Wyost

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	13/08/2025		SmPC	To update Section 4.8 of the SmPC to include the

[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/0000288202	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 4.8 of the SmPC to include the frequencies of osteonecrosis of the jaw, atypical fractures of the femur and new primary malignancy in patients with GCTB based on the results from study 20140114. In addition, the MAH took the opportunity to implement editorial changes to the PI in all languages to align with the reference product PI.				frequencies of osteonecrosis of the jaw, atypical fractures of the femur and new primary malignancy in patients with GCTB based on the results from study 20140114.
Variation type IB / EMA/VR/0000245925	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 B.II.e.5.a.2- Type IB- To add new pack-sizes of 3 vials (EU/1/24/1812/002) and 4 vials (EU/1/24/1812/003) for 120 mg solution for injection. Furthermore, Product Information in various languages has been aligned with QRD template.	04/02/2025		SmPC, Labelling and PL	