Recommendations of the SEC (Reproductive & Urology) made in its 35th meeting held on 11.09.2018 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
Medical Device Division			
1	CI/MD/2018/4626 Graphene incorporated natural rubber latex condom	M/s. Ethicare Clinical Trial Services, Ahmedabad	The firm presented their proposal for clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to condition that the firm shall carry out the interim analysis after completion of 30 days of trial on 30 couples. The interim report shall be reviewed by the committee.
2	4-MD/CT-217/2017-DC Natural Rubber Latex Male Condoms with 1% Glyceryl Trinitrate Gel	M/s. TTK Protective Devices Limited	The firm presented their proposal without clinical trial protocol as recommended by the SEC in the last meeting held on 25.04.18 as the source of GTN is different. The stability data submitted by the firm is not satisfactory. After detailed deliberation, the committee recommended that the firm should conduct clinical trial in India with proposed new source of GTN and accordingly protocol, should be submitted for review by the committee. Further, the stability data and manufacturing process of GTN gel needs to be resubmitted.
Fixed Dose Combination Division			
3	4-103/2017-DC Myo-insitol BP 550mg+D-chiro Inositol 13.8mg+Metformin Hcl IP 500mg+L-methylfolate calcium 0.5mg+Mecobalamin 750mcg film coated tablet	M/s. Akums Drugs & Pharmaceuticals	The firm presented their proposal before the committee. The committee noted that the individual drugs are not approved for the treatment of PCOS. The combination is also not approved anywhere in world. The standard treatment guidelines also do not recommend such FDC. Hence, the committee did not recommend for the proposed FDC.
4	FDC/ MA /18 /000003 Dutasteride + Sildosin (0.5mg/0.5mg + 4mg/8mg) capsules	M/s MSN laboratories	The firm did not turn up for the presentation.
Subsequent New Drugs Division			
5	12-61/2018-DC (Pt-Synokem-snd) Norethisterone 15mg film coated CR tablet	M/s Synokem	The firm presented the revised BA/BE study protocol and Phase III clinical trial protocol before the committee. The committee noted that the indication dysfunctional uterine bleeding shall be

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			reworded as heavy menstrual bleeding (HMB)/ Abnormal uterine bleeding (AUB). After detailed deliberation, the committee recommended for grant of permission to conduct the BA/BE study as per the protocol presented. Further, the committee noted that in clinical trial protocol the comparator/reference product should be Norethisterone 5mg t.i.d. with appropriate blinding. Accordingly, revised clinical trial protocol should be submitted to CDSCO for approval. Also, the firm should submit the BA/BE study report for review by the committee before initiation of Phase III clinical trial.