Ontozry

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
IB/0024	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/04/2024	n/a		
PSUSA/10921 /202309	Periodic Safety Update EU Single assessment - cenobamate	11/04/2024	n/a		PRAC Recommendation - maintenance

[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).

PSUSA/10921 /202303	Periodic Safety Update EU Single assessment - cenobamate	09/11/2023	12/01/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10921/202303.
IA/0020/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 product - Minor changes to an approved test procedure	27/11/2023	n/a		
IB/0019	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	31/07/2023	n/a		
IB/0018	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)	27/06/2023	05/10/2023	SmPC	
IB/0016/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation A.7 - Administrative change - Deletion of manufacturing sites	13/06/2023	n/a		
PSUSA/10921 /202209	Periodic Safety Update EU Single assessment - cenobamate	14/04/2023	n/a		PRAC Recommendation - maintenance

IB/0015	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	17/02/2023	n/a		
IB/0014/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/02/2023	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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 B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
PSUSA/10921 /202203	Periodic Safety Update EU Single assessment - cenobamate	27/10/2022	n/a		PRAC Recommendation - maintenance
IA/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	22/09/2022	n/a		
IB/0011	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	26/07/2022	n/a		
II/0009	Update of section 5.3 of the SmPC in order to update information on toxicity to reproduction and development based on final results from nonclinical study "Effects of Cenobamate (YKP3089) on Embryo-	07/07/2022	05/10/2023	SmPC	

	Fetal Development in Rats after Twice Daily Oral Administration". The RMP version 3.0 has been agreed. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10921 /202109	Periodic Safety Update EU Single assessment - cenobamate	05/05/2022	n/a		PRAC Recommendation - maintenance
IAIN/0007/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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	27/01/2022	n/a		
IB/0005/G	This was an application for a group of variations. B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter wit its	05/01/2022	n/a		

	corresponding test method as a result of a safety or quality issue B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IA/0006	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	15/12/2021	n/a		
T/0003	Transfer of Marketing Authorisation	11/10/2021	28/10/2021	SmPC, Labelling and PL	
IAIN/0002/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	07/07/2021	28/10/2021	Annex II and PL	
IAIN/0001	A.1 - Administrative change - Change in the name and/or address of the MAH A.1 - Administrative change - Change in the name and/or address of the MAH	12/05/2021	28/10/2021	SmPC, Labelling and PL	