Ivabradine Accord

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/0017	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	05/10/2023	n/a		
II/0016/G	This was an application for a group of variations.	31/08/2023		SmPC, Annex	The SmPC section 6.4, Annex II, IIIA and IIIB have been

[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).

	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF A.7 - Administrative change - Deletion of manufacturing sites			II, Labelling and PL	updated as follows: • change in storage conditions of the finished product from 'This medicinal product does not require any special storage conditions' to 'Store below 30°C' • Wessling Hungary Kft. Anonymus u. 6., Budapest, 1045, Hungary was removed as manufacturer responsible for batch release site of the finished product
IA/0015	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	22/04/2022	n/a		
IA/0014	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	22/04/2022	n/a		
IB/0013	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	01/03/2022	23/02/2023	SmPC, Labelling and PL	
R/0010	Renewal of the marketing authorisation.	16/12/2021	14/02/2022	SmPC, Labelling and PL	
IA/0012	A.7 - Administrative change - Deletion of manufacturing sites	06/01/2022	23/02/2023	Annex II and PL	

IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	20/10/2021	n/a		
IA/0009	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	27/07/2021	n/a		
IB/0008	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	15/03/2021	n/a		
IB/0007/G	This was an application for a group of variations. 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 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 B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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	06/11/2020	n/a		

	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) 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) B.I.c.1.z - Change in immediate packaging of the AS - Other variation 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				
IB/0006	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	22/01/2020	n/a		
IA/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/11/2019	n/a		
IAIN/0004/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	13/02/2019	04/02/2020	Annex II and PL	

	site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
T/0003	Transfer of Marketing Authorisation	18/01/2019	06/02/2019	SmPC, Labelling and PL	
IAIN/0002	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	05/04/2018	n/a		
IB/0001	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	23/03/2018	06/02/2019	SmPC and PL	