EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel 1A 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/0005	Amendments are introduced into the product information, in accordance with the respective amendments to the reference product, to include information on the clopidogrel metabolism pathway, the role of CYP2C19 genetic polymorphism on clopidogrel variability of response and the potential interaction between clopidogrel and CYP2C19 inhibitors including some proton pump inhibitors. Additionally, some minor amendments were made to up-date the product information with regard to QRD and to clear out the differences in wording in comparison to the reference product.	06/08/2010	n/a	SPC, Labelling, 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
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).	18/03/2010	16/09/2010		Please refer to the Assessment Report: Clopidogrel 1A Pharma-H-1054-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		
IA/0001	07_a_Replacement/add. of manufacturing site: Secondary packaging site, 07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	25/08/2009	n/a		
IA/0002	08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	24/08/2009	n/a	SPC, Labelling, PL	