Humira

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 /	C.I.7 Deletion of: - C.I.7.b a strength -	08/10/2025		SmPC,	To delete the 50 mg/ml strength from the Humira

[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/0000287800	Accepted C.I.7.b (Type IB) – To delete the 50 mg/ml strength from the Humira marketing authorisation (EU/1/03/256/001-010). In addition, the MAH took the opportunity to implement editorial changes to include a warning about polysorbates in the PI, in accordance with the Annex to the European Commission guideline on 'Excipients in the Labelling and Package Leaflet of Medicinal Products for Human Use'; update Annex A to correct errors; revise the contact information for the local representative in IS; and align the PI with the QRD template. Furthermore, updates were made to the PI in IS, CZ, FR, DE, and NL to incorporate the CZ translation of the INN in line with local HA requirements, correct typographic and grammatical errors, harmonize wording across different presentations and align with the QRD template.			Labelling and PL	marketing authorisation (EU/1/03/256/001-010). In addition, the MAH took the opportunity to implement editorial changes to include a warning about polysorbates in the PI, in accordance with the Annex to the European Commission guideline on 'Excipients in the Labelling and Package Leaflet of Medicinal Products for Human Use'; update Annex A to correct errors; revise the contact information for the local representative in IS; and align the PI with the QRD template.
Article 61(3) / EMA/N/0000249136	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.	20/03/2025	07/07/2025	PL	