



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Tyruko

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	02/03/2026		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/0000323162	variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a To update sections 4.4 of the SmPC in order to update a warning about PML in patients with prior treatment with immunosuppressive or immunomodulatory therapies based on final results from study 101MS411. C.I.2.a To update sections 4.8 of the SmPC to remove information on malignancies. and 5.1 of the SmPC o include a high-level summary of the design and main study			II, Labelling and PL	
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	results of the natalizumab observational program. In addition the RMP was updated to align with these changes and the details of the local representative in Slovenia has been updated.				
Variation type II / EMA/VR/0000292347	B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	15/01/2026			
Variation type IB / EMA/VR/0000275507	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	18/08/2025		SmPC, Annex II and PL	
Variation type IB / EMA/VR/0000280140	B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	07/08/2025			
Variation type II / EMA/VR/0000262179	B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted	17/07/2025			

Variation type IB / EMA/VR/0000269049	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	26/06/2025			
Variation type IB / EMA/VR/0000272886	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	17/06/2025			

	substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted				
Variation type IB / EMA/VR/0000273955	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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	10/06/2025			

Variation type II / EMA/VR/0000249262	B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted	25/04/2025			