

Recommendations of the SEC (Reproductive) made in its 03rd/26 meeting held on 24.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND-12011(13)/1/2026-eoffice Dienogest 2 mg Tablets	M/s. Bayers Pharmaceutical Pvt. Ltd	The firm presented Phase IV clinical trial report of drug Dienogest 2 mg Tablets with Protocol ID: 19837, Protocol Version 1.0 Date: 12-February-2025 before the committee. After detailed deliberation, the committee considered the result of the Phase IV clinical study
2.	ND-11011/4/2025-eoffice Ganirelix Acetate Solution for Injection 0.25 mg/0.5 ml	M/s. Organon (India) Private Limited	The firm did not attend the meeting.
3.	ND/MA/25/000149 Linzagolix Tablets 100 mg and 200 mg	M/s. Exemed Pharmaceuticals	In light of earlier recommendation dated 18.12.2025, the firm presented revised Phase-III Clinical trial protocol (Protocol ID: CT/2025/25 Protocol Version No: 01, dated 31-Dec-2025) before the committee. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial as per the revised protocol submitted by the firm, subject to the condition that the inclusion criteria listed at S. No. 2 be omitted. Further, the inclusion criteria at S. No. 4 should be repositioned to S. No. 2 for the purpose of enrolment. Accordingly, firm should submit revised Phase-III CT protocol to CDSCO.
SND Division			
4.	SND/CT/26/000005 Carbetocin injection 100 mcg/ml (Vials)	M/s. Precise Biopharma Pvt. Ltd.	The firm did not attend the meeting.
5.	SND/CT/ 26/000014 Dydrogesterone Extended Release Tablets 20 mg	M/s. Zydus Healthcare Limited	In continuation of earlier SEC recommendation dated 19.06.2025, the firm presented Phase IV Clinical Trial Protocol for indications Threatened miscarriage before the Committee.

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			After detailed deliberation, the committee recommended to conduct Phase IV Clinical trial study as per protocol presented by the firm for indication Threatened miscarriage.