EMA/691622/2011

European Medicines Agency decision

P/227/2011

of 28 September 2011

on the acceptance of a modification of an agreed paediatric investigation plan for dihydroartemisinin / piperaquine phosphate anhydride (EMEA-000153-PIP01-07-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/67/2009 issued on 20 April 2009,

Having regard to the application submitted by Sigma-Tau SpA on 26 May 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 August 2011, 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 deferral 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 deferral and 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 dihydroartemisinin / piperaquine phosphate anhydride, film-coated tablet, dispersible tablet, oral use, including changes to the deferral and 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 Sigma-Tau SpA, Via Pontina Km 30.400, 00040 Pomezia, Rome, Italy.

Done at London, 28 September 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/543863/2011

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

EMEA-000153-PIP01-07-M01

Scope of the application

Active substance(s):

Dihydroartemisinin / piperaquine phosphate anhydride

Condition(s):

Treatment of uncomplicated malaria caused by Plasmodium falciparum

Pharmaceutical form(s):

Film-coated tablet

Dispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Sigma-Tau SpA

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 26 May 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/67/2009 issued on 20 April 2009.

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

The procedure started on 15 June 2011.

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Scope of the modification

The new age-appropriate formulation has been defined; the age range of the waiver and some measures and timelines of the PIP have been modified. The deferral has been removed as redundant.

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 Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 12 August 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

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), 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 February 2014
Deferral for one or more studies contained in the paediatric investigation plan:	No