EMA/122320/2019

European Medicines Agency decision

P/0098/2019

of 22 March 2019

on the acceptance of a modification of an agreed paediatric investigation plan for neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; escherichia coli) / neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; escherichia coli) (rLP2086) (EMEA-001037-PIP02-11-M05) 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[1],

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

Having regard to the European Medicines Agency's decision P/0093/2013 issued on 29 April 2013, the decision P/0279/2014 issued on 28 October 2014, the decision P/0169/2015 issued on 7 August 2015, the decision P/0304/2015 issued on 21 December 2015 and the decision P/0013/2017 issued on 31 January 2017,

Having regard to the application submitted by Pfizer Europe MA EEIG on 25 October 2018 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 1 February 2019, 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.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; escherichia coli) / neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; escherichia coli) (rLP2086), suspension for injection, intramuscular use, 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.

EMA/PDCO/796639/2018
London, 1 February 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001037-PIP02-11-M05

Scope of the application

Active substance(s):

Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; *Escherichia coli*) / *Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086; subfamily B; *Escherichia coli*) (rLP2086)

Condition(s):

Prevention of invasive meningococcal disease caused by *N. meningitidis* serogroup B

Pharmaceutical form(s):

Suspension for injection

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 25 October 2018 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/0093/2013 issued on 29 April 2013, the decision P/0279/2014 issued on 28 October 2014, the decision P/0169/2015 issued on 7 August 2015, the decision P/0304/2015 issued on 21 December 2015 and the decision P/0013/2017 issued on 31 January 2017.

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

The procedure started on 4 December 2018.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Scope of the modification

Some measures and timelines 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 Norwegian Paediatric Committee member 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 annex 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 invasive meningococcal disease caused by *N. meningitidis* serogroup B

The waiver applies to:

- infants from birth to less than 2 months of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition

Prevention of invasive meningococcal disease caused by *N. meningitidis* serogroup B

2.1.1. Indication(s) targeted by the PIP

Active immunisation to prevent invasive meningococcal disease caused by *N. meningitidis* serogroup B

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

From 2 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	**Number of studies**	**Description**
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable
Clinical studies	10	**Study 1** Randomized, active-controlled, observer-blind trial, to describe immunogenicity, safety and tolerability of a meningococcal serogroup B bivalent (rLP2086) vaccine when administered to healthy toddlers aged 12 to less than 24 months of age, and the safety and immunogenicity of a booster dose of bivalent rLP2086 **Study 2** Randomized, active-controlled, observer-blind trial to describe immunogenicity, safety and tolerability of rLP2086 vaccine in healthy children aged 24 months to less than 10 years

		Study 3 Randomized, single-blind, placebo-controlled trial of the safety, immunogenicity, and tolerability of rLP2086 Vaccine at doses of 60 µg, 120 µg, and 200 µg in healthy adolescents aged 11 to less than 18 years **Study 4** Randomized, placebo-controlled, single-blind trial to assess the safety, tolerability, and immunogenicity of rLP2086 vaccine when administered in either 2- or 3-dose regimens in healthy subjects aged 11 to less than 19 years **Study 5** Randomized, active-controlled, observer-blind trial to assess the safety, tolerability, and immunogenicity of MCV4, Tdap vaccine and rLP2086 when administered concomitantly in healthy adolescents aged 10 to less than 13 years **Study 6** Randomized, active-controlled, observer-blind trial to assess the safety, tolerability, and immunogenicity of Gardasil (HPV) Vaccine when administered concomitantly with rLP2086 vaccine in healthy adolescents aged 11 to less than 18 years **Study 7** Randomized, placebo-controlled, single-blind trial to assess the safety, tolerability, and immunogenicity of Repevax vaccine and rLP2086 vaccine when administered concomitantly in healthy subjects aged 11 to less than 19 years **Study 8** Randomized, active-controlled, observer-blind trial to assess lot consistency, safety, tolerability, and immunogenicity of rLP2086 vaccine in healthy subjects aged 10 to less than 19 years **Study 9** Randomized, active-controlled, observer-blind trial to assess the safety and tolerability of rLP2086 vaccine in healthy subjects aged 10 to less than 26 years **Study 10** Dose-finding study to describe the immunogenicity, safety and tolerability of rLP2086 vaccine when administered to healthy infants aged 2 months
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 March 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes