EMA/387137/2011

European Medicines Agency decision

P/149/2011

of 9 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] (RotaTeq), (EMEA-000967-PIP01-10-M01) 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/68/2011 issued on 17 March 2011,

Having regard to the application submitted by Sanofi Pasteur MSD SNC on 4 April 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 May 2011, 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 rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] (RotaTeq), oral solution, oral 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 Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, 69367 Lyon Cedex 07, France.

Done at London, 9 June 2011

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

EMA/PDCO/343400/2011

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

EMEA-000967-PIP01-10-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted to the European Medicines Agency on 4 April 2011 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/68/2011 issued on 17 March 2011.

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

The procedure started on 20 April 2011.

Scope of the modification

The scope of the modification is a change in one measure.

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 Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 20 May 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 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 rotavirus enteritis

   Authorised indications:

   RotaTeq is indicated for the active immunisation of infants from the age of 6 weeks for prevention of gastroenteritis due to rotavirus infection

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 tube
EU/1/06/348/002	RotaTeq	-*-	Oral solution	Oral use	tube (LDPE)	2 ml	10 tubes

_*_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)