

## Zercepac

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
PSUSA/3010/202409	Periodic Safety Update EU Single assessment - trastuzumab	08/05/2025	n/a		PRAC Recommendation - maintenance
R/0039	Renewal of the marketing authorisation.	30/01/2025	04/04/2025		
IB/0040/G	This was an application for a group of variations.	03/12/2024	n/a		

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	<p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p>				
IB/0038	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/11/2024	n/a		
IB/0036/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product</p> <p>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</p>	27/09/2024	04/04/2025	SmPC and Labelling	

IA/0037	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	07/08/2024	n/a		
N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2024	04/04/2025	PL	
IB/0033	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/06/2024	n/a		
IA/0034/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	04/06/2024	n/a		
IB/0032	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	07/12/2023	n/a		
IB/0031/G	This was an application for a group of variations.	10/11/2023	n/a		

	<p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p>				
IB/0030/G	<p>This was an application for a group of variations.</p> <p>B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation</p> <p>B.I.a.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation</p>	12/09/2023	n/a		
II/0021	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	31/08/2023	n/a		
IA/0029	A.7 - Administrative change - Deletion of manufacturing sites	10/07/2023		Annex II	
IB/0028/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.f.1.e - Stability of FP - Change to an approved stability protocol</p>	04/07/2023	n/a		

IB/0027	B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	16/05/2023	n/a		
IB/0026	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	17/03/2023	n/a		
IA/0025	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/02/2023		SmPC	
II/0022	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	19/01/2023	n/a		
II/0020	Submission of the final report from study HLX02-BC01 in order to fulfil REC/006. This is a double-blind, randomised, parallel-controlled, multicentre, international, phase 3 study to compare the efficacy, safety, and immunogenicity of HLX02 versus EU-sourced Herceptin in combination with docetaxel.  C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/01/2023	n/a		
IA/0024	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	16/12/2022	n/a		
IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	16/12/2022	n/a		

	site				
II/0016	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	24/11/2022	n/a		
PSUSA/3010/202109	Periodic Safety Update EU Single assessment - trastuzumab	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0019/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.e.z - Change in container closure system of the Finished Product - Other variation</p>	07/04/2022	n/a		
IB/0018	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	04/02/2022	n/a		
II/0015/G	<p>This was an application for a group of variations.</p> <p>B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs</p>	13/01/2022	n/a		

	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				
II/0013/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>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</p>	11/11/2021	31/10/2022	Annex II	
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	28/10/2021	15/11/2021	SmPC and PL	
IB/0012/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p>	17/09/2021	n/a		

IB/0011	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	09/08/2021	15/11/2021	SmPC and PL	To update sections 4.6, 6.6 of the SmPC to update the safety information following assessment of the same change for the reference product.
IAIN/0010/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  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)	14/07/2021	15/11/2021	Annex II and PL	
II/0008	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	20/05/2021	15/11/2021	SmPC, Labelling and PL	
IB/0006	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	15/02/2021	n/a		
II/0003	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use)	11/02/2021	15/11/2021	SmPC, Labelling and	

	parenteral medicinal products, including biological/immunological medicinal products			PL	
IB/0009/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p>	29/01/2021	n/a		
IB/0007/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p>	27/01/2021	n/a		
IB/0005	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)	27/01/2021	15/11/2021	SmPC and PL	

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	04/12/2020	15/11/2021	SmPC and PL	
IB/0002	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	25/11/2020	n/a		
IB/0001/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	06/11/2020	15/11/2021	SmPC	