75th SEC (Analgesic & Rheumatology) Meeting scheduled to be held on 09.09.2021 at CDSCO (HQ), FDA Bhawan, Kotla road, New Delhi – 110 002

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/19/000004 Polmacoxib Capsules 2 mg	M/s Ajanta Limited	The firm presented their proposal of BE study protocol along with Phase III Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The firm should present the results of the BE study before the committee for further consideration of Phase III clinical trial protocol.
2.	12-01/21-DC (Pt-160) Enoxaparin. Rivaroxaban	IEC, Kokilaben Dhirubhai Ambani Hospital	The applicant presented their proposal of academic clinical trial before the committee. After detailed deliberation, the committee opined that the protocol presented is grossly inadequate and the applicant should clearly define safety, efficacy assessment and other parameters in the protocol. Accordingly, applicant should submit revised protocol to CDSCO for further review by the committee.
Biological Division			
3.	BIO/CT/20/000076 Omalizumab Injection	M/s Reliance Life Sciences	The firm presented the proposal for amendment in Phase IV Clinical Trial protocol. After detailed deliberation the committee recommended for grant of permission as per amended protocol version 3.0 dated 28.05.2021 with the condition that the firm should continue collection of data with respect to patient reported outcome in Asthma patients.
4.	BIO/CT18/FF/2020/22859 Infliximab	M/s Pfizer	The firm presented the proposal for marketing authorization of Infliximab with waiver of local Phase III and IV clinical trial in the country. The committee noted that the drug is approved in major ICH countries like USA, EU and Japan and the proposal was also deliberated in the pre submission meeting. After detailed deliberation the committee recommended for grant of marketing authorization with waiver of Phase III clinical trial subject to the condition that the firm should conduct Phase IV clinical trial as per CDSCO guidelines for similar biologics and the protocol shall be submitted within three months of obtaining the marketing approval.

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			Accordingly the firm should submit the protocol for approval.
5.	BIO/CT/21/000061 Adalimumab	M/s Intas	The firm presented the proposal for conduct of Phase III Clinical Trial (Protocol No. 0881-19, Version: 1.2). After detailed deliberation the committee recommended for grant of permission for the conduct of the study subject to the following conditions- 1. The firm should clarify the colour of the product. 2. Principal Investigator should be a Rheumatologist or a MD in Medicine with experience in Rheumatology. 3. 50% Clinical Trial sites from Govt.Hospitals/ institutions should be included in the study.
6.	BIO/IMP/20/0000023 Romosozumab Injection	M/s Amgen	The firm presented the proposal for Phase IV study waiver for Romosozumab Injection. The committee noted that the drug is already approved in the country with the condition to submit Phase IV Clinical Trial protocol within the 3 months of MA. The committee also opined that the data presented by the firm in Indian patients is inadequate and there are serious concerns regarding three cardiovascular system related deaths in the active arm. After detailed deliberation the committee did not consider the firm's proposal for Phase IV Clinical Trial waiver. Accordingly the firm should submit Phase IV Clinical Trial protocol to CDSCO for further consideration.
SND Division			
7.	SND/MA/21/000369 Etoricoxib Tablets 30 mg	M/s AET Laboratories	The firm presented the proposal of additional strength of Etoricoxib tablets 30mg along with the BE study report conducted with Etoricoxib tablets 120mg. The committee noted that the Etoricoxib tablets 30mg is already approved in EU, Australia and New Zealand. After detailed deliberation the committee recommended for grant of permission to manufacture and market Etoricoxib tablets 30mg for the treatment of symptomatic relief of osteoarthritis and rheumatoid arthritis, acute gouty arthritis, acute pain associated with dental surgery, primary dysmenorrhea.

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8.	12-38/2018-DC (Pt-Misc-SND) Crocin 650mg and Calpol 650mg	M/s GlaxoSmithKline Pharmaceuticals	The firm presented the justification along with data for Paracetamol Tablets 650mg before the committee. After detailed deliberation the committee opined that Paracetamol 650mg tablets is already used in the country since many years. Further, the dose of Paracetamol 650mg is prescribed in various standard textbooks. Hence the availability of Paracetamol Tablet 650mg in the market is acceptable.
FDC Division			
9.	FDC/CT/21/000006 Bioactive concentrate from small Marine Fish (Active) + Water for injection (Inactive) (Indication: 1. Degenerative rheumatic diseases of the joints:osteoarthrosis with diverse localization coxathrosis, gonarthrosis, small joints arthrosis; spondylosis, osteochonodrosis; 2. The period of convalescence (as adjuvant) after traumas and joint surgery) (0.1ml + 1.0ml) Solution for injection	M/s. Biotehnos Pvt. Ltd.	Firm didn't turn up for the presentation
GCT Division			
10.	CT/67/21 Online Submission Secukinumab	M/s. Novartis	The firm presented the proposal to conduct Phase IV Clinical Trial (Protocol No. CAIN457A02001B, Version: 0.0 dated 23 Sept 2020). After detailed deliberation the committee recommended for grant of permission to conduct

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			the long term extension study.