Zessly

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/0035	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	22/05/2024	n/a		
II/0033	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	16/05/2024	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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	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				
IB/0034	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	04/04/2024		SmPC and PL	
N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2023		PL	
IA/0031/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) 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	06/10/2023	n/a		

	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				
IAIN/0030/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	13/07/2023		Annex II and PL	
IB/0029	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	26/06/2023	n/a		
II/0028	n/a B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	14/04/2023	n/a		n/a
PSUSA/10759 /202208	Periodic Safety Update EU Single assessment - infliximab	14/04/2023	n/a		PRAC Recommendation - maintenance
R/0025	Renewal of the marketing authorisation.	13/10/2022	28/11/2022	SmPC, Labelling and	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Zessly

				PL	in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0026	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	24/11/2022	n/a		
IA/0024	A.7 - Administrative change - Deletion of manufacturing sites	01/06/2022	n/a		
II/0020	Submission of the updated RMP version 3.0 to remove the RABBIT registry as an additional pharmacovigilance activity in alignment with the updated version of the reference product Remicade RMP (v19) and to remove the BADBIR registry as an additional pharmacovigilance activity. 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	05/05/2022	n/a		
IB/0022	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	19/04/2022	n/a		

IB/0023	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	13/04/2022	28/11/2022	SmPC, Labelling and PL	
IB/0021/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	13/12/2021	28/11/2022	SmPC, Annex II, Labelling and PL	
IB/0019	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)	31/08/2021	n/a		
IB/0018	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/01/2021	n/a		

IAIN/0017	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/10/2020	19/10/2021	SmPC and PL	
PSUSA/10759 /201908	Periodic Safety Update EU Single assessment - infliximab	17/04/2020	n/a		PRAC Recommendation - maintenance
IB/0014	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	16/01/2020	15/10/2020	SmPC and PL	
IB/0015	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	18/12/2019	n/a		
IB/0013	B.I.z - Quality change - Active substance - Other variation	17/12/2019	n/a		
II/0011	Submission of the final study report of study GP11-301 including the results from treatment period 3, where all subjects continued to receive open-label Zessly (GP1111) treatment for an additional 24 weeks (Week 54 until Week 78). Study GP11-301 was a Phase 3 randomised, double-blind study assessing the efficacy, safety and immunogenicity of GP1111 and infliximab-EU in combination with methotrexate in patients with moderately to severely active rheumatoid arthritis	05/12/2019	n/a		The MAH has submitted complete comparative clinical safety and immunogenicity data up to week 78 together with a comprehensive analysis of the data in patients with RA. The treatment period 3 (TP3) relates to Week 54 onwards, where all patients received Zessly until the end of the treatment period at Week 78. Overall, there were no clinically meaningful differences between the three treatment groups in TP3. The treatment exposure, discontinuation, adverse event and laboratory value patterns are in line with what was reported from TP1

	who have had an inadequate response to methotrexate. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				and TP2. Also immunogenicity data post week 54 to week 78 were similar between treatment groups. No update to the product information was therefore considered necessary.
II/0009/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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	24/10/2019	n/a		
IB/0010/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	14/10/2019	15/10/2020	SmPC, Annex II, Labelling and PL	

	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/0007	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	14/06/2019	n/a		
IB/0008	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	10/05/2019	04/10/2019	SmPC and PL	
IA/0006	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	05/04/2019	n/a		
IB/0005	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	13/02/2019	04/10/2019	SmPC, Labelling and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0004/G	This was an application for a group of variations. 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.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	20/12/2018	n/a		
IB/0003	B.I.z - Quality change - Active substance - Other variation	30/10/2018	n/a		
IB/0002	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	12/10/2018	04/10/2019	SmPC and PL	
IB/0001/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	11/10/2018	04/10/2019	SmPC 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				