Fymskina

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 /	C. Safety, efficacy, pharmacovigilance	23/02/2026		SmPC and 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/0000324634	changes - C.z Other variation - Accepted C.z - to update sections 3 and 6.6 of the SmPC and corresponding section 6 and "instruction for administration" of the PL to correct minor inconsistencies in the visual description of the Fymskina pre-filled syringe solution and ensure consistent wording across all relevant sections.				
Variation type IA / EMA/VR/0000308904	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	18/11/2025			
Variation type IA_IN / EMA/VR/0000284868	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	10/07/2025		Annex II and PL	
Variation type IA / EMA/VR/0000285202	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	08/07/2025			
Variation type IB / EMA/VR/0000266712	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet	19/05/2025		SmPC and PL	To update section 4.5, 4.8 and 5.2 of the SmPC, to add drug-drug interaction information based on

	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 section 4.5, 4.8 and 5.2 of the SmPC, to add drug-drug interaction information based on results from study CNTO1275CRD1003 (a phase 1, open-label, drug interaction study to evaluate the effect of ustekinumab on cytochrome P450 enzyme activities following induction and maintenance dosing in participants with active Crohn's disease or ulcerative colitis) and to include patient exposure numbers based on results from study CNTO1275UCO3001 (a phase 3, randomised, double-blind, placebo-controlled, parallel-group, multicentre protocol to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderately to severely active ulcerative colitis), following the assessment of the same change for the reference product `Stelara'. Additionally, the MAH took the opportunity to update the information of the local representative for DE, the local representative for other EU countries, and introduced minor editorial changes to the PI in DE to correct for typographical errors.				results from study CNTO1275CRD1003 and to include patient exposure numbers based on results from study CNTO1275UCO3001, following the assessment of the same change for the reference product `Stelara'.

Variation type IB / EMA/VR/0000248050	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	03/03/2025		SmPC	