



Ivabradine Anpharm

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
WS/1352/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation</p>	03/05/2018	n/a		

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).



	<p>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</p> <p>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p>				
WS/1180	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>Update of the RMP with current information on epidemiology, post-authorisation exposure and post authorisation studies status including the due date of the final study report for Ivabradine Drug Utilisation Study. The Annex II has been updated accordingly. In addition the MAH took the opportunity to align the PI with the latest QRD template 10.0 and introduce minor updates to the ADR terms.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>	11/01/2018		SmPC, Labelling and PL	
PSUSA/1799/ 201704	Periodic Safety Update EU Single assessment - ivabradine	30/11/2017	n/a		PRAC Recommendation - maintenance

PSUSA/1799/ 201604	Periodic Safety Update EU Single assessment - ivabradine	01/12/2016	n/a		PRAC Recommendation - maintenance
WS/0932/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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</p> <p>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</p> <p>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</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p>	07/07/2016	n/a		
IAIN/0004	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	06/07/2016	08/05/2017	Annex II	

WS/0914	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>Update of sections 4.4 and 5.1 of the SmPC in order to update the information on retinal safety. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 9.1.</p> <p>C.1.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>	28/04/2016	08/05/2017	SmPC, Annex II, Labelling and PL	In this variation the MAH updated the Product information to indicate that to date there is no evidence of a toxic effect of long-term ivabradine treatment on the retina.
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