Recommendations of the SEC (Reproductive) made in its 06th/25 meeting held on 19.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2025/4852 8 Recombinant Human Chorionic Gonadotropin for Injection 3250 IU	M/s Bharat Serums And Vaccines Limited	The firm presented the proposal for addition of SKU of 3250 IU of the approved product Recombinant Human Chorionic Gonadotropin for injection (r-HCG) 6500 IU (Vial/PFS). The committee noted that there is no efficacy and safety data available with the firm for the addition of proposed SKU of 3250 IU of r-HCG injection. After detailed deliberation, the committee did not agree with the firm's request for the addition of proposed SKU of 3250 IU of the approved drug product.
2.	E-79599 Trinbelimab (Recombinant Anti Rho-D Immunoglobulin)	M/s Syngene International Limited	The firm presented the final CSR of Phase I clinical trial titled "A prospective, single-dose, single-period study to evaluate the pharmacokinetics and tolerability of Trinbelimab (Recombinant Anti Rho-D Immunoglobulin) of Bharat Serums and Vaccines Ltd, India in Healthy, Adult, Rhesus- D Negative Non Sensitized Postmenopausal Female Subjects" conducted vide Protocol No. SYNCD-003-23, Version 3.0 dated 03.08.2023. After detailed deliberation, the committee noted the results of the study presented by the firm.
SND Division			
3.	SND/MA/23/000175 Dydrogesterone IP 20mg / 30 mg	M/s AKUMS DRUGS & PHARMACEUTICALS LIMITED	In light of earlier SEC recommendations dated 20-07.2023, firm presented the BE-study report of both fasting and fed condition to consider for grant of permission to manufacture and marketing of Dydrogesterone Extended Release 20mg /30 mg Tablets before the Committee. After detailed deliberation, the Committee recommended to accept the result of both BE studies under fasting & fed condition.

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4.	SND/CT/25/000061 Dydrogesterone Modified Release Tablet 20 mg	M/s Abbott India Limited	Firm presented their proposal for grant of permission to conduct Phase-IV clinical trial along with Phase-IV CT protocol for indications Threatened miscarriage and Habitual miscarriage before the Committee. After detailed deliberation, the Committee recommended to conduct the Phase IV study with following changes in protocol: 1). Title of the study to be changed to Phase IV Protocol instead of Observational study. 2). Proposed protocol to include interim analysis of 25% patients population.
5.	SND/CT/25/000063 Dydrogesterone Extended Release Tablets 20 mg	M/s Zydus Healthcare Limited	As per SEC recommendation dated 05.11.2024 and CDSCO vide letter dated 24th January 2025 asked the firm to submit Phase IV Clinical Trial in Indications of Habitual miscarriage and Threatened miscarriage. The firm presented the Phase IV Clinical Trial Study vide protocol No. C2B05785, version no. 01 dated 06 May 2025 for indication Habitual miscarriage only before the committee. The firm informed that they will submit separately Phase IV CT protocol for indication of Threatened miscarriage. After detailed deliberation, the committee recommended to conduct Phase IV Clinical trial study as per protocol presented by the firm for indication Habitual miscarriage. Further, Committee recommended to submit Phase IV clinical trial protocol for indication of Threatened miscarriage to CDSCO within one month for further review by the Committee.
New Drugs Division			
6.	ND/MA/23/000113 FDC of Relugolix,	M/s Sun Pharmaceutical Industries Limited	In light of earlier SEC recommendation dated 20.03.2024, the firm presented Phase III Clinical trial report for

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	Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg)		manufacture and marketing of new drug FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg), before the committee. After detailed deliberation, the committee recommended for the grant of permission for manufacturing and marketing of drug FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg).