



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2036729

## European Medicines Agency decision

EMA/PE/0000228372

of 14 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for Borrelia outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

### **Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**



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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>1</sup>,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/0080/2024 issued on 15 March 2024,

Having regard to the application submitted by Pfizer Europe MA EEIG on 22 November 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for *Borrelia* outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

**Article 2**

This decision is addressed to Pfizer Europe MA EEIG, Boulevard De La Plaine 17, 1050 – Brussels, Belgium.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1804002 Corr<sup>1</sup>  
Amsterdam, 28 February 2025

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000228372

### Scope of the application

#### Active substance(s):

Borrelia outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine

#### Invented name and authorisation status:

See Annex II

#### Condition(s):

Prevention of Lyme disease

#### Pharmaceutical form(s):

Suspension for injection in pre-filled syringe

#### Route(s) of administration:

Intramuscular use

#### Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 22 November 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0080/2024 issued on 15 March 2024.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 2 January 2025.

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<sup>1</sup> 7 April 2025.



## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
  - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

## **Annex I**

**The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)**

# 1. Waiver

## 1.1. Condition:

Prevention of Lyme disease

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- suspension for injection in pre-filled syringe, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

# 2. Paediatric investigation plan

## 2.1. Condition:

Prevention of Lyme disease

### 2.1.1. Indication(s) targeted by the PIP

Active immunisation for the prevention of Lyme disease caused by *Borrelia* species

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Suspension for injection in pre-filled syringe

### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	<b>Study 1 (C4601009)</b> Randomised, placebo-controlled, observer-blind trial to evaluate safety, tolerability, and immunogenicity of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from 1 year to less than 5 years of age. <b>Study 2 (C4601003)</b> Multicentre, placebo-controlled, randomised, observer-blind trial to evaluate the safety, efficacy, immunogenicity, and lot consistency of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy participants from 5 years to less than 18 years of age (and adults).

	<p><b>Study 3 (C4601012)</b></p> <p>Randomised, placebo-controlled, observer-blind trial to evaluate the safety of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from 5 years to less than 18 years of age.</p> <p><b>Study 4 (VLA15-221)</b></p> <p>Randomised, observer-blind, placebo-controlled, multicentre trial to evaluate safety and immunogenicity of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from 5 years to less than 18 years of age (and adults).</p>
Modelling and simulation analyses	Not applicable.
Other studies	Not applicable.
Extrapolation plan	Not applicable.

### 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**