Zefylti

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/0000344196	transfer of marketing authorisation from CuraTeQ Biologics s.r.o. to CuraTeQ Biologics (Malta) Limited			PL	
Variation type IB / EMA/VR/0000333540	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	29/04/2026			
Variation type IB / EMA/VR/0000338323	Outcome: This was an application for a group of variations. Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the	14/04/2026			

	manufacturing process of the active substance - Q.I.b.2.a) Minor change to an analytical procedure for the active substance - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted				

	Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.c) Deletion of a non-significant or obsolete in-process control - Accepted				
Variation type IA / EMA/VR/0000322333	Outcome: This was an application for a group of	20/01/2026			

	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.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.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted				
Variation type IB / EMA/VR/0000296307	Outcome: C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a (Type IB) – To update Section 4.8 of the SmPC and Section 4 of the PL to add the adverse reaction 'Extramedullary haematopoiesis' with frequency 'Rare', following approval of the same change to the reference product, Neupogen. In addition, the MAH took the opportunity to implement editorial changes to align the address of the	26/09/2025	12/06/2026	SmPC, Annex II, Labelling and PL	To update Section 4.8 of the SmPC and Section 4 of the PL to add the adverse reaction 'Extramedullary haematopoiesis' with frequency 'Rare', following approval of the same change to the reference product, Neupogen.

	manufacturer of the biological active substance, listed in Annex II, with SPOR OMS, align the address of the MAH in Section 7 of the SmPC with the address in SPOR OMS, Labelling and PL, and implemented typographic and formatting corrections in line with the QRD template throughout the PI.				
Variation type IB / EMA/VR/0000291959	Outcome: B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	02/09/2025			
Article 61(3) / EMA/N/0000264207	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet to introduce a list of local representatives.	14/04/2025	12/06/2026	PL	