

Recommendations of the SEC (Reproductive & Urology) made in its 82nd meeting held on 25.05.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/21/000039 (Pt-1) Recombinant Anti Rho-D Immunoglobulin Injection 300 mcg (Liquid Injection)	M/s. Bharat Serums and Vaccines	In light of the earlier SEC recommendation dated 23.12.2022, the firm presented the proposal along with the request for removal of the condition-“the use of the drug should be avoided in patients with tachycardia (more than 100 beats/mins)”. The committee noted that the increased pulse rate reported in Phase IV study was due to blood loss post LSCS. After detailed deliberation, the committee recommended that the above mentioned condition recommended by the last SEC may be removed.
SND Division			
2.	SND/MA/22/000203 Estradiol Vaginal Inserts USP 4 mcg and 10 mcg	M/s. West-Cost Pharmaceuticals Works Ltd.	The firm presented the proposal for manufacturing and marketing of Estradiol Vaginal Inserts USP 4 mcg and 10 mcg for treatment of moderate to severe dyspareunia symptoms ovular and vaginal atrophy due to menopause along with justification for BE study and clinical trial waiver. After detailed deliberation, the committee recommended that the firm should submit the details as under: 1) Detailed justification for the proposed dose and proposed indication. 2) Detailed preclinical study data. Accordingly, the firm should submit the above details to CDSCO for further review by the committee.
3.	SND/MA/23/000109 Dydrogesterone SR tablets 20/30mg	M/s. Macmillon Pharmaceuticals Private Limited	The firm did not turn up for presentation.
4.	SND/MA/23/000076 Carbetocin Injection 100mcg/ml in Prefilled Syringes	M/s. Ferring Pharma Private Limited	The firm did not turn up for presentation.

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5.	12-109/2017-DC (Pt- Akums-SND) Febuxostat ER tablet 40/80mg	M/s. Akums Drugs & Pharmaceuticals Limited	In light of the earlier SEC recommendation dated 29-07-2021, the firm presented the Phase III clinical trial protocol. After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial as per the protocol presented with the condition that more government site should be included in the trial.
6.	SND/MA/23/000137 Dydrogesterone Sustained release tablet 20mg	M/s. Acme Formulation Pvt. Ltd.	The firm presented the proposal for manufacturing and marketing of Dydrogesterone sustained release tablet 20mg for the indication in the treatment of the endometriosis along with the BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial and BE study subject to following condition:- <ol style="list-style-type: none"> 1. Smokers and alcoholic should be removed from exclusion criteria 2. Only sterilized patients included in the study should be removed from inclusion criteria. Committee also suggested that the firm should monitor the size of endometrioma of participating subjects during the clinical trial.
FDC Division			
7.	04-75/2017-DC Myo-Inositol USP- NF 600mg +Metformin Hydrochloride IP 500mg (As sustained release) tablet	M/s. Eris Life Sciences	In light of the earlier SEC recommendation dated 24.11.2020, the firm presented the BE & CT reports before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and market the proposed product.
SND Division			
8.	SND/MA/23/000140 Dydrogesterone Sustained Release Tablets 20mg	M/s. Abbott India Limited.	The firm presented the proposal for manufacturing and marketing of Dydrogesterone Sustained release tablet 20mg with the BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to

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			<p>conduct the Phase III clinical trial and BE study as per the protocol presented with the condition that the firm should include more clinical trial sites and the sites should be geographically distributed across the country.</p> <p>Committee also suggested that the firm should monitor the size of endometrioma of participating subjects during the clinical trial.</p> <p>(Dr. Pikee Saxena didn't participate in the deliberation).</p>
9.	SND/MA/23/000120 Ormeloxifen Hydrochloride tablets 30mg	M/s. HII Lifecare Limited.	<p>The firm presented the proposal for manufacturing and marketing of Ormeloxifen Hydrochloride tablets 30mg for the additional indication of treatment of mastalgia and fibroadenoma along with the justification for waiver of clinical trial.</p> <p>During the deliberation the firm presented the published literature in support of the proposed indication for the product.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial for which the firm should submit Phase III clinical trial protocol to CDSCO, for further review by the committee.</p>
10.	SND/MA/21/000034 Letrozole Tablets 5mg	M/s. Akums Drugs	The firm did not turn up for presentation.