Remsima

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	Commission Decision Issued[2] /	Product Information affected[3]	Summary

[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).

						on	amended on		
Variation type IB / EMA/VR/0000335617					This was an application for a group of variations. Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.b) Addition or replacement of a batch control/testing site applying a biological/immunological/immunochemical analytical procedure for a biological finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted	21/04/2026			
Variation type IB /	Q.I.a.1 Change in the	30/03/							

EMA/VR/0000335410	manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted	2026			
Variation type II / EMA/VR/0000315906	B.IV.1 Change of a measuring or administration device - B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging - Accepted	19/03/2026			

Variation type II / EMA/VR/0000320816	This was an application for a group of variations. B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.z Other changes - Accepted 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.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted B.I.a.1 Change in the manufacturer of a starting	12/03/2026		Annex II	

	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.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted				
Variation type IA / EMA/VR/0000323741	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active	28/01/2026			

	substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b				

	Tightening of specification limits - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermedia te used in the manufacturing process of the active substance - B.I.b.2.b Deletion of a test procedure for the active substance or a starting material/reagent/ intermediate, if an alternative test procedure is already authorised. - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure -				

	Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted				
Variation type II / EMA/VR/0000310737	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.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted	22/01/2026			
Variation type II / EMA/VR/00002933	This was an application for a group of variations.	15/01/		Annex	

45	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.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.b Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological active substances - Accepted B.I.a.1 Change in the	2026		II	

	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.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted 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.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted				
Variation type II / EMA/VR/0000287806	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the	09/10/2025			

	finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted				
Variation type IB / EMA/VR/0000282566	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermedia	11/07/2025			

	te used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted				
Variation type IB / EMA/VR/0000276354	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.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	26/06/2025			
Variation type II / EMA/VR/0000264659	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place	19/06/2025			Type II (B.II.b.2) - Addition of Selvita Services Sp. z o.o. Ul. Profesora Michała Bobrzyńskiego 14, Kraków Małopolskie 30-348 Poland, as quality control release testing site for the finished product (all compendial methods except for sterility). Type II (B.II.b.2) - Addition of Pozlab Sp. z o.o. Ul. Kobaltowa 6 Zlotniki, Suchy Las, Wielkopolskie, 62-002 Poland, as quality control release testing site for the finished product (for sterility only). These changes only impact the powder for concentrate for solution for infusion presentations (EU/1/13/853/001-005). In addition, the Applicant has taken opportunity to make editorial changes to module 3.

	for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted				
Variation type IB / EMA/VR/0000267792	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	23/05/2025	09/07/2025	SmPC, Labelling and PL	To update sections 4.4 and 4.8 of the SmPC and section 4 of the Package Leaflet in order to add post-procedural complications (including infectious and non-infectious complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data following assessment of the same change for the reference product Remicade.

	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 4.4 and 4.8 of the SmPC and section 4 of the Package Leaflet in order to add post-procedural complications (including infectious and non-infectious complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data following assessment of the same change for the reference product Remicade. In addition, the MAH took the opportunity to implement other editorial changes to correct for grammatical				

	and/or typographical errors across the PI in EN, DE and IT. Language-specific editorial changes made in the PI of the reference product Remicade that were equally applicable to Remsima have been implemented accordingly.				
Variation type IA / EMA/VR/0000268907	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.c Deletion of a non-significant in-process test - Refused 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 - Refused	12/05/2025			
Variation type IB / EMA/VR/0000256124	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate	19/03/2025			

	used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted				
Variation type IA / EMA/VR/0000253465	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	03/03/2025	09/07/2025	Annex II and PL	
Variation type IB / EMA/VR/0000245253	This was an application for a group of variations. B.II.b) Manufacture - B.II.b.z Other variation - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished	17/02/2025			

	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								
PSUR / EMA/PSUR/0000317670									Maintenance