Recommendations of the SEC (Reproductive & Urology) made in its 84th meeting held on 20.07.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/ 37077 Trinbelimab Injection 300 mcg	M/s. Syngene International Limited	The firm presented the Phase I protocol 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 negative postmenopausal female subjects" vide protocol no SYNCD-003-23 version no 2.00 dated 10.04.2023. After detailed deliberation, the committee recommended to conduct the Phase I study subject to the following changes in the protocol- 1. The title should be amended to include Rh-D negative non sensitized postmenopausal female subjects. 2. The exclusion criteria should be modified so that Rh-D negative sensitized women are excluded from participation in the study. Accordingly, the firm should submit revised protocol to CDSCO for further approval.
SND Division			
2.	SND/MA/23/000008 Solifenacin Succinate oral solution 1mg/ml	M/s. Pure & Cure Pvt. Ltd.	The firm presented the proposal manufacturing and marketing of Solifenacin Succinate oral solution 1mg/ml along with justification for BE study and clinical trial waiver. The committee noted that the Solifenacin Succinate is BCS class 1 and as per the CDSCO guidelines, BE waiver can be granted for BCS class 1 drug. Committee also noted that Solifenacin tablets and Oro-dispersible granules are already approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Solifenacin Succinate oral solution 1mg/ml for already approved indication.

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3.	SND/MA/23/000164 Azithromycin Tablets 500 mg (New Indication)	M/s. Alembic Pharmaceuticals Ltd.	The firm presented the proposal for additional indication of Azithromycin tablets 500 mg i.e. "To prevent maternal infection in women undergoing planned vaginal delivery". The firm presented published literature and the results of international clinical trials data with subset Indian patients and requested for local clinical trial waiver along with the justification. After detailed deliberation, the committee did not recommend for approval of the proposed additional indication of Azithromycin tablets 500 mg as data was not adequate.
4.	SND/MA/23/000175 Dydrogesterone ER Tablet 30 mg (Additional Strength)	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented the proposal for manufacturing and marketing of Dydrogesterone ER tablet 30mg along with BE study protocol and clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of BE study as per the protocol presented. The firm should submit BE study report along with the clinical trial protocol for further consideration of the proposal.
5.	SND/MA/23/000166 Dydrogesterone MR Tablets 30 mg (Additional Strength)	M/s Abbott India Limited	The firm presented the proposal for manufacturing and marketing of Dydrogesterone MR tablet 30 mg along with BE study protocol and clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of BE study as per the protocol presented. The firm should submit BE study report along with the clinical trial protocol for further consideration of the proposal.
FDC Division			
6.	FDC/MA/18/000074 L-Methylfolate + Dehydroepiandrosterone (as sustained release) + Vitamin D3 (1mg + 75 mg + 2000IU) tablets	M/s. Synokem Pharmaceuticals	In light of earlier SEC recommendation dated 26.04.2023, the firm presented the supportive literatures as well as Phase III clinical trial protocol before the committee. The committee noted that the firm presented inadequate supporting literatures. After detailed deliberation, the committee

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			reiterated its earlier recommendations dated 26.04.2023. Accordingly, the firm should submit the detailed justification for the FDC along with more supportive literatures for further review by the committee.
Medical Device Division			
7.	MD/PostAppr/2023/ 14522 Hepa Sphere Embolization MicroSpheres, Embosphere Microspheres in vial	M/s. Merit Medical system India Pvt. Ltd.	The firm presented their proposal for extension of intended use of the product Hepa Sphere Embolization Micro Spheres & Embosphere Microspheres before the committee. After detailed deliberation, the committee observed that the proposal should be deliberated in presence of Oncology Surgeon, Surgical Gastroenterologist, Urologist & Interventional Radiologist.