Recommendations of the SEC (Reproductive) made in its 08th/25 meeting held on 18.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	MFG/MD/2022/61423 CERVICAL) CERCLAGE PESSARY (Feto Safe)	M/s. ZILLER MEDICAL INC	The applicant has requested for the grant of permission to manufacture the said device by M/s Ziller Medical Inc., Chennai in the country. The applicant presented the Clinical Investigation data generated on Indian population on the said device. After detailed deliberation, the committee opined that Clinical study data produced by the firm is not adequate to demonstrate the safety and performance of the device, due to the following concerns: 1. The selection of population is not appropriate. 2. Data produced was not robust to prove the patient safety. 3. Major Adverse events reported were not described properly in terms of maternal and neonatal outcomes. In view of the above, the committee opined that the firm shall generate additional multicentric clinical study data addressing the concerns raised by the experts. Accordingly, the applicant shall submit clinical study protocol for conduct of multicentric study to prove the safety and performance of the device.
New Drugs Division			
2.	ND/CT/25/000076 Elagolix Tablets 150 mg and 200 mg	M/s. MSN Laboratories Private Ltd.	In line with the condition of permission for manufacturing and marketing of drug Elagolix Sodium Tablets 150 mg & 200 mg, the firm presented Phase IV clinical trial protocol titled "A Multicentre, Open-Label, single arm Phase IV Clinical Trial to Assess the Safety and Effectiveness of Elagolix Tablets 200 mg for Treatment of Patients with Moderate to Severe Pain Associated with Endometriosis" (Vide protocol Number:017/MSN/ELGLX/2025, Version: 1.0, Dated: 03 rd July,2025) for Elagolix Sodium Tablets 150 mg & 200

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			mg, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented. The results of Phase IV Clinical Trial should be submitted to CDSCO for further review by the committee.
3.	ND-12011/2/2025-eoffice Mifepristone for induction of labour in late intrauterine fetal death (≥28 weeks POG)	Principal investigator, Dr. Reena Rani Punia, M/s Maulana Azad Medical College, Delhi	The Principal investigator, Dr. Reena Rani Punia presented protocol titled "To compare the efficacy of two regimens of mifepristone for induction of labour in cases of late intrauterine fetal death" before the committee. After detailed deliberation, the committee recommended that proposed research study may be allowed as per the protocol presented by PI with the condition that LFT and KFT should be repeated in the early postpartum period and applicant should submit revised protocol to CDSCO.
4.	ND-12011/3/2025-eoffice Mifepristone for induction of labour in Third Trimester	Principal investigator, Dr. Sangeeta Gupta, M/s Maulana Azad Medical College, Delhi	The Principal investigator, Dr. Sangeeta Gupta presented protocol titled "To compare the efficacy of mifepristone versus foley catheter for its effectiveness in cervical ripening in women with previous caesarean section", before the committee. After detailed deliberation, the committee recommended that proposed research study may be allowed as per protocol presented with the condition that PI should use single dose of mifepristone 200 mg as per published literature instead of the proposed 400 mg, and submit the revised protocol to CDSCO.