EMA/517/2018

# European Medicines Agency decision

P/0002/2018

of 4 January 2018

on the acceptance of a modification of an agreed paediatric investigation plan for artenimol / piperaquine phosphate anhydride (Eurartesim), (EMEA-000153-PIP01-07-M05) 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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# European Medicines Agency decision

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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/67/2009 issued on 20 April 2009, P/227/2011 issued on 28 September 2011, the decision P/265/2014 issued on 10 October 2014 and the decision P/0231/2016 issued on 9 September 2016,

Having regard to the application submitted by Alfasigma SpA on 20 November 2017 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 15 December 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.

(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 artenimol / piperaquine phosphate anhydride (Eurartesim), film-coated tablet, dispersible tablet, 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 Alfasigma SpA Via Pontina km 30.400, 00071 - Pomezia, Rome, Italy.

EMA/PDCO/767680/2017 Corr
London, 15 December 2017

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

EMEA-000153-PIP01-07-M05

## Scope of the application

**Active substance(s):**

Artenimol / piperaquine phosphate anhydride

**Invented name:**

Eurartesim

**Condition(s):**

Treatment of uncomplicated malaria caused by *Plasmodium falciparum*

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film-coated tablet

Dispersible tablet

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Alfasigma SpA

**Information about the authorised medicinal product:**

See Annex II

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## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Alfasigma SpA submitted to the European Medicines Agency on 20 November 2017 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/67/2009 issued on 20 April 2009, P/227/2011 issued on 28 September 2011, the decision P/265/2014 issued on 10 October 2014 and the decision P/0231/2016 issued on 9 September 2016.

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

The procedure started on 28 November 2017.

## Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

## 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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 annexes 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

# 1. Waiver

## *1.1. Condition:*

Treatment of uncomplicated malaria caused by *Plasmodium falciparum*

The waiver applies to:

- two subsets of the paediatric population; less than 6 months and from 12 months to less than 18 years of age;
- for film-coated tablet and dispersible tablet for oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

# 2. Paediatric Investigation Plan

## *2.1. Condition:*

Treatment of uncomplicated malaria caused by *Plasmodium falciparum*

### 2.1.1. Indication(s) targeted by the PIP

Treatment of uncomplicated malaria caused by *Plasmodium falciparum*

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

From 6 months to less than 12 months of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet and dispersible tablet for oral use

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 1 | Study 1:<br>Development of dispersible tablet. |
| Non-clinical | 0 | Not applicable. |
| Clinical | 1 | Study 2:<br>Open-label, pharmacokinetic, safety and efficacy study of 10/80 mg and 20/160 mg artenimol/piperaquine age-appropriate formulation (dispersible tablet) and crushed film coated artenimol/piperaquine tablet, in infant patients from 6 to less than 12 months with uncomplicated *P. falciparum* malaria. |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety and efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By June 2015 |
| Deferral for one or more studies contained in the paediatric investigation plan: | No |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of uncomplicated malaria caused by *Plasmodium falciparum*

Authorised indication(s):

- Eurartesim is indicated for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants 6 months and over and weighing 5 kg or more

## Authorised pharmaceutical form(s):

Film-coated tablet

## Authorised route(s) of administration:

Oral use