



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Vaxneuvance

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
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	15/09/2022	21/10/2022	SmPC, Annex II, Labelling	Please refer to Scientific Discussion

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	<p>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.</p> <p>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 and to include editorial changes in the product information.</p> <p>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one</p>			and PL	Vaxneuvance-H-C-5477-II-0001.
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		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	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	01/09/2022	n/a		

	biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
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 changes to an approved test procedure	19/07/2022	n/a		
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	