



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/343374/2017

European Medicines Agency decision

P/0156/2017

of 8 June 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for fluocinolone acetonide (EMEA-000801-PIP03-16) 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 726/2004¹,

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 CAMPHARM Limited on 21 October 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 May 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 deferral 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 deferral.
- (4) 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 fluocinolone acetonide, intravitreal implant in applicator, intravitreal 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 deferral for fluocinolone acetonide, intravitreal implant in applicator, intravitreal 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

A waiver for fluocinolone acetonide, intravitreal implant in applicator, intravitreal 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 4

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/91/2010 issued on 1 June 2010, including subsequent modifications thereof.

Article 5

This decision is addressed to CAMPHARM Limited, 11 Queens Road, CM14 4HE – Brentwood, United Kingdom.

EMA/PDCO/265899/2017

London, 19 May 2017

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

EMA-000801-PIP03-16

Scope of the application

Active substance(s):

Fluocinolone acetonide

Condition(s):

Treatment of chronic non-infectious uveitis

Pharmaceutical form(s):

Intravitreal implant in applicator

Route(s) of administration:

Intravitreal use

Name / corporate name of the PIP applicant:

CAMPARM Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, CAMPARM Limited submitted for agreement to the European Medicines Agency on 21 October 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 29 November 2016.

Supplementary information was provided by the applicant on 20 February 2017. 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 deferral in accordance with Article 21 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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 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 chronic non-infectious uveitis

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- intravitreal implant in applicator, intravitreal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic non-infectious uveitis

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye in children from 6 years

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Intravitreal implant in applicator

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of an intravitreal implant that delivers fluocinolone acetonide over a period of approximately 6 months to 1 year.
Non-clinical studies	0	Not applicable.
Clinical studies	1	Study 2: Open label study to evaluate the safety and efficacy of fluocinolone intravitreal implant in children and adolescents from 6 years to less than 18 years with chronic non-infectious uveitis affecting the posterior segment of the eye. (PSV-FAI-P01)
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:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes