EVKEEZA

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 / EMA/VR/0000315890	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the	05/01/2026			

[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).

	finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted				
Renewal - 5 year / EMA/R/0000293523		11/12/2025	23/02/2026	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of EVKEEZA in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Annual reassessment - H / EMA/S/0000288394		13/11/2025			
Variation type IA / EMA/VR/0000290207	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted 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	04/08/2025			

Variation type IB / EMA/VR/0000286193	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) - To implement changes to Section 6.6 of the SmPC and to the information intended for healthcare professionals only in the PL, by including more specific guidance on the appropriate volume of IV solution to be administered.	31/07/2025	23/02/2026	SmPC and PL	To implement changes to Section 6.6 of the SmPC and to the information intended for healthcare professionals only in the PL, by including more specific guidance on the appropriate volume of IV solution to be administered.
Variation type IB / EMA/VR/0000281636	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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	18/07/2025			
Variation type IB / EMA/VR/0000246158	This was an application for a group of variations. 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 B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	25/02/2025	23/02/2026	SmPC, Labelling and PL	

PSUR / EMA/PSUR/0000268966					Maintenance