Obodence

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB / EMA/VR/0000263754	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	06/05/2025		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 setting, a post-marketing observational study

[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).

	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.				(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.