EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel Acino Pharma

Procedural steps taken and scientific information after the authorisation

No	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 are submitted by the MAH To update section 4.2 "Posology and method of administration" and 5.1 "Pharmacodynamic properties" of clopidogrel SPC to include new paediatric information available for clopidogrel. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product.	22/07/2011	n/a	SPC	
IB/0006	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	29/04/2011	n/a	SPC, Annex II, PL	

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	of change(s) for which NO new additional data are submitted by the MAH To update the Summary of Product Characteristics (SmPC) and Package Leaflet 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) SPC 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) In addition, the deletion of DDPS number version and date was introduced in Annex IIB as requested by the EMA with the procedural announcement in October and November 2010. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product.				
WS/0052	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To add a new active substance manufacturer. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the	18/11/2010	18/11/2010		

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	AS that is supported by an ASMF				
WS/0053/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. - To change the genotoxic impurities specifications of the active substance; - To replace the current analytical method for the determination of genotoxic impurities acid in the active substance and finished product with a new one; - To change the genotoxic impurities specifications of the finished product. 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.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS, 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, B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range, B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	21/10/2010	21/10/2010		
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	06/08/2010	n/a	SPC, Labelling, PL	

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	of change(s) for which NO new additional data are submitted by the MAH To include information on the clopidogrel metabolism pathway, the role of CYP2C19 genetic polumorphism on clopidogrel variability of response and the potential interaction between clopidogrel and CYP2C19 inhibitors including some proton pump inhibitors. The MAH also took the oportunity to align with the originator products. Also, the date of marketing authorisation as well as the marketing authorization numbers were introduced.				
A20/0004	Pursuant to Article 20 of Regulation (EC) No 726/2004 of 31 March 2004, the European Commission requested on 18 March 2010, the opinion of the CHMP on measures necessary to ensure the quality of the above mentioned medicinal product further to GMP deficiencies of the API manufacturing site Glochem Industries Ltd. (Unit II). Article 20 Review	18/03/2010	29/03/2010		Please refer to the Assessment Report: Clopidogrel Acino Pharma-H-1172-A20-04-Assessment Report-Article 20
II/0003	To register a revised version of the ASMF for clopidogrel besilate from the existing active substance manufacturer, introducing changes in the manufacturing process of the active substance. Quality changes	21/01/2010	04/02/2010		
II/0002	To introduce a new active substance manufacturer. Quality changes	21/01/2010	04/02/2010		
IA/0001	07_a_Replacement/add. of manufacturing site: Secondary packaging site, 07_b_01_Replacement/add. of	14/10/2009	n/a		

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	manufacturing site: Primary packaging site - Solid forms				