

**Recommendations of the SEC (Analgesic & Rheumatology) made in its 79<sup>th</sup> meeting held on 12.01.2022 & 13.01.2022 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/MA/21/000076  Polmacoxib 2 mg capsules	M/s. Hetero lab	In light of earlier SEC recommendations dated 24.June.2021, the firm presented BE study results along with the Phase III clinical trial study protocol.  After detailed deliberation, the committee opined that:  1. Study sites should be geographically distributed. 2. 50% studies should be from Govt medical colleges/hospitals. 3. Principal investigators should be MS Orthopedics. 4. Sample size should be revised and power of the study should be increased. 5. Inclusion criteria should be revised. 6.The firm should submit published/innovator data/literature on safety profile of proposed study drug.  Accordingly, the firm should submit their response before the committee for further consideration.
2.	ND/MA/20/000011  Sugammadex Injection 100mg/ml	M/s. BDR Pharmaceuticals Internationals Ltd	The firm presented Phase III clinical trial report along with the proposal for grant of manufacturing and marketing permission of drug Sugammadex Injection 100 mg/ml.  After detailed deliberation, the committee opined that the proposal may be further discussed along with anesthesiologist for further consideration.
<b>Biological Division</b>			
3.	61/PMS/Johnson/15-BD  Golimumab	M/s. Johnson & Johnson	The firm presented clinical study report for PMS study permitted for Golimumab and the safety data generated with the study before the committee.  After detailed deliberation, the committee noted the same.
4.	BIO/CT04/FF/2021/24027  Adalimumab	M/s. Intas	In light of earlier SEC meeting dated 09.09.2021 and subsequent observations raised by the RCGM in its letter dated 18.10.2020 for difference in

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			<p>pharmacokinetic profile of the drug in experimental animals, the firm presented their justification before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should carryout PK evaluation on a sub-set of patients for continuation of the study for evaluation of other endpoints of Phase III study.</p> <p>Accordingly, the firm should submit revised Phase III clinical trial protocol for further review by the committee.</p>
5.	<p>4-59/Roche/PAC-r-Tocilizumab/2020-BD(Part-I)</p> <p>Tocilizumab Injection 162mg/0.9ml</p>	M/s. Roche Products (India) Pvt. Ltd	<p>The firm presented the proposal for modification of the dosage regimen to introduce weight based dosing schedule and also presented scientific evidence for the modification.</p> <p>The committee noted that the modified dosing schedule is approved by US FDA. After detailed deliberation, the committee recommended for grant of approval for the modification of dosage regimen.</p>
<b>SND Division</b>			
6.	<p>SND/MA/21/000495</p> <p>Cis-atracuriumBesylate Injection 20mg/10ml</p>	M/s. Naprod Life	The committee opined that the proposal should be deliberated along with anesthesiologists.
7.	<p>SND/MA/21/000145</p> <p>Tofacitinib tablets 10mg</p>	M/s. MSN Laboratories	The firm didn't turn up for presentation.
8.	<p>SND/MA/21/000537</p> <p>Tofacitinib tablets 10mg</p>	M/s. Synokem Pharma	<p>The firm presented the proposal for manufacturing and marketing of Tofacitinib Tablets 10mg along with BE Study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study of Tofacitinib Tablets 10mg as per protocol presented.</p>
<b>FDC Division</b>			
9.	<p>FDC/MA/21/000176</p> <p>Tramadol HCl + Acetaminophen (37.5mg+325mg)</p>	M/s. SciTech	<p>In light of earlier SEC recommendation dated 16.11.2021, the firm presented revised BE protocol before the committee.</p> <p>After detailed deliberation, the committee</p>

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	effervescent tablets		recommended for grant of permission to conduct the BE study. The results of BE study should be presented before the committee for further consideration.
<b>GCT Division</b>			
10.	CT/45/19 Online Submission (10991) Dated 27/02/21	M/s. Eli Lilly	The firm presented the protocol amendment I4V-MC-JAHX(d) dated 07-Nov-2020.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the amended protocol.
11.	CT/137/21Online Submission (28641) Dated 18/10/21	M/s. Dr.Reddy's	In light of earlier recommendation dated 14.12.2021, the firm presented their proposal before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial.
12.	CT/117/20 Online Submission (13258) Dated 27/10/21	M/s. Medpace	The firm presented the protocol amendment VIB0551.P3.S2, Version-7 dated 16-Aug-2021.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the amended protocol.
<b>Medical Device Division</b>			
13.	IMP/MD/2021/41354  Bioinductive Implant ( REGENETEN)	M/s. Smith & Nephew Healthcare Pvt. Ltd.	In light of earlier SEC recommendations dated 16.11.2021, the firm presented their proposal for grant of permission to import and market the proposed device before the committee.  After detailed deliberation, the committee recommended that the firm should submit outcome of interim analysis of the ongoing RCT with respect to proposed device in order to justify safety and effectiveness of the product.
14.	CI/MD/2021/49121  Nanocomposite Fibrous scaffold (NANOTEX BONE Graft)	M/s. Amrita Vishwa Vidyapeetham	The firm presented the proposal for pilot clinical investigation before the committee.  After detailed deliberation, the committee recommended that the firm should submit following data for further consideration: 1. Heavy metal toxicity study in animal model.

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			2. Published clinical data, post market surveillance data of similar implant available from other country.
15.	MD/PostAppr/2021/5862  Stimulan Kit and Stimulan Rapid Cure	M/s. Biocomposites India Pvt. Ltd.	<p>In light of earlier SEC recommendations dated 16.11.2021, the firm presented the proposal for post approval change in indication before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct pivotal clinical investigation of the proposed device in the country for additional indication.</p> <p>Accordingly, the firm should submit clinical investigation protocol for further review by the committee.</p>
16.	MFG/MD/2021/37336 Radiopaque Gelified Ethanol	M/s. Elevate scientific private limited	<p>In light of earlier SEC recommendations dated 24.06.2021 &amp; 25.06.2021, the firm presented their proposal for grant of permission to manufacture and market the proposed device before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the following:</p> <ol style="list-style-type: none"> <li>1. Preclinical study data on at least 2 animal species preferably one in mammal.</li> <li>2. Substantial equivalence data defining safety and efficacy of the proposed device over similar device available in Europe.</li> <li>3. Clinical investigation data generated from similar available device in Europe published in high index peer reviewed journals.</li> </ol>