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/2569	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	14/12/2023	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).

	authorisation, including the RMP - Other variation				
PSUSA/1799/202304	Periodic Safety Update EU Single assessment - ivabradine	30/11/2023	n/a		PRAC Recommendation - maintenance
IG/1674	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	06/11/2023	n/a		
IG/1670	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/10/2023	n/a		
IAIN/0017/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	27/01/2023	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/10/2021		PL	
PSUSA/1799/202004	Periodic Safety Update EU Single assessment - ivabradine	14/01/2021	n/a		PRAC Recommendation - maintenance
R/0014	Renewal of the marketing authorisation.	26/03/2020	20/05/2020		Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the benefit-risk balance of

					Ivabradine Anpharm in its approved indication(s) (please refer to the Summary of Product Characteristics) remains favourable and therefore the renewal of the marketing authorisation is recommended, subject to the conditions as detailed in Annex II. The renewal is recommended to be granted with unlimited validity.
WS/1641	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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)	11/07/2019	n/a		
N/0012	Notification Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/06/2019	20/05/2020	PL	
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	12/04/2019	n/a		
SW/0010		18/10/2018	07/01/2019	Annex II	The results of this DUS study showed an increase in adherence to the SmPC guidelines in the post-RMM period compared to the pre-RMM period. This increase in adherence was measured for all the four criteria under study. Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes

					to the conditions of the marketing authorisation were warranted.
PSUSA/1799/201804	Periodic Safety Update EU Single assessment - ivabradine	29/11/2018	n/a		PRAC Recommendation - maintenance
WS/1352/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. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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 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)	03/05/2018	n/a		
WS/1180	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of the RMP with current information on epidemiology, post-authorisation exposure and post	11/01/2018	07/01/2019	SmPC, Labelling and PL	

	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. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
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	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 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	07/07/2016	n/a		

	corresponding test method 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
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	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 4.4 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. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	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.