

Recommendations of the SEC (Analgesic & Rheumatology) made in its 81st meeting held on 22.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/000076 Polmacoxib 2 mg capsule	M/s. Hetero Lab	In light of SEC recommendations dated 12.01.2022 & 13.01.2022, the firm presented their revised Phase III CT protocol before the committee After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the presented protocol subject to condition that the Principal Investigator should be atleast an Associate Professor, MS Orthopedics.
2.	ND/MA/20/000011 Sugmamdex Injection 100 mg/ml	M/s. BDR Pharmaceutical International Pvt. Ltd.	In light of SEC recommendations dated 10.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug for the proposed indication subject to the condition that the product should be sold by retail under the prescription of the Anesthesiologist only.
SND Division			
3.	12-04/2017-DC(pt-Cipla-SND) Ropivacaine HCL monohydrate solution for infusion 2mg /ml (250ml) readyfusor device delivering 5ml/hr of drug product.	M/s. Cipla Limited	In light of SEC recommendations dated 10.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the Ropivacaine HCL monohydrate solution for infusion 2mg /ml (250ml) with readyfusor device delivering 5ml/hr of drug product.