EMA/579872/2016

European Medicines Agency decision

P/0232/2016

of 9 September 2016

on the acceptance of a modification of an agreed paediatric investigation plan for lanthanum carbonate hydrate (Fosrenol and associated names), (EMEA-000637-PIP02-10-M05) 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, the decision P/279/2011 issued on 28 November 2011, and the decision P/0057/2012 issued on 26 March 2012 and the decision P/0037/2014 issued on 5 March 2014,

Having regard to the application submitted by Shire Pharmaceutical Contracts Ltd on 26 April 2016 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 22 July 2016, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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, oral powder, oral use, including changes to the deferral, 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.

EMA/PDCO/667048/2013
London, 22 July 2016

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

EMEA-000637-PIP02-10-M05

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

Oral powder

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 26 April 2016 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 decision P/279/2011 issued on 28 November 2011, and the decision P/0057/2012 issued on 26 March 2012 and the decision P/0037/2014 issued on 5 March 2014.

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

The procedure started on 24 May 2016.

Scope of the modification

Some measures and timelines of the agreed Paediatric Investigation Plan have been modified and a new extrapolation study added.

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 and to the deferral 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 subsets of the paediatric population and condition 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.

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:

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

And to:

- Infants and children from 6 months to less than 10 years of age;
- for chewable tablets, oral powder, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

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 10 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Chewable tablets, oral powder

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a 250mg oral powder formulation.
Non-clinical studies	1	**Study 2** 6-week repeat-dose toxicity study in juvenile rats.

Area	Number of measures	Description
Clinical studies	1	**Study 3** Open-label study to investigate efficacy, safety and tolerability of lanthanum carbonate, and to assess pharmacokinetic profiles of lanthanum carbonate in hyperphosphataemic children and adolescents from 10 to less than 18 years of age with chronic kidney disease (CKD) on dialysis.
Extrapolation, modelling and simulation studies	1	**Study 4** Extrapolation from the dose-response in adult to paediatric chronic kidney disease (CKD) patients on dialysis.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2018
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 indication(s):

- Fosrenol is indicated in adult patients as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Fosrenol is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

Authorised pharmaceutical form(s):

Chewable tablet, oral powder

Authorised route(s) of administration:

Oral use