EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel Teva Pharma

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/0027/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	18/12/2015	22/01/2016	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).

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	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 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 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/0026	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	28/05/2015	22/01/2016	SmPC and PL	
IB/0025/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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 originally approved batch	05/12/2014	n/a		

	size B.I.a.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size 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 originally approved batch size				
T/0024	Transfer of Marketing Authorisation	07/10/2014	21/10/2014	SmPC, Labelling and PL	Transfer of Marketing Authorisation fom Teva Pharma B.V. (Utrecht) and Teva B.V (Haarlem).
PSUSA/820/201311	Periodic Safety Update EU Single assessment - ACETYLSALICYLIC ACID, CLOPIDOGREL	10/07/2014	n/a		PRAC Recommendation - maintenance
R/0019	Renewal of the marketing authorisation.	20/03/2014	08/05/2014	SmPC and PL	The safety and efficacy of clopidogrel have been demonstrated by several large clinical studies. The MAH has submitted an Addendum to Clinical Overview (ACO) to provide details of the efficacy and safety of Clopidogrel Teva Pharma since its approval. In the CHMP's view the provided data do not change the overall knowledge about the beneficial effect and safety profile of clopidogrel when used in the approved indications. The beneficial effect of Clopidogrel Teva Pharma remains in line with that of the originator product (Plavix), and is considered positive.
IB/0023/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	24/04/2014	21/10/2014	SmPC and PL	

	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 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/0021	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	09/04/2014	n/a		
IB/0020	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	07/01/2014	08/05/2014	SmPC and PL	
IB/0018/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 generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	21/10/2013	08/05/2014	SmPC and PL	

	new additional data is required to be submitted by the MAH				
IB/0017/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	08/05/2014	SmPC, Annex II, Labelling and PL	
IB/0015/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 A.7 - Administrative change - Deletion of manufacturing sites	26/04/2012	n/a		
IB/0014	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	29/03/2012	25/10/2012	SmPC and PL	

IB/0013	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)	26/08/2011	n/a	SmPC	
IB/0011/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	26/07/2011	n/a	SmPC and PL	
IA/0012	A.7 - Administrative change - Deletion of manufacturing sites	19/07/2011	n/a		
IA/0010/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.b - Replacement or addition of a	01/07/2011	01/07/2011	SmPC, Annex II, Labelling and PL	

	manufacturing site for the FP - Primary packaging site B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
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	11/04/2011	n/a	SmPC, Annex II and PL	The MAH has applied 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 medicinai products and other forms of interaction" and 5.2 "Pharmacokinetic properties" of clopidogrel/acetyisalicylic 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). In addition to the amendments to update the PI texts in line with the innovator, the MAH propose the removal of the version number of the PhV system approved included in Annex II as per EMA requirement. The MAH would also like to take 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.
IB/0008	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	15/10/2010	n/a	Annex II and PL	
IB/0007/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	17/08/2010	n/a		
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 of change(s) for which NO new additional data are submitted by the MAH	06/08/2010	n/a	SmPC and PL	
II/0001	addition of alternative manufcture for an intermediate and change in manufacturer process of intermediate Change(s) to the manufacturing process for the active substance	17/12/2009	06/01/2010		

IB/0005	IB_18_Replacement of an excipient with a comparable excipient	23/12/2009	n/a	SmPC and PL	
IA/0004	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	26/11/2009	26/11/2009	SmPC, Labelling and PL	
T/0003	Transfer of Marketing Authorisation	30/09/2009	19/11/2009	SmPC, Labelling and PL	The Marketing Authorisation Holder was transferred from HCS bvba to Teva Pharma B.V.
IB/0002	IB_02_Change in the name of the medicinal product	20/10/2009	n/a	SmPC, Annex II, Labelling and PL	