

Tocilizumab STADA

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 IA_IN /	This was an application for a group of	15/01/2026		SmPC, Annex	

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/0000320498	<p>variations.</p> <p>A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted</p> <p>B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted</p> <p>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted</p> <p>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted</p> <p>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product,</p>			II, Labelling and PL	
-------------------	--	--	--	----------------------	--

	<p>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</p> <p>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</p> <p>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</p>				
Variation type IB / EMA/VR/0000314438	<p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.f Addition or replacement of an in-process test as a result of a safety or quality issue - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes</p>	10/12/2025	N/A		

	to a test procedure (including replacement or addition) - Accepted				
Marketing Authorisation Transfer - H / EMA/T/0000295813	- Transfer of a marketing authorisation - transfer of marketing authorization from Biogen Netherlands B.V. to STADA Arzneimittel AG	23/09/2025	09/10/2025	SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000288251	- -				Maintenance