

Recommendations of the SEC (Analgesic & Rheumatology) made in its 91st meeting held on 14.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/32816 Anifrolumab 150mg/ml concentrate for solution for infusion	M/s. Astrazeneca	<p>The firm presented the proposal to import and marketing of the drug Anifrolumab concentrate for solution for infusion 150 mg/ml indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy with local clinical trial waiver.</p> <p>The firm presented the results of various clinical trials conducted in other countries.</p> <p>The drug is approved in United States, EU, Japan, Canada, UK, Australia etc</p> <p>The committee noted that there is no study data available in Indian population.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct clinical trial in Indian population.</p>
2.	91/Phase IV/Johnson/18-BD Golimumab	M/s. Johnson & Johnson	<p>The firm presented the results of Phase IV clinical trial conducted in India.</p> <p>After detailed deliberation, the committee noted the results of the study.</p>
3.	BIO/CT/22/000104 Denosumab 60 mg/ml injection	M/s. Enzene Biosciences Ltd.	<p>The firm presented the proposal for inclusion of following additional indications-</p> <ol style="list-style-type: none"> 1. Treatment to increase bone mass in men with osteoporosis at high risk of fracture. 2. Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. <p>The product Denosumab 60mg/ml is already approved for the indication “for the treatment of osteoporosis in postmenopausal women”.</p> <p>After detailed deliberation, the committee recommended for approval of proposed additional indications with condition that, firm should submit safety data of the drug for the proposed indication of “Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture” after</p>

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			one year for further review by the committee.
4.	BIO/CT/22/000158 Romosozumab 90 mg/ml injection	M/s. Amgen Technology Pvt. Ltd.	In light of SEC recommendation dated 10.02.2022, the firm presented the revised protocol for conduct of Phase IV study titled “An open-label, single-arm, multicenter Phase IV study to evaluate safety and tolerability of Romosozumab (EVENTITY®) in postmenopausal women in India with osteoporosis and a high risk of fracture”. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per revised protocol no. 20210025, version dated 19 September 2022 as presented by the firm.
5.	BIO/MA/22/000084 Adalimumab 40mg/0.4mg	M/s. Shilpa Biologicals Pvt. Ltd.	The firm presented the proposal to manufacture and marketing of the drug Adalimumab Injection 40 mg/0.4 ml, single use pre-filled syringe for the treatment of Rheumatoid Arthritis based on the results of Phase III local clinical trial. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug subject to the condition that firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of marketing approval.
SND Division			
6.	SND/MA/22/000245 Hydroxychloroquine Sulphate 100 mg Tablets	M/s. Laurus Labs Limited	The firm presented the therapeutic rationale along with the data of BE study conducted before the committee. After detailed deliberation, the committee recommended for approval of permission to manufacture and market Hydroxychloroquine Sulphate 100 mg Tablets for the applied indications with subject to condition that special care should be taken “for treatment of juvenile idiopathic arthritis (in combination with other therapies) discoid lupus erythematosus in case of paediatric population”.

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7.	SND/MA/21/000495 Cisatracurium Besylate Injection 20mg/10ml	M/s. Naprod Life Science	The firm presented their proposal of Phase IV clinical trial waiver for Cisatracurium Besylate Injection 20mg/10ml alongwith justification and some published literature before the committee. After detailed deliberation, the committee recommended that the firm should perform Phase IV clinical trial for the new indication "To provide skeletal muscle relaxation during mechanical ventilation in the ICU". Accordingly, the firm should submit the Phase IV clinical trial protocol as per the condition specified in the Form CT-23 permission.
GCT Division			
8.	CT/135/21 Online Submission (19733) Tofacitinib	M/s. Pfizer	The applicant presented protocol amendment 12 dated 06-05-2022 for protocol no A3921145 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
Medical Device Division			
9.	IMP/MD/2021/50521 Cross linked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18mg (Cingal)	M/s. Modi-Mundi Pharma Pvt. Ltd.	The proposal was deferred for next meeting.
10.	IMP/MD/2022/59985 Adhesion control barrier gels	M/s. Leader Biomedical & Surgery India Pvt. Ltd	The proposal was deferred for next meeting.
11.	CI/MD/2022/66273 Dry Socket surgical Dressing (ALVEOGL)	M/s. Septodent Healthcare	The proposal was deferred for next meeting.

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BA/BE Division			
12.	12-09/2022/BA-BE/Misc-18/DC Succinylcholine chloride injection 20mg/ml	M/s. Raptim Research Pvt. Ltd	The proposal was deferred for next meeting.
FDC Division			
13.	FDC/MA/22/000153 Tranexamic Acid 750mg + Mefenamic acid 375 mg tablets	M/s. Lupin Ltd	In light of earlier SEC recommendation dated 16.11.2022, firm presented their proposal along with justification. The committee opined that the product is not yet approved internationally and firm could not present any published literature on the FDC. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial and submit the data initially on at least 30 numbers of subjects. Accordingly, the firm should submit the Phase III CT protocol to CDSCO for further review by the committee.
GCT Division			
14.	CT/58/22 Online Submission (32802) Daxdilimab	M/s. PPD	The applicant presented Phase II clinical trial protocol no HZNP-DAX-204 version 1 dated 17-03-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as per presented protocol.
15.	CT/67/22 Online Submission (33255) Tildrakizumab 100mg/ml	M/s. Sun Pharma	In light of earlier SEC dated 13-09-2022, the applicant presented justification along with Phase III clinical trial protocol no. TILD19-19 amendment 1.1 (India Specific) dated 04/07/2022 (Inspire 2) before the committee. The committee noted that as per proposed protocol, Methotrexate/Leflunomide /SoC are already mentioned in protocol and to be provided in placebo arm as well as treatment arm throughout the treatment during conduct of the trial. The applicant agreed that DSMB recommendation to be submitted to CDSCO and more Govt. sites to be included in the study.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the study.
16.	CT/68/22 Online Submission (33217) Tildrakizumab 100mg/ml	M/s. Sun Pharma	<p>In light of earlier SEC dated 13-09-2022, the applicant presented justification along with revised Phase III clinical trial protocol no TILD-19-07 amendment 1.2 (India) dated 25/11/2022 (Inspire 1) before the committee.</p> <p>The committee noted that as per proposed protocol, Methotrexate/Leflunomide /SoC are already mentioned in protocol and to be provided in placebo arm as well as treatment arm throughout the treatment during conduct of the trial. The applicant agreed that DSMB recommendation to be submitted to CDSCO and more Govt. sites to be included in the study.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with revised protocol amendment 1.2 (India) dated 25/11/2022.</p>
New Drugs Division			
17.	No 12-10/17-Dc Remifentanil 1mg & 2mg for Injection	M/s. Themis	<p>In light of earlier opinion made by SEC dated 13.09.2022, the firm presented the data before the committee.</p> <p>The concurrent medication before and after the infusion and postmortem report was reviewed by the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit the report of concerned ethics committee in totality w.r.t the causality of the SAE. Accordingly, the firm needs to submit ethics committee report in totality to be reviewed by the committee.</p>