Remsima

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
IB/0139/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	18/01/2024	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).

	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol				
IAIN/0138	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	22/12/2023		Annex II and PL	
IB/0136/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.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	17/10/2023	n/a		
N/0137	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/10/2023		PL	
IA/0135/G	This was an application for a group of variations.	14/09/2023	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites 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 B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method				
IB/0134	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	14/09/2023	n/a		
II/0131/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening	31/08/2023	n/a		

	of the approved in-process test limits, which may have a significant effect on the overall quality of the AS				
IB/0132	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	14/07/2023	15/09/2023	SmPC	
IAIN/0130	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	29/05/2023	15/09/2023	Annex II and PL	
IB/0128/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	23/05/2023	n/a		
IAIN/0129	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	12/05/2023	15/09/2023	Annex II and PL	

IB/0127	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	28/04/2023	n/a		
IB/0126/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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	14/04/2023	15/09/2023	SmPC and PL	
PSUSA/10759 /202208	Periodic Safety Update EU Single assessment - infliximab	14/04/2023	n/a		PRAC Recommendation - maintenance
IAIN/0125	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/03/2023	n/a		
IB/0121/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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	16/02/2023	15/09/2023	SmPC	
IAIN/0124	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	06/02/2023	n/a		

	site				
IAIN/0123/G	This was an application for a group of variations. 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 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	17/01/2023	15/09/2023	Annex II and PL	
IAIN/0122	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	09/01/2023	n/a		
IB/0120	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	22/12/2022	n/a		
IB/0118/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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	25/11/2022	15/09/2023	SmPC	

	stability protocol				
II/0117/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	10/11/2022	n/a		
IB/0116	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	27/09/2022	15/09/2023	SmPC and PL	
IB/0115/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	26/07/2022	n/a		

	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
IB/0114/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.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/05/2022	15/07/2022	SmPC, Labelling and PL	Sections 4.4, 4.5 and 4.6 of the SmPC, Section 2 of the PL and the Patient Reminder Card have been updated with information regarding administration of live vaccines to infants exposed to infliximab during pregnancy. The RMP was updated accordingly.
IB/0113	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	22/03/2022	n/a		
II/0111	Submission of the final report from study CT-P13 4.2; An Observational, Prospective Cohort Study to Evaluate Safety and Efficacy of Remsima in Patients with Rheumatoid Arthritis (study report excluding the joint analysis of patients in the PERSIST study). C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	10/03/2022	n/a		

N/0112	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/02/2022	15/07/2022	PL	
II/0101/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/12/2021	n/a		
IB/0109	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/12/2021	n/a		
IB/0110/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	06/12/2021	15/07/2022	SmPC, Annex II, Labelling and PL	

	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				
II/0103/G	This was an application for a group of variations. Submission of the final Clinical Safety Reports (CSRs) for CT-P13 registry studies in Inflammatory Bowel Disease (IBD), Ankylosing Spondylitis (AS) and Rheumatoid Arthritis (RA) initiated with the objective of assessing long-term safety in these indications: • Final report for CT-P13 4.3 (EU and Korean IBD Registry) • Final report for CT-P13 4.4 (EU and Korean AS Registry) • Final report for BSRBR-RA Registry • Final report for RABBIT Registry C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	30/09/2021	n/a		The current variation concerns the final study reports of post-authorization safety studies and registries listed as category 3 in Risk Management Plan (RMP), to investigate the long-term safety of infliximab in Rheumatoid Arthritis (BSRBR-RA, RABBIT), Inflammatory Bowel Disease (CT-P13 4.3), and Ankylosing Spondylitis (CT-P13 4.4). Observational data derived from these four non-interventional studies did not reveal any new or unexpected safety findings.

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0107	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	21/09/2021	n/a		
N/0106	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2021	15/07/2022	PL	
IA/0108	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	01/09/2021	n/a		
IB/0105/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol	12/08/2021	15/07/2022	SmPC	

	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				
IA/0104/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	24/06/2021	n/a		
IB/0102	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	04/05/2021	n/a		
II/0095	Addition of a new posology for the rheumatoid arthritis indication that does not include IV induction doses. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/03/2021	30/04/2021	SmPC and PL	A population pharmacokinetic and pharmacokinetic/pharmacodynamic modelling and simulation predicted comparable infliximab exposure (AUC over 8 weeks) and efficacy (DAS28 and ACR20 response) from Week 6 onward in rheumatoid arthritis patients treated with Remsima 120 mg given without intravenous loading doses of infliximab when compared with Remsima 3 mg/kg given intravenously at Weeks 0, 2 and 6, and then every 8 weeks. Therefore, the posology for the rheumatoid arthritis

					subcutaneous formulation has been amended to reflect that treatment initiations can done with intravenous or subcutaneous loading doses. When subcutaneous loading is used, Remsima 120 mg should be given as a subcutaneous injection followed by additional subcutaneous injections at 1, 2, 3 and 4 weeks after the first injection, then every 2 weeks thereafter. If intravenous loading doses of infliximab are given to initiate treatment, 2 intravenous infusions of infliximab 3 mg/kg should be given 2 weeks apart. The first treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the second intravenous administration. The recommended maintenance dose for Remsima subcutaneous formulation is 120 mg once every 2 weeks. Treatment of patients with Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis should be initiated with IV infusions of infliximab
IB/0100	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	06/04/2021	n/a		
II/0096/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 B.I.b.1.z - Change in the specification parameters	25/02/2021	n/a		

	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.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				

IB/0099/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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)	19/02/2021	30/04/2021	SmPC, Annex II, Labelling and PL	
IB/0098/G	This was an application for a group of variations. B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	26/01/2021	n/a		
IB/0097	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	05/01/2021	30/04/2021	SmPC, Labelling and PL	
IAIN/0094	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/10/2020	30/04/2021	SmPC and PL	
II/0093/G	This was an application for a group of variations. B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening	22/10/2020	n/a		

	of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IB/0092	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	04/09/2020	n/a		
N/0089	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/08/2020	30/04/2021	PL	
IA/0091/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 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	07/08/2020	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.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.c.2.a - Change in the specification parameters and/or limits of the immediate packaging of the AS - Tightening of specification limits B.II.c.2.b - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is already authorised B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State				
II/0082	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/06/2020	24/07/2020	SmPC and PL	Please refer to Scientific Discussion Remsima EMEA/H/C/002576/II/0082.
IAIN/0090/G	This was an application for a group of variations.	10/07/2020	30/04/2021	Annex II and	

	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 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			PL	
II/0088/G	This was an application for a group of variations. B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	02/07/2020	n/a		
N/0087	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/05/2020	24/07/2020	PL	
IB/0084/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	05/05/2020	24/07/2020	SmPC, Labelling and PL	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IB/0086	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	21/04/2020	n/a		
PSUSA/10759 /201908	Periodic Safety Update EU Single assessment - infliximab	17/04/2020	n/a		PRAC Recommendation - maintenance
II/0074	Submission of the final clinical study report for C1231002 (PERSIST) study, an observational cohort study designed to evaluate real life drug persistence in biologic naive rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis patients receiving CT-P13 or those switched to CT-P13 from stable treatment with Remicade (reference medicinal product). C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/04/2020	n/a		No new safety information was identified from the submitted data. This study was listed as EU RMP in order to further characterise the safety profile of CT-P13 including long-term safety and Important identified risks: serious infections including sepsis (initially including tuberculosis), demyelinating disorders and malignancy but there was a small sample size resulting from early study termination. The most frequent treatment related adverse drug reactions of serious infections and infusion reactions are already adequately addressed in the Product Information. No meaningful information on demyelinating disorders and malignancy were identified. The CHMP stressed that the

					submitted results were limited, however, cconsidering the totality of the safety data available for CT-P13 and the infliximab originator, it is anticipated that additional data that could have been gathered if this study would have been conducted for the full time period planned, would likely have been limited.
II/0073	Submission of the final clinical study report for C1231001 (CONNECT-IBD) study; a non-interventional study designated as a Post Authorisation Safety Study conducted voluntarily to capture data from real-world clinical practice to characterise the population and document drug utilisation patterns. In addition, available safety data and data on the effectiveness of CT-P13 in the context of standard of care utilisation of Remicade (reference medicinal product) was collected in patients with Crohn's disease or ulcerative colitis. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/04/2020	n/a		This study had been used as a data source to investigate the long-term safety and effectiveness in inflammatory bowel disease (Crohn's disease or ulcerative colitis) with emphasis on TB and other serious infection. While the inherent limitations exist in relation to group size, selection bias within each treatment group (CT-P13 vs Remicade) and sub-group size (UC vs CD) for any comparisons, the study confirmed that the safety profiles for each treatment group were consistent with the expected safety profile of infliximab and did not identify any new safety risk.
II/0080/G	This was an application for a group of variations. B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting	12/03/2020	n/a		

	material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				
IA/0085	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)	11/03/2020	n/a		
IB/0081/G	This was an application for a group of variations. 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 B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	21/02/2020	24/07/2020	SmPC and PL	

II/0075/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.II.b.5.e - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product B.II.f.1.e - Stability of FP - Change to an approved stability protocol	06/02/2020	n/a		
IAIN/0083	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	29/01/2020	n/a		

	site				
IB/0078	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	16/12/2019	24/07/2020	SmPC and PL	
X/0062	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form Annex I_2.(e) Change or addition of a new route of administration	19/09/2019	22/11/2019	SmPC, Annex II, Labelling and PL	
IA/0077/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.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification 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.1.c - Change in the specification parameters	05/11/2019	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
IB/0076/G	This was an application for a group of variations. B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	11/10/2019	n/a		
IAIN/0072	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/09/2019	n/a		
IB/0071/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a	28/08/2019	22/11/2019	SmPC and Labelling	

	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.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0070	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	19/06/2019	n/a		
IB/0068/G	This was an application for a group of variations. 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) 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	03/06/2019	16/09/2019	SmPC, Annex II and PL	
N/0069	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/05/2019	n/a		
IAIN/0067	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	28/03/2019	n/a		

	site				
IAIN/0066	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/03/2019	16/09/2019	SmPC and PL	
II/0063	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/03/2019	n/a		
IB/0064/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.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	18/02/2019	16/09/2019	SmPC, Annex II, Labelling and PL	
IAIN/0065/G	This was an application for a group of variations. 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 -	07/02/2019	16/09/2019	Annex II and PL	

	Not including batch control/testing 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				
II/0060/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS 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.d - Change in test procedure for AS or	31/01/2019	n/a		

	starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS 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 B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				
IB/0061	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	04/12/2018	16/09/2019	SmPC, Labelling and PL	

IB/0058/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/11/2018	n/a		
IB/0057	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	27/09/2018	n/a		
IAIN/0059	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/09/2018	n/a		
IB/0055/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	21/09/2018	16/09/2019	SmPC, Labelling and PL	

PSUSA/10106 /201801	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	06/09/2018	n/a		PRAC Recommendation - maintenance
IA/0056/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	30/08/2018	n/a		
IB/0054/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	30/08/2018	n/a		

	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
II/0052	To submit the final report from study CT-P13 3.4, listed as a category 3 study in the RMP. A Randomized, Double-Blind, Parallel-Group, Phase 3 Study to Demonstrate Noninferiority in Efficacy and to Assess Safety of CT-P13 Compared to Remicade in Patients with Active Crohn's Disease. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	19/07/2018	n/a		The non-inferiority of efficacy was demonstrated in the primary endpoint and the comparability of the secondary efficacy endpoints supported the biosimilarity with Remicade. Mean serum concentrations were comparable and the results of biomarkers were generally similar between the treatment groups. The overall safety profile in this study was consistent with the known safety profile of Remicade; there were no new or unexpected safety findings observed in this study and no update to the product information was considered necessary.
II/0051	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	12/07/2018	n/a		
R/0047	Renewal of the marketing authorisation.	26/04/2018	21/06/2018	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Remsima in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0050	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	01/03/2018	30/04/2018	SmPC, Annex II and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0049	A.1 - Administrative change - Change in the name and/or address of the MAH	16/02/2018	30/04/2018	SmPC, Labelling and PL	
II/0048	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	15/02/2018	n/a		
II/0045	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	08/02/2018	n/a		
IAIN/0046	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/09/2017	n/a		
PSUSA/10106 /201701	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	01/09/2017	n/a		PRAC Recommendation - maintenance
II/0042/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and	29/06/2017	n/a		

	biological/immunological medicinal products				
IA/0044	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	24/05/2017	30/04/2018	Annex II	
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/02/2017	30/04/2018	PL	
II/0039	Update of the RMP (v 7.0) to merge the RMPs for Remsima and Inflectra. The variation leads to amendments to the Risk Management Plan (RMP). C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	15/12/2016	n/a		Inflectra and Remsima are two biosimilar infliximab products. The MAHs for these two products will share the safety database and from 2016 will submit a single PSUR covering both products. Accordingly the MAHs have integrated the RMPs into a single RMP covering both products. The proposed post-authorisation pharmacovigilance development plan is sufficient to identify and characterise the risks of the product. There are no changes to the routine and additional risk minimisation measures as a consequence of the integration of the separate RMPs to form the Remsima/Inflectra RMP version 7.0.
IB/0040	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	01/12/2016	n/a		
IB/0038	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	04/10/2016	23/01/2017	SmPC, Labelling and	

	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	
PSUSA/10106 /201601	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	02/09/2016	n/a		PRAC Recommendation - maintenance
IB/0037	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	28/07/2016	n/a		
II/0036	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	28/07/2016	n/a		
IB/0034/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/04/2016	n/a		
II/0029	Submission of a final clinical study report B2P13111 (Extension Study of the Phase I/II Clinical Study of CT P13 in Treatment of Patients with Rheumatoid Arthritis (Japan)) in order to fulfil the post approval measure MEA 006.	25/02/2016	n/a		

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
PSUSA/10106 /201507	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	11/02/2016	n/a		PRAC Recommendation - maintenance
IB/0033/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of 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	28/01/2016	23/01/2017	SmPC, Annex II, Labelling and PL	
II/0032	B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol	28/01/2016	23/01/2017	SmPC, Labelling and PL	Remsima may be stored at temperatures up to a maximum of 25°C for a single period of up to 6 months, but not exceeding the original expiry date. The new expiry date must be written on the carton. Upon removal from refrigerated storage, Remsima must not be returned to refrigerated storage.

IB/0030/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	27/11/2015	n/a		
IB/0028	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/10/2015	n/a		
II/0025	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	24/09/2015	n/a		
II/0022/G	This was an application for a group of variations.	24/09/2015	n/a		

	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
PSUSA/10106 /201501	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	10/09/2015	n/a		PRAC Recommendation - maintenance
IA/0026/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.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new	24/07/2015	n/a		

	specification parameter to the specification with its corresponding test method 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				
IAIN/0027	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	16/07/2015	n/a		
IB/0024	B.I.c.1.z - Change in immediate packaging of the AS - Other variation	16/07/2015	n/a		
IB/0021	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	10/03/2015	10/12/2015	SmPC, Labelling and PL	
IB/0020	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/03/2015	n/a		
PSUSA/10106 /201407	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	12/02/2015	n/a		PRAC Recommendation - maintenance
II/0013/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The	22/01/2015	10/12/2015	Annex II	

	change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
IB/0017/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	12/01/2015	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
IB/0018	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	09/12/2014	10/12/2015	SmPC	
IB/0019	Update of section 4.4 of the SmPC to update the warning on fibrotic stricture further to the submission of the final result of European National Crogn's Observational Registry (ENCORE) following the same update to the originator. In addition the contact details of the local representative in Austria was updated 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	05/12/2014	10/12/2015	SmPC, Labelling and PL	
II/0015	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	20/11/2014	n/a		
PSUV/0010	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance

IB/0014/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	08/09/2014	16/12/2014	SmPC, Labelling and PL	
IA/0012/G	This was an application for a group of variations. B.I.b.z - Change in control of the AS - Other variation B.I.b.z - Change in control of the AS - Other variation B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph	01/08/2014	n/a		

	of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State				
IB/0011/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 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) 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	17/07/2014	16/12/2014	SmPC, Annex II, Labelling and PL	

II/0008/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/06/2014	n/a		
II/0007/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/06/2014	n/a		
IB/0009/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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	13/06/2014	16/12/2014	SmPC and PL	
II/0001/G	This was an application for a group of variations.	22/05/2014	n/a		

	Addition of a manufacturing site for the fill, finish and secondary packaging of the finished product B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
II/0006	Submission of the final study report of Study CT P13 1.2: a randomized, double-blind, parallel-group, Phase 1 study to evaluate the initial pharmacokinetics, efficacy, and safety of CT P13 compared with Remicade when co-administered with methotrexate in patients with active rheumatoid arthritis in order to fulfil the post-authorisation measure MEA 001. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	20/03/2014	n/a		Results of the final week 102 report of Study CT P13 1.2 showed that Cmax values were comparable in groups after Doses 1, 2 and 3 with a spike in Cmax in both treatment groups at Dose 2 (Week 2). CT-P13 showed a pharmacodynamic profile that is similar to Remicade. The trial is too small to draw any conclusions on the efficacy and safety of CT-P13 relative to the reference product. The results with respect to efficacy and safety variables in this study do not, however, provide grounds to reconsider the conclusions drawn to date on the therapeutic similarity of CT-P13 and the reference product.
IB/0005	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	27/01/2014	n/a		

IB/0002/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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	07/01/2014	16/12/2014	SmPC	
IB/0004	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	16/12/2013	16/12/2014	SmPC, Labelling and PL	