EMA/826074/2011

European Medicines Agency decision

P/245/2011

of 21 October 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for furosemide (EMEA-000982-PIP01-10) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/245/2011

of 21 October 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for furosemide (EMEA-000982-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by KidzPharma Inc. on 7 June 2010 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 9 September 2011, 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 furosemide, orodispersible tablet, 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 furosemide, orodispersible tablet, 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 KidzPharma, Inc., 42 E. Depot Street, 60061 - Vernon Hills, Illinois, United States.

Done at London, 21 October 2011

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

EMA/PDCO/578095/2011

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

EMEA-000982-PIP01-10

Scope of the application

Active substance(s):

Furosemide

Condition(s):

Treatment of fluid retention

Pharmaceutical form(s):

Orodispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

KidzPharma Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, KidzPharma Inc. submitted for agreement to the European Medicines Agency on 7 June 2010 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 July 2010.

Supplementary information was provided by the applicant on 4 July 2011.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 member(s) 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 annex(es) and appendix.

London, 9 September 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 fluid retention

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 months of age;
- for orodispersible tablet, 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 fluid retention

2.1.1. Indication(s) targeted by the PIP

Treatment of fluid retention when a prompt and effective diuresis is required. This includes cardiac, pulmonary, hepatic and renal oedema, peripheral oedema due to mechanical obstruction or venous insufficiency or hypertension.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Orodispersible tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of orodispersible tablet(s).
Non-clinical	0	Not applicable.
Clinical	5	Study 2: Single blind, randomised, single centre, single-dose, placebo controlled cross-over trial to evaluate acceptability and palatability of Furosemide-free orodispersible tablet (ODT) in healthy children from 3 to less than 18 years of age. Study 3: Randomised, two-period, two-sequence, single dose, cross-over trial to evaluate bioequivalence of furosemide orodispersible tablet (FOT) administered without water versus a marketed furosemide reference formulation (furosemide tablets) administered with water in healthy adult volunteers. Study 4: Randomised, two-period, two-sequence, single dose, cross-over trial to evaluate bioequivalence of furosemide orodispersible tablet (FOT) administered with water versus a marketed furosemide reference formulation (furosemide tablets) administered with water in healthy adult volunteers. Study 5:

		Randomised, two-period, two-sequence, single dose, cross-over trial to evaluate bioequivalence of furosemide orodispersible tablet suspended in apple sauce versus furosemide orodispersable tablet administered in the mouth cavity as designed in healthy adult volunteers. Study 6: Open-label, single dose trial to evaluate acceptability and palatability of furosemide orodispersible tablet in children from 3 to less than 18 years of age.

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 November 2012.
Deferral for one or more studies contained in the paediatric investigation plan:	No