

**Recommendations of the SEC (Analgesic & Rheumatology) made in its 76<sup>th</sup> meeting held on 12.10.2021 at CDSCO HQ, New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/MA/20/000017 Triamcinolone Hexacetonide Injection USP 20 mg/ml	M/s Abbott	<p>In light of SEC recommendation dated 24.07.2019 &amp; 23.06.2020, the firm presented BE study report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug subject to the condition that firm should conduct 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 product.</p>
<b>Biological Division</b>			
2.	BIO/CT/18/FF/2021/2 3792 Etanercept	M/s. SRS Pharmaceuticals Pvt. Ltd.	<p>The firm presented their proposal for import and marketing of the drug Etanercept with local clinical trial (Phase III) waiver before the committee.</p> <p>The committee observed that the firm has not presented any safety and efficacy data in the Indian population and there is no unmet medical need for consideration of waiver of local Phase III clinical trial in the country.</p> <p>After detailed deliberation, the committee did not recommend for grant of marketing authorization with local clinical trial waiver.</p>
<b>FDC Division</b>			
3.	FDC/CT/21/000006 Bioactive concentrate from small Marine Fish (Active) + Water for injection (Inactive) (Indication: 1. Degenerative rheumatic diseases of	M/s. Biotechnos Pvt. Ltd.	<p>In light of earlier recommendation, the firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee opined that;</p> <p>1. The firm did not present any scientific rationale of the proposed FDC in the management of</p>

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	the joints:osteoarthrosis with diverse localization coxathrosis, gonarthrosis, small joints arthrosis; spondylosis, osteochonodrosis; 2. The period of convalescence (as adjuvant) after traumas and joint surgery) (0.1ml + 1.0ml) Solution for injection		osteoarthritis of knee joints. 2. The data presented was inadequate and not convincing for the proposed indication. 3. The proposed FDC has not been recommended in any standard treatment guidelines.  In view of above, the committee did not recommend for approval of the proposed FDC.
4.	FDC/MA/21/000131 Promethazine Hydrochloride IP +Aspirin (5mg+150mg) tablets	M/s. Meyer Organics Pvt. Ltd.	The firm presented their proposal before the committee. The committee noted that the firm has proposed altogether new formulation as a combikit which becomes a new proposal. The committee also noted that the firm had not applied yet for the proposed combikit to CDSCO and therefore it was not deliberated.  After detailed deliberation, the committee reiterated its earlier recommendation dated 28.07.2021 and did not recommend for approval of the FDC of Promethazine Hydrochloride IP +Aspirin (5mg+150mg) tablets.
<b>GCT Division</b>			
5.	CT/44/19 Online Submission (10933) Baricitinib	M/s. Eli Lilly	The firm presented their proposal for protocol amendment before the committee.  After detailed deliberation, the committee recommended for approval of proposed protocol no:I4V-MC-JAHV, protocol amendment (d) dated 07-Nov-2020.
<b>Medical Device Division</b>			
6.	IMP/MD/2021/4135 4 Bioinductive Implant (	M/s Smith & Nephew Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.

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7.	CI/MD/2021/46278 Clinifibre suture	M/s Healthium Medtech Limited	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee observed that protocol submitted by firm has many discrepancies. Protocol should be modified with inclusion and exclusion criteria, aims &amp; primary and secondary objectives, primary and secondary outcomes and study to be focused on suture only. The PI should be preferably included from high volume ACL care centre/ sports injury management centre.</p>