EMA/75623/2013

European Medicines Agency decision

P/0037/2013

of 27 February 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for azithromycin (EMEA-001298-PIP01-12) 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 and on the granting of a waiver for azithromycin (EMEA-001298-PIP01-12) 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 Only for children pharmaceuticals on 10 April 2012 under Article 15(1) of Regulation (EC) No 1901/2006 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 11 January 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing 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 azithromycin, age-appropriate dosage form for parenteral use, 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

A waiver for azithromycin, age-appropriate dosage form for parenteral use, 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 granted.

Article 3

This decision is addressed to Only for children pharmaceuticals, 10 avenue de Verdun, 75010 – Paris, France.

Done at London, 27 February 2013

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

EMA/PDCO/745895/2012

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

EMEA-001298-PIP01-12

Scope of the application

Active substance(s):

Azithromycin

Condition(s):

Prevention of bronchopulmonary dysplasia

Pharmaceutical form(s):

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Only for children pharmaceuticals

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Only for children pharmaceuticals submitted for agreement to the European Medicines Agency on 10 April 2012 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 15 May 2012.

Supplementary information was provided by the applicant on 2 October 2012. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 10 January 2013.

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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 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 European Medicines Agency, together with its annex and appendix.

London, 11 January 2013

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: prevention of bronchopulmonary dysplasia

The waiver applies to:

- the paediatric population from 29 weeks gestational age to less than 18 years;
- for age-appropriate dosage form for parenteral use, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: prevention of bronchopulmonary dysplasia

2.1.1. Indication(s) targeted by the PIP

Prevention of bronchopulmonary dysplasia

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

From birth to less than 29 weeks of gestational age.

2.1.3. Pharmaceutical form(s)

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1 Development of an age-appropriate dosage form for parenteral use.
Non-clinical	0	Not applicable.
Clinical	1	Measure 2 Multi-centre, randomised, placebo controlled safety and efficacy trial of azithromycin for the prevention of bronchopulmonary dysplasia in ventilated (continuous positive airway pressure or intubated ventilation) preterm infants of less than 29 weeks gestational age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No