Uzpruvo

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	10/04/2026		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/0000335760	finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IA / EMA/VR/0000323598	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active	03/02/2026			

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active				

	substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted				
Variation type IB / EMA/VR/0000316264	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 and	22/12/2025	30/01/2026	SmPC and PL	To update Sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC and sections 2 and 3 of the Package Leaflet to include the indication “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”, following assessment of the same change for the reference product Stelara.

	sections 2 and 3 of the Package Leaflet to include the indication "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", following assessment of the same change for the reference product Stelara. In addition, the MAH took the opportunity to implement editorial changes: • To correct a sentence in section 4.8 of the SmPC of the 45 mg vial, 45 mg PFS and 90 mg PFS in line with the SmPC of the 130 mg vial •To correct the details of the local representative in Poland in all package leaflets (change from STADA Pharm Sp. z.o o.to STADA Pharm Sp. z o.o.) • To move the injection site "buttocks" to the description for cases where a caregiver is giving the injection in section 2 of the Instructions for Administration/Use of the 45 mg vial, 45 mg PFS and 90 mg PFS • To delete "(legs)" after the injection site "upper thigh" The MAA proposes to delete "(legs)" in section 2 of the Instructions for Administration/Use of the 45 mg vial, 45 mg PFS and 90 mg PFS line with Stelara • To make minor editorial changes in SmPC and PL in line with Stelara and QRD template for the EN Product Information and the translated Product Information (CS, DA, DE, ES, FI, FR, LT, LV,				

	MT, NO, PT and RO).				
Variation type IB / EMA/VR/0000309634	This was an application for a group of variations. B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted 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	26/11/2025			
Variation type IB / EMA/VR/0000308833	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	11/11/2025	30/01/2026	SmPC	To extend the shelf-life of Uzpruvo 130 mg concentrate for solution for infusion (EU/1/23/1784/005), in accordance with the approved stability protocol, from 18 months to 24 months when stored at 2°C – 8°C, inclusive of 7 days of storage at room temperature up to 30°C.
Variation type II / EMA/VR/0000269651	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted	25/09/2025			

Variation type IB / EMA/VR/0000268254	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 - To update sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD1003, and sections 4.8 and 5.1 of the SmPC to include patient exposure numbers based on results from study CNTO1275UCO3001, following approval of the same change for the reference product Stelara. Additionally, the MAH took the opportunity to update the contact details for ET and LV in the list of local representatives and to align the wording for Figure 2 in the instructions for administration for the 45 mg vial presentation with the wording of the 45 mg pre-filled syringe. Furthermore, the MAH took the opportunity to make minor editorial amendments in the DA, ET, FI and PT product information for alignment with the QRD template and to correct the way one excipient is presented to align with other approved strengths.	16/05/2025	30/01/2026	SmPC, Labelling and PL	To update sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD1003, and sections 4.8 and 5.1 of the SmPC to include patient exposure numbers based on results from study CNTO1275UCO3001, following approval of the same change for the reference product Stelara.

Variation type IB / EMA/VR/0000261203	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	22/04/2025	30/01/2026	SmPC	
Variation type IB / EMA/VR/0000255909	This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	18/03/2025			
Variation type IA_IN / EMA/VR/0000255737	This was an application for a group of variations. B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted B.II.b.1 Replacement or addition of a	11/03/2025	30/01/2026	PL	

	manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted				
Variation type IB / EMA/VR/0000246116	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.z Minor change in the manufacturing process of a sterile finished product after the primary packaging step - Accepted	18/02/2025			