Recommendations of the SEC (Analgesic & Rheumatology) made in its 87th meeting held on 17.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/22/000057 Tofacintib Tablet 5mg (Additional Indication)	M/s. Pfizer Limited	The firm presented their proposal for approval of additional indication "Treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy" for already approved drug product Tofacitinib tablets 5mg before the committee. The committee noted that based on global clinical data and favorable risk benefit ratio, use of Tofacitinib tablets 5mg BID for Ankylosing Spondylitis (AS) has been approved in 37 countries including US, EU, UK and Taiwan. After detailed deliberation, the committee recommended for grant of import and marketing permission of Tofacitinib tablets 5mg for the proposed additional indication subject to condition that the firm should conduct Phase IV clinical trial for the proposed indication. Accordingly, the firm should submit Phase IV clinical trial protocol before marketing.
FDC Division			
2.	FDC/MA/22/000179 Combikit of Esomeprazole Magnesium Trihydrate 20mg/20mg/20mg+Naproxen sodium 500mg/375mg/250mg (immediate release) tablets	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
GCT Division			
3.	CT/66/19 Online Submission (16807) Baricitinib	M/s. Eli Lilly	The proposal for protocol amendment was deferred & same would be deliberated in upcoming meeting in presence of Rheumatologist.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
4.	IMP/MD/2020/237/72 Biodegradable, implantable balloon	M/s. Stryker India Private Limited	In light of earlier SEC recommendation dated 10.02.2021, the firm presented their proposal for grant of permission to import and market the proposed product before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product in the country with the condition that the firm should conduct Phase IV Post Marketing Clinical Investigation on Indian population. Accordingly, the firm should submit Phase IV Post Marketing Clinical Investigation protocol to this office within 3 months from the date of approval for further review by the committee.
GCT Division			
5.	CT/66/19 Online Submission (18330) Baricitinib	M/s. Eli Lilly	The proposal for compliance with CT-NOC conditions was deferred & same would be deliberated in upcoming meeting in presence of Rheumatologist.