



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

WEZENLA

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification ¹ issued on | Commission Decision Issued ² / amended on | Product Information affected ³ | Summary |
|--------------------|--|--|--|---|--|
| II/0003/G | This was an application for a group of variations. B.IV.1.c (Type II) - To add an autoinjector (AI/Pen) to be used for the subcutaneous administration of 45 mg (0.5 mL) of Ustekinumab, which is an integrated part of the primary packaging of the medicinal product. | 16/01/2025 | | SmPC, Labelling and PL | The SmPC Annex I has been updated to add reference to the new presentations for 45 mg (0.5 mL) and 90 mg (1 mL) solutions for injection in pre-filled pens. The Labelling, Package leaflet and Annex A have been updated accordingly. |

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).



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| | <p>B.IV.1.c (Type II) - To add an autoinjector (AI/Pen) to be used for the subcutaneous administration of 90 mg (1 mL) of Ustekinumab, which is an integrated part of the primary packaging of the medicinal product.</p> <p>The requested group of variations proposed amendments to the Summary of Product Characteristics, Labelling, Package Leaflet and Annex A and to the Risk Management Plan (RMP).</p> <p>B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging</p> <p>B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging</p> | | | | |
| IB/0004/G | <p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a</p> | 25/11/2024 | | SmPC and PL | |

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| | generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | | | | |
| II/0001 | B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS | 14/11/2024 | n/a | | |
| IB/0002 | B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol | 19/08/2024 | | SmPC | |