

Recommendations of the SEC (Analgesic & Rheumatology) made in its 04th/24 meeting held on 03.04.2023 at CDSCO HQ, New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/90/23 Online Submission (38667) Anifrolumab (MEDI-546)	M/s. AstraZeneca	The firm did not turn up for presentation.
Biological Division			
2.	BIO/CT21/BO/2023/39673 Adalimumab 40 mg/0.4 ml solution for injection	M/s. Shilpa Biologicals Private Limited	<p>In light of earlier SEC recommendation dated 8th & 9th Nov. 2023, the firm presented the proposal for extrapolation to following additional indications in line with the innovator product along with first PSUR data -</p> <ol style="list-style-type: none"> 1. Juvenile Idiopathic Arthritis (JIA) 2. Ankylosing spondylitis (AS) and axial spondyloarthritis without radiographic evidence of AS. 3. Psoriatic Arthritis (PsA) <p>The committee noted that the firm has not submitted protocol to conduct Phase-IV study as per the condition of marketing authorization permission granted to the firm.</p> <p>After detailed deliberation, the committee recommended that the firm shall submit protocol to conduct Phase-IV study for evaluation by the committee. Proposal for extrapolation of additional indications shall be considered after submission of Phase-IV clinical trial protocol.</p>
SND Division			
3.	SND/IMP/22/000034 Cross linked Sodium Hyaluronic acid Injection 60mg/3ml	M/s. LG Chem Life Science India Private Limited	<p>The firm presented the proposal for import and marketing permission of cross linked Sodium Hyaluronic Acid injection 60mg/3ml along with justification for CT waiver before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit clinical data on caucasian population including India to CDSCO for further</p>

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			review by the committee.
4.	SND/MA/23/000241 Paracetamol Oral Suspension IP 500mg/5ml	M/s. Naxpar Pharma Private Limited	<p>The firm presented the proposal for manufacturing and marketing permission of Paracetamol oral suspension IP 500mg/5ml along with justification for CT and Bioequivalence study waiver before the committee.</p> <p>The firm stated that the similar formulation is approved in the UK and Ireland.</p> <p>After detailed deliberation, the committee noted that formulation which is approved in the UK is indicated for adult and adolescents over 16 years of age population. Therefore, the committee recommended that the firm should conduct Bioequivalence study with the UK approved product for which the firm should submit BE protocol to CDSCO for further review by committee.</p> <p>Further, the proposed indication should be inline with the innovator product.</p>
New Drugs Division			
5.	ND/MA/20/000017 Triamcinolone Hexacetonide Injection Suspension 20mg/ml	M/s. Abbott	<p>The firm presented the amendment in Phase-IV clinical trial protocol for inclusion of 40 mg dose of Triamcinolone Hexacetonide injectable suspension USP.</p> <p>After the detailed deliberation, the committee recommended for grant of permission to amend the Phase IV clinical trial protocol from protocol No. TRIA-422-0200, version 3.0 dated 08.11.2022 to protocol No. TRIA-422-0200, version 4.0 dated 14.12.2023.</p>
FDC Division			
6.	FDC/CT/21/000006 Bioactive concentrate from small Marine Fish 0.1mL + Water for injection 1mL solution for injection	M/s. Biotechnos Pvt. Ltd.	In light of earlier Technical Committee meeting recommendation dated 18.01.2022, wherein the committee recommended for grant of permission to conduct the proposed Phase III clinical trial of the drug.

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			<p>Accordingly, the firm has presented their proposal along with Phase III clinical trial report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market of the proposed FDC.</p>
BA/BE Division			
7.	<p>File No. 12-09/2024/BA-BE/MISC-27/DC</p> <p>BABE/CT05/FF/2023/40806</p> <p>Tizanidine Extended-Release Tablets 12 mg</p>	<p>M/s. Aizant Drug Research Solutions Private Limited, Telangana, India-500100</p>	<p>The firm presented Bio-availability study protocol No. 134A-01-TMR-1001, version No. 1.0 and dated 05.09.2023 for pilot fasting bio-availability study.</p> <p>After detailed deliberation, the committee recommended to conduct the comparative bio-availability study as presented by the firm.</p>