Obodence

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
Article 61(3) /	Outcome:	31/07/2026		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/N/0000365631	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives.				
Variation type IB / EMA/VR/0000337495	Outcome: This was an application for a group of variations. Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.b) Addition or replacement of a batch control/testing site applying a biological/immunological/immunochemical analytical procedure for a biological finished product - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted	31/03/2026			

Variation type IA / EMA/VR/0000323727	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	28/01/2026			
Variation type IB / EMA/VR/0000319278	Outcome: 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 (Type IB) - To update Section 4.4 of	05/01/2026	13/05/2026	SmPC	To update Section 4.4 of the SmPC regarding treatment discontinuation following assessment of the same change for the reference product Prolia.

	the SmPC regarding treatment discontinuation following assessment of the same change for the reference product Prolia. Additionally, the MAH takes the opportunity to align the PI with the QRD template, and to update the PI in DA, DE, ET, FI, IS, and RO to correct typographic errors.				
Variation type IB / EMA/VR/0000312464	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted	26/11/2025	13/05/2026	SmPC and PL	
Variation type IB / EMA/VR/0000291542	Outcome: 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 To update sections 5.1, of the SmPC to include the wording regarding study results of glucocorticoid-induced osteoporosis paediatric patients following assessment of the same change for the reference product.	05/09/2025	13/05/2026	SmPC	To update sections 5.1, of the SmPC to include the wording regarding study results of glucocorticoid-induced osteoporosis paediatric patients following assessment of the same change for the reference product. Additionally, the MAH takes the opportunity to align the PI with the QRD template, to make minor editorial changes in section 4.2, 4.8 and 5.2 of the SmPC and to update the PI in DE, FR, and HU to correct typographic errors.

	Additionally, the MAH takes the opportunity to align the PI with the QRD template, to make minor editorial changes in section 4.2, 4.8 and 5.2 of the SmPC and to update the PI in DE, FR, and HU to correct typographic errors.				
Variation type IB / EMA/VR/0000278398	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted	20/06/2025			
Variation type IA / EMA/VR/0000276241	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	05/06/2025			
Variation type IB / EMA/VR/0000263754	Outcome: 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	06/05/2025	13/05/2026	SmPC, Labelling and PL	To update sections 4.2, 4.4, 4.6, 4.8, 5.1, 6.4, 6.5, and 10 of the SmPC, section 9 of the Labelling, and sections 2, 4, and 5 of the PL to update safety information including a warning regarding hypocalcaemia, reports of life-threatening events and fatal cases occurred in the post marketing

	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 sections 4.2, 4.4, 4.6, 4.8, 5.1, 6.4, 6.5, and 10 of the SmPC, section 9 of the Labelling, and sections 2, 4, and 5 of the PL to update safety information including a warning regarding hypocalcaemia, reports of life-threatening events and fatal cases occurred in the post marketing setting, a post-marketing observational study (20090522) results, and the information regarding osteonecrosis of the jaw accordingly following assessment of the same change for the reference product Prolia via procedures EMEA/H/C/001120/II/0099 and EMEA/H/C/001120/II/0100. In addition, the MAH has taken the opportunity to introduce editorial corrections in all languages to align with the QRD guideline, to make an editorial correction in Italian language to align with the reference product PI, to correct an image in the German PI (section IIIB), and to correct typographic errors in the Bulgarian PI.				setting, a post-marketing observational study (20090522) results, and the information regarding osteonecrosis of the jaw accordingly following assessment of the same change for the reference product Prolia via procedures EMEA/H/C/001120/II/0099 and EMEA/H/C/001120/II/0100.