ARIKAYCE liposomal

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
R/0014	Renewal of the marketing authorisation.	27/03/2025	02/06/2025	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of ARIKAYCE liposomal in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

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PSUSA/10882 /202409	Periodic Safety Update EU Single assessment - amikacin (centrally authorised product only)	08/05/2025	n/a		PRAC Recommendation - maintenance
IA/0013/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	04/10/2024	n/a		
PSUSA/10882 /202309	Periodic Safety Update EU Single assessment - amikacin (centrally authorised product only)	11/04/2024	n/a		PRAC Recommendation - maintenance
IA/0012	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	10/04/2024	n/a		
PSUSA/10882 /202209	Periodic Safety Update EU Single assessment - amikacin (centrally authorised product only)	26/04/2023	29/06/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10882/202209.
II/0008/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.e - Change in the specification parameters	20/10/2022	n/a		

	and/or limits of the finished product - Change outside the approved specifications limits range				
IB/0007/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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	31/05/2022	n/a		

	specification parameter to the specification with its corresponding test method B.I.c.z - Container closure system of the AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
PSUSA/10882 /202109	Periodic Safety Update EU Single assessment - amikacin (centrally authorised product only)	05/05/2022	n/a		PRAC Recommendation - maintenance
IB/0005	C.z - Safety, Efficacy, Pharmacovigilance changes - Other variation	20/10/2021	14/10/2022	SmPC, Labelling and PL	
IA/0004	A.7 - Administrative change - Deletion of manufacturing sites	24/08/2021	n/a		
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/07/2021	n/a		
IA/0001/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.7 - Administrative change - Deletion of manufacturing sites	01/06/2021	n/a		