

EMA/65467/2013

European Medicines Agency decision

P/0031/2013

of 26 February 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for hydrocortisone, (EMEA-001283-PIP01-12) 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 Diurnal Limited on 10 April 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 January 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 hydrocortisone, granules, oral 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 waiver for hydrocortisone, granules, oral 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

This decision is addressed to Diurnal Limited, Cardiff Medicentre, Heath Park, CF14 4UJ – Cardiff, United Kingdom.

Done at London, 26 February 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/725308/2012

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

EMA-001283-PIP01-12

Scope of the application

Active substance(s):

Hydrocortisone

Condition(s):

Treatment of adrenocortical insufficiency

Pharmaceutical form(s):

Granules

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Diurnal Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Diurnal Limited submitted for agreement to the European Medicines Agency on 10 April 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 15 May 2012.

Supplementary information was provided by the applicant on 19 October 2012. 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 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 agreed 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 annexes and appendix.

London, 11 January 2013

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 Adrenocortical Insufficiency

The waiver applies to:

- the paediatric population from 6 years to less than 18 years of age;
- for granules, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Adrenocortical Insufficiency

2.1.1. Indication(s) targeted by the PIP

Replacement therapy in the treatment of adrenal insufficiency

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

From birth to less than 6 years of age

2.1.3. Pharmaceutical form(s)

Granules

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Study 1: Open-label, randomized, crossover single-dose study in dexamethasone-suppressed healthy adults to compare the pharmacokinetics of hydrocortisone granules to immediate-release hydrocortisone tablets. Study 2: Open-label study to measure peak and 4-hour cortisol levels after single dose administration of hydrocortisone granules in neonates and children less than 6 years of age with adrenal insufficiency.

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 October 2016.
Deferral for one or more measures contained in the paediatric investigation plan:	No.