Recommendations of the SEC (Analgesic & Rheumatology) made in its 78th meeting held on 14.12.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	Ibuprofen	PvPI, IPC	The recommendation of signal review panel, PVPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO may request the State Drugs Controllers to direct the manufacturers of the drug ibuprofen to include adverse reaction Stevenson Johnson Syndrome (SLS)/Toxic Epidermal Necrolysis (TEN) in the package insert of the product.
2.	12-01/21-DC (Pt-160) Enoxaparin, Rivaroxaban	M/s. Kokilaben Ambani Hospital, Mumbai	The applicant presented their proposal in light of earlier recommendations dated 09.09.2021. After detailed deliberation, the committee recommended that the methodology section is incomplete; sample size needs to be recalculated. The methodology section should include proper exclusion and inclusion criteria, the patient with only ACLR reconstruction should be included, patients with obesity also should be excluded. Presently the study period is short, which should be extended. During follow-up; patients symptoms such as calf pain and swelling should be also noted. There is no mention of role of CT scan in patients with PE or asymptomatic PE, the type of graft for ACL reconstruction semitendinosus, gracilis or quadriceps graft should also be mentioned. Accordingly, the revised proposal should be submitted by the firm for deliberation.
3.	ND/MA/21/000178 Polmacoxib 2mg capsules	M/s. Macleods Pharma Ltd	The firm presented their proposal along with Phase III CT protocol and BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the BE study. The firm should present the results of BE study before the committee for further consideration of Phase III CT protocol.
Biological Division			
4.	61/PMS/Johnson/15-BD Golimumab	M/s. Johnson & Johnson	The proposal was deferred to the next meeting. The committee opined to invite one Rheumatologist in next SEC meeting for deliberation of the proposal.
5.	BIO/CT04/FF/2021/24027 Adalimumab	M/s. Intas	The proposal was deferred to the next meeting. The committee opined to invite one Rheumatologist in next SEC meeting for deliberation of the proposal.
6.	4-59/Roche/PAC-r-Tocilizumab/2020-BD (Part-I) Tocilizumab Injection 162 mg/0.9ml	M/s. Roche Products (India) Pvt Ltd	The proposal was deferred to the next meeting. The committee opined to invite one Rheumatologist in next SEC meeting for deliberation of the proposal.
FDC Division			
7.	FDC/MA/18/000076 FDC of Euphorbia Prostrata Extract + Lidocaine (10mg + 30mg) cream	M/s. Panacea Biotec Ltd.	In light of earlier recommendations of SEC dated 22.07.2020 & 23.07.2020, the firm presented their proposal along with the revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. The design of the proposed Phase III CT study should be double blind, randomized controlled comparative clinical trial. 2. Physical examination including peri rectal examination along with diet modification should be clearly mentioned in the protocol. 3. Proposed active treatment period and follow-up period should be justified depending on nature of Hemorrhoids. 4. Rescue medication should be clearly defined. 5. During the washout period, the pain medications should be taken off. Accordingly, the firm should submit the revised Phase III CT protocol for further review by the committee.

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8.	FDC/MA/21/000176 Tramadol HCl + Acetaminophen (37.5 mg + 325 mg) effervescent tablet	M/s. Sci Tech	The firm didn't turn up for presentation.
9.	4-46/2018-DC RopivavaineHCl Eq. to Anhydrous RopivacaineHCl+ Dextrose (7.5 mg +80 mg)	M/s. Neon Laboratories	The firm presented the active PMS proposal before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed study.
GCT Division			
10.	CT/45/19 Online Submission (10991) Baricitinib	M/s. Eli Lilly	The firm submitted the justification in light of earlier recommendations of SEC dated 17.07.2021. After detailed deliberation, the committee recommended that opinion of Radiologist should be sought in next SEC meeting for further review of the proposed protocol amendment.
11.	CT/124/21 Online Submission (28351) Tofacitinib	M/s. Pfizer	In light of earlier recommendations of SEC dated 16.11.2021, the firm presented their justification for Phase III clinical trial before the committee. **Assessment of risk versus benefit to the patients:** The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial as presented before the committee. **Innovation vis-a-vis existing therapeutic:** To assess the sustained efficacy of Tofacitinib versus placebo in Sjia patients, as measured by time to sJIA flare in the double-blind randomized withdrawal phase. **Unmet need:** The Tofacitinib used for treatment of Systemic Juvenile Idiopathic Arthritis (Sjia) with Active Systemic Features in children and adolescent subjects.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the following conditions. 1. Efficacy, safety and tolerability to be evaluated under the proposed protocol and for PK study separate protocol to be submitted. 2. Only Quantiferon-TB Gold (QFT) test should be carried out to exclude latent/active TB patients for proposed study. 3. Urine pregnancy test should be carried out for child bearing potential women in the study and if positive results obtain, confirmation should be done by Serum Pregnancy test.
12.	CT/135/21 Online Submission (28555) Tofacitinib	M/s. Pfizer	The firm presented their Phase 2/3 follow up (roll over) Clinical Trial protocol no. A3921145, Protocol Amendment 11, dated 26 May 2021 before the committee. **Assessment of risk versus benefit to the patients-** The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial as presented before the committee. **Innovation vis-a-vis existing therapeutic-** The primary objective of this study is to determine the long term safety and tolerability for treatment of the sign and symptoms of JIA. **Unmet need -**The Tofacitinib used for treatment of Systemic Juvenile Idiopathic Arthritis (Sjia) With Active Systemic Features In Children And Adolescent Subjects. After detailed deliberation, the committee recommended to conduct the study subject to the following conditions. 1. Efficacy, safety and tolerability will be evaluated under the proposed study protocol and for pharmacokinetic exploratory objective, separate protocol to be submitted for approval to conduct the pharmacokinetic study. 2. Only QuantiFERON-TB Gold (QFT) test should be carried out to exclude

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			latent/active TB for proposed study. 3. Urine Pregnancy test should be carried out for child bearing potential women in the study and if positive results obtain, confirmation should be done by Serum pregnancy test.
13.	CT/137/21 Online submission (28641)	M/s. Dr. Reddy's	The firm presented their Phase I clinical trial proposal before the committee. After detailed deliberation, the committee opined to invite one Rheumatologist in next SEC meeting for further review of proposed study.
Medical Device Division			
14.	CI/MD/2021/46278 Clinifibre suture	M/s. Healthium Medtech Limited	In light of earlier SEC recommendations dated 12.10.2021, the firm presented their proposal for post marketing clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the post marketing clinical investigation of the proposed device in the country.