Vaxneuvance

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/01/2025		PL	
IB/0027	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	05/11/2024	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).

IB/0026	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	13/09/2024	n/a		
PSUSA/10975 /202401	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)	05/09/2024	n/a		PRAC Recommendation - maintenance
IB/0025	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	03/09/2024	n/a		
IB/0024	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	17/07/2024	n/a		
IB/0023	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	03/07/2024	n/a		
IB/0022	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/06/2024	n/a		
II/0020	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	06/06/2024	n/a		
IB/0019/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging	16/02/2024	n/a		

	components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.1.z - Change in immediate packaging of the finished product - Other variation				
PSUSA/10975 /202307	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)	08/02/2024	n/a		PRAC Recommendation - maintenance
IB/0018	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	16/11/2023	22/11/2024	SmPC	
PSUSA/10975 /202301	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0016	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	14/08/2023	n/a		
IB/0014	B.IV.1.z - Change of a measuring or administration device - Other variation	28/04/2023	n/a		
II/0013/G	This was an application for a group of variations. Grouped application comprising two type II variations as follows:	30/03/2023	26/04/2023	SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

	- To update sections 4.2, 4.4, 4.8, 5.1 of the SmPC in order to add safety data on recipients of haematopoietic stem cell transplant (HSCT) based on final results from study V114-022, listed as a category 3 study in the RMP; This is a Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of Vaxneuvance in Recipients of Allogeneic Hematopoietic Stem Cell Transplant. - To update sections 4.2, 5.1 of the SmPC in order to update the information regarding a 3-dose regimen based on final results from study V114-026; a Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 3-dose Regimen of Vaxneuvance in Healthy Infants. The Package Leaflet is updated accordingly. The RMP version 3.0 (consolidated) has been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0011	To update sections 4.2 and 5.1 of the SmPC in order to update the information for immune response after subcutaneous administration based on final results from study V114-P033 (EudraCT: 2019-003644-68), in accordance with Article 46 of the paediatric regulation. V114-P033 is a phase 3 Active-Comparator controlled study to evaluate the Safety,	30/03/2023	26/04/2023	SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

	Tolerability, and Immunogenicity of V114 in Healthy Japanese Infants. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10975 /202207	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)	09/02/2023	n/a		PRAC Recommendation - maintenance
IB/0012	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	29/11/2022	n/a		
IA/0010	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/11/2022	n/a		
II/0001	Extension of indication to include treatment of infants, children and adolescents from 6 weeks to less than 18 years of age for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media for Vaxneuvance. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet	15/09/2022	21/10/2022	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion Vaxneuvance-H-C-5477-II-0001.

	and to include editorial changes in the product information. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0008	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	16/09/2022	26/04/2023	SmPC	Product information was updated to reflect the extension of shelf-life for Vaxneuvance suspension for injection in pre-filled syringe from 24 months to 30 months.
II/0007/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	01/09/2022	n/a		
PSUSA/10975 /202201	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (15 valent, adsorbed)	01/09/2022	n/a		PRAC Recommendation - maintenance
IB/0005	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	19/07/2022	n/a		

	changes to an approved test procedure				
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	01/07/2022	n/a		
IG/1515	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	14/06/2022	n/a		
IB/0003	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	22/04/2022	21/10/2022	SmPC, Labelling and PL	