Izamby

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 /	Outcome:	24/08/2026		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/0000365352	Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted				
Variation type IB / EMA/VR/0000307311	Outcome: This was an application for a group of 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 - to update section 5.1 of the SmPC to include the wording agreed following finalisation of procedure	20/11/2025		SmPC and PL	

	EMA/VR/0000267398 following approval of the agreed wording via procedure EMEA/H/C/001120/P46/045 for parent product Prolia. C.I.3.z - to update section 4.4 of the SmPC to implement the wording agreed by the EMA following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00000954/202409 for parent product Prolia. In addition, editorial changes have been performed in section 4.2 and 5.2 to align the PI to parent product, polysorbate number (E432) has been included alignment with QRD 10.4 has been performed. Moreover, some language specific changes were applied in BG, CS, DA, DE, EL, ES, ET, FI, FR, HR, HU, IT, LT, LV, MT, NL, NO, PT, RO, SK, PL, SL, SV annexes to align the related language to the parent product counterpart.				
Variation type IB / EMA/VR/0000300531	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II. FINISHED PRODUCT - B.II.z To update Module 3.2.A.1 for a biotech medicinal product - Accepted	06/11/2025			

Variation type IB / EMA/VR/0000301808	Outcome: B.II.e) Container closure system - B.II.e.z Other variation - Accepted	10/10/2025			
Article 61(3) / EMA/N/0000288023	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	29/07/2025		PL	