CAMZYOS

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, please 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 HUMAN AND VETERINARY MEDICINAL	30/05/2025		SmPC and PL	

[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/0000266373	PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update the heading of Figure 3 in section 4.2 of the SmPC from 'every three months' to 'subsequent visits' following the approval of the procedure EMEA/H/C/005457/II/0011. In addition, the list of local representatives in the Package Leaflet was updated with editorial and formatting corrections.				
Variation type IA / EMA/VR/0000258170	This was an application for a group of variations. B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.a Tightening of specification limits - Accepted B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted	12/03/2025	N/A		
Variation type IA / EMA/VR/0000246153	B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer - Accepted	23/01/2025			
