EMA/662067/2017

European Medicines Agency decision

P/0317/2017

of 31 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for methoxy polyethylene glycol - epoetin beta (Mircera), (EMEA-000172-PIP01-07-M03) 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, the decision P/0263/2012 issued on 20 November 2012 and the decision P/0049/2017 issued on 6 March 2017,

Having regard to the application submitted by Roche Registration Limited on 23 June 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 September 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 and to the waiver and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the waiver.

(3) It is therefore appropriate to adopt a decision on the granting of a deferral.

[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, including changes to the waiver, 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

A deferral 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 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, AL7 1TW- Welwyn Garden City, United Kingdom.

EMA/PDCO/434425/2017
London, 15 September 2017

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

EMEA-000172-PIP01-07-M03

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 23 June 2017 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 decision P/0263/2012 issued on 20 November 2012 and the decision P/0049/2017 issued on 6 March 2017.

The application for modification proposed changes to the agreed paediatric investigation plan and to the waiver and proposed a deferral.

The procedure started on 18 July 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a paediatric subset has been removed. A deferral has been granted.

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 and to the waiver in the scope set out in the Annex I of this opinion;
   - to grant a deferral, the details of which are 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 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:

- the paediatric population from birth to less than 3 months of age;
- 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 3 months 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-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	Study 1 Dose-finding study: non-randomized, open label, multicenter, multiple dose study in children with chronic kidney disease on haemodialysis treatment (NH19707).

		Study 2 Open-label, single-arm, multicentre study to ascertain the starting dose of Mircera in paediatric patients with chronic kidney disease on dialysis or not yet on dialysis (NH19708).
Extrapolation, modelling and simulation studies	1	Study 3 (added in procedure EMEA-000172-PIP-01-07-M03) Population PK, linear PK and longitudinal population PK/PD model
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:	No
Date of completion of the paediatric investigation plan:	By April 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

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