



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Wainzua

### 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 <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB /	B.II.f.1.b Extension of the shelf life of the	26/01/2026		SmPC,	

<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).



EMA/VR/0000314198	finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted			Labelling and PL	
Variation type IA / EMA/VR/0000314781	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	02/12/2025	N/A		
Variation type IB / EMA/VR/0000272685	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	17/06/2025	N/A		
Variation type IB / EMA/VR/0000273467	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	13/06/2025	N/A		
Variation type IA / EMA/VR/0000266042	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	15/04/2025	N/A		
PSUR / EMA/PSUR/0000296602	- -				Maintenance

