EMA/273229/2010

European Medicines Agency decision

P/64/2010

of 3 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for iron, aqua carbonate hydroxy oxo starch sucrose complex (EMEA-000100-PIP01-07-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/64/2010

of 3 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for iron, aqua carbonate hydroxy oxo starch sucrose complex (EMEA-000100-PIP01-07-M01) 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 European Medicines Agency's decision P/23/2009 issued on 23 February 2009,

Having regard to the application submitted by Novartis Europharm Limited on 4 February 2010 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 19 March 2010, 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 iron, aqua carbonate hydroxy oxo starch sucrose complex, powder for oral suspension, 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB, United Kingdom.

Done at London, 3 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/273229/2010

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

EMEA-000100-PIP01-07-M01

Scope of the application

Active substance(s):

Iron, aqua carbonate hydroxy oxo starch sucrose complex

Condition(s):

Hyperphosphataemia in chronic kidney disease

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 4 February 2010 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/23/2009 of 23 February 2009. The application for modification proposed changes.

The procedure started on 18 February 2010.

Scope of the modification

Some timelines of the original opinion have been modified.

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

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 the changes proposed by the applicant regarding the timelines of the paediatric investigation plan,

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its appendix(ces).

London, 19 March 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

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

1. Condition(s)

Hyperphosphataemia in chronic kidney disease

2. Waiver

2.1. Condition

Hyperphosphataemia in chronic kidney disease

The waiver applies to:

- Preterm newborn infants, term newborn infants (from birth to less than 28 days),
- for powder for oral suspension for 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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Hyperphosphataemia in chronic kidney disease

3.1.1. Indication targeted by the PIP

Treatment of hyperphosphataemia in chronic kidney disease

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

From 1 month to less than 18 years.

3.1.3. Pharmaceutical form(s)

Powder for oral suspension for oral use

3.1.4. Studies

Area	Number of studies	Description
Quality	2	Development of a formulation containing a maximum of 1.5% ethanol. Development of an age appropriate strength lower than 1000 mg.
Non-clinical	2	13 week toxicity study in cynomolgus monkeys. Pre- and postnatal development study in rats (gestation day 6 to lactation day 20).
Clinical	2	Open-label, cross-over, 8 week comparative study of 'iron, aqua carbonate hydroxy oxo starch sucrose complex' with phosphate binder to evaluate efficacy and safety in children from 1 month to less than 18 years of age with hyperphosphataemia in end stage chronic kidney disease treated with dialysis. This is followed by a 10 month safety extension.

Area	Number of studies	Description
		Open-label, cross-over, comparative study of 'iron, aqua carbonate hydroxy oxo starch sucrose complex' with phosphate binder to evaluate efficacy and safety in children from 1 month to less than 18 years of age with hyperphosphataemia in chronic kidney disease stage III and IV including patients with renal transplantation. This is followed by a 10 month safety extension.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes