Xerava

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 IB /	C.9 Introduction of, or change(s) to, the	13/03/2026			

[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/0000327434	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) - To provide an updated RMP (version 4.1) to update the indication to include use in adolescents (12 - 17 years) throughout the RMP as agreed during Type II variation EMA/VR/0000265697. - To update routine risk minimisation measures to reflect the newly approved SmPC wording on paediatric indication. - To update Part II Module SIII to include the ongoing Phase 2 clinical study CS434-2023-001 to evaluate the safety and tolerability of intravenous eravacycline in children from 8 years to less than 18 years with complicated intra-abdominal infections (cIAI). - To update the milestones with a footnote that both the study completion and final report for the Category 3 Study-NC-IHMA-2018-01 will be submitted in Q2 2026. - To update the name of the MAH.				

Variation type II / EMA/VR/0000265697	C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension of indication to include treatment of complicated intra-abdominal infections (cIAI) from the age of 12 years weighing at least 50 kg for XERAVA, based on final results from study TP-434-028; this is a phase 1, open-label, multicenter study to determine the pharmacokinetics and safety of intravenous eravacycline in children with suspected or confirmed bacterial infection. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.4.	13/11/2025	18/12/2025	SmPC and PL	Please refer to Scientific Discussion 'Xerava-H-C-004237-VR/0000265697'
Variation type IA / EMA/VR/0000308231	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	28/10/2025			
Variation type IB / EMA/VR/0000285584	This was an application for a group of variations.	25/07/2025			

	B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative and/or quantitative composition - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				

Variation type IA / EMA/VR/0000252170	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted	17/02/2025			