EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Possia

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/0343	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	17/01/2013	n/a		
WS/0342	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/01/2013	n/a		
WS/0317/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.	13/12/2012	n/a		

[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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	B.I.a.1.z Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.c.1.a Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.a.1.f Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
WS/0292	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.3 and 4.8 of the SmPC in order to add safety information regarding hypersensitivity including angioedema. The Package Leaflet was proposed to be updated in accordance.	20/09/2012	24/10/2012	SPC, Annex II, PL	Several events which could possibly be associated with hypersensitivity reactions coming from postmarketing and clinical trials experience were reported by the MAH. From the 75 cases reported 12 were considered serious and 3 were identified as possibly related to treatment with ticagrelor. These events included angioedema as adverse hypersensitivity event and were all retrieved from post-marketing experience. Based on these results the CHMP supported the inclusion of “hypersensitivity including angioedema” under frequency “uncommon” in section

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	In addition, the MAH took the opportunity to propose minor corrections in sections 4.8, 5.1 and 5.2 of the SmPC and to bring the PI in line with the latest QRD template version 8.0. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				4.8 of the SmPC.
IB/0007	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	13/07/2012	n/a		
WS/0260/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. -To introduce a change in the manufacturing process of the active substance. -To introduce a change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	21/06/2012	21/06/2012		
WS/0246	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	24/05/2012	24/05/2012		

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	-To introduce a change in the manufacturing process of the finished product. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation				
IG/0151/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	29/02/2012	n/a		
IA/0003	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	03/02/2012	n/a		
IG/0124/G	This was an application for a group of variations. C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	18/11/2011	n/a		
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As	17/10/2011	n/a	SPC, Annex II, PL	

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	packaged for sale (supported by real time data)				