



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Kefdensis

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 IA_IN /	This was an application for a group of	04/03/2026		Annex II and	

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/0000334923	<p>variations.</p> <p>Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) -</p> <p>Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted</p> <p>Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted</p>			PL	
Variation type IA / EMA/VR/0000323793	<p>This was an application for a group of variations.</p> <p>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.b Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. - Accepted</p> <p>B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the</p>	13/02/2026			

	<p>finished product - B.II.b.5.z Minor change of an analytical procedure for an in-process control - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted</p> <p>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</p> <p>A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted</p>				
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