Steqeyma

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 variation	16/04/2026		SmPC	

[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/0000334207	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IB / EMA/VR/0000333316	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.a) Minor change in the manufacturing process - Accepted	10/04/2026			
Variation type IA_IN / EMA/VR/0000325409	Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted	10/02/2026			
Variation type IA / EMA/VR/0000321385	B.II.e.3 Change in test procedure for the immediate packaging of the finished product	09/02/2026			

	- B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Refused 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 B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted				
Variation type II / EMA/VR/0000293236	This was an application for a group of variations. B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.c The change requires assessment of the comparability of a biological/immunological medicinal product	15/01/2026		SmPC and PL	

	or the change in batch size requires a new bioequivalence study - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted				
Variation type II / EMA/VR/0000293190	This was an application for a group of variations. 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.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.II.c.3 Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Other variation - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or	11/12/2025			

	intermediate used in the manufacturing process of the active substance - B.I.a.3.c The change requires assessment of the comparability of a biological/immunological active substance - Accepted 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.z Other variation - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted				
Variation type II / EMA/VR/0000292238	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	11/12/2025		SmPC, Labelling and PL	The SmPC has been updated to reflect the new pre-filled pen presentations, the updated storage conditions, the extended shelf-life, and to include a Polysorbate warning statement in line with the guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. The Labelling and PL have been updated accordingly. Additionally, a correction has been introduced to the

	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted 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 B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - 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.a Secondary packaging site - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted				PL.

	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted				
Variation type IA_IN / EMA/VR/0000312582	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	17/11/2025			
Variation type IB / EMA/VR/0000306826	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.c Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance - Accepted	31/10/2025			
Variation type IB / EMA/VR/0000294529	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	23/09/2025		SmPC	

	medicinal product in accordance with an approved stability protocol - Accepted				
Variation type IB / EMA/VR/0000280935	This was an application for a group of 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.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.2.a - To update sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC to extend the indication to include treatment of moderately to severely active Crohn’s disease in paediatric patients weighing at least 40 kg, to align the PI with the same changes approved for the reference product Stelara. The package leaflet and RMP are updated accordingly. In addition, the MAH has taken the opportunity to update the details of the	06/08/2025	11/09/2025	SmPC and PL	

	local representative for Sweden. C.I.11.z - To align the RMP with the latest approved RMP of duplicate product Qoyovlma in order to align the dossiers of the two products.				
Variation type II / EMA/VR/0000272089	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	24/07/2025			
Variation type II / EMA/VR/0000263478	This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits	24/07/2025			

	applied during the manufacture of the finished product - B.II.b.5.e Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted				
Variation type IB / EMA/VR/0000272410	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 4.5, 4.8 and 5.2 of the SmPC to add drug-drug interaction information based on results from study CNTO1275CRD1003 and to include patient exposure numbers based on results from study CNTO1275UCO3001 following assessment of the same change for the reference product Stelara. In addition, the MAH took the opportunity to implement editorial changes across the PI, including an amendment to the description of liquid	12/06/2025	11/09/2025	SmPC and PL	To update sections 4.5, 4.8 and 5.2 of the SmPC to add drug-drug interaction information based on results from study CNTO1275CRD1003 and to include patient exposure numbers based on results from study CNTO1275UCO3001 following assessment of the same change for the reference product Stelara. In addition, the MAH took the opportunity to implement editorial changes across the PI, including an amendment to the description of liquid dripping when the needle cap is removed from the Pre-filled Syringe device.

	dripping when the needle cap is removed from the Pre-filled Syringe device. These changes apply to all languages. Further editorial changes, such as the correction of grammatical and typographical errors, as well as adjustments to align with the reference PI, were made to the PI in DE, CS, EL, ES, FR, LV, NL, PL, PT, RO, SK, and SV. Furthermore, the MAH included a warning statement on the polysorbate threshold based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'				