Rixathon

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 /	This was an application for a variation	10/07/2025		Annex II	To align the RMP with that of the reference product

[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/0000249103	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 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.				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.
Variation type II / EMA/VR/0000254599	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	26/06/2025			

	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				
Variation type IB / EMA/VR/0000261990	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	15/05/2025		SmPC, Annex II, Labelling and PL	

	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 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	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	N/A		
Variation type IB / EMA/VR/0000249064	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	03/04/2025	N/A		

	(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 active substance-replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IA_IN / EMA/VR/0000243018	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	N/A		