Rixathon

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0071	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2023		PL	
IB/0070	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	15/12/2023	n/a		

[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).

WS/2536	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.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	09/11/2023		SmPC	
IB/0068	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	25/09/2023	n/a		
IG/1665/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	14/09/2023		Annex II	

	(excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
PSUSA/2652/ 202211	Periodic Safety Update EU Single assessment - rituximab	22/06/2023	23/08/2023		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2652/202211.
WS/2505/G	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.6 - Administrative change - Change in ATC Code/ATC Vet Code C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	13/07/2023		SmPC	
IB/0065	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	15/03/2023	n/a		

WS/2307	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/01/2023	24/02/2023	SmPC	
WS/2387	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	09/02/2023	n/a		
PSUSA/2652/ 202111	Periodic Safety Update EU Single assessment - rituximab	23/06/2022	17/08/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/2652/202111.
IB/0061	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	21/07/2022	n/a		
WS/2271/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	21/07/2022	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0060	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	16/06/2022	n/a		
IG/1519	A.7 - Administrative change - Deletion of manufacturing sites	31/05/2022	17/08/2022	Annex II	
WS/2273	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	19/05/2022	17/08/2022	SmPC and PL	
IB/0057	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	10/05/2022	n/a		

R/0053	Renewal of the marketing authorisation.	16/12/2021	24/02/2022	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Rixathon in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
WS/2135/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.e - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of an in-process test which may have a significant effect on the overall quality of the AS	28/10/2021	n/a		
IB/0051	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/08/2021	n/a		
PSUSA/2652/202011	Periodic Safety Update EU Single assessment - rituximab	24/06/2021	20/08/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2652/202011.
IB/0050	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	16/08/2021	24/02/2022	SmPC, Labelling and	To update section 6.6 of the SmPC to add new instructions on the injections, in line with the reference product.

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH			PL	
WS/2061/G	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.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	03/06/2021	20/08/2021	SmPC, Annex II, Labelling and PL	The product information was updated as follows: update of sections 6.3 and 6.4 of the Summary of Product Characteristics, update of section 9 of the labelling, update of sections 2, 4 and 5 of the Package Leaflet In addition editorial corrections were introduced and addition in Annex II 'The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.'
IB/0049	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	12/05/2021	n/a		
WS/1996	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.z - Changes in the manufacturing process of the AS - Other variation	04/02/2021	n/a		

IB/0045	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	09/12/2020	n/a		
IB/0044	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	24/11/2020	n/a		
WS/1875/G	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.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by	03/09/2020	09/10/2020	SmPC, Labelling and PL	

	the MAH				
IB/0043	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	31/08/2020	n/a		
IB/0041	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/08/2020	n/a		
IB/0038	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	11/06/2020	n/a		
PSUSA/2652/ 201911	Periodic Safety Update EU Single assessment - rituximab	11/06/2020	n/a		PRAC Recommendation - maintenance
IB/0040	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	04/06/2020	n/a		
IB/0039	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	03/06/2020	n/a		
IG/1212	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	20/02/2020	n/a		

IB/0033	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	08/01/2020	n/a		
IB/0032	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	16/12/2019	n/a		
IB/0031	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	08/11/2019	n/a		
WS/1678	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.e.2 - Introduction of a post approval change management protocol related to the AS	07/11/2019	n/a		
IB/0030	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	24/09/2019	n/a		
IB/0029	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	10/09/2019	n/a		
WS/1599	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered	05/09/2019	n/a		

	elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0026/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	29/08/2019	23/09/2019	SmPC, Annex II, Labelling and PL	
IB/0028	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	09/08/2019	n/a		
IB/0025/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test	19/07/2019	n/a		

	period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS				
WS/1642/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	18/07/2019	n/a		
PSUSA/2652/201811	Periodic Safety Update EU Single assessment - rituximab	14/06/2019	n/a		PRAC Recommendation - maintenance
IB/0022	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	30/05/2019	23/09/2019	Annex II	
IB/0023	B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	14/05/2019	23/09/2019	SmPC	
IG/1084/G	This was an application for a group of variations.	05/04/2019	n/a		

	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IAIN/0018	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	25/02/2019	23/09/2019	Annex II and PL	
WS/1528	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.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	31/01/2019	n/a		
WS/1480	This was an application for a variation following a worksharing procedure according to Article 20 of	17/01/2019	n/a		

	Commission Regulation (EC) No 1234/2008. B.II.g.2 - Introduction of a post approval change management protocol related to the finished product				
WS/1462	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.e.2 - Introduction of a post approval change management protocol related to the AS	06/12/2018	n/a		
IB/0016	B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method	22/10/2018	n/a		
WS/1452	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.z - Change in test procedure for the finished product - Other variation	13/09/2018	n/a		
WS/1335	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of final study reports for studies GP13-302 (a randomized, double-blind, parallel-group safety study with the aim to specifically address a	12/07/2018	n/a		

	potential safety risk of a switch from treatment with originator rituximab (Mabthera/Rituxan) to treatment with GP2013) and GP13-201 (a 52-week multicenter, randomized, double-blind, parallel-arm, comparative study in patients with active Reumathoid Arthritis (RA) refractory or intolerant to standard DMARDs and one or up to three anti-TNFs therapies). The RMP (version 3.1) has been updated accordingly. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IG/0939/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/06/2018	n/a		
PSUSA/2652/ 201711	Periodic Safety Update EU Single assessment - rituximab	14/06/2018	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a	23/04/2018	n/a		

	biological/immunological medicinal product				
IG/0878/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	11/12/2017	n/a		
IB/0007	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	14/11/2017	n/a		
IB/0004	B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	14/10/2017	20/09/2018	SmPC	
IG/0850/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/10/2017	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
WS/1243	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.2 - Introduction of a post approval change management protocol related to the finished product	28/09/2017	n/a		
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/09/2017	n/a		
IB/0001	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	04/08/2017	n/a		