



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enrylaze

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 IB /	Q.II.f.1.b) Extension of the shelf life of the	16/02/2026		SmPC	

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/0000326972	finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IB / EMA/VR/0000313532	<p>This was an application for a group of variations.</p> <p>B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted</p> <p>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.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted</p>	04/12/2025			
Variation type II / EMA/VR/0000290212	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.d Substantial change to or replacement of a biological/	20/11/2025			

	immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted				
Variation type IB / EMA/VR/0000286426	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	16/09/2025			
Variation type IB / EMA/VR/0000262831	<p>This was an application for a group of variations.</p> <p>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.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted</p> <p>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</p> <p>B.I.a.1 Change in the manufacturer of a</p>	23/06/2025			

<p>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.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted</p> <p>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted</p> <p>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active</p>				
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	<p>substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted</p>				
Variation type IA / EMA/VR/0000264646	<p>This was an application for a group of variations.</p> <p>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 for which the manufacturer/importer is responsible do not include batch release - Accepted</p> <p>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</p>	25/04/2025			
Variation type IA / EMA/VR/0000254057	<p>This was an application for a group of variations.</p> <p>A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance,</p>	04/03/2025			

starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Refused

A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Refused

B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Refused

B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Refused

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 for which the manufacturer/importer is responsible do not include batch release - Refused

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

B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Refused

B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Refused

B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Refused

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 - Refused

