

Recommendations of the SEC (Analgesic & Rheumatology) made in its 94th meeting held on 15.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/18-DC (Pt-337) Tramadol associated Hiccups	Pharmacovigilance Programme of India (PvPI)	<p>The recommendation of SRP was deliberated in the SEC meeting dated 11.04.2019.</p> <p>In light of earlier SEC meeting the SRP recommendation was appraised to the committee along with the additional data as received from PvPI-IPC.</p> <p>After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controller to direct the manufacturers of the drug to include Tramadol associated Hiccups in the PIL of the drug marketed in the country.</p>
Biological Division			
2.	BIO/IMP/22/000131 Guselkumab Solution for Injection 100 mg/ml in Single-use Pre-filled syringe and Prefilled Pen	M/s. Johnson & Johnson Pvt. Ltd.	<p>The firm presented the proposal for import and market of the drug Guselkumab Solution for Injection 100 mg/ml indicated for Psoriatic Arthritis with local clinical trial waiver.</p> <p>The committee noted that the drug is approved in USA, Japan, EU, Canada, Switzerland and Australia.</p> <p>The firm has presented the results of various clinical trials conducted in other countries.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the following information for further evaluation by the committee-</p> <ol style="list-style-type: none"> 1. Safety data from the Phase IV trial of other countries including asian patients 2. Ethnicity wise data from the clinical trial conducted.
3.	BIO/CT/22/000128 Tocilizumab Injection 80mg/4mL, 200mg/10mL and 400mg/20mL	M/s. Reliance Life Sciences Ltd.	<p>The firm presented the proposal to conduct Phase III clinical trial titled "A prospective, multicenter, randomized, double blind, two arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-055 (Tocilizumab) with RoActemra/Actemra in patients with active rheumatoid arthritis on a stable</p>

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			<p>dose of methotrexate vide protocol no RLS/RA/2022/02 version 1.0 dated 28 Sep 2022.</p> <p>After detailed deliberation, the committee recommended for approval of presented Phase III study protocol with the following changes in the exclusion criteria that –</p> <ol style="list-style-type: none"> 1. The patients with only major elective surgery should be excluded from the study. 2. Instead of a cross over study, a direct comparison of the test arm and the reference arm should be done. 3. Non-responders figures in each arm should be included in final analysis. Since number of non responders are not known prior, hence figures should be avoided in the study design. <p>Accordingly, the firm should submit the revised protocol to CDSCO.</p>
4.	BIO/CT/23/000009 Adalimumab Injection 100 mg/mL	M/s. Enzene Biosciences Ltd.	<p>The firm presented the proposal to conduct Phase IV clinical trial titled “A prospective, multicenter, Open labelled, Phase IV safety & efficacy Study to evaluate Biosimilar Adalimumab injection of Enzene Biosciences Ltd. in subjects with active Ankylosing Spondylitis (AS)” vide protocol ALK29/ENZ129-ADA2; Ver 1.0 dated 15-Jan-2023.</p> <p>After detailed deliberation, the committee recommended for approval of presented Phase IV study protocol with the changes in the exclusion criteria that the patients with latent TB should be excluded from the study.</p> <p>Accordingly, the firm should submit the revised protocol to CDSCO.</p>
5.	BIO/CT04/FF/2022/3 5435 Denosumab 60mg/ml Injection	M/s. Synergen Bio Pvt. Ltd	The firm did not turn up for the presentation.
GCT Division			
6.	CT/130/22 Online Submission (34532)	M/s. Enzene Bioscience	The firm presented the proposal to conduct Phase I clinical trial vide protocol number: ALK22/ENZ215-DEN

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	Denosumab		<p>version number 4.0 date 03 Oct 2022.</p> <p>The applicant informed that the study drug Denosumab is already approved in the country and the data generated from the study to be submitted to USFDA and EMA for marketing approval.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions-</p> <ol style="list-style-type: none"> 1. The Phase of the study should be modified from Phase I to BA/BE study and exclusion criteria no. 11 should be revised as per NACO guidelines for loss of blood before dosing). Accordingly, India specific protocol addendum is required to be submitted to CDSCO. 2. The study should be conducted only up-to 25 subjects from the country.
7.	CT/148/22 Online Submission (34897) Ianalumab (VAV4736)	M/s. Novartis	<p>The firm presented the proposal to conduct Phase III clinical trial vide protocol number: CVAY736F12302, Version Number 00 (Original Protocol) dated 23 Aug 2022.</p> <p>After detailed deliberation, the committee recommended that the applicant is required to revise the CSP wrt to exclusion criteria- as follows- Patients with overlap syndromes, any subjects of SLE who is also positive for anti-phospholipid antibodies, anti cardiolipin, anti-2gp1 and lupus anticoagulant, p- and c-ANCA, etc and have risk factors for thromboembolism should be excluded. Accordingly, the applicant should submit revised protocol to CDSCO for further review by the committee.</p>
SND Division			
8.	SND/MA/22/000369 CisatracuriumBesylate injection 2mg/1ml	M/s. Themis Medicare Ltd.	<p>The firm presented its proposal of manufacture and marketing of the drug product Cisatracurium Besylate Injection 2mg/ml (pack size 5ml/10ml vial) for the additional indication "To provide skeletal</p>

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	(5ml, 10ml vial)		<p>muscle relaxation during mechanical ventilation in the ICU” along with clinical trial waiver justification and some published literature before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of manufacture and marketing permission of the drug product Cisatracurium Besylate Injection 2mg/ml (pack size 5ml/10ml vial) for proposed additional indication subject to condition that the firm should conduct Phase IV clinical trial after marketing approval of the applied drug product. Accordingly, the firm should submit the Phase IV clinical trial protocol to CDSCO for approval.</p>
9.	SND/CT/23/000001 Nimesulide Granules for oral suspension 100mg	M/s. Dr. Reddy’s Laboratories Ltd.	The firm did not turn up for the presentation.
Medical Device Division			
10.	CI/MD/2023/82607 Titanium Interference Screw, Fixed Loop UHMWPE Suture Titanium Button	M/s. Healthium Medtech Limited	<p>The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.</p>
11.	CI/MD/2023/83773 Knotted UHMWPE Suture Titanium Anchor	M/s. Healthium Medtech Limited	<p>The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.</p>
12.	CI/MD/2023/83667 Knotted UHMWPE Suture Anchor	M/s. Healthium Medtech Limited	<p>The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee.</p> <p>After detailed deliberation, the committee</p>

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			recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.
13.	CI/MD/2023/85968 Knotted UHMWPE Suture PEEK Anchor, Knotted UHMWPE Suture PLDLA+β-TCP Anchor	M/s. Healthium Medtech Limited	The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.
14.	CI/MD/2023/82576 Peek button open and Peek button closed	M/s. Healthium Medtech Limited	The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.
15.	CI/MD/2023/82596 Helysis PEEK (PEEK Interference Screw) &Helysis PLDA+β-TCP	M/s. Healthium Medtech Limited	The firm presented its proposal for Post-Marketing Clinical Investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.
16.	CI/MD/2023/86158 Knotless PEEK Anchor with PEEK Tip, Knotless PLDLA-BTCP Anchor with PEEK Tip	M/s. Healthium Medtech Limited	The firm presented its proposal for post-marketing clinical investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.