Inflectra

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/0118	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	10/09/2024	n/a		
IB/0117/G	This was an application for a group of variations.	31/07/2024	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.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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/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	17/04/2024		SmPC and PL	
IB/0115/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.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	27/11/2023	n/a		
IA/0114	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	29/09/2023	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
IA/0113/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.7 - Administrative change - Deletion of manufacturing sites 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	29/09/2023	n/a		
IB/0112	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		
IB/0111	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	16/05/2023	n/a		
PSUSA/10759 /202208	Periodic Safety Update EU Single assessment - infliximab	14/04/2023	n/a		PRAC Recommendation - maintenance
IB/0110	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	22/12/2022	n/a		

	re-test period/storage period supported by real time data				
II/0108/G	This was an application for a group of variations. 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 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	24/11/2022	n/a		
IB/0107/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.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	29/04/2022	21/10/2022	SmPC and PL	Sections 4.4, 4.5 and 4.6 of the SmPC, Section 2 of the PL and the Patient Reminder Card were updated with information regarding administration of live vaccines to infants exposed to infliximab during pregnancy.

IB/0106	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/0105	Submission of the final report from study CT-P13 4.2; An Observational, Prospective Cohort Study to Evaluate Safety and Efficacy of Inflectra in Patients with Rheumatoid Arthritis (study report excluding the joint analysis of patients in the PERSIST study). The submission of the study report addresses MEA 007.6. 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		
IB/0103	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/0104/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	18/11/2021	21/10/2022	SmPC, Annex II, Labelling and PL	

	new additional data is required to be submitted by the MAH				
II/0100/G	This was an application for a group of variations. Submission of the final 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; one study for Remsima® and one study for Inflectra®) • Final report for CT-P13 4.4 (EU and Korean AS Registry; one study for Remsima® and one study for Inflectra®) • Final report for BSRBR-RA Registry (one study equally applicable to Remsima® and Inflectra®) • Final report for RABBIT Registry (one study equally applicable to Remsima® and Inflectra®) 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	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.

	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				
N/0101	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/09/2021	22/10/2021	PL	
IA/0102	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	31/08/2021	n/a		
IA/0099/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/0098	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/06/2021	n/a		

IB/0097	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	19/05/2021	n/a		
IB/0096	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)	05/03/2021	22/10/2021	SmPC, Labelling and PL	
II/0094/G	This was an application for a group of variations. 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.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.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	25/02/2021	n/a		

	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.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
IB/0095	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	28/01/2021	n/a		
IAIN/0093	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/10/2020	22/10/2021	SmPC and PL	
N/0090	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/09/2020	22/10/2021	PL	
IB/0091	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	08/09/2020	n/a		
IB/0092	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	07/09/2020	n/a		
IA/0089/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	03/08/2020	n/a		

	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.c.2.a - Change in the specification parameters and/or limits of the immediate packaging of the AS - Tightening of specification limits				
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		
PSUSA/10759 /201908	Periodic Safety Update EU Single assessment - infliximab	17/04/2020	n/a		PRAC Recommendation - maintenance
II/0080	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	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

	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				infliximab and did not identify any new safety risk.
II/0079	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.
IA/0087	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)	13/03/2020	n/a		
II/0081/G	This was an application for a group of variations.	06/02/2020	n/a		

	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				
IB/0086	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/12/2019	n/a		
IB/0084	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	09/12/2019	10/08/2020	SmPC, Annex	

	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 and PL	
IA/0083/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 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	30/10/2019	n/a		

IB/0082/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	25/10/2019	n/a		
IB/0078/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	28/08/2019	10/08/2020	Annex II and Labelling	
IB/0077	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/0075/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	07/06/2019	16/09/2019	SmPC, Annex II and PL	

	manufacturing sites 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.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)				
N/0076	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	16/09/2019	PL	
IB/0074	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/04/2019	16/09/2019	SmPC and PL	
II/0072	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/0073/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	18/02/2019	16/09/2019	SmPC and PL	

	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				
II/0070/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 starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test	31/01/2019	n/a		

	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/0068/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		
N/0071	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/10/2018	16/09/2019	PL	

IB/0069	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	18/10/2018	16/09/2019	SmPC and PL	
IB/0067	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	18/10/2018	n/a		
IB/0065/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	24/09/2018	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/0066/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	31/08/2018	n/a		

	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				
IB/0063/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	30/08/2018	n/a		
T/0064	Transfer of Marketing Authorisation	17/07/2018	30/07/2018	SmPC, Labelling and	

				PL	
II/0061	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/0060	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/0056	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 Inflectra in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0059	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	27/02/2018	08/05/2018	SmPC and PL	

II/0057	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/0054	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		
IA/0058	A.7 - Administrative change - Deletion of manufacturing sites	11/12/2017	n/a		
N/0055	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/11/2017	08/05/2018	PL	
PSUSA/10106 /201701	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	01/09/2017	n/a		PRAC Recommendation - maintenance
IAIN/0053	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	20/07/2017	08/05/2018	Annex II and PL	
II/0050/G	This was an application for a group of variations. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.b.3.a - Change in the manufacturing process of	29/06/2017	n/a		

	the finished or intermediate product - Minor change in the manufacturing process				
IA/0052	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	08/05/2018	Annex II	
N/0049	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2017	08/05/2018	Labelling and PL	
IB/0048	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	21/12/2016	n/a		
II/0047	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.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	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/0046	C.I.2.a - Change in the SPC, Labelling or PL of a	22/09/2016	12/12/2016	SmPC and PL	

	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				
PSUSA/10106 /201601	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	02/09/2016	n/a		PRAC Recommendation - maintenance
N/0045	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/08/2016	12/12/2016	PL	
IB/0044	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	28/07/2016	n/a		
II/0041	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		
N/0043	Update of the package leaflet with revised contact details of the local representatives for Belgium, Germany, Spain, Ireland, Luxembourg, the Netherlands, Austria and Portugal. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/06/2016	12/12/2016	PL	
IG/0693	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		

II/0034	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. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	25/02/2016	n/a		
PSUSA/10106 /201507	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	11/02/2016	n/a		PRAC Recommendation - maintenance
II/0037	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	12/12/2016	SmPC, Labelling and PL	Inflectra 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, Inflectra must not be returned to refrigerated storage.
IG/0645	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	17/12/2015	n/a		
IB/0038/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	15/12/2015	12/12/2016	SmPC, Annex II, Labelling and PL	

	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				
IB/0035/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/0033	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	06/10/2015	n/a		

II/0030	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/0026/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.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/09/2015	n/a		
PSUSA/10106 /201501	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	10/09/2015	n/a		PRAC Recommendation - maintenance
IA/0032/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	24/07/2015	n/a		

	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 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				
IB/0029	B.I.c.1.z - Change in immediate packaging of the AS - Other variation	09/07/2015	n/a		
IAIN/0031	A.1 - Administrative change - Change in the name and/or address of the MAH	01/07/2015	23/09/2015	SmPC, Labelling and PL	
IG/0555	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	22/05/2015	n/a		
IB/0025	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/03/2015	n/a		
IB/0024	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	09/03/2015	23/09/2015	SmPC	

	(supported by real time data)				
IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/02/2015	n/a		
PSUSA/10106 /201407	Periodic Safety Update EU Single assessment - infliximab (biosimilars)	12/02/2015	n/a		PRAC Recommendation - maintenance
II/0015/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.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	22/01/2015	23/09/2015	Annex II	

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
IB/0020/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 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	09/01/2015	n/a		
IB/0022	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	06/01/2015	23/09/2015	SmPC and PL	
II/0017	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		
IA/0019/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 -	30/10/2014	n/a		

	Tightening of in-process limits B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
PSUV/0012	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
IA/0014/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.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)	25/09/2014	23/09/2015	Annex II	
IG/0477	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	03/09/2014	n/a		
IB/0013/G	This was an application for a group of variations. Update of section 4.4 of the SmPC to mention that	10/07/2014	30/09/2014	SmPC and PL	

	cases of active tuberculosis have been reported in patients treated with infliximab during and after treatment for latent tuberculosis. Update of section 4.4 and 4.8 of the SmPC to mention that the vast majority of HSTCL cases have occurred in patients with Crohn's disease or ulcerative colitis. The Package leaflet is updated accordingly. Furthermore the MAH took the opportunity to update the details of the local representative in Austria. 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				
II/0009/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/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		
IB/0011/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	17/06/2014	30/09/2014	SmPC	
II/0003/G	This was an application for a group of variations. 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	22/05/2014	n/a		

	release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
II/0007	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/0010/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	17/03/2014	30/09/2014	SmPC	
IAIN/0006	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	10/01/2014	n/a		

	PSMF location				
IB/0005	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	06/01/2014	n/a		
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	30/09/2014	SmPC, Labelling and PL	
IAIN/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/10/2013	n/a		
IAIN/0001/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	11/10/2013	30/09/2014	Annex II and PL	