Recommendations of the SEC (Analgesic & Rheumatology) made in its 93rd meeting held on 14.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000073 Ibuprofen Sodium Dihydrate 256mg tablets & Ibuprofen Sodium Dihydrate 512mg tablets	M/s. Lyrus Life Science	In light of earlier SEC recommendation dated 23.06.2022, the firm presented its proposal for grant of permission to manufacture and market drug Ibuprofen Sodium Dihydrate 256mg tablets & Ibuprofen Sodium Dihydrate 512mg tablets along with bioequivalence study results. After detailed deliberation, the committee recommended for grant of permission to manufacture and market drug Ibuprofen Sodium Dihydrate 256mg tablets & Ibuprofen Sodium Dihydrate 512mg tablets subject to condition that the firm should conduct active post marketing surveillance for which protocol should be submitted to CDSCO within three months of approval of the drug.
2.	ND/MA/21/000076 Polmacoxib 2mg Capsules	M/s. Hetero Labs	The firm presented the Phase III clinical trial report of Polmacoxib 2mg in Patients with Idiopathic (Primary) Osteoarthritis of Hip/Knee before the committee. After detailed deliberation, the committee noted that: 1. Polmacoxib 2mg capsule is approved by South Korea on September 2015. 2. The firm has completed BE study comparing the Polmacoxib 2mg capsule with Acelex (Polmacoxib 2mg capsule) manufactured by Crystal Genomics, Korea in adult male subjects under fasting condition. 3. Phase III clinical trial result showed that efficacy of the Polmacoxib 2mg capsule is comparable with Celecoxib 200mg and thus establishing non inferiority of Polmacoxib 2mg capsule compared to Celecoxib 200 mg. 4. No death or serious adverse events (SAEs) were reported in the Phase III clinical trial. A total

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			of 30 adverse events (AEs) were reported. 13 AEs in Polmacoxib 2mg capsule and 17 AEs in Celecoxib 200 mg. All AEs were mild in severity. Accordingly, the committee recommended for the grant of permission to manufacture and market Polmacoxib 2mg capsule for treatment of Idiopathic (Primary) Osteoarthritis of Hip/Knee subject to the condition that firm should conduct Phase IV clinical trial and submit the Phase IV clinical trial protocol before the committee within 3 months of approval.
Medical Device Division			
3.	CI/MD/2022/76970 3-D Scaffold matrix	M/s. EffecMed Private Limited	The firm presented its proposal for pivotal clinical investigation of the proposed medical device in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of pivotal clinical investigation of the proposed medical device in the country on Indian Population.
4.	CI/MD/2019/17174 Serioss® (Bone Void Filler)	M/s. Serigen Mediproducts Pvt. Ltd	The firm presented pilot clinical investigation report of the proposed medical device before the committee. After detailed deliberation, the committee recommended following: 1. Follow-up period of pilot clinical investigation study should be increased to one year. 2. Pre operative CT scan & post operative CT scan at one year may be shown in all 10 cases along with all other records and findings of all 10 patients should be conducted and included in the report. Accordingly, firm should submit updated pilot clinical investigation report of proposed study for further review by the committee.

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BA/BE Division			
5.	12-09/2023/BA BE/Misc-01/DC Tramadol Hydrochloride Prolonged Release Capsules 200 mg	M/s. Lambda Therapeutic Research Limited.	The firm presented its proposal for conduct of BE study for export purpose with Tramadol Hydrochloride prolonged release capsules 200mg before the committee. After detailed deliberation, the committee has recommended for the conduct of the study with the condition that the PI qualification should be MD Pharmacology/ Medicine. Also the centre should have adequate emergency respiratory care facility along with experts from respiratory medicine.
FDC Division			
6.	FDC/MA/22/000153 Tranexamic Acid 750mg+ Mefenamic Acid 375 mg tablets	M/s. Lupin Ltd.	In light of the earlier SEC recommendation dated 14.12.2022, the firm presented its proposal along with Phase III clinical trial study protocol before the committee in presence of Gynecologist. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial study on 30 subjects with following conditions: 1. To provide the percentage of patients with primary dysmenorrhoea and menorrhagia amongst all patients presenting with dysmenorrhea and menorrhagia. 2. Shape and size of sanitary pad should be defined. Preferably standard pads must be provided to all study subjects 3. Patients with adenomyosis may be included as it is the commonest cause of combined dysmenorrhea with menorrhagia. 4. More Govt. sites should be included geographically distributed. Accordingly, revised protocol should be submitted to CDSCO for approval. The result of the study on 30 patients should be presented before the committee for review for permission for continuation of the clinical trial on more number of subjects.

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GCT Division			
7.	CT/24/21 Online Submission (22468) Tofacitinib	M/s. Pfizer	The applicant presented protocol amendment 7 dated 22-August-2022 to the protocol no. A3921165 before the committee. After detailed deliberation, the committee recommended that proposed protocol amendment along with previous protocol should be sent via mail to the committee members for review and comments/recommendation.