

EMA/468799/2014

European Medicines Agency decision

P/0231/2014

of 5 September 2014

on the agreement of a paediatric investigation plan and on the granting of a waiver for trifarotene (EMEA-001492-PIP01-13) 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 agreement of a paediatric investigation plan and on the granting of a waiver for trifarotene (EMA-001492-PIP01-13) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Galderma International on 10 June 2013 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 July 2014, 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 trifarotene, cream, cutaneous 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 trifarotene, cream, cutaneous 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 Galderma International, Les Templiers, 2400 route des Colles, 06410 - Biot, France.

Done at London, 5 September 2014

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/262748/2014 **Corr**

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

EMA-001492-PIP01-13

Scope of the application

Active substance(s):

Trifarotene

Condition(s):

Treatment of acne

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name / corporate name of the PIP applicant:

Galderma International

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Galderma International submitted for agreement to the European Medicines Agency on 10 June 2013 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 17 July 2013.

Supplementary information was provided by the applicant on 28 April 2014. The applicant proposed modifications to the paediatric investigation plan.



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 Norwegian Paediatric Committee member agrees 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 and appendix.

London, 18 July 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of acne

The waiver applies to:

- the prepubertal paediatric population;
- cream, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of acne

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 puberty to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	4	Study 1 Single-blind, randomised, placebo and active controlled trial to evaluate efficacy and safety of different concentrations of trifarotene compared to placebo and tazarotene in children (and adults) with acne vulgaris. Study 2 Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of trifarotene compared to vehicle in children from puberty to less than 18 years of age (and adults) with acne vulgaris.

Area	Number of measures	Description
		Study 3 Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of trifarotene compared to vehicle in children from puberty to less than 18 years of age (and adults) with acne vulgaris. Study 4 Open-label, non-comparative trial to evaluate safety of trifarotene in children from puberty to less than 18 years of age (and adults) with acne vulgaris.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No