



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Klisyri

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/0021	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	24/09/2024	n/a		
IB/0020	C.I.11.z - Introduction of, or change(s) to, the	17/09/2024	17/09/2025	Annex II	

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).



	obligations and conditions of a marketing authorisation, including the RMP - Other variation				
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/08/2024	17/09/2025	PL	
II/0014/G	This was an application for a group of variations. 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 B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	25/07/2024	n/a		
PSUSA/10943 /202312	Periodic Safety Update EU Single assessment - tirbanibulin	11/07/2024	n/a		PRAC Recommendation - maintenance
IA/0018/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	09/05/2024	n/a		

	product - Minor changes to an approved test procedure				
IB/0017/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate 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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/04/2024	n/a		
IA/0015	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/02/2024	n/a		
PSUSA/10943/202306	Periodic Safety Update EU Single assessment - tirbanibulin	11/01/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10943/202212	Periodic Safety Update EU Single assessment - tirbanibulin	06/07/2023	n/a		PRAC Recommendation - maintenance
IAIN/0012	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/07/2023	n/a		

IA/0011	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	11/05/2023	n/a		
IB/0009/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	24/03/2023	n/a		

	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation				
PSUSA/10943 /202206	Periodic Safety Update EU Single assessment - tirbanibulin	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0007/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol 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	05/01/2023	n/a		
IA/0008	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	22/12/2022	n/a		
PSUSA/10943 /202112	Periodic Safety Update EU Single assessment - tirbanibulin	07/07/2022	n/a		PRAC Recommendation - maintenance
IAIN/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	01/06/2022	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	17/02/2022	n/a		

	site				
IB/0002	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)	18/01/2022	13/01/2023	SmPC	
IAIN/0001	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	12/11/2021	n/a		