Cimzia

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II / EMA/VR/0000310696	Outcome: This was an application for a group of variations.	16/04/2026		SmPC and PL	Cimzia is not bound by rheumatoid factor (RF, an autoantibody that interacts with the Fc region of IgGs), does not form immune complexes with RF

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Withdrawn C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: C.I.4: Update of section 5.1 of the SmPC with data from a post-hoc clinical efficacy analysis on comparative and placebo-controlled studies and a systematic literature review. In addition, the MAH took the opportunity to update Section 4.2 of the SmPC in accordance with the CHMP Opinion under EMA/PAM/0000263734. C.I.4: Update of section 5.1 of the SmPC with new non-clinical in vitro data demonstrating Cimzia's mechanism of action in support to the efficacy clinical observations collected in the post-hoc analysis.				and is not subject to RF–dependent clearance by macrophages in vitro. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000323956	Outcome: A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a	09/02/2026			

	manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000317201	Outcome: B.II.e.5 Change in pack size of the finished product - B.II.e.5.b Deletion of pack size(s) - Accepted B.II.e.5 Change in pack size of the finished product - B.II.e.5.b Deletion of pack size(s) - Accepted B.IV Medical Devices - B.IV.z Other variation - Accepted	26/01/2026		SmPC, Labelling and PL	
Variation type IA / EMA/VR/0000275168	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material,	27/05/2025			

	reagent or excipient (when mentioned in the dossier)* - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Article 61(3) / EMA/N/0000268015	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative.	28/04/2025	26/03/2026	PL	