Recommendations of the SEC (Reproductive & Urology) made in its 48th meeting held on 30.01.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name &Drug Name, Strength	Firm's Name	Recommendation
New Drug Division			
1	12-39/17- DC Film coated tablets of dry extract of Cimicifuga rhizome	M/s. G.S. Pharmabutor Pvt. Ltd.,	In light of recommendation of the committee dated 15.10.2019, the firm presented their request for waiver of PK studies. It was also presented by the firm that details about the purified extract (fraction) profile of the product for the four ingredients will be submitted by the firm in next month. The committee after detailed deliberation recommended that the firm should make presentation on all the seven points raised by the committee on 15.10.2019, including details of attempts made by the firm to conduct the PK study to consider the matter further.
2	12-01/12-DC (Pt-9 Dapoxetine) Dapoxetine	PSC	The committee deliberated the matter in detail and recommended for continued marketing of the drug in the country.
SND Division			
3	SND/MA/19/000187 Metformin Prolonged Release Tablet 500mg	M/s. Eris Lifesciences	Firm presented their proposal with local clinical trial waiver along with many published clinical trial reports, recommendations of various national and International societies of Gynecology/Endocrinology etc. The committee opined that the systematic/meta-analysis and other available evidences in various published literature demonstrates that the drug will be useful for the proposed indication of PCOS with established insulin resistance. After detailed deliberation, the committee recommended for approval of drug for additional indication –in PCOS patients with established insulin resistance subject to the condition that the following words should be mentioned conspicuously in the package insert. "There are no adequate and well-controlled studies in pregnant women with Metformin & Metformin should not be used during pregnancy unless clearly needed".

Agenda No	File Name &Drug Name, Strength	Firm's Name	Recommendation
4	SND/IMP/19/000091 Estriol Tablet 1mg/2mg (Additional Strength)	M/s. Torrent Pharma Ltd.	Firm presented their proposal for import and marketing of Estriol tablet 1mg/2mg. The committee noted that Estriol succinate is very old drug approved in India in 1980. Estriol tablet 1mg and 2mg are already marketed in many countries in EU. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Estriol tablets 1mg/2mg.
5	SND/MA/19/000155 PentosanPolysulfate Sodium 10mg/ml sterile solution (Additional Dosage form & Route)	M/s Swati Sepntose	Firm has presented their proposal for manufacturing and marketing of Pentosan Polysulfate Sodium 10mg/ml sterile solution requesting local clinical trial waiver. After detailed deliberation the committee recommended that the firm should submit the animal toxicity study data and also detailed clarification regarding withdrawal of the product from EU along with supporting documents to consider the matter further.
6	SND/MA/19/000156 Progesterone Injection 50mg/2.37ml (22.35mg/ml) (add. Strength)	M/s Sun Pharma	Firm was not ready for presentation.
7	12-63/2018-DC (pt-Synokem SND) Estradiol valerate 4gm SR Tablet	M/s. Synokem Pharmaceuticals	In light of recommendations of the committee dated 26.11.2019, the firm presented the revised Phase III Clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to the following conditions: 1. Inclusion criteria should be revised to include patients with HbA1c less than 6.5%. 2. Patients with breast or ovarian carcinoma should be excluded.
8	12-51/2014-DC (Pt-Synokem-SND) Norethisterone 10 mg film coated CR tablet	M/s. Synokem Pharmaceuticals	In light of recommendations of the committee dated 29.08.2019, the firm presented the reports of multiple dose PK study before the committee. The firm presented the clinical trial data earlier before the committee on 25.04.2018. After detailed deliberation, based on

Agenda No	File Name &Drug Name, Strength	Firm's Name	Recommendation
			clinical trial and PK study data, the committee recommended for grant of permission to manufacture and market Norethisterone 10 mg film coated CR tablet.
FDC Division			
9	04-34/2017-DC Sildenafil+Dapoxetine (100mg/50mg/50mg+60mg /60mg/30mg) Film Coated Tablet	M/s. Ajanta Pharma.	The firm presented the Bioequivalence study as well as Clinical Trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of proposed three strengths of the FDC. Dr Rajeev Sood did not participate in deliberation.
10	FDC/MA/19/0000129 Silodosin + Solifenacin Ph. Eur. (8mg+ 5mg) Capsules	M/s. Sun Pharma	In light of the earlier SEC recommendation dated 26.11.2019, firm presented detailed justification with published reports in support of two arm comparative study and justification of BE study waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed two arm study of proposed FDC Vs Silodosin.