Artesunate Amivas

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/0016	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	25/06/2024		SmPC	
IB/0015	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	25/04/2024	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).

IA/0013/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	06/03/2024	n/a		
II/0011	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	11/01/2024	n/a		
PSUSA/10958 /202306	Periodic Safety Update EU Single assessment - artesunate	11/01/2024	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/11/2023		Labelling	
PSUSA/10958 /202212	Periodic Safety Update EU Single assessment - artesunate	20/07/2023	05/10/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10958/202212.
IAIN/0009	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	04/10/2023		Annex II and PL	

IAIN/0007	A.1 - Administrative change - Change in the name and/or address of the MAH	16/08/2023		SmPC, Labelling and PL	
II/0004	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	06/07/2023	05/10/2023	SmPC	
IB/0005	C.z - Safety, Efficacy, Pharmacovigilance changes - Other variation	03/07/2023	n/a		
IB/0006	B.I.b.z - Change in control of the AS - Other variation	16/06/2023	n/a		
IB/0002	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/03/2023	04/04/2023		
PSUSA/10958 /202206	Periodic Safety Update EU Single assessment - artesunate	12/01/2023	n/a		PRAC Recommendation - maintenance