EMA/398291/2015

European Medicines Agency decision

P/0142/2015

of 10 July 2015

on the acceptance of a modification of an agreed paediatric investigation plan for ciclosporin (EMEA-000575-PIP01-09-M03) 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/49/2010 issued on 6 April 2010, the decision P/161/2011 issued on 4 July 2011 and the decision P/0238/2012 issued on 22 October 2012.

Having regard to the application submitted by Santen SAS on 27 February 2015 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 May 2015, 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 ciclosporin, eye drops, emulsion, ocular 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 Santen SAS, 1 rue Pierre Fontaine - Bâtiment Genavenir IV, 91058 – Evry Cedex, France.

Done at London, 10 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/174275/2015
London, 22 May 2015

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

EMEA-000575-PIP01-09-M03

Scope of the application

Active substance(s):

Ciclosporin

Condition(s):

Treatment of keratoconjunctivitis sicca

Treatment of vernal keratoconjunctivitis

Pharmaceutical form(s):

Eye drops, emulsion

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Santen SAS

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Santen SAS submitted to the European Medicines Agency on 27 February 2015 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/49/2010 issued on 6 April 2010, the decision P/161/2011 issued on 4 July 2011 and the decision P/0238/2012 issued on 22 October 2012.

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

The procedure started on 24 March 2015.

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Scope of the modification

Some 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 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 keratoconjunctivitis sicca

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for eye drops, emulsion for ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.2. Condition: Treatment of vernal keratoconjunctivitis

The waiver applies to:

- Children from birth to less than 4 years of age;
- for eye drops, emulsion for ocular use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition : Treatment of vernal keratoconjunctivitis

2.1.1. Indication targeted by the PIP

Treatment of active severe vernal keratoconjunctivitis with severe keratitis

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

From 4 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Eye drops, emulsion

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Double masked randomized multicenter dose regimen placebo controlled study to assess the efficacy and safety of ciclosporin (NOVA22007) in paediatric patients from 4 to less than 18 years of age with active severe vernal keratoconjunctivitis with severe keratitis

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 December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	No