Voxzogo

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 /	B.II.g.5 Implementation of changes foreseen	17/11/2025		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/0000300615	in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted				
Variation type IB / EMA/VR/0000280939	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted	17/07/2025	N/A		
Variation type IB / EMA/VR/0000268773	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	27/05/2025		SmPC	
Variation type IA_IN / EMA/VR/0000246741	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished	30/01/2025	N/A		

	product - B.II.b.1.a Secondary packaging site - Accepted				