EMA/2920/2017

European Medicines Agency decision

P/0049/2017

of 6 March 2017

on the refusal of a modification of an agreed paediatric investigation plan for methoxy polyethylene glycol - epoetin beta (Mircera), (EMEA-000172-PIP01-07-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0049/2017

of 6 March 2017

on the refusal of a modification of an agreed paediatric investigation plan for methoxy polyethylene glycol - epoetin beta (Mircera), (EMEA-000172-PIP01-07-M02) 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/26/2009 issued on 23 February 2009 and the decision P/0263/2012 issued on 20 November 2012,

Having regard to the application submitted by Roche Registration Limited on 21 September 2016 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 24 February 2017, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, an opinion on the refusal of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the refusal 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, 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, are hereby refused.

Article 2

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

EMA/PDCO/116513/2017
London, 24 February 2017

Final opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan

EMEA-000172-PIP01-07-M02

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

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 21 September 2016 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 and the decision P/0263/2012 issued on 20 November 2012.

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

An Opinion was adopted by the Paediatric Committee on 16 December 2016 for the above mentioned product. Roche Registration Limited received the Paediatric Committee Opinion on 21 December 2016.

On 20 January 2017 Roche Registration Limited submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 26 January 2017.

A meeting with the Paediatric Committee took place on 23 February 2017.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

   to maintain its opinion and

   - to refuse the changes proposed by the applicant regarding the paediatric investigation plan.

   The Norwegian Paediatric Committee member agrees 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 remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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 (PIP)

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.
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 indication(s):

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

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use

Intravenous use