Tigecycline Accord

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IA_IN /	This was an application for a group of	25/09/2025		Annex II and	

[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).

EMA/VR/0000300796	variations. B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted			PL	
Variation type IB / EMA/VR/0000285855	This was an application for a group of variations. B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.b.2 Change in test procedure for active	31/07/2025	N/A		

	substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted				

Variation type IB / EMA/VR/0000273034	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Implementation of an agreed wording, no new data submitted - Accepted C.I.z - To update section 5.1 of the SmPC in line with the "Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections" published on the EMA website. Furthermore, the MAH has taken the opportunity to update section 9 of the SmPC with the date of latest renewal: 25 November 2024. In addition, the MAH has taken the opportunity to update the details of the local representative for Greece in the package leaflet.	05/06/2025		SmPC and PL	
Variation type IA / EMA/VR/0000265607	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	15/04/2025	N/A		
Variation type IA / EMA/VR/0000244119	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Refused	23/01/2025	N/A		
