

Clopidogrel Hexal

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/0009	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	22/07/2011	n/a	SPC	
IB/0008	According to CHMP communication from 02 December 2010 amendments are introduced in the Summary of Product Characteristics (SmPC) and the Package Leaflet (PL) to update sections 4.2 "Posology and method of administration", 4.4 "Special warnings and precaution for use", 4.5 "Interaction with other medicinal products and other forms of interaction" and 5.2 "Pharmacokinetic	12/05/2011	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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	properties" of clopidogrel/acetylsalicylic acid (ASA) of the SmPC 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. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product. 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				
A20/0006	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 Hexal-H-1139-A20-06- Assessment Report-Article 20

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	Article 20 Review				
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	06/08/2010	n/a	SPC, Labelling, PL	
A20/0006	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 Hexal-H-1139-A20-06- Assessment Report-Article 20
II/0005	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	20/01/2010	03/02/2010		
II/0004	To introduce a new active substance manufacturer. Quality changes	20/01/2010	03/02/2010		

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IA/0003	07_a_Replacement/add. of manufacturing site: Secondary packaging site, 07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	11/09/2009	n/a		
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		