Namuscla

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/0017	A.7 - Administrative change - Deletion of manufacturing sites	07/10/2024	n/a		
IA/0016/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or	02/10/2024	n/a		

[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).

	deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
R/0014	Renewal of the marketing authorisation.	22/06/2023	09/08/2023		Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the benefit-risk balance of Namuscla in its approved indication(s) (please refer to the Summary of Product Characteristics) remains favourable and therefore the renewal of the marketing authorisation is recommended, subject to the conditions as detailed in Annex II. The renewal is recommended to be granted with unlimited validity.
PSUSA/10738 /202212	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	06/07/2023	n/a		PRAC Recommendation - maintenance
IA/0015	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	12/05/2023	n/a		
IB/0012	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	20/02/2023	09/08/2023	Annex II	

IB/0011	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/11/2022	n/a		
PSUSA/10738 /202112	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	07/07/2022	n/a		PRAC Recommendation - maintenance
IA/0010/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	10/05/2022	n/a		
IA/0009/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved	02/05/2022	n/a		

	manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
PSUSA/10738 /202012	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	08/07/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10738 /202006	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	14/01/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10738 /201912	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	09/07/2020	n/a		PRAC Recommendation - maintenance
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/06/2020	n/a		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/04/2020	13/07/2020	PL	
PSUSA/10738 /201906	Periodic Safety Update EU Single assessment - mexiletine (centrally authorised products only)	16/01/2020	n/a		PRAC Recommendation - maintenance
IAIN/0001/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	17/07/2019	13/07/2020	Annex II and PL	

	manufacturing sites B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer				