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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	22/12/2025		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/0000300682	variations. 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.a Implementation of wording agreed by the competent authority - Accepted 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.z. To update section 4.4 of the SmPC to implement the warning about treatment discontinuation, following denosumab discontinuation, decrease in bone mineral density (BMD) is expected, leading to an increased risk for fractures as agreed by the PRAC following the outcome PSUSA/00000954/202409 for denosumab (PSUSA/00000954/202409). Section 4.4 has been modified in order to update			Labelling and PL	

	warning about treatment discontinuation. Following denosumab discontinuation, decrease in bone mineral density (BMD) is expected, leading to an increased risk for fractures. C.I.2.a To update Section 5.1 of the SmPC in order to add new information for pediatric patients as denosumab should not be used for this indication, following the assessment of the same change for the reference product, version dated 18.06.2025.				
Variation type IB / EMA/VR/0000313388	This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z The in-process limits for hardness are proposed to be widened from 65-85 N to 45-85 N. The lower limits will be at 45N and therefore closer to the limits in the finished product specifications (25-85 N) - 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 B.II.b.5 Change to in-process tests or limits applied during the manufacture of the	16/12/2025	N/A		

	finished product - B.II.b.5.b Addition of a new test(s) and limits - 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 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				