Rolcya

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	27/11/2025		SmPC and PL	

[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/0000293149	variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 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 section 4.8 of the SmPC following assessment of the same changes for the reference product Prolia (EMEA/H/C/001120/II/100). C.I.2.a - to update section 5.1 of the SmPC following assessment of the same changes for the reference product Prolia (EMA/VR/0000267398). In addition, the MAH implemented editorial changes in the national languages to align the PI to the				

	related language of the reference product. Moreover, Annex A for Jubbonti has been amended as requested by the Agency. Finally, the contact details of the Italian local representative have been updated in section 6 of the Package Leaflet.				
Variation type IB / EMA/VR/0000295626	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	23/10/2025	N/A		
Variation type IB / EMA/VR/0000301296	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 section 4.4 of the SmPC following assessment of the same change for the reference product Prolia during the procedure EMEA/H/C/PSUSA/00000954/202409. In addition, minor editorial changes were	07/10/2025		SmPC	

	performed in DE, EL, HR and HU annexes to align them with their related originator's PIs. Finally, the date of the first authorisation was included in section 9 of the SmPC.				