EMA/646943/2012

European Medicines Agency decision

P/0263/2012

of 20 November 2012

on the acceptance of a modification of an agreed paediatric investigation plan for methoxy polyethylene glycol - epoetin beta (Mircera), (EMEA-000172-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.

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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/26/2009 issued on 23 February 2009,

Having regard to the application submitted by Roche Registration Limited on 12 July 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 5 October 2012, 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 methoxy polyethylene glycol - epoetin beta (Mircera), solution for injection, intravenous use, subcutaneous 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 Roche Registration Limited, 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 20 November 2012

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

EMA/PDCO/475063/2012

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

EMEA-000172-PIP01-07-M01

Scope of the application

Active substance(s):

Methoxy polyethylene glycol - epoetin beta

Invented name:

Mircera

Condition(s):

Treatment of symptomatic anaemia associated with chronic kidney disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Roche Registration Limited

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, Roche Registration Limited submitted to the European Medicines Agency on 12 July 2012 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/26/2009 issued on 23 February 2009.

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

The procedure started on 9 August 2012.

Scope of the modification

Some measures of the agreed PIP 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 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(es) and appendix.

London, 5 October 2012

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 symptomatic anaemia associated with chronic kidney disease

The waiver applies to:

- All subsets of the paediatric population from birth to less than 2 years of age;
- for solution for injection for intravenous and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of symptomatic anaemia associated with chronic kidney disease

2.1.1. Indication(s) targeted by the PIP

Treatment of symptomatic anaemia associated with chronic kidney disease.

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection for intravenous and subcutaneous use.

It is the Applicant's responsibility to use appropriate formulation strengths in the clinical study(ies) to ensure dosing accuracy.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.

Area	Number of studies	Description
Clinical	2	**Study 1:** Dose-finding study: non-randomized, open label, multicenter, multiple dose study in children with chronic kidney disease on hemodialysis treatment (NH19707). **Study 2:** Confirmatory study: randomized controlled, open-label, multi-center, parallel group study to confirm the optimal starting dose of MIRCERA administered once a month iv or sc for the maintenance treatment of anemia in paediatric patients with chronic kidney disease not on dialysis or paediatric patients on dialysis (PD and HD) who had been receiving a stable treatment with an approved erythropoiesis stimulating agent (NH19708).

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 January 2018
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of symptomatic anaemia associated with chronic kidney disease

   Authorised indications:

   MIRCERA is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/07/400/008	Mircera	50 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (167 µg/ml)	1 pre-filled syringe
EU/1/07/400/009	Mircera	75 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (250 µg/ml)	1 pre-filled syringe
EU/1/07/400/010	Mircera	100 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (333 µg/ml)	1 pre-filled syringe
EU/1/07/400/011	Mircera	150 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (500 µg/ml)	1 pre-filled syringe
EU/1/07/400/012	Mircera	200 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (667 µg/ml)	1 pre-filled syringe
EU/1/07/400/013	Mircera	250 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (833 µg/ml)	1 pre-filled syringe
EU/1/07/400/017	Mircera	30 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (100 µg/ml)	1 pre-filled syringe
EU/1/07/400/018	Mircera	40 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (133 µg/ml)	1 pre-filled syringe
EU/1/07/400/019	Mircera	60 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (200 µg/ml)	1 pre-filled syringe

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/07/400/020	Mircera	120 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (400 µg/ml)	1 pre-filled syringe
EU/1/07/400/021	Mircera	360 µg/0.6 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (600 µg/ml)	1 pre-filled syringe
EU/1/07/400/022	Mircera	30 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (100 µg/ml)	3x1 pre-filled syringes
EU/1/07/400/023	Mircera	50 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (167 µg/ml)	3x1 pre-filled syringes
EU/1/07/400/024	Mircera	75 µg/0.3 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (250 µg/ml)	3x1 pre-filled syringes