

Recommendations of the SEC (Analgesic & Rheumatology) made in its 02nd/25 meeting held on 25.02.2025 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-15011(12)/5/2024-eoffice Dy no 45788 Tocilizumab 162mg/0.9ml (r-DNA origin)	M/s. Cipla Ltd.	In light of earlier SEC recommendation dated 08.11.2023 & 09.11.2023, the firm presented the scientific justification for the study and sample size for the proposed PMS study. The committee noted that in India, Giant Cell Arteritis (GCA) is relatively rare compared to Western populations. After detailed recommendation the committee recommended for grant of permission to conduct the PMS titled "A post-marketing active surveillance of Tocilizumab in patients of giant cell arteritis (GCA)" vide study code CP/01/23 version 01 dated 12.06.2023 as per the protocol presented by the firm.