ELREXFIO

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 II /	C.I HUMAN AND VETERINARY MEDICINAL	13/11/2025		SmPC and PL	Not applicable

[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/0000294591	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to add progressive multifocal leukoencephalopathy to the list of adverse drug reactions (ADRs) with the frequency uncommon based on clinical trials and post-marketing data-sources. In accordance with the updated data cut-off of September 10, 2024, the incidence rates for all listed adverse reactions have been revised. The Package Leaflet is updated accordingly.				
Variation type IA_IN / EMA/VR/0000278463	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	11/09/2025	10/09/2025	Annex II and PL	
Variation type II / EMA/VR/0000280555	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.j Changes to quality control testing arrangements for a biological active substance: replacement or	04/09/2025	N/A		

	addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted				
Renewal - 1 year / EMA/R/0000269600	- Renewal - Accepted Renewal of marketing authorisation	24/07/2025	10/09/2025		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 ELREXFIO, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
Variation type IB / EMA/VR/0000285949	This was an application for a group of variations. 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 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	21/07/2025	10/09/2025	SmPC	

Variation type IB / EMA/VR/0000246959	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.2 After first opening (supported by real time data) - Accepted	04/04/2025	10/09/2025	SmPC and PL	
Variation type IA / EMA/VR/0000237706	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	06/03/2025	N/A		
PSUR / EMA/PSUR/0000268954	- -				Maintenance