IMULDOSA

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 /	Q.II.f.1.b) Extension of the shelf life of the	11/05/2026		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/0000341697	finished product - Q.II.f.1.b.2 After first opening (supported by real time data) - Accepted				
Variation type II / EMA/VR/0000321341	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	23/04/2026			
Variation type IA / EMA/VR/0000326169	This was an application for a group of variations. E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted	27/02/2026			

	Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.j) Addition or replacement of a batch control/testing site of the – the active substance or – intermediate of an active substance or – starting material of a biological active substance applying physicochemical and/or microbiological analytical procedures - Refused Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.a) Minor change of in-process control limits - Refused Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.b) Change within the specification acceptance criteria - Accepted Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.a) Minor change to an analytical procedure for the active substance				

	- Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.b) Addition of new in-process control and limits with its corresponding analytical procedure - Refused Q.II.e.7 Change in manufacturer, sterilisation process or supplier of packaging components (when mentioned in the dossier) - Q.II.e.7.a) Addition or replacement of a manufacturer or supplier - Accepted				
Variation type IA / EMA/VR/0000333088	This was an application for a group of variations. Q.II.e.3 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules) - Q.II.e.3.b Change that does not affect the product information - Accepted Q.II.e.3 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules) - Q.II.e.3.b Change that does not affect the product information - Accepted	20/02/2026			
Variation type IB / EMA/VR/0000313404	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal	19/12/2025	15/01/2026	SmPC and PL	To extend the indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who

	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 extend the indication to include treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies. The change follows the approval of the same change for the reference product Stelara. Consequently, Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated accordingly.				have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies. The change follows the approval of the same change for the reference product Stelara. Consequently, Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated. The Package Leaflet is updated accordingly.
Variation type IB / EMA/VR/0000306938	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 - Accepted	04/12/2025			

Variation type IB / EMA/VR/0000280923	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	04/09/2025			
Variation type II / EMA/VR/0000276498	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	04/09/2025			
Variation type IB / EMA/VR/0000272232	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	23/06/2025	15/01/2026	SmPC	
Variation type IB / EMA/VR/0000274978	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	05/06/2025	15/01/2026	SmPC and PL	To update of sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD1003 and to update sections 4.8 and 5.1 to include

	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 of sections 4.5 and 5.2 of the SmPC in order 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 update sections 4.8 and 5.1 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). The PL is updated accordingly. The change follows assessment of the same change for the reference product Stelara. Additionally, the MAH took the opportunity to update the wording of the polysorbate warning in Section 2 of the PL, in line with the EC excipient guideline, and to implement minor editorial changes throughout the PI to align with the QRD template.				patient exposure numbers based on results from study CNTO1275UCO3001. The PL is updated accordingly. The change follows assessment of the same change for the reference product Stelara. Additionally, the MAH took the opportunity to update the wording of the polysorbate warning in Section 2 of the PL,

Variation type IB / EMA/VR/0000266943	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	03/06/2025	15/01/2026	SmPC	