RoActemra

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 IB /	Q.IV.3.b) Change to the specification for a	16/03/2026			

[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).

EMA/VR/0000333958	medical device (part) that is not part of the final product specifications - Q.IV.3.b.z Other variation - Accepted				
Variation type II / EMA/VR/0000261482	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 Submission of the final report for study ML28664 (RABBIT), listed as a category 3 study in the RMP. This was a non-interventional post-authorisation safety study aimed at collecting and analysing safety data related to the use of tocilizumab in rheumatoid arthritis patients in Germany. The RMP version 30.0, 30.1, 30.2, 30.3 and 30.4 have also been submitted. In addition, the MAH removed the education materials from the RMP and PI as agreed by PRAC during procedure PSUSA/00002980/202204. Furthermore, the MAH took the opportunity to introduce editorial and formatting changes to the PI and to align the wording used for the pre-filled syringe and the pre-filled pen, as well as to update the list of local representatives in the Package Leaflet. The MAH also added selected pictograms for the instruction for use in a separate part of the	12/02/2026		SmPC, Annex II and PL	Please refer to Scientific Discussion EMA/VR/0000261482 The MAH removed the education materials from the RMP and PI, the patient card was kept and updated in Annex II. The MAH added selected pictograms in a separate part of the package leaflet, as an additional opportunity to guide the patient in the instruction for use. The wording used for the pre-filled syringe and the pre-filled pen were aligned. QRD updates and editorial and formatting changes were also done to the PI. The list of local representatives in the Package Leaflet was updated. For more information, please refer to the Summary of Product Characteristics.

	package leaflet. In response to third RSI and following PRAC decision the MAH restored the patient card as educational material and updated the RMP (version 30.3) and the product information accordingly.				
Variation type IB / EMA/VR/0000315063	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	05/01/2026			
Variation type IA / EMA/VR/0000313523	B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted	01/12/2025			
Variation type II / EMA/VR/0000272226	This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a	24/07/2025			

	starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.b Downscaling down to 10-fold - Accepted 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, reagent or excipient (when mentioned in the dossier)* - Accepted				
Variation type IA / EMA/VR/0000254616	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	29/04/2025		Annex II	

	a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IA / EMA/VR/0000254621	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - 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	03/04/2025		Annex II	
Variation type IA / EMA/VR/0000240448	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Refused A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a	21/01/2025			

	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) - Refused				
PSUR / EMA/PSUR/0000288251					Maintenance