



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Vevzuo

### 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/<br>Notification<br><sup>1</sup> issued on | Commission<br>Decision<br>Issued <sup>2</sup> /<br>amended on | Product<br>Information<br>affected <sup>3</sup> | Summary |
|---------------------|----------|----------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------|---------|
| Variation type IB / | Outcome: | 17/09/2026                                         |                                                               | SmPC and PL                                     |         |

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EMA/VR/0000371063                        | <p>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</p> <p>C.2.a (Type IB) – To update section 4.8 of the SmPC and section 4 of the PL to include “Injection site reactions” to the list of adverse drug reactions (ADRs) with frequency “uncommon” following assessment of the same change for the reference medicinal product Xgeva.</p> |            |  |      |                                                                                                                                                                                                                                                                                                                                                                                                    |
| Variation type IB /<br>EMA/VR/0000338067 | <p>Outcome:</p> <p>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</p> <p>C.2.a (Type IB) – To update sections 4.8 and 5.1 of the SmPC to incorporate details of Study 7 conducted to evaluate the long-term safety profile of denosumab, following assessment of the same change for the</p>                                             | 27/03/2026 |  | SmPC | To update sections 4.8 and 5.1 of the SmPC to incorporate details of Study 7 conducted to evaluate the long-term safety profile of denosumab, following assessment of the same change for the reference product XGEVA. In addition, the applicant has taken the opportunity to implement minor editorial changes in sections 4.5, 4.8, 5.1 and 5.2 of the SmPC in line with the reference product. |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |            |  |    |  |
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|                                          | reference product XGEVA. In addition, the applicant has taken the opportunity to implement minor editorial changes in sections 4.5, 4.8, 5.1 and 5.2 of the SmPC in line with the reference product.                                                                                                                                                                                                                                                                                                                                                      |            |  |    |  |
| Variation type IB /<br>EMA/VR/0000332209 | Outcome:<br>Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product - Q.II.d.1.z Other variation - Accepted                                                                                                                                                                                                                                                                                                                                                                                                     | 24/03/2026 |  |    |  |
| Variation type IA /<br>EMA/VR/0000338446 | Outcome:<br>This was an application for a group of variations.<br><br>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<br>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.b Tightening of specification limits - Accepted | 23/03/2026 |  |    |  |
| Article 61(3) /<br>EMA/N/0000326544      | Outcome:<br>- Notification acc. Article 61(3) - Accepted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 13/02/2026 |  | PL |  |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |  |                              |  |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|------------------------------|--|
|                                          | Update of the package leaflet with revised contact details of local representatives.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |            |  |                              |  |
| Variation type IB /<br>EMA/VR/0000307328 | Outcome:<br>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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted                                                                                                                                                                                                                                                                                  | 11/11/2025 |  |                              |  |
| Variation type IB /<br>EMA/VR/0000290491 | Outcome:<br>This was an application for a group of variations.<br><br>B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted<br>B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted<br><br>B.II.e.5.a.2 (Type IB) – To add a new pack-size of 4 vials for Vevzuo 120 mg solution for injection (EU/1/25/1945/003). The annexes are updated accordingly. In addition, the | 28/08/2025 |  | SmPC,<br>Labelling and<br>PL |  |

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|  | MAH took the opportunity to implement editorial changes to change the footer font in the SmPC and the page numbering format in Annex A. B.II.e.5.a.1 (Type IA_IN) – To add a new pack-size of 3 vials for Vevzuo 120 mg solution for injection (EU/1/25/1945/002). The annexes are updated accordingly. |  |  |  |  |
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