Recommendations of the SEC (Reproductive) made in its 02nd/26 meeting held on 26.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	IMP/MD/2025/154782 Nitrile Male condoms	M/s. Reckitt Benckiser (India) Private Limited	The firm presented the proposal for grant of permission to import for marketing of the Investigational medical device viz. Nitrile Male condoms (Brand name: Durex), manufactured at M/s. Innolatex (Thailand) Limited, Thailand. The said device is approved for marketing in countries viz. USA, UK, Australia, Canada, etc. The firm has presented the Global Clinical study data and Post-Marketing Surveillance data generated on the said device. After detailed deliberation, the committee recommended for consideration of said proposal
Biological Division			
2.	BIO/CT04/FF/2025/52574 Trinbelimab Injection 300 mcg/mL in Pre-filled Syringe.	M/s. Intas Pharmaceuticals Ltd	The firm presented the proposal to for grant of permission to conduct Phase I clinical trial titled "An open label, balanced, randomized, two-treatment, single-dose, Parallel-group comparative bioavailability study of Trinbelimab Anti-Rh(o)D immunoglobulin (test product-T) of Intas Pharmaceuticals Limited, India with AntiD PFS (reference product- R) in normal, healthy, adult, human participants" as per protocol No. 0353-25, Version 1.0 dated 18 September 2025. After detailed deliberation, the committee recommended grant of permission to conduct the Phase I clinical trial as per the presented protocol.
SND Division			
3.	SND/CT21/FF/2025/52559 SND/MA/25/000254 Dydrogesterone Mouth Dissolving Tablets 10 mg	M/s. Zydus Healthcare Limited	Firm presented their proposal for the Manufacturing and marketing of Dydrogesterone mouth dissolving Tablets 10mg along with the BE protocol No: BIOS/2025/188 dated.29.10.2025 and request for CT wavier. After detailed deliberation the committee recommended for grant of permission to conduct BE study subject to condition that

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			ultrasound breast examination should be done instead of mammography in screening. The BE report shall be presented before the committee for review
4.	SND/CT/25/000149 SND/CT04/FF/2025/53847 Carbetocin injection 100 mcg/ml (Pre Filled Syringes)	M/s. Precise Biopharma Pvt. Ltd.	Firm presented proposal for grant of permission to conduct Phase IV Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended grant of permission to conduct Phase IV Clinical Trial as per the protocol presented by the firm with the following conditions- (i) Number of study participants should be at least 200. (ii) Firm should include more number of clinical trial sites and at least 50% should be government sites and should be geographically distributed.
FDC Division			
5.	FDC/CT/25/000130 Ferrous fumarate IP eq. to elemental iron 40mg + Folic acid IP 500mcg + Dry Vitamin A Acetate IP eq. Vitamin A 400mcg + Vitamin C (Ascorbic acid) IP 65mg + Vitamin D Stabilised IP eq. to Vitamin D3 (Cholecalciferol) 400 IU + Thiamine mononitrate IP eq. to Thiamine 1.6mg + Riboflavin IP 2.3mg + Niacinamide IP 11mg + Trituration of Cyanocobalamin (1.0%) in Gelatin IP eq. to Vitamin B12 (Cyanocobalamin) 4mcg + Zinc oxide IP eq. to Zinc 15 mg + Potassium Iodide IP	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal along with Phase III CT protocol before the committee. After detailed deliberation, the committee considered the rationality of the proposed FDC and recommended for grant of permission to conduct Phase III CT study. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.

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	eq. to iodine 0.1600 mg + Vitamin E 50 % powder IP eq. to Vitamin E (Tocopheryl Acetate) 10 mg + Vitamin B6 (Pyridoxine HCL) 1.9 mg + Cupric Sulphate USP eq. to copper 1.7 mg + Sodium selenite BP eq. to selenium 40 mcg Tablets		
6.	FDC/MA/22/000421 Norethindrone Acetate USP 0.5 mg + Estradiol (as Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg + Relugolix 40 mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 04.07.2024 and as per condition of Form CT-23 dated 11.12.2025, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.