Recommendations of the SEC (Reproductive) made in its 07th/24 meeting held on 21.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/38351 Trinbelimab Injection 300mcg/150mcg vial and PFS	M/s. Bharat Serums And Vaccines Limited	In light of earlier SEC recommendation dated 19.10.2023 and 04.06.2024, the firm presented the detailed casualty analysis of 8 neonatal complications observed in neonates delivered to mothers who have received antenatal administration of Trinbelimab Injection 300mcg/150mcg in the RhYTHM study- a Real World observational study on Rh-negative pregnant women in India. After detailed deliberation, the committee recommended for approval of usage of Trinbelimab injection 300mcg 150mcg during pregnancy with the updated indication as "Trinbelimab injection is indicated to prevent Rh negative women from forming antibodies to foetal Rh positive red blood cells, that may pass into the maternal blood during pregnancy, childbirth, abortion or certain other sensitizing events".
2.	E-Receipt No.: 10335 Foligraf® 900 IU (66.0µg)/ 1.5mL Solution for Injection in Prefilled Pen [Follicle Stimulating Hormone]	M/s. Veeda Clinical Research Limited	The firm presented the results of the Phase-1 clinical study titled as - "A randomized, open label, balanced, two-treatment, two-period, two-sequence, single dose, crossover, bioequivalence study of Foligraf® 900 IU (66.0 µg) / 1.5mL solution for injection in Prefilled Pen [Follicle Stimulating Hormone (Human Recombinant)] of Bharat Serums and Vaccines Limited, India and GONAL-f® 900 IU (66.0 µg) / 1.5 mL solution for injection in pre-filled pen of Merck Serono at a dose of 300 IU in healthy, adult, female, human subjects" as per protocol No. 21-VIN-0318, version 01 Date: 12.10.2021. After detailed deliberation, the committee

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			noted the results of the study presented by the firm.
SND Division			
3.	SND/MA/24/000021 Drotaverine Hydrochloride 120, 160 & 240mg	M/s. Martin & Harris Labs Limited	The firm presented the proposal for grant of manufacture and market of Drotaverine Hydrochloride extended release tablets, 120mg, 160mg and 240 mg along with bioequivalence protocol and justification for waiver of Phase-III clinical trial before the committee. During presentation, the firm informed that firm has obtained BE NOC vide BE/SND/24/2022 dated 13.05.2022 from CDSCO. Based on the BE NOC, firm has conducted BE study with two test formulations T1: Drotaverine Hydrochloride Extended Release Tablets, 240 mg (once a day) and T2: Drotaverine Hydrochloride Extended Release Tablets, 160 mg (once a day) with reference formulation R: DROTIN (Drotaverine HCl) Tablets 80 mg (thrice a day) in healthy adult human subjects under fasting and fed conditions and the BE study results were outside the acceptable range. Therefore, the firm submitted the application with revised formulation. After detailed deliberation, the committee opined that the firm should submit summary of changes made with earlier formulations & BE protocol versus the applied new formulation & BE protocol respectively along with supporting evidence/documents to CDSCO for further review by the committee.
4.	SND/MA/23/000196 Dydrogesterone Tablets kit (Each kit contains: Part (A)1 Dydrogesterone Tablet 40mg + Part (B)14 Dydrogesterone Tablets 10 mg	M/s. Mankind Pharma Limited	In light of earlier SEC recommendations dt 30.04.2024, the firm presented the revised Phase III clinical trial protocol before the committee. The committee noted that Dydrogesterone tablet 40 mg is not approved anywhere in the world for Threatened Miscarriage. However, the Dydrogesterone tablet 10 mg is already approved in the country on 06.04. 2018. Further, the committee noted that the

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			proposed dose Dydrogesterone 40 mg is very high and may lead to intolerance, adverse drug reaction, SAEs. The clinician increase/titrate the dose regimen based on the patient's response/condition and also patients rarely need 40mg stat dose. After detailed deliberation, the committee opined that there is no need of such combikit. Hence, the committee recommended that the proposal of the firm may not be considered.
FDC Division			
5.	FDC/CT/21/000074 Tamsulosin Hydrochloride IP 0.4mg (as prolonged release pellets) + Tadalafil IP 5mg (as film coated tablet)	M/s. Sun Pharma	In light of earlier SEC recommendation dated 30.11.2021 and as per condition of Form CT-23 dated 02.07.2021, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
6.	FDC/MA/23/000330 Relugolix 40 mg + Estradiol Hemihydrate Eq. to Estradio USP 1 mg + Norethindrone Acetate 0.5 mg Tablets	M/s. Macmillon Pharmaceuticals Pvt. Ltd.	In light of the earlier SEC recommendation dated 21.02.2024, the firm presented the proposal along with BE study report and Phase III CT study protocol before the committee. After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol, the committee opined that "The firm should change the comparator as the selected comparator is not equivalent to three drug combination in terms of mechanism of action as well as action produced." Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.