

Recommendations of the SEC (Analgesic & Rheumatology) made in its 45th meeting held on 19.12.2018 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New Drug Division			
1	12-76/13-DC (Pt.B) Iguratimod 25mg	Ajanta Pharma	Firm presented their proposal along with results of BE study & local Clinical trial. After detailed deliberation, committee recommended for grant of permission to manufacture & market Iguratimod 25mg tablets for active rheumatoid arthritis symptoms subject to condition that the firm should conduct phase IV clinical trial to further assess safety & efficacy of the drug in post market scenario. Accordingly the phase IV clinical trial protocol should be submitted within 6 months for review by the committee.
Fixed Dose Combination Division			
2	FDC/MA/18/000006 Dicyclomine + Tapentadol (20mg + 50mg & 10mg + 25mg) capsules	M/s. Wockhardt	The firm did not turn up for the presentation.
Subsequent New Drugs Division			
3	12-97/2017-DC (Pt-Synokem-snd) Oxaceprol SR Tablet 600mg (modified dosage form)	M/s Synokem Pharmaceuticals Ltd.	The firm presented the results of BE study in Fasting and Fed conditions along with the protocol for Clinical trial. After detailed deliberation the committee recommended for grant of permission to conduct clinical trial subject to the conditions that patients with OA of knee should only be included in the trial and the principal investigators should be Orthopaedician / Rheumatologist and more Government sites

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			geographically distributed should be included. Accordingly revised protocol should be submitted to CDSCO for approval.
4	12-93/2015-DC (Pt-Troikaa-SND) Ketorolac Tromethamine Sublingual Tablet 30mg	M/s Troikaa Pharmaceuticals	The firm presented their report of pivotal BE study of Ketorolac Tromethamine Sublingual Tablet 30mg Compared with 30mg/ml I.M injection of the drug. After detailed deliberation committee recommended that the firm should conduct a phase III Clinical trial with the sublingual tablets in the proposed indications. Accordingly protocol should be submitted for review by the committee.
5	SND/IMP/18/000017 Diclofenac sodium 2% Topical solution	M/s Sayre Therapeutics Ltd.	The firm presented their proposal for import and marketing of Diclofenac sodium 2% Topical solution along with clinical data generated with the product. The product is already approved in USA. The diclofenac diethylamine topical solution (2%) is already approved and marketed in the country. After detailed deliberation the committee recommended for grant of permission to import and market the product for the same indication as approved in USA
Biological Division			
6	BIO/Form 44/BO/2018/10139 Etanercept	M/s Lupin	In light of the recommendation of SEC meeting held on 28.11.2018, the firm presented their justification\clarification and requested for marketing authorization based on the Phase I and III clinical trial data generated in GCT with

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			India as one of the participating countries. It was clarified that, Phase I CT was conducted with the formulation manufactured by them in India. After detailed deliberation committee recommended for the grant of permission to manufacture and market the drug product subject to condition that the firm should conduct Phase IV CT in 300 patients. Accordingly, Phase IV CT protocol should be submitted for review by the committee before grant of permission.

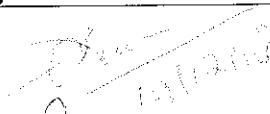
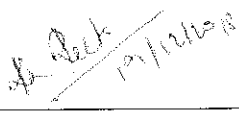
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S.No	SEC –Experts Name & Designation	Signature
1.	Dr. R. K. Arya, Director, Dept. of Orthopaedics Sports Injury Center, VMMC & Safdarjung Hospital, New Delhi	 19/12/18
2.	Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi	 19/12/18
3.	Dr. Chandralekha, Professor & Head NDMC Medical college and Hindurao hospital, New Delhi	 19/12/18
4.	Dr. Vijay Kumar Jain, Associate Professor, Dept. Of Orthopaedics, RML Hospital, New Delhi	 19/12/18
5.	Dr. K. H. Reeta, Professor, Department of Pharmacology, AIIMS , New Delhi	 19/12/18