



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strimvelis

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 /	This was an application for a group of	04/07/2025		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/0000282063	<p>variations.</p> <p>B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted</p> <p>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</p>			PL	
Variation type IB / EMA/VR/0000252655	<p>B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted</p>	26/03/2025		SmPC, Annex II, Labelling and PL	