



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Paxneury

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
Variation type IA_IN /	Outcome:	14/07/2026		SmPC and 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/VR/0000361407	Q.II.a.1 Change or addition of imprints, bossing (embossing/debossing) or other markings including replacement, or addition of inks used for product marking - Q.II.a.1.a) Changes in imprints, bossing (embossing/debossing) or other markings - Accepted				
Variation type IB / EMA/VR/0000278994	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	30/07/2025			
Variation type IB / EMA/VR/0000279172	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - to provide an updated Environmental Risk Assessment report.	20/06/2025			