Yesintek

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	07/11/2025		SmPC and PL	To update Sections 4.1, 4.5, 4.8 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/0000290988	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 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				SmPC by removing the wording "or have medical contraindications to such therapies" from the therapeutic indication for Crohn's disease, adding drug-drug interaction information based on the results of study CNTO1275CRD1003, and including patient exposure data derived from study CNTO1275UCO3001. The changes follow approval of the same changes for the reference product Stelara, as reflected in procedures II/107 and II/108. To extend the shelf life of Yesintek 130 mg/26 mL concentrate for solution for infusion and Yesintek 45 mg/0.5 mL solution for injection (EU/1/24/1892/001, 004), in accordance with the approved stability protocol, from 18 to 24 months when stored at 5°C ± 3°C.