EMA/52891/2014

European Medicines Agency decision

P/0087/2014

of 4 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21) (EMEA-001061-PIP01-10-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/284/2011 issued on 30 November 2011,

Having regard to the application submitted by Vifor Fresenius Medical Care Renal Pharma on 22 November 2013 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 February 2014, 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 sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21), powder for oral suspension, chewable tablet, 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 Vifor Fresenius Medical Care Renal Pharma, 7 - 13 Boulevard Paul-Emile Victor, 92521 - Neuilly-sur-Seine Cedex, France.

Done at London, 4 April 2014

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

EMA/52891/2014

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

EMEA-001061-PIP01-10-M01

Scope of the application

Active substance(s):

Sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21)

Condition(s):

Treatment of hyperphosphataemia

Pharmaceutical form(s):

Powder for oral suspension

Chewable tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Vifor Fresenius Medical Care Renal Pharma

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Vifor Fresenius Medical Care Renal Pharma submitted to the European Medicines Agency on 22 November 2013 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/284/2011 issued on 30 November 2011.

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

The procedure started on 18 December 2013.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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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 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 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 and appendix.

London, 14 February 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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:

- preterm newborn infants / term newborn infants (from birth to less than 28 days of age);
- for powder for oral suspension, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 6 years of age;
- for chewable tablets, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: treatment of hyperphosphataemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperphosphataemia in patients with chronic kidney disease.

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for oral suspension;

Chewable tablets.

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of a powder for oral suspension.
Non-clinical studies	0	Not applicable.

Area	Number of studies	Description
Clinical studies	1	**Study 2** Double-blind, randomised, multicentre, placebo controlled trial to evaluate efficacy and safety of PA21 in children from 1 month to less than 18 years of age with hyperphosphataemia in chronic kidney disease, with a 24-week open-label extension to evaluate safety.
Extrapolation, modelling & simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 October 2016.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.