EMA/187222/2011

European Medicines Agency decision

P/68/2011

of 17/03/2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] (RotaTeq) (EMEA-000967-PIP01-10) 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 Sanofi Pasteur MSD SNC on 29 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] (RotaTeq), oral solution, oral 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 waiver for rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] (RotaTeq), oral solution, oral 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

This decision is addressed to Sanofi Pasteur MSD, 8 rue Jonas Salk, 69007 Lyon, France.

Done at London, 17 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/825417/2010

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

EMEA-000967-PIP01-10

Scope of the application

Active substance(s):

Rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8]

Invented name:

RotaTeq

Condition(s):

Prevention of rotaviral enteritis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Sanofi Pasteur MSD SNC

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD submitted for agreement to the European Medicines Agency on 29 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 15 July 2010.

Supplementary information was provided by the applicant on 6 December 2010.

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 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(es) and appendix.

London, 18 February 2011

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 rotaviral enteritis

The waiver applies to:

- Infants from birth to less than 6 weeks of age and children from 32 weeks to less than 18 years of age,
- for oral solution, oral use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition

Prevention of rotaviral enteritis.

2.1.1. Indication(s) targeted by the PIP

Active immunisation of infants from age of 6 weeks until the age of 32 weeks for the prevention of gastroenteritis due to rotavirus infection.

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

From 6 weeks to less than 32 weeks of age.

2.1.3. Pharmaceutical form(s)

Oral solution.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	3	Study 1: Protocol V260-019 "Post Marketing Evaluation of the Short-Term Safety of RotaTeq (Rotavirus Vaccine, Live, Oral, Pentavalent)" Study 2: Pooled efficacy analysis of data from 2 completed phase 3 pre-marketing studies in subjects who received the 3rd dose of RotaTeq between

Area	Number of studies	Description
		26 weeks and 32 weeks of age. Study 3: Pooled safety analysis of data from 3 completed pre-marketing studies in subjects who received the 3rd dose of RotaTeq between 26 weeks and 32 weeks of age.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2011
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of rotaviral enteritis

   Authorised indications:

   RotaTeq is a vaccine given to babies from 6 weeks to 26 weeks of age to prevent gastroenteritis (diarrhoea and vomiting) due to rotavirus infections. RotaTeq is given according to official recommendations

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/06/348/001	RotaTeq	_ * _	Oral solution	Oral use	Tube (LDPE)	2 ml	1
EU/1/06/348/002	RotaTeq	_ * _	Oral solution	Oral use	Tube (LDPE)	2 ml	10

_*_One 2-ml dose contains:
rotavirus type* G1 not less than 2.2×10^6 IU[1, 2]
rotavirus type* G2 not less than 2.8×10^6 IU[1, 2]
rotavirus type* G3 not less than 2.2×10^6 IU[1, 2]
rotavirus type* G4 not less than 2.0×10^6 IU[1, 2]
rotavirus type* P1A[8] not less than 2.3×10^6 IU[1, 2]

* human-bovine rotavirus reassortants (live), produced in Vero cells.
[1] Infectious Units
[2] As lower confidence limit (p = 0.95)