



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel Teva Generics B.V.

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/0010/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	21/10/2013		SmPC and PL	

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).



	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				
IB/0009/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 are 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 are submitted by the MAH	15/08/2013		SmPC, Annex II, Labelling and PL	
IAIN/0008	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/06/2013	n/a		
IB/0006/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 B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size	25/05/2012	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites				
IB/0007	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	26/03/2012	n/a	SmPC and PL	
IB/0005/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 B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	24/10/2011	n/a		
IB/0004	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	08/09/2011	n/a	SmPC	
IB/0002/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 are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	26/07/2011	n/a	SmPC and PL	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IA/0003	A.7 - Administrative change - Deletion of manufacturing sites	19/07/2011	n/a		
IB/0001	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 are submitted by the MAH	11/04/2011	n/a	SmPC, Annex II, Labelling and PL	To amend the SmPC and PIL texts in line with the texts recently approved for the innovator product Plavix to update sections 4.2 "Posology and method of administration", 4.4 "Special warnings and precautions for use", 4.5 "Interaction with other medicinal products and other forms of interaction" and 5.2 "Pharmacokinetic properties" of clopidogrel/acetylsalicylic acid (ASA) to include new information on the variability of response to clopidogrel due to either genetic variations of the CYP2C19 enzyme or concomitant use of drugs that inhibit the CYP2C19 enzyme such as proton pump inhibitor (PPI). In addition, section 4.8 has been amended with minor details on the CURE study. Additional changes have been added to the SmPC and Package Leaflet in order to bring it in line with the revised QRD template (version 7.3). Additionally, the MAH takes the opportunity to make the following changes: - EU numbers were included in section 8 of the SmPC and section 12 of the Labelling. - Annex II: version of the PhV system approved has been removed as per EMA requirement for CPs - PIL: the company name of the Teva local representatives in Austria and Germany has been updated. The MAH also takes the opportunity to propose some additional minor amendments in the translated PI texts in some languages which have been introduced in the

					translated PI texts due to readability and compliance with the innovator text and QRD.
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Medicinal product no longer authorised