Erbitux

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 /	A. ADMINISTRATIVE CHANGES - A.7	28/01/2026		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/0000323569	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			PL	
Variation type II / EMA/VR/0000291784	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.3 Including batch control/testing for a biological/immunological product and any of the test methods performed at that site is a biological / immunological / immunochemical method - Accepted B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.3 Sterile medicinal products and biological/ immunological medicinal products - Accepted	04/12/2025		Annex II and PL	

Variation type IA / EMA/VR/0000314715	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	28/11/2025	N/A		
Variation type IB / EMA/VR/0000294109	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	19/09/2025	N/A		
Variation type IB / EMA/VR/0000273782	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	16/06/2025	N/A		