Clopidogrel Sandoz

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
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 active substance that is supported by an ASMF	18/11/2010	06/12/2010		
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.	21/10/2010	05/11/2010		

[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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	Harmonization of the active substance and finished product specifications of the genotoxic impurities between AS manufacturers and FP manufacturer. Additionally the analytical method used for the determination of genotoxic impurities has been changed. B.I.b.2.e - Change in test procedure for active substance or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate, 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 active substance, 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.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)				
IB/0010	C.I.2.a - Change in the SPC, Labelling or	06/08/2010	n/a	SPC, Labelling,	

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	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			PL	
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/06/2010	n/a	PL	
IA/0008	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/04/2010	n/a		
A20/0007	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 Sandoz-H-1174-A20-07-Assessment Report-Article 20
II/0004	To introduce a new active substance manufacturer. Quality changes	20/01/2010	09/02/2010		
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	09/02/2010		

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IA/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/01/2010	n/a		
IA/0001	07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms, 07_a_Replacement/add. of manufacturing site: Secondary packaging site	14/10/2009	n/a		
IA/0002	07_a_Replacement/add. of manufacturing site: Secondary packaging site, 07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	14/10/2009	n/a		
IA/0003	08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	13/10/2009	n/a	Annex II, PL	