Alyftrek

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 /	Q.II.f.1.b) Extension of the shelf life of the	30/03/2026		SmPC	

[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/0000338822	finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IB / EMA/VR/0000315339	This was an application for a group of 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.z Other variation - Accepted 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 B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. -	16/01/2026			

	Accepted				
Variation type IB / EMA/VR/0000315468	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	17/12/2025		SmPC	
Variation type IB / EMA/VR/0000304508	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To update Section 4.4 of the SmPC and Section 2 of the PL to reconcile a discrepancy in the SmPCs for Alyftrek and Kaftrio related to 'Depression and other psychiatric disorders'. In addition, the MAH took the opportunity to implement editorial change to the PI by (1) removing the local representatives in the PL, (2) adding the date of first authorisation and (3) correct translation errors in the FR and DE PI.	14/11/2025		SmPC and PL	To update Section 4.4 of the SmPC and Section 2 of the PL to reconcile a discrepancy in the SmPCs for Alyftrek and Kaftrio related to 'Depression and other psychiatric disorders'. In addition, the MAH took the opportunity to implement editorial change to the PI by (1) removing the local representatives in the PL, (2) adding the date of first authorisation and (3) correct translation errors in the FR and DE PI.
Variation type IB / EMA/VR/0000302870	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To provide the initial study OECD 308 (VX-121-TX-035: Aerobic Transformation of VX-121 in Aquatic Sediment Systems at 12°C) and interim updated VX-121 Environmental Risk Assessment (ERA) reports.	30/10/2025			
