

EMA/557959/2016

European Medicines Agency decision

P/0231/2016

of 9 September 2016

on the acceptance of a modification of an agreed paediatric investigation plan for dihydroartemisinin / piperazine phosphate anhydride (Eurartesim), (EMA-000153-PIP01-07-M04) 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 European Medicines Agency's decision P/67/2009 issued on 20 April 2009, the decision P/227/2011 issued on 28 September 2011 and the decision P/265/2014 issued on 10 October 2014,

Having regard to the application submitted by Sigma-Tau SpA on 2 May 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 22 July 2016, 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 dihydroartemisinin / 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 Sigma-Tau SpA, Via Pontina km 30.400, 00071 - Pomezia, Rome, Italy.

EMA/PDCO/503621/2016

London, 22 July 2016

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

EMA-000153-PIP01-07-M04

Scope of the application

Active substance(s):

Dihydroartemisinin / piperazine 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:

Sigma-Tau SpA

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sigma-Tau SpA submitted to the European Medicines Agency on 2 May 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/67/2009 issued on 20 April 2009, the decision P/227/2011 issued on 28 September 2011 and the decision P/265/2014 issued on 10 October 2014.

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

The procedure started on 24 May 2016.

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