EMA/175677/2020

European Medicines Agency decision

P/0157/2020

of 17 April 2020

on the agreement of a paediatric investigation plan for polymyxin B (EMEA-002595-PIP01-19) 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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on the agreement of a paediatric investigation plan for polymyxin B (EMEA-002595-PIP01-19) 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 application submitted by The GARDP Foundation on 17 April 2019 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2020, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for polymyxin B, powder for solution for injection, intravenous 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, is hereby agreed.

Article 2

This decision is addressed to The GARDP Foundation, Chemin Louis Dunant 15, 1202 - Geneve Switzerland.

EMA/PDCO/665587/2019
Amsterdam, 28 February 2020

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-002595-PIP01-19

Scope of the application

Active substance(s):

Polymyxin B

Condition(s):

Treatment of infections due to aerobic Gram-negative bacteria

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

The GARDP Foundation

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, The GARDP Foundation submitted for agreement to the European Medicines Agency on 17 April 2019 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 28 May 2019.

Supplementary information was provided by the applicant on 28 November 2019. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) of said Regulation.

   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 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of infections due to aerobic Gram-negative bacteria

2.1.1. Indication(s) targeted by the PIP

Treatment of infections due to aerobic Gram-negative bacteria in paediatric patients with limited therapeutic options.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1:** Open-label, single dose study to evaluate the pharmacokinetics and safety of intravenous polymyxin B in hospitalised patients from birth to less than 18 years of age receiving parenteral antibiotic therapy to treat a confirmed or suspected significant bacterial infection of any clinical site (PedPolyB01) **Study 2:** Randomised, open-label, active-controlled multiple dose trial to evaluate the pharmacokinetics, safety and efficacy of intravenous polymyxin B compared to colistin in hospitalised patients from birth to less than 12 years of age with confirmed or suspected carbapenem-resistant Gram-negative bacterial bloodstream infections (PedPolyB02)

Extrapolation, modelling and simulation studies	1	**Study 3:** Modelling and simulation study for dose selection of polymyxin B in the treatment of infections due to aerobic Gram-negative bacteria in paediatric patients from birth to less than 18 years of age (PedPolyBpk01).
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2026
Deferral for one or more measures contained in the paediatric investigation plan:	No