Yescarta

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 / EMA/VR/0000285857	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	13/11/2025		SmPC and Annex II	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).

	No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL 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 4.4 of the SmPC in order to add a reference statement to current institutional / national guidelines for the monitoring and management of CRS, neurologic events and ICANS. In addition, the MAH took the opportunity to introduce clarification and administrative updates across the PI, including Annex II.				
Variation type IA_IN / EMA/VR/0000303531	B.II.g) Design Space and post approval change management protocol - B.II.g.3 Deletion of an approved change management protocol related to the finished product - Accepted	07/10/2025			
Variation type II / EMA/VR/0000255932	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological	24/07/2025		SmPC, Labelling and PL	The SmPC section 6.4 has been updated as follows: Yescarta/Tecartus may be stored a single time at -80 °C (± 10 °C), for up to 90 days. After storage at -80 °C (± 10 °C), the product must be used within the 90-day period or the labelled expiration date, whichever comes first. After these dates, the product must not be used and must be discarded. The Labelling and Package Leaflet have been

	medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted				updated accordingly.
Variation type IB / EMA/VR/0000265127	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted	12/06/2025	N/A		

Variation type II / EMA/VR/0000242383	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.d Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted - - Accepted	27/03/2025	N/A		Not applicable