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
II/0019	Update of Annex II.D (conditions or restrictions with regard to the safe and effective use of the medicinal product), based on the submission of the final study results of the imposed post-authorisation efficacy study MR903-9501; removal of this PAES from Annex II.D. Study MR903-9501 is	25/04/2025		Annex II and PL	Please refer to the Scientific Discussion of procedure No. EMEA/H/C/004325/II/0019

[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).

	a non-interventional multi-national, prospective, mixed methods study on the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose. This update is also supported by Real World Evidence (RWE) from literature and European Take-Home Naloxone (THN) programs demonstrating the effectiveness of Nyxoid in a real-world setting. The labelling and Package Leaflet are amended accordingly. The Risk Management Plan (RMP) is also revised to version 3.2. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
Variation type IA / EMA/VR/0000264680	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 - Refused	22/04/2025	N/A		
Variation type IA / EMA/VR/0000264075	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities	03/04/2025	N/A		

	for which the manufacturer/importer is responsible do not include batch release - Accepted				
Article 61(3) / EMA/N/0000253983	- Notification acc. Article 61(3) - Update of the package leaflet with revised contact details of local representatives.	25/03/2025		PL	
Variation type IA_IN / EMA/VR/0000247136	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	30/01/2025	N/A		