

**Recommendation of the SEC (Analgesic & Rheumatology) made in its 102<sup>nd</sup> meeting held on 08.11.2023 & 09.11.2023 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/MA/20/000017  Triamcinolone Hexacetonide injectable suspension USP 20mg/ml	M/s. Abbott	The firm presented the proposal for amendment in package insert vides version no. 2.0, dated 26th May 2023. After detailed deliberation, the committee recommended for grant of approval for the proposed amendment in package insert as presented by the firm subject to the condition that the total dose to the patient at one or multiple sites including the cumulative dose should not exceed 40 mg and not to be repeated to the patients with in one month and the firm to conduct the Phase IV CT on 40mg dose.
<b>Biological Division</b>			
2.	Dy no 6903  Tocilizumab 162mg/0.9ml	M/s. Cipla	The firm presented the protocol for conduct of post marketing active surveillance of Tocilizumab titled “A post marketing active surveillance of Tocilizumab in patients of giant cell arteritis” vide study code CP/01/23 version 01 dated 12.06.2023.  After detailed deliberation, the committee opined that the firm should submit scientific justification/rationale for the study and sample size.  Accordingly the firm should submit the revised protocol to CDSCO for further evaluation by the committee.
3.	BIO/CT21/FF/2023/3 7090  Adalimumab 100mg/ml (Additional indication)	M/s. Enzene	In light of earlier SEC recommendation dated 05.10.2023, the firm presented the proposal for extrapolation of additional indication of Juvenile idiopathic arthritis.  After detailed deliberation, the committee recommended for approval of the indication with waiver of Phase III trial with the condition that the firm should conduct PMS study for assessing the safety and efficacy in Indian juvenile population and accordingly the firm should submit PMS study protocol to CDSCO within 3 months of approval of

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			the additional indication.
4.	4-77/Dr. Reddy's/PAC-R- Prolia/2021-BD  Denosumab 60 mg/ml	M/s. DRL	<p>The firm presented their proposal for amending the warning statement for Denosumab (Prolia)60 mg/ml Subcutaneous Injection from current statement "To be used by Rheumatologist, Orthopedicians and Endocrinologists" to "To be sold by retail on the prescription of a registered medical specialist experienced in treating the disease(s) per the approved label".</p> <p>After detailed deliberation, the committee recommended for approval of amending the warning statement of the product as follows "To be sold by retail on the prescription of an Endocrinologist/ Rheumatologist/ Orthopedician/ Internal medicine/ Gynaecologist only"</p> <p>The committee also recommended that the label should have clear warning of:</p> <ol style="list-style-type: none"> <li>I. Risk of flare up of latent infection / latent tuberculosis.</li> <li>II. Effect lasts only 6 months and discontinuation of medicine may increase osteoporotic fractures.</li> </ol>
5.	BIO/CT04/FF/2023/3 7174  Denosumab 60 mg/ml	M/s. Lupin Ltd.	<p>The firm presented the protocol to conduct PK/PD study titled "Single dose study to compare pharmacokinetic, pharmacodynamic and immunogenicity of Denosumab 60 mg prefilled syringe solution for injection (60 mg/mL) and Prolia® (Denosumab) 60 mg solution for injection (60 mg/mL) in pre-filled syringe in healthy adult male subjects" vide Protocol No. C1B03215, Version 01 dated 15 Jun 23.</p> <p>After detailed deliberation, the committee recommended for conduct of the PK/PD study as presented by the firm with the condition that-</p> <p>Screening test must include Ankle Brachial Index test to rule out peripheral</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			artery disease in exclusion criteria.  Accordingly, the firm should submit the revised protocol to CDSCO.
6.	39/PMS/Roche/13-BD (Part-II)  Rituximab	M/s. Roche	The firm presented the report (CSR Version 1.0 dated April 2023) of the conducted PMS study titled “An Open Label, Prospective, Post Marketing study to evaluate the safety, tolerability and efficacy Of Rituximab with Glucocorticoids in adult patients with Wegener’s Granulomatosis (Granulomatosis With Polyangiitis-GPA) Or microscopic polyangiitis” vide Protocol No. ML28550  After detailed deliberation, the committee noted and agreed the results of the presented study.
7.	BIO/CT21/BO/2023/39673  Adalimumab 100mg/mL	M/s. Shilpa	The firm presented the proposal for extrapolation of indications in line with the innovator approved indications for Adalimumab 100mg/mL approved in India for the indication of Rheumatoid Arthritis (RA) in adult patients.  The committee noted that the firm has recently launched the drug product in the market and not yet submitted the first PSUR. After detailed deliberation, the committee recommended that the firm should submit PSUR data for first six months for consideration of approval for the additional indications.
<b>Medical Device Division</b>			
8.	MFG/MD/2023/88849  Closed loop Anesthesia Delivery System (CLADS)	M/s. Clarity Medical Pvt. Ltd.	The firm presented proposal for grant of permission to manufacture the medical device CLADS (Closed Loop Anesthesia Delivery System) integrated with Patient monitor for maintaining an adequate depth of anesthesia by constantly adjusting dose of anesthetic drug delivery system to the patient.  The said device is a software which is to be integrated with the patient monitor and

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>syringe pump as add on software. It is an add on software and there is no predicate device approved by Central Licensing Authority. The firm presented 6000 patient data of the device used in the Indian population generated before commencement of regulation of the device. The data was found adequate by the committee for the claim proposed by the applicant.</p> <p>The committee recommended for approval of the proposal however the firm shall submit detailed documentation on the Software user manual including basic safety indication, assistance, etc.</p>
<b>BA/BE Division</b>			
9.	<p>File No. 12-09/2023/BA-BE/MISC-27/DC</p> <p>(BABE/CT05/FF/2023/38328)</p> <p>Etoricoxib + Thiocolchicoside SR Capsule 60mg + 8mg</p>	<p>M/s. Dr. Reddy's Laboratories Limited, Telangana.</p>	<p>The firm presented their proposal along with the protocol of the BE Study for export purpose.</p> <p>After deliberation the committee recommended for grant of permission to carryout the BE study (for Export purpose, only) with condition to include Serum NT-pro BNP to rule out inclusion of subjects with chronic heart failure/ left ventricular systolic dysfunction.</p>