Vaxelis

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 / EMA/VR/0000296327	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted	29/09/2025	N/A		

[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).

Variation type II / EMA/VR/0000266450	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 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.f Change outside the approved specifications limits range for the active substance - 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.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3	18/09/2025		SmPC, Annex II, Labelling and PL	Section 2 of the SmPC, Annex IIIA, IIIB and Annex A are updated to reflect the dose of IPV components expressed in DU/ml obtained by the new optimized parallel line method. A footnote is added in the SmPC and Annex A to clarify that the actual quantity of D-antigen as such has not changed but that only the test method and read-out have changed. As indicated above, details of the antibiotic reduction will be updated later in a separate application closer to market implementation. Annex II is also implemented to reflect the change in name of a manufacturer of active substance. For more information, please refer to the Summary of Product Characteristics.

	Updated certificate from an already approved manufacturer - 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.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.z Other variation - 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.c.3 Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Other variation - Accepted 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 B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - 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.d Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted				
Variation type II / EMA/VR/0000280941	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.3 Extension of storage period of a biological/ immunological active substance not in accordance with an approved stability protocol - Accepted	11/09/2025	N/A		
Variation type IA / EMA/VR/0000288350	B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted	29/07/2025	N/A		
Variation type IA / EMA/VR/0000287287	B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted	21/07/2025	N/A		

Variation type II / EMA/VR/0000267802	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted	10/07/2025	N/A		
Variation type II / EMA/VR/0000264032	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	12/06/2025	N/A		

	in the manufacture of a biological/immunological product - Accepted				
Variation type IB / EMA/VR/0000258986	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	09/04/2025	N/A		
Variation type IB / EMA/VR/0000245751	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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	25/02/2025	N/A		
Variation type IB / EMA/VR/0000241029	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	13/01/2025	N/A		
Variation type IB / EMA/VR/0000241038	B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	07/01/2025	N/A		
Variation type IB / EMA/VR/0000238967	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z	13/12/2024	N/A		

	Other variation - Accepted				
Variation type IA / EMA/VR/0000237576	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	09/12/2024	N/A		
Variation type IB / EMA/VR/0000234644	B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	21/11/2024	N/A		