

Recommendations of the SEC (Analgesic & Rheumatology) made in its 84th meeting held on 19.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/22/000025 Triamcinolone Hexacetonide Injectable Suspension 20 mg/ml	M/s Abbott Healthcare Pvt. Ltd.	<p>The firm presented the proposal to conduct Phase IV study with the drug before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study subject to following conditions:</p> <ol style="list-style-type: none"> 1. The firm should modify exclusion criteria to exclude patients with significant (requiring surgical correction) deformity of the target joint. 2. The firm should modify secondary objective as patient global scale assessment from baseline to weeks 1, 4, 8 and 12.
2.	ND/MA/22/000011 Bucillamine Tablets 50 mg & 100 mg	M/s Optimus Pharma Pvt. Ltd	<p>In light of earlier SEC recommendation dated 10.02.2022, the firm presented their proposal for conduct of Phase III clinical trial and BE study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study as per the protocol presented and also recommended for grant of permission to conduct the proposed clinical trial subject to following conditions:</p> <ol style="list-style-type: none"> 1. The firm should revise two arms study as Arm 1 (Intervention arm)- Methotrexate and Bucillamine and Arm 2 (Comparator arm)- Methotrexate 2. In both arms, the dose of Methotrexate should be as per standard treatment. 3. The firm should compare patient response & review after 8 weeks of the study. 4. The firm should exclude patients who progress to systematic illness or who shows a flaring of disease

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			<p>activity before 8 weeks of therapy and should be discontinued from the study and drop out should be notified</p> <p>The firm should provide standard treatment to patients in case of failure of SOC / disease progression.</p>
3.	ND/MA/22/000073 Ibuprofen Sodium Dihydrate 256 mg tablets & Ibuprofen Sodium Dihydrate 512 mg tablets	M/s Lyrus Life Sciences Pvt Ltd	<p>The firm presented their proposal along with justification for BE & CT waiver, published literature including comparison data of Ibuprofen with proposed drug before the committee.</p> <p>The committee noted that the drug is approved in USA, Australia, U.K etc. and also noted that published PK study and clinical trial data demonstrated that the drug has better solubility profile, similar safety efficacy profile, earlier onset of action compared to plain Ibuprofen in pain indications.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct bioequivalence study for which protocol should be submitted to CDSCO for further consideration by the committee.</p>
4.	12-01/18-DC (Pt-337)-Tramadol & Urinary Retention	SRP-NCC-PvPI	<p>The SRP recommendation received from PvPI was deliberated by the committee.</p> <p>After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers of the drug to include urinary retention as adverse drug reaction in the corresponding package insert of the drug.</p>
5.	12-01/18-DC (Pt-337)-Mefenamic acid & Fixed Drug Eruption	SRP-NCC-PvPI	<p>The SRP recommendation received from PvPI was deliberated by the committee.</p> <p>After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct manufacturers of the drug to include Fixed drug Eruption as adverse drug reaction in the corresponding package insert of the drug.</p>
FDC Division			

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6.	FDC/MA/22/000070 Dicyclomine Hydrochloride + Paracetamol +Tramadol Hydrochloride (50mg+10mg+325mg) capsules	M/s AKUMS DRUGS	The firm didn't turn up for presentation.