EMA/878696/2011

European Medicines Agency decision

P/279/2011

of 28 November 2011

on the acceptance of a modification of an agreed paediatric investigation plan for lanthanum carbonate hydrate (Fosrenol and associated names), (EMEA-000637-PIP02-10-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/284/2010 issued on 3 December 2010,

Having regard to the application submitted by Shire Pharmaceutical Contracts Ltd on 28 July 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 14 October 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.

(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 lanthanum carbonate hydrate (Fosrenol and associated names), chewable tablets, granules, oral 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 Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, RG24 8EP – Basingstoke, United Kingdom.

Done at London, 28 November 2011

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

EMA/PDCO/746425/2011

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

EMEA-000637-PIP02-10-M01

Scope of the application

Active substance(s):

Lanthanum carbonate hydrate

Invented name:

Fosrenol and associated names

Condition(s):

Treatment of hyperphosphataemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Chewable tablets

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shire Pharmaceutical Contracts Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceutical Contracts Ltd submitted to the European Medicines Agency on 28 July 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/284/2010 issued on 3 December 2010.

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

The procedure started on 16 August 2011.

Scope of the modification

Some measures 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 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, 14 October 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 Hyperphosphataemia

The waiver applies to:

- Paediatric population from birth to less than 6 months of age;
- for chewable tablets, granules, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Hyperphosphataemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperphosphataemia.

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)

Chewable tablets, granules, oral use.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of a 250mg granule formulation.
Non-clinical	1	6-week repeat-dose toxicity study in juvenile rats.
Clinical	1	Open-label, crossover study to compare efficacy, safety, tolerability of lanthanum carbonate and calcium carbonate, and to assess pharmacokinetic profiles of lanthanum carbonate in hyperphosphataemic children and adolescents aged 6 months to less than 18 years) with CKD on dialysis.

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 Dec 2014.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of hyperphosphataemia

Authorised indications:

Fosrenol is indicated as a phosphate binding agent for use in the control of hyperphosphataemia in patients ≥6 months with chronic renal failure that are on haemodialysis or CAPD. Fosrenol is also indicated in patients ≥6 months with CKD who are not on dialysis, who have serum phosphate levels ≥ 1.78 mmol/L and in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

Invented name	**Strength**	**Pharmaceutical form**	**Route of administration**
Fosrenol	250mg, 500mg, 750mg, 1000mg	Chewable tablet	Oral use

RMS: Sweden