



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

KANJINTI

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
R/0022	Renewal of the marketing authorisation.	15/12/2022	03/02/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of KANJINTI in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

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).



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.f.1.e - Stability of FP - Change to an approved stability protocol B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - 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	02/12/2021	n/a		
IB/0020/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	18/11/2021	16/12/2021	SmPC and PL	

IB/0018	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	23/08/2021	16/12/2021	SmPC and PL	To update sections 4.6 and 6.6 of the SmPC and healthcare professionals information of the PL to update section of Fertility, pregnancy and lactation, for clarity purposes and Special precautions for disposal and other handling, to provide clarity, following assessment of the same change for the reference product
IB/0017	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	15/01/2021	16/12/2021	SmPC, Annex II, Labelling and PL	
IB/0016	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	18/12/2020	n/a		
IB/0015	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	29/06/2020	n/a		
IA/0014	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	19/12/2019	n/a		
IB/0013	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)	06/11/2019	27/10/2020	SmPC and PL	

PSUSA/3010/201809	Periodic Safety Update EU Single assessment - trastuzumab	29/05/2019	25/07/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/3010/201809.
IA/0012	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	26/04/2019	n/a		
IB/0010	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	25/04/2019	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/04/2019	25/07/2019	PL	
IB/0009	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	15/03/2019	n/a		
IB/0008	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	07/02/2019	n/a		
II/0006/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	17/01/2019	25/07/2019	Annex II	

	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.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				
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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	14/09/2018	25/07/2019	SmPC and PL	
IB/0003	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	31/08/2018	n/a		
IAIN/0004	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	17/08/2018	25/07/2019	Annex II and PL	
IB/0002/G	This was an application for a group of variations. B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other	20/07/2018	25/07/2019	SmPC	

	variation B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
IB/0001	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	13/07/2018	n/a		