European Medicines Agency

Doc. Ref. EMEA/99507/2009
P/26/2009

EUROPEAN MEDICINES AGENCY DECISION

of 23 February 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for methoxy polyethylene glycol - epoetin beta, MIRCERA (EMEA-000172-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Roche Registration Limited on 8 February 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 January 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for methoxy polyethylene glycol - epoetin beta, MIRCERA, solution for injection, intravenous and subcutaneous (IV and SC), the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for methoxy polyethylene glycol - epoetin beta, MIRCERA, solution for injection, intravenous and subcutaneous (IV and SC), the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom.

Done at London, 23 February 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human U

Doc. Ref. EMEA/PDCO/639144/2008
EMEA-000172-PIP01-07

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER

Scope of the application

Active substance:
Methoxy polyethylene glycol - epoetin beta

Invented name:
MIRCERA

Condition(s):
Symptomatic anaemia associated with chronic kidney disease

Pharmaceutical form(s):
Solution For Injection

Route(s) of administration:
Intravenous and subcutaneous (IV and SC)

Name/corporate name of the PIP applicant:
Roche Registration Limited

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration Limited submitted for agreement to the EMEA on 08 February 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 8 May 2008.

Supplementary information was provided by the applicant on 31 October 2008.

A meeting with the Paediatric Committee took place on 7 January 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

2. 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 are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annexes and appendix.

London, 9 January 2009

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

A. CONDITION(S)

Symptomatic anaemia associated with chronic kidney disease

B. WAIVER

- **Condition**

Symptomatic anaemia associated with chronic kidney disease

The waiver applies to:

- Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months)
- 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 are not feasible.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Symptomatic anaemia associated with chronic kidney disease

- **Proposed PIP indication**

Treatment of symptomatic anaemia associated with chronic kidney disease

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 to less than 18 years

- **Formulation(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.

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Dose-finding study: non-randomized, open label, multicenter, multiple dose study in children with chronic kidney disease on hemodialysis treatment. 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.

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By June 2013**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/07/400/001	Mircera	50 µg /1 ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (50 µg/ml)	1 vial
EU/1/07/400/002	Mircera	100 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (100 µg/ml)	1 vial
EU/1/07/400/003	Mircera	200 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (200 µg/ml)	1 vial
EU/1/07/400/004	Mircera	300 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (300 µg/ml)	1 vial
EU/1/07/400/005	Mircera	400 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (400 µg/ml)	1 vial
EU/1/07/400/006	Mircera	600 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (600 µg/ml)	1 vial
EU/1/07/400/007	Mircera	1000 µg/1ml	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (1000 µg/ml)	1 vial
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/1/07/400/014	Mircera	400 µg/0.6 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (667 µg/ml)	1 pre-filled syringe
EU/1/07/400/015	Mircera	600 µg/0.6 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (1000 µg/ml)	1 pre-filled syringe
EU/1/07/400/016	Mircera	800 µg/0.6 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (1333 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 ìg/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 ìg/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/1/07/400/020	Mircera	120 ìg/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 ìg/0.6 ml	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (600 µg/ml)	1 pre-filled syringe