Nulojix

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	16/04/2026		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).

EMA/N/0000341345	Update of the package leaflet to introduce a list of local representatives.				
Variation type IB / EMA/VR/0000319121	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted 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 - Accepted	27/01/2026			
Variation type IA_IN / EMA/VR/0000310664	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	07/11/2025			
Variation type II / EMA/VR/0000278035	This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used	04/09/2025			

	in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where				

	no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted				
Variation type IB / EMA/VR/0000265587	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	28/05/2025			
Variation type IB / EMA/VR/0000247733	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	04/03/2025			
PSUR / EMA/PSUR/0000305012					Maintenance