Zercepac

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
IA/0029	A.7 - Administrative change - Deletion of manufacturing sites	10/07/2023		Annex II	
IB/0028/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test	04/07/2023	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

	period/storage period or storage conditions - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol				
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 -	16/12/2022	n/a		

	Replacement/addition of a site where batch control/testing takes place				
IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/12/2022	n/a		
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	This was an application for a group of variations. 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 B.II.e.z - Change in container closure system of the Finished Product - Other variation	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	This was an application for a group of variations. 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 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	13/01/2022	n/a		
II/0013/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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	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	This was an application for a group of variations.	17/09/2021	n/a		

	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				
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) parenteral medicinal products, including biological/immunological medicinal products	11/02/2021	15/11/2021	SmPC, Labelling and PL	
IB/0009/G	This was an application for a group of variations. 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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process 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	29/01/2021	n/a		
IB/0007/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	27/01/2021	n/a		

	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
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	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	06/11/2020	15/11/2021	SmPC	