ABSIMKY

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, please 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.I.2 Change(s) in the Summary of Product	05/06/2025		SmPC and PL	To update of sections 4.5 and 5.2 of the SmPC in

[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/0000275179	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 (IB) - 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				order to add drug-drug interaction information based on results from study CNTO1275CRD1003 and to update sections 4.8 and 5.1 to include 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,

	excipient guideline, and to implement minor editorial changes throughout the PI to align with the QRD template.				
Variation type IB / EMA/VR/0000266072	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	28/05/2025		SmPC	