EMA/284196/2015

European Medicines Agency decision

P/0125/2015

of 5 June 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for Norovirus GI.1 virus-like particle antigen / Norovirus GII.4 virus-like particle antigen (EMEA-001609-PIP01-14) 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 Takeda Vaccines, Inc. on 11 April 2014 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 17 April 2015, 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 Norovirus GI.1 virus-like particle antigen / Norovirus GII.4 virus-like particle antigen, 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 Norovirus GI.1 virus-like particle antigen / Norovirus GII.4 virus-like particle antigen, 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 Norovirus GI.1 virus-like particle antigen / Norovirus GII.4 virus-like particle antigen, 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 Takeda Vaccines, Inc., One Takeda Parkway, 60015 - Deerfield, Illinois, United States of America.

Done at London, 5 June 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/72722/2015 Corr
London, 17 April 2015

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

EMEA-001609-PIP01-14

Scope of the application

Active substance(s):

Norovirus GI.1 virus-like particle antigen / Norovirus GII.4 virus-like particle antigen

Condition(s):

Prevention of acute norovirus gastroenteritis

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Takeda Vaccines, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Takeda Vaccines, Inc. submitted for agreement to the European Medicines Agency on 11 April 2014 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 21 May 2014.

Supplementary information was provided by the applicant on 22 January 2015. The applicant proposed modifications to the paediatric investigation plan.

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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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Icelandic and the Norwegian Paediatric Committee members agree 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.

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 acute norovirus gastroenteritis

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- Suspension for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of acute norovirus gastroenteritis

2.1.1. Indication(s) targeted by the PIP

Active immunisation to prevent acute norovirus gastroenteritis.

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

From 6 weeks to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of a suspension for injection for use in children from 6 weeks to less than 9 years of age
Non-clinical studies	1	**Study 2:** Fertility and early embryonic development study in rabbits with postnatal follow-up on pups from birth to weaning
Clinical studies	9	**Study 3:** Double-blind, randomised controlled trial to evaluate safety and immunogenicity of the human norovirus vaccine [types GI.1 / GII.4] (recombinant, adjuvanted, adsorbed) [NoV vaccine] in children from 9 to less than 18 years of age (and in adults) (NOR-208) **Study 4:** Double-blind, randomised, dosage-, regimen- and adjuvant- justification study to evaluate safety and immunogenicity of NoV vaccine candidate formulations in

		infants, toddlers and children from 6 weeks to less than 9 years of age (NOR-202) **Study 5:** Randomised, double-blind (Arms 1 and 3)/open label (Arm 2) trial to evaluate safety and immunogenicity of the NoV vaccine and to evaluate the effect of co-administration with routine infant vaccines in children from 6 weeks to less than 6 years of age (NOR-206) **Study 6:** Open-label, randomised, long-term follow-up trial to evaluate safety, immunogenicity, and booster dose of NoV vaccine in children who previously participated in study NOR-206 (NOR-207) **Study 7:** Randomised, double-blind (Arms 1 and 3 within each Cohort)/open label (Arm 2 within each Cohort) trial to evaluate safety and immunogenicity of the NoV vaccine and to evaluate the effect of co-administration according to different schedules with routine infant vaccines in children from 6 weeks to less than 7 months of age (NOR-309) **Study 8:** Open-label, randomised, long-term follow-up trial to evaluate safety, immunogenicity, and booster dose of NoV vaccine in children who previously participated in study NOR-309 (NOR-310) **Study 9:** Randomised, double-blind (Arms 2- 5)/open label (Arm 1) trial to evaluate safety and immunogenicity of the NoV vaccine and to evaluate the effect of co-administration with MMR+ Varicella or DTaP and pneumococcal conjugate vaccines (PCV) in children from 12 months to less than 9 years of age (NOR-312) **Study 10:** Double-blind, randomised, placebo-controlled trial to evaluate safety, efficacy and immunogenicity of the NoV vaccine when co-administered with routine infant vaccines in children from 6 to less than 13 weeks of age (NOR-315) **Study 11:** Open-label, randomised trial to evaluate long-term safety and immunogenicity, and booster dose of the NoV vaccine in children from 6 weeks to less than 9 years of age NOR-318)
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:	Yes
Date of completion of the paediatric investigation plan:	By August 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes