

Recommendations of the SEC (Reproductive & Urology) made in its 42th meeting held on 18.06.2019 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New Drugs Division			
1	ND/MA/18/000029 Flibanserin 10mg tablets	M/s Hetero	In light of the recommendation of the committee on 26.03.2019, the firm presented their proposal and the committee re-deliberated the matter in detail. The committee reiterated its earlier recommendation for grant of permission to manufacture and marketing of the drug subject to fulfillment of the following conditions: 1. The firm should submit the results of the Bio equivalence study along with the Phase IV protocol with detailed safety, efficacy assessment criteria, sample size justification, Informed Consent Form for the partners and details of sites with feasibility assessment regarding availability of patients. 2. Study should be conducted under the supervision of Urologist, Gynecologist & Psychiatrist, one being the Principal investigator, other two being co-investigators. 3. The test product should be preceded by placebo run in the study. The product should be sold by retail under the prescription of Urologist /Gynecologist / Psychiatrist.
SND Division			
2	SND/MA/18/000032 Ulipristal Acetate 30mg tablet (add. Strength & Indication)	M/s Synokem Pharmaceutica l Ltd.	The firm has presented their proposal along with protocol for Phase III clinical trial. The committee after detailed deliberation recommended for grant of permission to conduct the trial.
Medical Device Division			
3	IMP/MD/2018/4240 Cervical Ripening Balloon	M/s Cook India Medical Pvt. Ltd., Chennai	The firm has presented their proposal for grant of permission to import the proposed product i.e., Cervical Ripening Balloon. After detailed deliberation committee recommended for the approval of the product subject to the condition that firm

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			will conduct post marketing clinical investigation in India as per MDR 2017 for which they shall submit the protocol.
4	CI/MD/2018/8919 AQUABEAM Robotic System	M/s JSS Medical Research India Pvt. Ltd.,	The firm has presented their proposal for conduct of clinical investigation on AQUABEAM Robotic System. After detailed deliberation committee recommended for grant of permission to conduct the proposed clinical investigation subject to submission of revised protocol to CDSCO including following details:- 1. Objectives should be restricted as a pilot study for safety and feasibility instead of overall surgeon experience 2. The model no. of the proposed investigational device should be mentioned 3. The number of subjects shall be not less than 50 As proposed by the presenter on behalf of sponsor the study will be followed by a randomized controlled clinical investigation at multiple centers.
FDC Division			
5	04-73/2017-DC Tadalafil+Dapoxetine (20mg/20mg/10mg+60mg/30mg/30mg) Film Coated Tablet	Ajanta Pharma	The firm presented their proposal along with results of clinical trial and bioequivalent study. After detailed deliberation the committee recommended for grant of permission to manufacture the FDC of Tadalafil + Dapoxetine (20mg/20mg/10mg+60mg/30mg/30mg) film coated tablets for the treatment of coexisting Erectile Dysfunction and Premature Ejaculation. The product to be sold by retail under the prescription of Urologists/Psychiatrists only.

S.No	SEC –Experts Name & Designation	Signature
1.	Dr. Anup Kumar Kundu, Prof. & Head, Dept. of Urology, IPGMER & SSKM, Kolkata	
2.	Dr.PikeeSaxena, Professor, Dept. Of Obstetrics &Gynaecology, Lady Harding College, New Delhi.	
3.	Dr. Lakhbir Dhaliwal, Prof. & Head, Dept. of Obstetrics &Gynaecology, PGIMER Chandigarh	
4.	Dr. SeemaSinghal, Assistant Professor, Dept. Of Obstetrics &Gynaecology, AIIMS, New Delhi	
5.	Dr. Rajeev Sood, Prof. & Head, Dept. of Urology, Dr. RML Hospital & PGIMER, New Delhi	
6.	Dr. A. K. Mandal, Prof. & Head, Dept. of Urology, PGIMER, Chandigarh	
7.	Dr. C. D. Tripathi, Prof. & Head, Department of Pharmacology VMMC&Safdarjung Hospital, New Delhi	
8.	Dr. Renuka Malik, Professor, Dept. of Obstetrics &Gynaecology, RML Hospital, New Delhi	