Xerava

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
T/0028	Transfer of Marketing Authorisation	26/09/2024	24/10/2024	SmPC, Labelling and PL	
IAIN/0027	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	20/08/2024	24/10/2024	Annex II and PL	

[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).

	responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10718 /202308	Periodic Safety Update EU Single assessment - eravacycline	25/04/2024	20/06/2024	PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10718/202308.
IB/0026/G	This was an application for a group of variations. 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.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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	03/06/2024	n/a		
IAIN/0024	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 -	11/05/2023	29/04/2024	Annex II and PL	

	Not including batch control/testing				
R/0023	Renewal of the marketing authorisation.	23/02/2023	12/04/2023	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 Xerava in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10718 /202208	Periodic Safety Update EU Single assessment - eravacycline	16/03/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10718 /202202	Periodic Safety Update EU Single assessment - eravacycline	29/09/2022	n/a		PRAC Recommendation - maintenance
IB/0021/G	This was an application for a group of variations. B.II.b.z - Change in manufacture of the Finished Product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	21/07/2022	n/a		
IA/0020/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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	30/05/2022	n/a		

	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 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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10718 /202108	Periodic Safety Update EU Single assessment - eravacycline	10/03/2022	n/a		PRAC Recommendation - maintenance
IB/0017/G	This was an application for a group of variations. B.I.d.1.z - Stability of AS - Change in the re-test	26/10/2021	n/a		

	period/storage period or storage conditions - Other variation 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				
PSUSA/10718 /202102	Periodic Safety Update EU Single assessment - eravacycline	30/09/2021	n/a		PRAC Recommendation - maintenance
II/0012	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/07/2021	29/06/2022	SmPC	
IAIN/0016/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes 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	09/06/2021	29/06/2022	SmPC, Annex II, Labelling and PL	
IAIN/0015	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	10/05/2021	n/a		
T/0013	Transfer of Marketing Authorisation	08/04/2021	16/04/2021	SmPC, Labelling and	

				PL	
PSUSA/10718 /202008	Periodic Safety Update EU Single assessment - eravacycline	11/03/2021	n/a		PRAC Recommendation - maintenance
X/0009	Annex I_2.(c) Change or addition of a new strength/potency	10/12/2020	11/02/2021	SmPC, Annex II, Labelling and PL	
PSUSA/10718 /202002	Periodic Safety Update EU Single assessment - eravacycline	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0008	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	27/03/2020	n/a		
PSUSA/10718 /201908	Periodic Safety Update EU Single assessment - eravacycline	12/03/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10718 /201902	Periodic Safety Update EU Single assessment - eravacycline	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0006	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	06/06/2019	n/a		
IB/0004	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)	25/04/2019	28/02/2020	SmPC	
IB/0003	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	15/04/2019	n/a		

	re-test period/storage period supported by real time data				
IB/0002	B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue	28/03/2019	n/a		
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	04/03/2019	28/02/2020	SmPC, Labelling and PL	