Trazimera

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
IAIN/0021	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	12/01/2024		Annex II and PL	
R/0020	Renewal of the marketing authorisation.	26/01/2023	20/03/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

[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).

					Trazimera in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0019	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	17/10/2022	20/03/2023	SmPC	
PSUSA/3010/ 202109	Periodic Safety Update EU Single assessment - trastuzumab	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0017/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	22/11/2021	20/12/2021	SmPC, Annex II and PL	
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/10/2021	20/12/2021	PL	
IB/0014	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/03/2021	20/12/2021	SmPC and PL	

IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	05/03/2021	20/12/2021	Annex II and PL	
IB/0013	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	11/01/2021	20/12/2021	SmPC and PL	
II/0011	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	05/03/2020	22/01/2021	Annex II	
IB/0010	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)	04/02/2020	22/01/2021	SmPC and PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2019	22/01/2021	PL	
IA/0009/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 B.II.e.3.a - Change in test procedure for the	11/10/2019	n/a		

	immediate packaging of the finished product - Minor changes to an approved test procedure				
PSUSA/3010/ 201809	Periodic Safety Update EU Single assessment - trastuzumab	29/05/2019	31/07/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/3010/201809.
IB/0008	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	26/06/2019	n/a		
IB/0007	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	11/04/2019	31/07/2019	SmPC, Labelling and PL	
II/0005	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	14/03/2019	31/07/2019	SmPC, Labelling and PL	
II/0002	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	24/01/2019	n/a		
IB/0003	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a	30/10/2018	n/a		

	biological/immunological medicinal product				
IB/0004	B.I.z - Quality change - Active substance - Other variation	29/10/2018	n/a		
IAIN/0001	A.1 - Administrative change - Change in the name and/or address of the MAH	14/09/2018	31/07/2019	SmPC, Labelling and PL	