Qoyvolma

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	22/07/2025	05/09/2025	SmPC and PL	To update sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the

[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/0000280926	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 (Type IB) - To update sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC to extend the indication to include the treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg. The PL and RMP were updated accordingly. These changes follow the assessment of the same changes to the reference product, Stelara (EMEA/H/C/000958/II/0108). Additionally, the MAH took the opportunity to implement editorial updates, including language-specific				SmPC to extend the indication to include the treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg. The PL and RMP were updated accordingly. These changes follow the assessment of the same changes to the reference product, Stelara (EMEA/H/C/000958/II/0108). Additionally, the MAH took the opportunity to implement editorial updates, including language-specific changes introduced in the PI of the reference product Stelara that are equally applicable to Qoyvolma, a revision to the description of liquid dripping when the needle cap is removed from the pre-filled syringe device in the PL, an update to the contact information for the Local Representative for SE, and included a warning statement in the SmPC and the PL 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'. To update sections 4.5, 4.8, 5.1 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 (EMEA/H/C/000958/II/0107).

	changes introduced in the PI of the reference product Stelara that are equally applicable to Qoyvolma, a revision to the description of liquid dripping when the needle cap is removed from the pre-filled syringe device in the PL, an update to the contact information for the Local Representative for SE, and included a warning statement in the SmPC and the PL 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'. C.I.2.a (Type IB) - To update sections 4.5, 4.8, 5.1 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 (EMEA/H/C/000958/II/0107). Additionally, the MAH took the opportunity to implement editorial updates, to include language-specific changes introduced in the PI of the reference product Stelara that are equally applicable to Qoyvolma,				
Variation type IB / EMA/VR/0000279799	B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	17/07/2025	N/A		

Variation type IB / EMA/VR/0000279804	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	11/07/2025	N/A		