Stoboclo

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 /	C.I.2 Change(s) in the Summary of Product	14/01/2026		SmPC	To update Section 4.4 of the SmPC in view of

[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/0000320514	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 the SmPC in view of available data on a reduction in bone mineral density following denosumab discontinuation. The change follows approval of the same change for the reference product Prolia. In addition, the MAH has implemented editorial changes in the DE and HU Product Information to align with the reference product.				available data on a reduction in bone mineral density following denosumab discontinuation. The change follows approval of the same change for the reference product Prolia.
Variation type IB / EMA/VR/0000315041	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted	16/12/2025	N/A		

Variation type II / EMA/VR/0000287188	This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted 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	02/10/2025		SmPC and PL	The SmPC sections 6.3 and 6.6 have been updated to reflect the extension of the shelf-life (54 months) and the revised storage conditions (allowing for 63 days at 30 °C with the possibility of re-refrigeration for a maximum of 3 days if necessary). The PL has been updated accordingly.
Variation type IB / EMA/VR/0000291992	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	19/09/2025		SmPC, Annex II, Labelling and PL	

	submitted by the MAH - Accepted C.I.2.a – to update section 5.1 of the SmPC following the adoption of the same changes for the reference product, Prolia (case no. EMA/VR/0000267398). Editorial changes introduced in the Prolia PI, which are equally applicable to the Stoboclo PI, have likewise been implemented throughout. In addition, the MAH has taken this opportunity to introduce editorial updates to the Stoboclo PI, including rewording of the storage period at room temperature, revision of the address format and correction of grammatical and typographical errors across the PI.				
Article 61(3) / EMA/N/0000295849	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised details of local representatives.	15/09/2025		PL	
Variation type IB / EMA/VR/0000268596	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	04/09/2025	N/A		
Variation type IB / EMA/VR/0000265206	B.II.b.2 Change to importer, batch release arrangements and quality control testing of	03/07/2025	N/A		

	the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type II / EMA/VR/0000255109	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted	12/06/2025	N/A		
Article 61(3) / EMA/N/0000266444	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised	02/05/2025		PL	

	contact details of local representatives and removal of grey-shading of manufacturers in section '6. Contents of the pack and other information'.				