Yaxwer

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:	01/09/2026		SmPC,	

[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/0000363063	This was an application for a group of variations. Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted			Labelling and PL	
Variation type IB / EMA/VR/0000358701	Outcome: C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b - to update the RMP to maintain alignment with the reference product RMP (XGEVA EU RMP version 37.1, dated on 19	13/08/2026			

	September 2025), which was revised based on the results of completed studies (20101102 and 20140114), including incorporation of new safety data for osteonecrosis of the jaw and atypical femoral fracture and removal of the corresponding safety concerns.				
Variation type IA / EMA/VR/0000356583	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-	21/07/2026			

	process test and limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Refused				
Variation type IB / EMA/VR/0000323052	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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	06/02/2026			
Variation type IB / EMA/VR/0000313316	Outcome: This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the	10/12/2025			

	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.a Tightening of in-process 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.a Tightening of in-process 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.z The in-process limits for hardness are proposed to be widened from 65-85 N to 45-85 N. The lower limits will be at 45N and therefore closer to the limits in the finished product specifications (25-85 N) - Accepted				