EMA/795938/2012

European Medicines Agency decision

P/0004/2013

of 21 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for propranolol hydrochloride (EMEA-000511-PIP01-08-M04) 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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on the acceptance of a modification of an agreed paediatric investigation plan for propranolol hydrochloride (EMEA-000511-PIP01-08-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/194/2009 issued on 7 October 2009, the decision P/51/2010 issued on 7 April 2010, the decision P/202/2010 issued on 27 October 2010, and the decision P/0143/2012 issued on 23 July 2012,

Having regard to the application submitted by Pierre Fabre Dermatologie on 6 November 2012 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 7 December 2012, 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 propranolol hydrochloride, 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 Pierre Fabre Dermatologie, 45 Place Abel Gance, 92100 - Boulogne, France.

Done at London, 21 January 2013

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

EMA/PDCO/755241/2012

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

EMEA-000511-PIP01-08-M04

Scope of the application

Active substance(s):

Propranolol hydrochloride

Condition(s):

Treatment of haemangioma

Pharmaceutical form(s):

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pierre Fabre Dermatologie

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pierre Fabre Dermatologie submitted to the European Medicines Agency on 6 November 2012 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/194/2009 issued on 7 October 2009, the decision P/51/2010 issued on 7 April 2010, the decision P/202/2010 issued on 27 October 2010, and the decision P/0143/2012 issued on 23 July 2012.

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

The procedure started on 5 December 2012.

Scope of the modification

Some measures and timelines of the original paediatric investigation plan have been modified.

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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 do 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 and appendix.

London, 7 December 2012

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: treatment of haemangioma

The waiver applies to:

- preterm newborn infants / term newborn infants (from birth to less than 35 days);
- for oral solution for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

The waiver applies to:

- the paediatric population (from 11 months to less than 18 years of age);
- for oral solution for oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition: treatment of haemangioma

2.1.1. Indication(s) targeted by the PIP

Treatment of proliferating infantile haemangiomas requiring systemic therapy.

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

From 35 days to less than 11 months of age.

2.1.3. Pharmaceutical form(s)

Solution for oral use.

2.1.4. Measures

Area	Number of measures	Description
Quality	2	Measure 1) Study to Evaluate the Compatibility and Stability of the Formulation in the Presence of Milk. Measure 2) Study to Evaluate the Palatability of a New Propranolol Hydrochloride Formulation (Solution).
Non-clinical		Not applicable.

Clinical	3	Measure 3) An Open-Label, Monocentric, Randomized, Single Dose, Two-way Crossover Study to Evaluate the Pharmacokinetic Parameters of a New Propranolol Hydrochloride Formulation (Solution) Compared to the Reference Propranolol Hydrochloride Formulation (Tablet). Measure 4) A Randomised, Controlled, Double-Blinded, Multidose, Multicentre Study in Paediatric Subjects from 35 Days to less than 11 months of Age with Proliferating Infantile Hemangiomas (IHs) Requiring Systemic Therapy to Compare 4 regimens of Propranolol to Placebo and to Evaluate Efficacy and Safety. Measure 5) A Multicentre, Open-Label, Multiple-Dose Study to Evaluate the Pharmacokinetics of Propranolol in Paediatric Subjects from 35 Days to less than 11 months of Age Treated for Proliferating Infantile Hemangiomas (IHs) Requiring Systemic Therapy.

3. Follow-up, completion and deferral of PIP

Potential long-term safety and efficacy issues in relation to paediatric use for consideration in the Risk Management Plan/Pharmacovigilance activities:	Yes
Date of completion of the paediatric investigation plan:	By May 2012
Deferral for one or more measures contained in the paediatric investigation plan:	No