Zadenvi

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	03/10/2025		SmPC,	To update Section 5.1 of the SmPC to include

[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/0000296770	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 C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted C.I.2.a (Type IB) – To update Section 5.1 of the SmPC to include information on the safety and effectiveness of the product based on a study conducted in paediatric patients with glucocorticoid-induced osteoporosis. This update follows the assessment and approval of the same change for the reference product, Prolia. C.I.3.z (Type IB) – To update Section 4.4 of the SmPC to add a warning about the reduction in bone mineral density following			Labelling and PL	information on the safety and effectiveness of the product based on a study conducted in paediatric patients with glucocorticoid-induced osteoporosis. This update follows the assessment and approval of the same change for the reference product, Prolia. To update Section 4.4 of the SmPC to add a warning about the reduction in bone mineral density following discontinuation of denosumab. This change implements wording agreed by the CHMP, following the outcome of PSUSA/00000954/202409.

	discontinuation of denosumab. This change implements wording agreed by the CHMP, following the outcome of PSUSA/00000954/202409. Additionally, the MAH has implemented editorial changes throughout the PI to correct typographical errors and ensure alignment with the QRD template.				