



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Idefirix

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 /	This was an application for a group of	12/06/2025	N/A		

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/0000273534	variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted 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				
Variation type II / EMA/VR/0000258130	This was an application for a group of variations. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.I.b.1 Change in the specification	05/06/2025			

	parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.e Change outside the approved specifications limits range - Accepted 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 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 B.I.b.2 Change in test procedure for active				
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	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 B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.f Change outside the approved specifications limits range for the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted				
Variation type IA / EMA/VR/0000275284	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted	02/06/2025	N/A		
Renewal - 1 year / EMA/R/0000249767	- Renewal -	25/04/2025	25/06/2025	SmPC, Annex	The CHMP agreed with the extension of the due dates for SOB003 (Long-term efficacy and safety

	Renewal of marketing authorisation			II and PL	study investigating 1year graft survival rate in kidney transplant patients treated with Idefirix) and for ANX 001 (Long-term graft survival in patients who have undergone kidney transplantation after Idefirix administration). The proposed new due dates are February 2027 (SOB 003) and February 2032 (ANX 001). The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Idefirix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
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