

Recommendations of the SEC (Analgesic & Rheumatology) made in its 64th meeting held on 11.08.2020 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-76/13/DC (Pt.B/Phase IV) Iguratimod Tablets 25mg	M/s Ajanta Pharma	Fir did not turn up for presentation.
SND Division			
2.	SND/MA/20/00016 1 Lidocaine Spray 10% w/v	M/s Zydus Healthcare	Firm presented the proposal of manufacturing and marketing of Lidocaine Spray 10%. w/v After detailed deliberation the committee recommend for grant of permission to manufacture and market of the Lidocaine Spray 10% Subject to condition, that the firm should conduct a Phase IV clinical trial for which protocol should be submitted within three months of approval for review by the committee. As regard to obstetrics indication, the firm should submit clarification on the specific condition /indication being proposed.
3.	SND/MA/20/00004 3 Tapentadol Nasal Spray 225 mg/ml	M/s Torrent	In light of earlier 62 nd SEC 06.07.2020 recommendations, firm presented the detail of raw data, primary and secondary end analysis etc of the clinical trial. After detailed deliberation, committee recommended for gant of permission to manufacture and marketing Tapentadol Nasal spray 225mg/ml for treatment of moderated to severe post- operative pain in hospital admitted patients subject to condition that the firm shall submit and present phase IV CT protocol and packge insert of the product before launching the product for marketing. The product should

			be sold only prescription of Medical Specialist for use in hospital/ institutional setup only
Biological Division			
4.	4-218/Reliance/13-BD (Part-I) Infliximab	M/s Reliance Life Sciences Ltd	Firm presented their follow up report of Phase III clinical trial. After deliberation, committee noted the follow up report of the study.
5.	X-11026/84/2020-BD Rituximab	M/s IPCA Laboratories Ltd.	Pre submission meeting
FDC Division			
6.	FDC/IMP/19/00001 1 Articaine Hydrochloride + Epinephrine Bitartrate (40mg + 0.018mg) injection	M/s. Septodont Healthcare India Pvt. Ltd.	Firm did not turn up for presentation
Medical Device Division			
7.	CI/MD/2020/19373 Bioactive sythetic bone graft granules	M/s SynThera Biomedical Private Limited	In light of recommendation of the committee dated 23.06.20, the firm presented their justification before the committee. After detailed deliberation, the committee recommended that firm should present detailed animal study data including Mutagenicity and Immunogenicity as per international standards applicable for new medical devices for further consideration.