EMA/179753/2013

European Medicines Agency decision

P/0093/2013

of 29 April 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver 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) 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 application submitted by Pfizer on 30 November 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 March 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Pfizer, Ramsgate Road, CT13 9NJ – Sandwich, United Kingdom.

Done at London, 29 April 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/12088/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver and a deferral

EMEA-001037-PIP02-11

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

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer submitted for agreement to the European Medicines Agency on 30 November 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 January 2013.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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

2. The measures and timelines of the agreed 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.

London, 15 March 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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;
- for suspension for injection;
- on the grounds that the specific medicinal product is likely to be ineffective;
- 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 immunization 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	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	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 **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

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes