Dyrupeg

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
Marketing Authorisation Transfer - H /	Outcome:	28/05/2026	12/06/2026	SmPC, Labelling and	

[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/T/0000344226	transfer of marketing authorisation from CuraTeQ Biologics s.r.o. to CuraTeQ Biologics (Malta) Limited			PL	
Variation type II / EMA/VR/0000326010	Outcome: This was an application for a group of variations. Q.II.b.4 Change in the batch size (including batch size ranges) of the finished product - Q.II.b.4.c) The change requires assessment of the comparability of a biological finished product or the change in batch size requires a new bioequivalence study - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a	16/04/2026			

	non-significant or obsolete in-process control - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a non-significant or obsolete in-process control - Accepted				
Variation type IB / EMA/VR/0000333463	Outcome: This was an application for a group of variations. Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.b) Addition or replacement of a batch control/testing site applying a biological/immunological/immunochemical analytical procedure for a biological finished product - Accepted	16/03/2026			
Variation type IA / EMA/VR/0000316341	Outcome: This was an application for a group of	10/12/2025			

	variations. 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 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 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 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 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 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				

	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) - Accepted B.II.c.3 Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination - Accepted				
Variation type IB / EMA/VR/0000296284	Outcome: This was an application for a group of variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation -	14/11/2025			

	Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation -				

	Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Withdrawn				
Variation type IB / EMA/VR/0000290219	Outcome: B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	20/08/2025			
Article 61(3) / EMA/N/0000290486	Outcome: - Notification acc. Article 61(3) - Accepted Update of the Package Leaflet, section 'Instructions for Use', for the medicinal product Dyrupeg 6 mg Solution for injection pre-filled syringe to provide clarity for healthcare professionals and to align with the approved label. Additionally, the MAH took the opportunity to introduce minor editorial changes, such as linguistic amendments and corrections, as well as updates to the list of local representatives.	11/08/2025	12/06/2026	PL	
Article 61(3) / EMA/N/0000271851	Outcome: - Notification acc. Article 61(3) - Accepted	12/05/2025	12/06/2026	PL	

	Update of the package leaflet with revised contact details of local representatives.				
Article 61(3) / EMA/N/0000267131	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet to introduce a list of local representatives and to add the manufacturer (batch release site) already present in Annex II to section '6. Contents of the pack and other information' of the package leaflet.	24/04/2025	12/06/2026	PL	