EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel/Acetylsalicylic acid Teva

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
IA/0002	A.7 - Administrative change - Deletion of manufacturing sites	15/03/2016		Annex II and PL	
IAIN/0001	A.1 - Administrative change - Change in the name and/or address of the MAH	11/02/2016		SmPC, Labelling 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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