Recommendations of the SEC (Analgesic & Rheumatology) made in its 92nd meeting held on 12.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000115 Polmacoxib Capsule 2mg	M/s Precise Biopharma Pvt. Ltd.	The firm presented results of the Bioequivalence Study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the Polmacoxib Capsule 2mg as per protocol submitted by the firm.
2.	12-10/17-DC Remifentanil 1mg & 2mg for Injection	M/s Themis	In light of earlier SEC meeting dated 14.12.2022, the committee opined that the firm should submit the report of concerned ethics committee in totality w.r.t the causality of the SAE. In-light of above, the firm presented the causality assessment report alongwith data of SAE before the committee. The committee reviewed the causality assessment report of the SAE presented by the firm. The committee also reviewed institutional ethics committee report. After detailed deliberation, the committee recommended for grant of permission to import and market Remifentanil 1mg & 2mg Injection in the country subject to following conditions: 1. The firm should submit revised prescribing information mentioning that there are reported cases of adverse cardiovascular events associated with patients of hypertension, diabetes. 2. The firm should conduct focused pharmacovigilance study and quarterly report to be submitted to CDSCO.
3.	12-01/18-DC (Pt-337) Paracetamol	PvPI, IPC	The recommendation of signal review panel, PvPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to instruct the manufacturers of the drug to

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			incorporate Paracetamol associated Fixed Drug Eruption (FDE) in the PIL of the drug marketed in the country.
4.	12-01/18-DC (Pt-337) Piroxicam	PvPI, IPC	The recommendation of signal review panel, PvPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to instruct the manufacturers of the drug to incorporate Piroxicam associated Fixed Drug Eruption (FDE) in the PIL of the drug marketed in the country.
Biological Division			
5.	BIO/CT/20/00003 Tocilizumab Injection (162 mg/0.9m L Prefilled Syringes)	M/s. Cipla Limited	The firm presented their proposal for waiver of condition for conduct of Phase IV study which was given as a condition of import and market permission of Tocilizumab Injection (162mg/0.9mL Prefilled Syringes) indicated for Giant Cell Arthritis (GCA) with justification that they are facing challenges in recruitment of patients of GCA as it is an extremely rare disease with very low prevalence in India. After detailed deliberation, the committee recommended to waive off the condition for conduct of Phase IV study as mentioned in import and marketing permission of the drug considering that Giant Cell Arthritis is very rare disease and there is challenge in recruitment of patients. Further the committee recommended that the firm should conduct an active surveillance study and should submit data on first 10 patients once completed. Accordingly, the firm should submit protocol to CDSCO for evaluation.
SND Division			
6.	SND/IMP/22/000057 Tofacitinib Tablets 5mg	M/s Pfizer Limited	The firm presented the proposal of Phase IV Clinical Trial waiver of import and marketing permission alongwith its justification, global clinical data and PMS exposure data available in Indian population, before the committee. After detailed deliberation, the committee recommended that waiver of the said Phase IV Clinical trial may be

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			considered, but the firm should submit Periodic Safety Update Report (PSUR) of the drug in the particular indication to CDSCO at regular intervals.
7.	SND/MA/22/000007 Tofacitinib Extended Release Tablets 11 mg	M/s Sun Pharmaceuticals	The firm presented its proposal for active PMS study protocol titled "A multi-centric, active post marketing surveillance study to assess the safety and efficacy of Tofacitinib extended release tablets 11mg for the treatment of adult patients with rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis" before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the active PMS study as per the protocol presented.
8.	SND/MA/22/000239 Benzdamine Hydrochloride	M/s Zuventus Healthcare	In light of earlier recommendation of SEC held on 13.09.2022 firm presented the data of the allergic reaction associated with the applied product. After detailed deliberation the committee recommended for grant of permission to manufacturing and marketing of the drug Benzydamine Hydrochloride mouthwash 0.15% w/v for the applied indications.
GCT Division			
9.	CT/117/20 Online Submission (20520) Inebilizumab	M/s. Medpace	The firm presented the proposed protocol amendment to study protocol no. VIB0551.P3.S2, Amendment 8 dated 30Jun2022 (MITIGATE) before the committee. After detailed deliberation, the committee recommended for the approval of the protocol amendment with condition that the SAEs are to be reported to CDSCO as per provisions of the NDCTR, 2019. On firm's request and considering the rare nature of the indication, the committee agreed that no. of subjects may be reduced to 10 from initially approved number of 20 from the country.
Medical Device Division			
10.	IMP/MD/2021/50521 (MD-14) & IMP/MD/2022/73312 (MD-26)	M/s Modi-Mundipharma Pvt. Ltd.	The firm presented its proposal for grant of permission to import and market the proposed product in the country before the committee.

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	Cross linked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18mg (Cingal)		After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product Cross linked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18mg (Cingal) in the country with the condition that firm should conduct Phase IV post marketing clinical investigation of the proposed product in the country on Indian population. Accordingly, firm should submit post Marketing clinical investigation protocol to CDSCO within 3 months from date of grant of permission for further review by the SEC.
11.	IMP/MD/2022/59985 Adhesion control barrier gels	M/s leader Biomedical & Surgery India Pvt. Ltd.	The firm didn't turn up for presentation.
12.	CI/MD/2022/66273 Dry Socket Surgical Dressing(ALVEOGYL)	M/s Septodont Healthcare India Pvt. Ltd.	The firm presented their proposal for pivotal clinical investigation of the proposed product in the country on Indian population before the committee. After detailed deliberation, committee recommended for grant of permission for conduct of Pivotal Clinical Investigation of the proposed product Dry Socket Surgical Dressing (ALVEOGYL) in the country on Indian population. Accordingly, firm should submit pivotal clinical investigation report to this office for further review by the committee.
13.	CI/MD/2022/75448 3-D scaffold matrix	M/s. EffecMed Private Limited	The firm presented its proposal for pivotal clinical investigation of the proposed product in the country on Indian population before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of pivotal clinical investigation of the proposed product 3-D scaffold matrix in the country on Indian population. Accordingly, firm should submit pivotal clinical investigation report to this office

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			for further review by the committee.
14.	IMP/MD/2021/41651 INNOTERE 3D Scaffold	M/s Avana Medical Devics Pvt. Ltd.	In light of earlier SEC recommendations dated 25.06.20022, the firm presented their proposal for grant of permission to import and market the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product INNOTERE 3D Scaffold in the country with the condition that firm should conduct Phase IV post marketing clinical investigation of the proposed product in the country on Indian population. Accordingly, firm shall submit Post Marketing Clinical Investigation protocol to CDSCO within 3 months from date of grant of permission for further SEC review.
BA/BE Division			
15.	12-09/2022/BA-BE/Misc-18/DC Succinylcholine Chloride Injection 20 mg/mL	M/s Raptim Research Pvt. Ltd., Navi Mumbai – 400710	The firm presented its proposal for conduct of BABE study for export with Succinylcholine Chloride Injection 20 mg/mL in healthy volunteers before the committee. After detailed deliberation, the committee noted that there is invasive procedure like arterial cannulation involved in the study. Also there are several SAEs reported with the study drug including cardiac arrest. In view of the above, the committee did not recommend the conduct of above study in healthy volunteers.