EMA/202411/2017

European Medicines Agency decision

P/0099/2017

of 11 April 2017

on the acceptance of a modification of an agreed paediatric investigation plan for trifarotene (EMEA-001492-PIP01-13-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/0231/2014 issued on 5 September 2014,

Having regard to the application submitted by Galderma R&D on 5 December 2016 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 24 February 2017, 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 waiver.

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

Changes to the agreed paediatric investigation plan for trifarotene, cream, cutaneous use, including changes to the waiver, 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 Galderma R&D, Les Templiers, 2400 route des Colles, 06410 – Biot France.

EMA/PDCO/823855/2016
London, 24 February 2017

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

EMEA-001492-PIP01-13-M01

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 R&D

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Galderma R&D submitted to the European Medicines Agency on 5 December 2016 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0231/2014 issued on 5 September 2014.

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

The procedure started on 3 January 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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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 waiver in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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.

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 paediatric population from birth to less than 9 years of age;
- 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 9 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 (RD.06.SPR.18223)** Single-blind, randomised, placebo and active controlled trial to evaluate efficacy and safety of different concentrations of trifarotene compared to placebo and tazarotene in paediatric patients (and adults) with acne vulgaris. **Study 2 (RD.06.SPR.18251)** Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of trifarotene compared to vehicle in paediatric patients from 9 to less than 18 years of age (and adults) with acne vulgaris.

Area	Number of measures	Description
		Study 3 (RD.06.SPR.18252) Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of trifarotene compared to vehicle in paediatric patients from 9 to less than 18 years of age (and adults) with acne vulgaris. **Study 4 (RD.06.SPR.18250)** Open-label, non-comparative trial to evaluate safety of trifarotene in paediatric patients from 9 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 January 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No