



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
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		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	14/03/2019		SmPC, Labelling and	

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).



	multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products			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 biological/immunological medicinal product	30/10/2018	n/a		
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		SmPC, Labelling and PL	