Riximyo

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:	03/09/2026		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/0000355500	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site,			PL	

	manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted 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 Type IA, E.5 - Deletion of Sandoz GmbH, Schaftenau as batch release and storage site for finished product. Type IA, E.5 - Deletion of Boehringer Ingelheim Pharma GmbH & Co. KG as active substance manufacturer. Type IA, E.5 - Deregistration of Sartorius				

	Stedim BioOutsource Limited, Glasgow as quality control testing site for IPC testing of active substance. Type IA, E.5 - Deregistration of Novartis Pharmaceutical Manufacturing GmbH, Langkampfen as quality control testing site for stability testing of finished product. Type IB, C.2.a – Alignment of Annex IID with changes already approved in the RMP of reference product Mabthera. Furthermore, language specific editorial changes, introduced in alignment with the reference product, were added for DE, FR, HU, PT, RO, SK and contact details for the local representatives of SL and IE were updated. Finally, the MAH took the opportunity to correct an error in our approved dossier and delete 23A Appendices Stein from Module 2.				
Variation type IB / EMA/VR/0000349754	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.g.5 Implementation of changes foreseen in a post-approval change management protocol (PACMP) - Q.II.g.5.c) Implementation of change foreseen in a PACMP via Type IB notification - Accepted	23/07/2026			

Variation type IB / EMA/VR/0000340177	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.d) Deletion of a non-significant or an obsolete specification attribute - Accepted	04/06/2026			
Variation type II / EMA/VR/0000323474	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.g) Additional regulatory tools - Q.II.g.2 Introduction of a post approval change management protocol related to the finished product (PACMP) - Accepted	16/04/2026			
Variation type IB / EMA/VR/0000332261	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	16/04/2026			

	No 1234/2008. Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted				
Variation type IA / EMA/VR/0000308303	Outcome: A. ADMINISTRATIVE CHANGES - A.7 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	19/11/2025			
Variation type IB / EMA/VR/0000249103	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted	10/07/2025	11/06/2026	Annex II	To align the RMP with that of the reference product by updating the ATC code, removing the important identified risks `Hepatitis B (HBV) reactivation (all indications)', `Hypogammaglobulinemia (non-oncology indications)', 'administration route error (NHL/CLL)' and missing information `Long-term use in Granulomatosis with polyangiitis (GPA)/ microscopic polyangiitis (MPA) patients (GPA/MPA)' `Relapses' (for GPA/MPA) from the list of safety concerns. To remove the targeted follow-up questionnaire (TFUQ) details and the additional risk minimization measures HCP educational leaflet and

	To align the RMP with that of the reference product by updating the ATC code, removing the important identified risks `Hepatitis B (HBV) reactivation (all indications)', `Hypogammaglobulinemia (non-oncology indications)', 'administration route error (NHL/CLL)' and missing information `Long-term use in Granulomatosis with polyangiitis (GPA)/ microscopic polyangiitis (MPA) patients (GPA/MPA)' `Relapses' (for GPA/MPA) from the list of safety concerns. To remove the targeted follow-up questionnaire (TFUQ) details and the additional risk minimization measures HCP educational leaflet and Patient educational leaflet, Annex IID is updated accordingly.				Patient educational leaflet, Annex IID is updated accordingly.
Variation type II / EMA/VR/0000254599	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	26/06/2025			

Variation type IB / EMA/VR/0000261990	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.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.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - to update sections 4.1, 4.2, 4.3, 4.4, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC, Annex II, Labelling and Package Leaflet, following assessment of the same changes for the reference product MabThera (EMEA/H/C/000165/II/0201/G). In addition, the MAH introduced the polysorbate content warning in section 2 and 4.4 of the SmPC as well as in section 2 of the Package Leaflet in accordance with the update of the Annex to the guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (as per Amendment from 17 Apr 2024). Moreover, the list of local representatives in section 6 of the Package Leaflet with changes of contact details for the following countries: Luxembourg, Czech	15/05/2025	11/06/2026	SmPC, Annex II, Labelling and PL	

	Republic, Denmark/Norway/Island/Sweden, Italy, Cyprus and the deletion of United Kingdom (NI) according to the QRD template 10.4.				
Variation type IB / EMA/VR/0000261094	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	08/05/2025			
Variation type IB / EMA/VR/0000249064	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the	03/04/2025			

	active substance-replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IA_IN / EMA/VR/0000243018	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.a Implementation of wording agreed by the competent authority - Refused	05/02/2025			