EMA/760982/2011

European Medicines Agency decision

P/243/2011

of 30 September 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for lorcaserin (EMEA-001098-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

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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 application submitted by Arena Pharmaceutical Enterprises Limited on 13 December 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and 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 21 of said Regulation 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 deferral 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 deferral.

(4) 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 lorcaserin, 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 deferral for lorcaserin, 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

A waiver for lorcaserin, 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 4

This decision is addressed to Arena Pharmaceutical Enterprises Limited, 100 New Bridge Street, EC4V 6JA London, United Kingdom.

Done at London, 30 September 2011

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

EMA/PDCO/527994/2011

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

EMEA-001098-PIP01-10

Scope of the application

Active substance(s):

Lorcaserin

Condition(s):

Treatment of obesity

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Arena Pharmaceutical Enterprises Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Arena Pharmaceutical Enterprises Limited submitted for agreement to the European Medicines Agency on 13 December 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 19 January 2011.

Supplementary information was provided by the applicant on 01 July 2011. The applicant proposed modifications to the paediatric investigation plan and the request for a waiver.

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 deferral in accordance with Article 21 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and 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 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 obesity

The waiver applies to:

- The paediatric population from birth to less than 2 years of age
- for tablet, oral 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.

1.2. Condition: Treatment of obesity

The waiver applies to:

- The paediatric population from 2 to less than 6 years of age
- for 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 obesity

2.1.1. Indication(s) targeted by the PIP

Treatment of obesity

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

From 6 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Tablet
- Age-appropriate formulation to be developed for the paediatric subset from 6 to less than 12 years of age (flavoured liquid formulation, chewable tablet or orally disintegrating form).

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Age-appropriate formulation to be developed for the paediatric subset from 6 to less than 12 years of age (flavoured liquid formulation, chewable tablet or orally disintegrating form).
Non-clinical	1	Study 2: 42-day toxicity study in juvenile rats, followed by a 4-week recovery period.
Clinical	4	Study 3: Open-label, uncontrolled, single dose study to evaluate pharmacokinetic parameters and safety of lorcaserin in obese post-pubertal children from Tanner stage equal or above 2 to less than 18 years of age. Study 4: Double-blind, randomised, multicentre, placebo-controlled trial to assess the safety and efficacy of lorcaserin in conjunction with lifestyle modifications for weight loss in obese post-pubertal children from Tanner stage equal or above 2 to less than 18 years of age, who have previously failed to respond to lifestyle modification measures alone. Study 5: Open-label, placebo-controlled, single ascending dose study of the safety, tolerability and pharmacokinetics of lorcaserin in obese pre-pubertal children from 6 years old to a Tanner stage 1. Study 6: Double-blind, randomised, multicentre, placebo-controlled trial to assess the safety and efficacy of lorcaserin in conjunction with lifestyle modifications for weight loss in obese pre-pubertal children from 6 years old to a Tanner stage 1, who have previously failed to respond to lifestyle modification measures alone.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2026
Deferral for one or more studies contained in the paediatric investigation plan:	Yes