Tremfya

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 /	This was an application for a group of	23/03/2026		PL	

[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/0000321306	variations. 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.z Other changes - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted				
Variation type IB / EMA/VR/0000316716	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	12/01/2026			
Variation type IB / EMA/VR/0000300713	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, reagent or excipient (when mentioned in the dossier)* - Accepted	17/10/2025	18/12/2025	Annex II and PL	

	B.II.b) Manufacture - B.II.b.z Other variation - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted 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.z Other changes - Accepted				
Extension of marketing authorisation / EMA/X/0000248626	This was an application for a group of variations. 2. Changes to strength, pharmaceutical form and route of administration - (c) change or addition of a new strength/potency - Accepted C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension application to add a new strength of 45 mg/0.45 mL grouped with an extension of indication for Tremfya 100 mg for injection in pre-filled syringe to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for	16/10/2025	18/12/2025	SmPC, Labelling and PL	Please refer to the scientific discussion: Tremfya EMA/X/0000248626

	systemic therapy based on results from study CNTO1959PSO3011. This is a Phase 3, multicenter, randomized, placebo- and active comparator-controlled study evaluating the efficacy, safety, and pharmacokinetics of subcutaneously administered guselkumab for the treatment of plaque psoriasis in paediatric participants (≥6 to <18 years of age). As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC for Tremfya 100 mg for injection in pre-filled syringe are updated. Update of the sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC for Tremfya 100 mg OnePress solution for injection in pre-filled pen and Tremfya 100 mg PushPen solution for injection in pre-filled pen to reflect the paediatric data available for the treatment of plaque psoriasis in children. Editorial changes were also implemented. The Package Leaflet and Labelling are updated in accordance. Version 14.1 of the RMP is agreed.				
Variation type IB / EMA/VR/0000281222	This was an application for a group of variations. 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 B.II.b.2.c Replacement or addition of a	02/10/2025	18/12/2025	Annex II and PL	

	manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted 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.z Other changes - Accepted				
Variation type II / EMA/VR/0000257541	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 Update of sections 4.2, 4.5, 4.8, 5.1, and 5.2 of the SmPC in order to add subcutaneous induction dosing for the ulcerative colitis (UC) indication based on interim results from study CNTO1959UCO3004 (ASTRO) listed as a category 3 study in the RMP; this is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of guselkumab subcutaneous induction therapy in participants with moderately to severely active UC; the Package Leaflet is updated accordingly. The RMP version 13.1 is agreed.	18/09/2025	20/10/2025	SmPC and PL	The SmPC Section 4.2 is updated to include a subcutaneous induction dose regimen of 400 mg (given as two consecutive injections of 200 mg each) at Week 0, Week 4 and Week 8 for the ulcerative colitis indication. This change of posology is supported by results from the ASTRO study. Efficacy results from the ASTRO study are reflected in SmPC Section 5.1. No new safety concerns were identified in the ASTRO study, immunogenicity results from this study are included in SmPC section 4.8. For more information, please refer to the Summary of Product Characteristics.

Variation type IB / EMA/VR/0000278107	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	04/09/2025			
Variation type II / EMA/VR/0000257669	This was an application for a group of variations. B.IV.1 Change of a measuring or administration device - B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted	24/07/2025	20/10/2025	SmPC, Labelling and PL	The SmPC sections 1,2,3,6 and 8 have been updated to reflect the new presentations containing 100 mg guselkumab in a pre-filled pen (PushPen) as well as the addition of a device name (OnePress) for the existing presentations containing 100 mg guselkumab in a pre-filled pen.

PSUR / EMA/PSUR/0000305076					Maintenance