



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Skytrofa

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
Renewal - 5 year /	Outcome:	23/07/2026	14/09/2026	SmPC, Annex	

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/R/0000339532	- Renewal - Accepted Renewal of marketing authorisation			II and PL	
PSUR / EMA/PSUR/0000311154	EURD: PSUSA/00010969/202508 Active substance: lonapegsomatropin Outcome: Maintenance	12/03/2026			Maintenance
Variation type IB / EMA/VR/0000314063	Outcome: B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.z Other variation - Accepted	15/12/2025			
Variation type IA / EMA/VR/0000314576	Outcome: 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.a Minor changes to an approved test procedure - Accepted	28/11/2025			
Variation type IB / EMA/VR/0000295864	Outcome: 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	02/10/2025			

	procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted				
Variation type IB / EMA/VR/0000278999	Outcome: 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	09/07/2025			
Variation type IB / EMA/VR/0000253916	Outcome: 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	10/03/2025			
Variation type IB / EMA/VR/0000244892	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	07/02/2025			