EMA/650134/2010

# European Medicines Agency decision

P/202/2010

of 27 October 2010

on the acceptance of a modification of an agreed paediatric investigation plan for propranolol hydrochloride, (EMEA-000511-PIP01-08-M02) 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.**

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

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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/194/2009 issued on 7 October 2009, and the decision P/51/2010 issued on 7 April 2010,

Having regard to the application submitted by Pierre Fabre Dermatologie on 15 June 2010 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 10 September 2010, 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, 27 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/516419/2010

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

EMEA-000511-PIP01-08-M02

## 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 15 June 2010 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 July 2010.

## Scope of the modification

Some measures 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 agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subsets of the paediatric population and conditions 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, 10 September 2010

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. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 2 | Study to Evaluate the Compatibility and Stability of the Formulation in the Presence of Milk<br><br>Study to Evaluate the Palatability of a New Propranolol Hydrochloride Formulation (Solution) |
| Non-clinical | | Not applicable. |
| Clinical | 3 | Study 1)<br><br>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)<br><br>Study 2)<br><br>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<br><br>Study 3)<br><br>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

| | |
|---|---|
| Measures to address long term follow-up of in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By July<br><br>2011 |
| Deferral for one or more studies contained in the paediatric investigation plan: | No |