Recommendations of the SEC (Analgesic & Rheumatology) made in its 80th meeting held on 10.02.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000011 Sugammadex Injection 100 mg/ml	M/s. BDR Pharmaceuticals Internationals Ltd.	In light of the SEC recommendations dated 12.01.2022 & 13.01.2022, the firm presented Phase III clinical trial report along with the proposal for grant of manufacturing and marketing permission of drug Sugammadex Injection 100mg/ ml before the committee. After detailed deliberation, the committee recommended the following- • The firm should present the data regarding the blood pressure and heart rate in the subjects enrolled in Sugammadex arm. • Statistical analysis should be re-analysed after considering the normality. • The firm should submit the reason for not enrolling patient at Kolkata Medical College along with the undertaking from Principal Investigator of this site. Accordingly, the firm should submit above documents to CDSCO for further review by the committee.
2.	ND/MA/22/000011 Bucillamine Tablets 50 mg & 100 mg	M/s. Optimus Pharma Pvt. Ltd	The firm presented the proposal for conduct of Phase III clinical trial protocol and BA/BE protocol before the committee. After detailed deliberation, the committee recommended the following- • The firm should submit published literature, adequate safety, efficacy , toxicity and SAEs data of the drug etc. • The firm should modify point 18 of exclusion criteria in the proposed CT protocol. Accordingly, the firm should submit above documents to CDSCO for further review by the committee.
Biological Division			

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3.	BIO/CT04/FF/2022/30050 Denosumab	M/s. Enzene Biosciences	The firm presented the proposal for conduct of Phase IV clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission for the conduct of Phase IV CT as per the protocol ALK23/DEN 23 protocol version 1.0 subject to the condition that the patients who were prior treated with Denosumab should be excluded from the study.
4.	BIO/CT/21/000158 Romosozumab	M/s. Amgen Technology Pvt. Ltd.	The firm presented the proposal for conduct of Phase IV clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the following changes in the protocol- 1. Primary endpoint should be Safety. 2. Dose of Vit-D3 and Calcium should be defined. 3. Some Govt. institutes/hospitals should be included in the proposed study. Accordingly, the firm should submit the revised CT protocol to CDSCO for further review.
SND Division			
5.	SND/MA/21/000495 Cis-atracurium Besylate Injection 20mg/10ml	M/s. Naprod Life	The firm presented the proposal of Cis-atracurium Besylate Injection 20mg/10ml for additional indication, requesting local clinical trial waiver before the committee. The committee noted that the proposed additional indication was already approved in countries such as Canada, Australia etc. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Cis-atracurium Besylate Injection 20mg/10ml, indicated for in-patients as an adjunct to general anaesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during or mechanical ventilation in the ICU, subject to condition that the firm should conduct the Phase IV clinical trial for the indication to provide skeletal muscle relaxation during mechanical

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			ventilation in the ICU. Accordingly, the firm should submit the Phase IV clinical trial protocol within 3 months after approval for further review.
6.	SND/MA/22/000007 Tofacitinib ER Tablets 11mg	M/s. Sun Pharma	The firm presented the proposal for manufacturing and marketing of Tofacitinib ER Tablets 11mg along with BE Study report before the committee. The drug Tofacitinib ER Tablets 11mg is approved in US. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Tofacitinib ER Tablets 11mg for the following indication:- 1. Rheumatoid Arthritis: It is indicated for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have an inadequate response or intolerance to one or more TNF blockers. 2. Psoriatic Arthritis: It is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have an inadequate response or intolerance to one or more TNF blockers. 3. Ulcerative Colitis: It is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or intolerance to one or more TNF blockers. Also, the firm should conduct the Active PMS study. Accordingly, the firm should submit Active PMS Study protocol within 03 months after approval of the product.
7.	12-04/2017-DC (Pt-Cipla-SND) Ropivacaine HCL monohydrate solution for infusion 2 mg/ml	M/s. Cipla Ltd	The firm presented the report of the Phase III clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should submit the in-vitro data on safety of drug delivery through the Ropivacaine Readyfusor device in comparison with the other/existing delivery system. Further, the firm should submit the updated package insert with the warning/handling on use of the device as mentioned in the package insert of the

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			product marketed internationally.
FDC Division			
8.	FDC/MA/21/000084 Alcohol IP 36.8% v/w+ Ketoprofen IP 2.5%w/w Gel	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of the earlier SEC recommendations dated 24.06.2021 and 25.06.2021, the firm presented the rationale and justification for proposed FDC along with request for clinical trial waiver. The firm informed that the innovator's product also contains alcohol as 36.8% as per the testing conducted by the firm in their laboratory, however the concentration of alcohol is not mentioned in Innovator's product. After detailed deliberation, the committee recommended that the firm should conduct a randomized, comparative Phase III clinical trial comparing the proposed FDC with the innovator's product. Accordingly, the firm should submit Phase III CT protocol for review by the committee.
9.	FDC/MA/18/000076 FDC of Euphorbia Prostrata Extract 10mg + Lidocaine 30mg cream	M/s. Panacea Biotec Ltd.	In light of the earlier SEC recommendations dated 14.12.2021, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should revise the design of Phase III CT protocol as recommended earlier by the committee i.e. double blind, randomized, controlled, comparative clinical trial. Accordingly, the firm should submit revised Phase III CT protocol to CDSCO for further review by the committee.
GCT Division			
10.	CT/142/21 Online Submission (28745) Secukimunab	M/s. Novartis	The firm presented Phase III clinical trial protocol before the committee. **Assessment of risk versus benefit to the patient-** As the test drug is already approved in the country, the safety profile of trial drug, may justify the conduct of the proposed trial. **Innovations Vs existing therapeutic option-** The primary objective of the study is to demonstrate the superiority of Secukinumab compared to placebo based

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			on Modified Peripheral SpondyloArthritis Response Criteria 40 (mPSpARC40) response at week 16 in participant with active pSpA. **Unmet medical need in the country-** The trial drug may be an alternative treatment option in subject with active Peripheral SpondyloArthritis. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented.
11.	CT/124/21 Online Submission (28351) Tofacitinib	M/s. Pfizer	In light of earlier SEC recommendation dated 14.12.2021, the firm presented their justification for not submitting separate protocol for PK study before the committee. After detailed deliberation, the committee opined that the firm should submit separate undertaking to CDSCO for the same and recommended for grant of permission to conduct the study as per the protocol presented subject to the following conditions- 1. Only Quantiferon-TB Gold(QFT) test should be carried out to exclude latent/active TB patients for proposed study. 2. Urine pregnancy test should be carried out for childbearing potential women in the study and if positive results obtain, confirmation should be done by Serum Pregnancy test.