CAPVAXIVE

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 /		21/05/2026			

[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/0000338839	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.k) Addition or replacement of a storage site of the Master Cell Bank and/or Working Cell Banks - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted				
Variation type II / EMA/VR/0000294070		26/03/2026	30/04/2026	SmPC and PL	Please refer to Scientific Discussion

	Outcome: C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension of indication to include active immunization of children and adolescents 2 to less than 18 years of age for CAPVAXIVE, based on final results from study V116-013 (P013V116); this is a phase 3, randomized, double-blind study to evaluate the safety, tolerability, and immunogenicity of V116 in children and adolescents with increased risk of pneumococcal disease; as a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1, and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.				EMA/VR/0000294070
Variation type IA / EMA/VR/0000331985	Outcome: Q.II.e.3 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules) - Q.II.e.3.b Change that does not affect the product information - Accepted	23/02/2026			

Variation type IB / EMA/VR/0000305088	Outcome: B.II.g.4 Changes to an approved change management protocol - B.II.g.4.b Minor changes to an approved change management protocol that do not change the strategy defined in the protocol - Accepted	06/11/2025			
Variation type IB / EMA/VR/0000301373	Outcome: B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted	16/10/2025			
Variation type IB / EMA/VR/0000296295	Outcome: 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	06/10/2025	30/04/2026	SmPC and PL	To extend the shelf-life of the Capvaxive finished product in accordance with the approved stability protocol, from 30 to 36 months when stored in a refrigerator (2°C – 8°C).

Variation type IA / EMA/VR/0000285849	Outcome: B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted	28/07/2025			
Variation type IB / EMA/VR/0000281543	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products - Accepted	18/07/2025			
Variation type II / EMA/VR/0000267723	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the	10/07/2025	30/04/2026	SmPC and PL	SmPC new text - Section 4.8 Safety in adults with increased risk for pneumococcal disease An additional study, Protocol 008, was conducted to evaluate CAPVAXIVE in pneumococcal vaccine naïve adults 18 to 64 years of age with one or more prespecified chronic medical conditions known to

	Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.8 and 5.1 of the SmPC in order to update immunogenicity and safety information based on the final results from study V116-008 (EUCT: 2022-502791-22-01); this is a phase 3, randomized, double-blind, active comparator-controlled clinical study to evaluate the safety, tolerability, and immunogenicity of V116 in pneumococcal vaccine-naïve adults 18 to 64 years of age with increased risk for pneumococcal disease. In addition, the MAH took the opportunity to introduce editorial changes to the PI and to update the list of local representatives in the Package Leaflet.				increase the risk of pneumococcal disease. The safety profile of CAPVAXIVE was generally comparable to PCV15 followed by PPSV23 and generally similar to the profile observed in the pivotal studies. - Section 5.1 Adults with increased risk for pneumococcal disease Protocol 008 In a double-blind study, 518 individuals 18 to 64 years of age with one or more prespecified chronic medical conditions known to increase the risk of pneumococcal disease (diabetes mellitus, chronic heart disease, chronic kidney disease, chronic liver disease, or chronic lung disease) were randomised in a 3:1 ratio to receive either CAPVAXIVE followed by placebo 8 weeks later, or PCV15 followed by PPSV23 (PCV15+PPSV23) 8 weeks later. The study participants had not previously received any pneumococcal vaccines other than routine childhood PCVs. CAPVAXIVE was immunogenic for all 21 serotypes contained in the vaccine, as assessed by serotype specific OPA GMTs at 1 month postvaccination with CAPVAXIVE. CAPVAXIVE elicited immune responses that were generally comparable to PCV15+PPSV23 for the 13 common serotypes and higher for the 8 serotypes unique to CAPVAXIVE as assessed by OPA GMTs at 1 month postvaccination with CAPVAXIVE and 1 month postvaccination with PCV15+PPSV23. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000267597		10/06/2025	30/04/2026	SmPC and PL	

	Outcome: 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				
Variation type IA / EMA/VR/0000264668	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.a Tightening of in-process limits - Accepted	28/04/2025			
PSUR / EMA/PSUR/0000296567	EURD: PSUSA/00011121/202506 Active substance: pneumococcal polysaccharide conjugate vaccine (21-valent) Outcome: Maintenance	15/01/2026			Maintenance