EMA/196390/2014

European Medicines Agency decision

P/0115/2014

of 6 May 2014

on the acceptance of a modification of an agreed paediatric investigation plan for methyl aminolevulinate hydrochloride (EMEA-000698-PIP02-10-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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on the acceptance of a modification of an agreed paediatric investigation plan for methyl aminolevulinate hydrochloride (EMEA-000698-PIP02-10-M01) 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/0017/2012 issued on 25 January 2012,

Having regard to the application submitted by Photocure ASA on 18 December 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 March 2014, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 methyl aminolevulinate hydrochloride, cream, cutaneous use, including changes to the deferral, 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 Photocure ASA, Hoffsveien 4, NO 0275 - Oslo, Norway.

Done at London, 6 May 2014

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

EMA/PDCO/18586/2014

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

EMEA-000698-PIP02-10-M01

Scope of the application

Active substance(s):

Methyl aminolevulinate hydrochloride

Condition(s):

Treatment of acne vulgaris

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Photocure ASA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Photocure ASA submitted to the European Medicines Agency on 18 December 2013 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0017/2012 issued on 25 January 2012.

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

The procedure started on 21 January 2014.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan were 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 and to the deferral 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 and appendix.

London, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 acne vulgaris

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- for cream for cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: treatment of acne vulgaris

2.1.1. Indication(s) targeted by the PIP

Treatment of acne vulgaris.

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cream for cutaneous use.

2.1.4. Studies

Area	Number of studies	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	3	**Study 1: PC TA206/11** Double blinded, prospective, randomized efficacy and safety trial in patients from 12 years of age with acne vulgaris comparing Visonac-photodynamic therapy (PDT) to vehicle cream-PDT. **Study 2: PC TA301/13** Double blinded, prospective, randomized, repeated use efficacy and safety trial in patients from 12 years of age with acne vulgaris comparing Visonac PDT to vehicle cream PDT.

Area	Number of studies	Description
		Study 3: PC TA302/13 Double blinded, prospective, randomized efficacy and safety trial in patients from 12 years of age with acne vulgaris comparing Visonac-PDT to vehicle cream-PDT.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes