Arsenic trioxide 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/0012	A.7 - Administrative change - Deletion of manufacturing sites	03/12/2024		Annex II and PL	
R/0009	Renewal of the marketing authorisation.	25/07/2024	19/09/2024		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Arsenic trioxide Accord in the approved indication remains

[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).

					favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/07/2024	19/09/2024	PL	
IB/0008/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 B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - 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 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.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	28/06/2022	n/a		
IB/0007	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	10/05/2022	23/05/2023	SmPC and PL	

	the MAH				
IB/0006	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)	03/05/2022	23/05/2023	SmPC	
IB/0005	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	01/04/2021	21/06/2021	SmPC, Annex II, Labelling and PL	
IB/0004	B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	24/08/2020	21/06/2021	SmPC and PL	
IB/0002	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/08/2020	n/a		
IAIN/0003	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	17/06/2020	21/06/2021	Annex II and PL	