Nyxoid

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
IG/1593	A.1 - Administrative change - Change in the name and/or address of the MAH	24/02/2023		SmPC, Labelling and PL	
PSUSA/10657 /202205	Periodic Safety Update EU Single assessment - naloxone (for use in non-medical settings)	12/01/2023	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).

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IA/0016	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)	11/11/2022	n/a		
R/0014	Renewal of the marketing authorisation.	21/07/2022	15/09/2022	SmPC, Annex II, Labelling and PL	
IB/0013	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/12/2021	03/02/2022	Annex II and PL	
IA/0012	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	09/07/2021	n/a		
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	05/02/2021	03/02/2022	Annex II and PL	
PSUSA/10657 /202005	Periodic Safety Update EU Single assessment - naloxone (for use in non-medical settings)	26/11/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10657 /201905	Periodic Safety Update EU Single assessment - naloxone (for use in non-medical settings)	16/01/2020	n/a		PRAC Recommendation - maintenance
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/11/2019	09/03/2020	PL	

IB/0008	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/09/2019	n/a		
IAIN/0006	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	05/04/2019	09/03/2020	Annex II and PL	
IB/0005/G	This was an application for a group of variations. B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	11/03/2019	09/03/2020	SmPC and PL	
PSUSA/10657 /201805	Periodic Safety Update EU Single assessment - naloxone (for use in non-medical settings)	17/01/2019	n/a		PRAC Recommendation - maintenance
T/0004	Transfer of Marketing Authorisation	25/10/2018	22/11/2018	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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/03/2018	n/a		

	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 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				
IB/0001	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	10/01/2018	22/11/2018	SmPC	