Erelzi

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
PSUSA/10795 /202302	Periodic Safety Update EU Single assessment - etanercept	12/10/2023	11/12/2023		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10795/202302.
IB/0050	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	08/12/2023		SmPC, Annex II, Labelling	

[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).

	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			and PL	
IB/0048	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/08/2023	n/a		
IAIN/0049/G	This was an application for a group of variations. 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 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.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 A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	01/08/2023	11/12/2023	Annex II and PL	

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)				
IB/0046/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.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	04/05/2023	n/a		
IB/0045	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	17/02/2023	n/a		

IB/0043	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	08/09/2022	17/07/2023	SmPC and PL	
II/0042/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	21/07/2022	17/07/2023	SmPC and PL	The SmPC section 6.5 has been updated to include the new syringe, autoinjector and describe the needle shield. Editorial changes are also made to section 3, pharmaceutical form, of the SmPC to bring it in line with the current QRD template version. The Package Leaflet (PL) is updated accordingly.
WS/2271/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting	21/07/2022	n/a		

	material/intermediate				
II/0040/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.e - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of an in-process test which may have a significant effect on the overall quality of the AS	21/07/2022	n/a		
IA/0039	B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	20/04/2022	n/a		
R/0037	Renewal of the marketing authorisation.	27/01/2022	04/04/2022	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Erelzi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0038/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.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	13/01/2022	n/a		

IB/0036	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	24/06/2021	n/a		
IB/0035/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	12/05/2021	19/10/2021	SmPC and PL	
IB/0034	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)	18/02/2021	n/a		
IAIN/0033/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.3.a - Change(s) in the SPC, Labelling or PL	30/10/2020	19/10/2021	SmPC and PL	

	intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority				
IB/0032	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	09/10/2020	19/10/2021	SmPC, Annex II, Labelling and PL	
PSUSA/10795 /202002	Periodic Safety Update EU Single assessment - etanercept	03/09/2020	n/a		PRAC Recommendation - maintenance
IAIN/0031	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	28/08/2020	n/a		
IB/0030	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	03/08/2020	30/09/2020	Annex II	
IB/0029/G	This was an application for a group of variations. 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 B.II.f.1.e - Stability of FP - Change to an approved stability protocol	15/07/2020	30/09/2020	SmPC	

IA/0028	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/06/2020	n/a		
IAIN/0026	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	10/04/2020	n/a		
IA/0025	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	18/03/2020	n/a		
II/0024/G	This was an application for a group of variations. 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.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	12/03/2020	n/a		

IB/0022	B.IV.1.z - Change of a measuring or administration device - Other variation	28/01/2020	n/a		
IB/0023	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/12/2019	n/a		
PSUSA/10452 /201901	Periodic Safety Update EU Single assessment - etanercept (biosimilars)	19/09/2019	14/11/2019	SmPC and PL	Please refer to Benepali Erelzi EMEA/H/C/PSUSA/00010452/201901 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0021	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	08/10/2019	30/09/2020	SmPC, Annex II, Labelling and PL	
II/0018	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	26/09/2019	n/a		
IA/0020	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)	14/06/2019	n/a		
IB/0019	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	16/05/2019	14/11/2019	SmPC, Labelling and PL	

	new additional data is required to be submitted by the MAH				
IA/0017	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	10/05/2019	n/a		
IB/0015	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	12/04/2019	n/a		
IA/0014/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.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.III.2.c - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.	28/03/2019	n/a		
IB/0013	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/02/2019	n/a		

PSUSA/10452 /201807	Periodic Safety Update EU Single assessment - etanercept (biosimilars)	14/02/2019	n/a		PRAC Recommendation - maintenance
IA/0012	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	04/01/2019	n/a		
PSUSA/10452 /201801	Periodic Safety Update EU Single assessment - etanercept (biosimilars)	06/09/2018	n/a		PRAC Recommendation - maintenance
IA/0010	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/09/2018	n/a		
IB/0009/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.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	30/07/2018	n/a		
IB/0008/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.c - Change to in-process tests or limits	30/05/2018	n/a		

	applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test 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/0006	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	28/03/2018	11/07/2018	SmPC and PL	
II/0005/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	01/02/2018	n/a		

	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
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	17/11/2017	11/07/2018	SmPC and PL	
IB/0003	B.II.z - Quality change - Finished product - Other variation	10/10/2017	n/a		
IB/0002/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	10/10/2017	n/a		
IB/0001/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within 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	28/07/2017	11/07/2018	SmPC, Labelling and PL	

	the range of the currently approved pack sizes				