Vaxchora

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:	09/07/2026		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/0000351203	C.1 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a Union referral procedure - C.1.z Other variation - Accepted C.I.z – to update sections 1 and 3 in the SmPC, Labelling, the heading in the Package Leaflet as well as section 6 according to the revised EDQM standard terms for pharmaceutical forms. The pharmaceutical form has been updated as follows: from "Effervescent powder and powder for oral suspension", to "Powder and effervescent powder for oral suspension". In addition, the MAH took the opportunity to apply minor terminology alignments in the Package Leaflet of the Swedish and Hungarian annexes to ensure consistency across the product information and with the approved English version.			Labelling and PL	
Variation type IB / EMA/VR/0000315467	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.f Changes to quality control testing arrangements for the	19/12/2025			

	active substance-replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IB / EMA/VR/0000282352	Outcome: This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	23/09/2025		SmPC	
Variation type IA / EMA/VR/0000301162	Outcome: B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted	23/09/2025			
Article 61(3) / EMA/N/0000269332	Outcome: - Notification acc. Article 61(3) - Accepted Update of the Package Leaflet (no amendment to text) in line with results of readability user testing report.	04/06/2025			

PSUR / EMA/PSUR/0000296628	EURD: PSUSA/00010862/202506 Active substance: cholera vaccine, oral, live Outcome: Maintenance	15/01/2026			Maintenance