



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Degevma

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:	29/09/2026			

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/0000377457	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.z Other variation - Accepted C.9.z (Type IB) – To update the RMP by aligning the list of safety concerns with the RMP of the reference product Xgeva.				
Variation type IB / EMA/VR/0000370263	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) 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 and section 4 of the Package Leaflet to add injection site reactions as adverse drug reaction with frequency “uncommon” following assessment of the same changes for reference product Xgeva (EMA/VR/0000320535). Additionally, the MAH updated section 9 of the SmPC to add the date of first authorisation. Moreover, the MAH has also taken the opportunity to apply minor editorial amendments in the DA, DE, FR, HR, HU, IS, IT and LV PI annexes.	24/09/2026		SmPC, Labelling and PL	

Variation type IB / EMA/VR/0000365816	Outcome: This was an application for a group of variations. Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.a) Change of specification acceptance criteria - Accepted Q.II.e) Container closure system - Q.II.e.z Other variation - Accepted	25/08/2026			
Variation type IB / EMA/VR/0000360796	Outcome: Q.I.b.3 Change to an in-house reference standard/preparation for a biological active substance - Q.I.b.3.e) Other change to the qualification protocol for the preparation/replacement of an in-house reference standard or preparation - Accepted	17/08/2026			
Variation type IB / EMA/VR/0000316534	Outcome: 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	19/02/2026			

Variation type IB / EMA/VR/0000309771	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 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 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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	05/02/2026			
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Variation type IA / EMA/VR/0000323045	Outcome: This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted	22/01/2026			
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