Unit: Technical Assessment Unit

Public assessment report for biological products

Vaxneuvance

Administrative information:

Trade name of the medicinal product:	Vaxneuvance
Marketing Authorization holder	Merck Sharp and Dohme B.V. Waarderweg 39 2031 BN Haarlem - The Netherlands
Applied Indication(s):	• for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age. • for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older. .
Pharmaceutical form(s) and strength(s):	- Suspension for injection in prefilled syringe - Pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F 2 mcg/0.5ml Pneumococcal polysaccharide serotype 6B 4 mcg/0.5ml conjugated to CRM 197 carrier protein ~30 mcg/0.5ml
Registration track	Fast track
Type of registration (EMA/FDA – Local)	EMA approved

List of abbreviations

PnPs	Pneumococcal polysaccharide
CRM197	Carrier protein
DS	Drug substance
GMP	Good manufacturing practice

PD	Pharmacodynamics
PFS	Prefilled syringe
DP	Drug Product

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Dossier initial submission and evaluation process:

-The product was submitted for registration via Fast track pathway
-The dossier was initially received by the registration administration units on 21.7.2024.

1. General introduction about the product including brief description of the AI, its mode of action and indications

The V114 drug substances are composed of pneumococcal polysaccharide (PnPs) serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A,19F, 22F, 23F, and 33F individually conjugated to CRM197 carrier protein. Each purified conjugate bulk is a distinct drug substance referred to as the serotype-specific monovalent bulk conjugate (MBC). Proper Name: Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein], adsorbed.

2. Quality aspects:

- **Manufacturer**

- Drug substance (DS) is manufactured according to current Good Manufacturing Practices (cGMP) at MSD International GmbH,T/A MSD Ireland (Brinny) at its facilities located at Brinny, Innishannon, Cork,Ireland – Ireland.

-Vaxneuvance as finished product is manufactured at MSD International GmbH, T/A MSD Ireland (Carlow), Dublin Road, Carlow, Co.Carlow, Ireland

- Manufacturing of both DS and DP are performed in accordance with cGMP regulations.

- **Stability**

Drug substance:

- Approved shelf life:

Serotype	Shelf life
1	5 years
3	10 years
4	5 years
5	4 years
6A	5 years
6B	4 years
7F	5 years
9V	5 years
14	10 years
18C	5years
19A	5years
19F	5 years
22F	5years
23F	5 years
33F	10 years

-Approve storage conditions: ≤–60 °C

Drug Product:

-Approved shelf life: 36 months °C

- **Approve storage conditions**: Store in a refrigerator (2 °C – 8 °C). Do not freeze.

3. Non –Clinical aspect & Clinical aspect:

-Overall, the primary PDs studies provided adequate evidence that V114 induces functional antibody activity, which is expected to protect against pneumococcal infection. Repeat-dose toxicity studies as well as developmental and reproductive studies in rats at doses up to 17 times the infant human dose and up to 200 times the adult human dose on a mcg/kg basis, which included an evaluation of single dose toxicity and local tolerance, revealed no hazards to humans.

-In conclusion the overall benefit/risk of Vaxnuevance conclusion the overall benefit/risk of Vaxneuvance is favorable for:
-Active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.
-Active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.

4.General Conclusion and Recommendations if any:
Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:
https://www.ema.europa.eu/en/documents/overview/vaxneuvance-epar-medicine-overview_en.pdf