Vyjuvek

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 /	Outcome:	08/06/2026		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/0000343420	This was an application for a group of variations. Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted			Labelling and PL	
Variation type II / EMA/VR/0000284864	Outcome: 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	16/10/2025			
Variation type IA / EMA/VR/0000284675	Outcome: A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a	29/07/2025			

	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				
Variation type IA_IN / EMA/VR/0000281025	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	26/06/2025		Annex II and PL	
Variation type IA_IN / EMA/VR/0000278984	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	12/06/2025			