

**Recommendations of the SEC (Reproductive & Urology) made in its 87<sup>th</sup> meeting held on 19.10.2023 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/MA/22/000171  Relugolix Film Coated Tablets 40mg	M/s. Synokem	<p>In line with earlier SEC (Reproductive and Urology) recommendations dated 23-03-2023, the firm presented Relugolix 40 mg tablet bioequivalence study results along with request for local phase III clinical trial waiver before the committee.</p> <p>After detailed deliberation, the committee noted that there is no data with respect to efficacy and safety.</p> <p>Hence, the committee recommended that the firm should conduct phase III clinical trial for the proposed indication with randomized active control clinical trial and accordingly, firm should submit the clinical trial protocol to CDSCO for further consideration.</p>
<b>Biological Division</b>			
2.	BIO/CT21/FF/2023/3 8351 Trinbelimab	M/s. BSV	<p>The firm presented their proposal for inclusion of indication of pregnancy in already approved indication. The indication proposed by firm is as follows- "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 <b>pregnancy</b>, childbirth, abortion or certain other sensitizing events".</p> <p>After detailed deliberation, the committee recommended that firm should submit substantial data proving the safety of patients in proposed indication.</p>
3.	4-07 /Merck / APC-R- Follitropinalfa and Lutropinalfa /2023- BD  Follitropinalfa and Lutropinalfa (Pergoveris Prefilled Pen)	M/s. Merck Specialties Pvt. Ltd.	<p>The firm presented their proposal for update in the prescribing information in line with changes approved by EMA for Follitropinalfa (r-DNA origin) and Lutropinalfa (r-DNA origin) injection (Pergoveris) (450IU + 225IU)/0.72mL, (300 IU + 150 IU)/0.48 mL, (900 IU + 450 IU)/1.44 mL.</p> <p>After detailed deliberation, the committee recommended for approval of updated Package Insert Version 2.0 dated April</p>

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			2023.
<b>FDC Division</b>			
4.	FDC/MA/22/000068  Silodosin 8mg + Solifenacin Succinate 5mg Tablets	M/s. Savi Health	<p>In the light of earlier SEC recommendation dated 26.04.2023, the firm presented their proposal along with revised Phase III clinical trial protocol with change in study design, sample size, inclusion criteria and CRO before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with revised protocol.</p> <p>The firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>
5.	FDC/MA/22/000366  Pyridoxine HCl IP (ER) 20mg + Doxylamine succinate (ER) 20mg tablets	M/s. Akums Drugs & Pharmaceutical Ltd.	<p>In light of earlier SEC recommendation dated 31.01.2023, the firm presented BE study report.</p> <p>The committee noted that the said FDC is already approved in US, Canada, etc.</p> <p>After detailed deliberation, the committee considered the Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC.</p>
6.	FDC/MA/23/000297  Dutasteride IP (as film coated tablet) + Silodosin JP (as film coated tablet) + Tadalafil IP (as film coated tablet) (0.5mg+8mg+2.5mg/ 0.5mg+8mg+5mg) capsule	M/s. Malik Lifesciences Pvt. Ltd.	<p>The firm presented their proposal along with BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for conducting the BE study.</p> <p>The result of the BE study should be submitted to CDSCO for further review and consideration on conduct of Phase III clinical trial.</p>

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7.	FDC/MA/21/000175  Silodosin JP 8mg +Tadalafil IP 5mg hard gelatin capsule	M/s. Sun Pharma Laboratories Ltd.	<p>In light of earlier SEC recommendation dated 26.08.2021, the firm presented their proposal along with Phase III CT report before the committee.</p> <p>The firm informed that BE report has already been presented on 26.08.2021 and the same was considered by the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.</p>