiterated its earlier recommendation dated 25.02.2021. Accordingly, the firm should present the case with proper addressal of the issue. It should also meet the regulatory requirements.
SND Division			
3.	SND/MA/19/000124 Medroxy progesterone Acetate Sustained Release (SR) Tablet 30 mg	M/s. Synokem	The firm didn't turn up for the presentation.
4.	12-14/2021-DC (Pt-misc-SND) Ulipristal acetate 5mg tablet	M/s. Synokem	In light of earlier SEC recommendation dated 26.08.2021, the firm presented post marketing surveillance data including liver function test and peer reviewed published literature for Ulipristal Acetate Tablets 5mg. After detailed deliberation, the committee recommended for revocation of the suspension allowing manufacture and market of Ulipristal Acetate Tablets 5mg for restricted use as recommended by European Medicines Agency which indicates that the medicine can only be used to treat uterine fibroids in premenopausal women for whom surgical procedures (including uterine fibroid embolisation) are not appropriate or have not worked. The medicine must not be

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			used for controlling symptoms of uterine fibroids while awaiting surgical treatment. The warning should be included in educational materials for doctors, package insert & label that, this drug has been associated with irreversible liver damage even leading to death, so caution must be used when this drug is prescribed & LFT should be done prior to giving this drug & there should be every 15 days monitoring of the LFT & drug should be stopped in case of elevated LFT.
FDC Division			
5.	FDC/MA/21/000087 Each 5gram contains: Sildenafil Citrate IP Eq. to Sildenafil 100 mg + Dapoxetine Hydrochloride eq. to Dapoxetine 60 mg oral Jelly	M/s. Ajanta Pharma Ltd.	In light of the earlier recommendations of SEC dated 25.06.2021 and 28.06.2021, the firm presented their proposal along with BE study report. After detailed deliberation, committee recommended for grant of permission for manufacturing & marketing of the proposed FDC.
6.	FDC/IMP/20/000045 Dydrogesterone + Estradiol (2.5 mg + 0.5 mg) tablets	M/s. Abbott	In light of the earlier recommendations of SEC dated 25.06.2021 and 28.06.2021, the firm presented their proposal along with Phase IV CT protocol. Committee noted that the firm had proposed the names of the sites without taking the consent of the investigators. The firm should revise the list of investigators and submit the same to CDSCO. After detailed deliberation, the committee recommended for grant of permission for conducting the Phase IV CT study with the condition that more Government sites should be included in the study..
Medical Device Division			
7.	CI/MD/2021/35989 Sterile Disposable Foley Balloon Catheter (Infection stop)	M/s. Weinnovate Bio Solutions Pvt.Ltd	In light of the earlier recommendations of SEC dated 25.06.2021 & 28.06.2021, the firm presented their proposal to conduct the Phase IV clinical investigation before the committee. After detailed deliberation, committee recommended the grant of permission to conduct the Phase IV clinical investigation in the country with the condition that the sample size should be minimum 400 at minimum 5

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			investigation sites.
8.	IMP/MD/2021/13990 Uventa Urethral Stent	M/s. Innovative Therapeutics Pvt. Ltd.	<p>In light of the earlier recommendations of SEC dated 24.11.2020, 25.06.2021 & 28.06.2021, the firm presented their proposal before the committee.</p> <p>After detailed deliberation, committee recommended that the firm should conduct pivotal clinical investigation with the proposed product on Indian population.</p> <p>Accordingly, the firm should submit the clinical investigation protocol for review by the committee.</p>