Bomyntra

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:	21/08/2026		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/0000367571	C.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.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) – To update section 4.8 of the SmPC in order to add 'Injection site reactions' to the list of adverse drug reactions (ADRs) with frequency uncommon. The Package Leaflet is updated accordingly. The change follows approval of the same change for the reference product (Xgeva). In addition, the MAH took the opportunity to implement the following editorial changes in the product information: (1) correction of a typographical error in section 2 of the SmPC to align it with the reference product; (2) inclusion of the date of first authorisation in the HU SmPC; and (3) correction of a reference to the reference product in section 4.8 of the NL SmPC.				
Variation type IB / EMA/VR/0000355822	Outcome: C.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.2.a)	09/07/2026		SmPC and PL	

	Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) – To update sections 3, 4.8, 5.1, 6.6, 8, and 9 of the SmPC and sections 1,2, and 4 of Package leaflet (PFS & vial) following assessment of the same change for the reference product Xgeva along with minor editorial changes to align with the reference product. • Section 3 of the SmPC is updated to differentiate between the two registered pharmaceutical forms: vial and pre-filled syringe, in line with the reference product (EMA/VR/0000280127) • Sections 4.8 and 5.1 of SmPC have been updated with study data, in line with reference product (EMEA/H/C/002173/II/0084). • Section 6.6 of SmPC has been updated with text, in line with reference product (EMEA/H/C/002173/II/0082/G). • Section 8 of SmPC has been updated with the correct EU numbers format as requested by the Agency. Annex A is updated accordingly. • Date of First authorisation has been updated in Section 9 of SmPC. • Sections 1, 2, and 4 of Package leaflet have been updated with minor editorial changes to align with wording of reference product.				

Variation type IB / EMA/VR/0000324856	Outcome: Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.d) Deletion of a non-significant or an obsolete specification attribute - Accepted	13/02/2026			
Variation type IA / EMA/VR/0000316344	Outcome: This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.d Deletion	22/12/2025			

	of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Refused B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				