Posaconazole AHCL

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
IB/0014	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	08/11/2024		SmPC and PL	
R/0011	Renewal of the marketing authorisation.	22/02/2024	09/04/2024	SmPC, Annex	Based on the review of data on quality, safety and efficacy,

[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).

				II and PL	the CHMP considered that the benefit-risk balance of Posaconazole AHCL in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0012/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation 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	08/02/2024	09/04/2024	SmPC, Labelling and PL	
IA/0010/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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)	09/10/2023	29/02/2024	Annex II and PL	
IA/0008	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	21/12/2022	29/02/2024	SmPC	
IB/0007/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	01/08/2022	29/02/2024	SmPC and PL	

	authorisation, including the RMP - Other variation 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 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				
IA/0006	A.7 - Administrative change - Deletion of manufacturing sites	31/01/2022	15/07/2022	Annex II and PL	
IB/0005/G	This was an application for a group of variations. 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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	26/01/2022	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites				
IAIN/0004	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	19/10/2021	15/07/2022	SmPC and PL	
IB/0003	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	11/08/2021	15/07/2022	SmPC and PL	To update section 4.8 of the SmPC in line with the reference product with 'pseudoaldosteronism' as an adverse event in post-marketing experience, following a review of six case reports in the scientific literature of concurrent hypertension and hypokalemia in patients treated with posaconazole.
IA/0002	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	12/12/2019	n/a		
II/0001	B.I.z - Quality change - Active substance - Other variation	05/12/2019	n/a		