



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Theralugand

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 /	C.1 Change(s) in the summary of product	01/04/2026		Labelling	

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/0000334498	<p>characteristics, labelling or package leaflet intended to implement the outcome of a Union referral procedure - C.1.z Other variation - Accepted</p> <p>Type IB (C.I.z) - To replace national language expressions for reference time zone in calibration and expiry dates to the common expression "CET" or "CEST". Additionally, the MAH has taken the opportunity to correct two clerical errors in the Product Information translation into the Slovak language that had not been observed during linguistic review phase of the marketing authorisation procedure. Lastly, the MAH has taken the opportunity to update Annex IIIA, outer labelling, section 12 to add grey-shading to the container size across all EEA languages to align with the English PI.</p>				
Variation type IA / EMA/VR/0000323617	<p>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</p>	23/01/2026			

