Tuznue

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 /	Outcome:	14/08/2026			

[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/0000362250	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To update the RMP to update the safety concerns in alignment with the RMP of the reference product Herceptin.				
Variation type IB / EMA/VR/0000355520	Outcome: C.2 Change(s) in the summary of product characteristics, labelling or package leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) – To update sections 2, 4.4 and 6.1 of the SmPC, section 3 of the Labeling, and sections 2 and 6 of the PL to include information regarding polysorbates used as excipients in accordance with the	14/07/2026		SmPC, Annex II, Labelling and PL	

	Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use', following approval of the same change for the reference product. In addition, the MAH has taken the opportunity to remove Kymos Pharma Services, S.L. from the list of manufacturers responsible for batch release in Annex II and the PL, as Kymos is not responsible for batch release. There are no changes to the responsibilities of the manufacturers of Tuznue.				
Variation type IB / EMA/VR/0000339359	Outcome: Q.II.b.4 Change in the batch size (including batch size ranges) of the finished product - Q.II.b.4.a) Up to 10-fold increase compared to the originally approved batch size - Accepted	05/05/2026			
Variation type IA / EMA/VR/0000324479	Outcome: This was an application for a group of variations. Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.a) Minor change of in-process control limits - Accepted Q.I.a.4 Change to in-process controls	18/02/2026			

	applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.a) Minor change of in-process control limits - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted				
Variation type IB / EMA/VR/0000313839	Outcome: 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	20/01/2026			
Variation type IB / EMA/VR/0000301399	Outcome: B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological	23/10/2025	04/05/2026	SmPC	

	medicinal product in accordance with an approved stability protocol - Accepted				
Article 61(3) / EMA/N/0000303396	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet to introduce a list of local representatives.	09/10/2025	04/05/2026	PL	
Variation type IB / EMA/VR/0000287118	Outcome: B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative and/or quantitative composition - Accepted	25/07/2025			
Variation type IB / EMA/VR/0000272239	Outcome: This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted	16/06/2025			

Variation type IB / EMA/VR/0000261150	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 procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	07/05/2025			
Variation type IB / EMA/VR/0000264280	Outcome: This was an application for a group of variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted	05/05/2025			
Variation type IB / EMA/VR/0000247419	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	20/03/2025			

Variation type IB / EMA/VR/0000250711	Outcome: This was an application for a group of variations. 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 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 B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	20/02/2025	04/05/2026	SmPC	