Recommendations of SEC (Analgesic & Rheumatology) made in its 77th meeting held on 16.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-295/Reliance/15-BD(Pt-I) Etanercept	M/s. Reliance Life Sciences	The firm presented the clinical study report of Phase III clinical trial. The Committee noted that the drug is already permitted for manufacturing in the country. After detailed deliberation, the committee noted the results.
2.	61/PMS/Johnson/15-BD Golimumab	M/s Johnson & Johnson	The firm didn't turn up for presentation.
3.	BIO/CT21/FF/2021/24679 Denosumab	M/s. Reliance Life Sciences	In light of earlier recommendation dated 24.06.2021 and 25.06.2021, the firm presented additional data before the committee. The committee noted that there is significant patient dropout in the study due to the Covid-19 pandemic and no meaningful conclusion could be drawn on the outcome of the study. After detailed deliberation, the committee did not recommend for grant of marketing authorization for the drug.
SND Division			
4.	SND/MA/21/000491 Nimesulide Granules for Oral Suspension 100mg	M/s. Dr. Reddy's Laboratories	The firm presented their proposal for permission to manufacture and market Nimesulide Granules for Oral Suspension 100 mg for inflammatory condition including joint disorders such as rheumatoid arthritis, post-operative painful condition and fever. The firm presented their BE study report along with justification for clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug subject to the condition that firm should conduct Phase IV clinical trial.

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			Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the product.
FDC Division			
5.	4-36/2018-DC Levobupivacaine HCl eq. to Levobupivacaine+Dextrose (5mg+80mg)	M/s. Neon Laboratories	The firm presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC
6.	FDC/MA/21/000176 Tramadol HCl 37.5mg + Acetaminophen 325mg effervescent tablets	M/s. SciTech	The firm presented their proposal along with BE study protocol before the committee. The firm informed that the proposed product is approved in UK and EU. The committee noted that the firm did not present full BE study protocol. Further, the comparator in the study is a conventional tablet which may not be appropriate. After detailed deliberation, the committee recommended that the firm should change the comparator with the internationally approved FDC in effervescent form and present the revised protocol before the committee for further consideration.
7.	FDC/MA/18/000076 FDC of Euphorbia Prostrate Extract + Lidocaine (10mg+ 30 mg) cream	M/s. Panacea Biotech Ltd.	The firm did not turn up for presentation.
GCT Division			
8.	CT/124/21 Online Submission (28351) Tofacitinib	M/s. Pfizer	The firm presented their proposal for Phase III clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should submit the following for further review: 1.Proper justification for pharmacokinetics analysis in the proposed study. 2. Specify the purpose for PK sample for internal exploratory purposes and not

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			mentioning its results under clinical reports as mentioned in CSP.
Medical Device Division			
9.	IMP/MD/2021/41354 Bio-inductive Implant (REGENETEN)	M/s. Smith & Nephew Healthcare Pvt. Ltd.	In light of earlier SEC recommendations dated 17.08.2021, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should submit following: 1. Clinical investigation data generated from the proposed device and published in the high index peer reviewed journal in detail. 2. Interim report/analysis of the ongoing RCT with respect to applied device.
10.	IMP/MD/2021/41651 INNOTERE3D Scaffold	Avana Medical Devices Pvt. Ltd	The firm presented their proposal for grant of permission to import and market the proposed device in the country before the committee. The committee observed that the published data submitted by the firm is inadequate. After detailed deliberation, the committee recommended that the firm should submit following: 1. Data generated from the device and published in the high index peer reviewed journals in regards to biocompatibility, efficacy and safety. 2. Post market surveillance data generated by the manufacturer in the countries where the proposed device is used.
11.	MD/PostAppr/2021/5862 Stimulan Kit and Stimulan Rapid Cure	Biocomposites India Pvt. Ltd	The firm presented their proposal for post approval change in indication before the committee. The committee observed that the published data presented by the firm is inadequate. After detailed deliberation, the committee recommended that the firm should submit data generated from the device and published in the high index peer reviewed journals for soft tissue

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			infection only.