EMA/692933/2013

European Medicines Agency decision

P/0299/2013

of 29 November 2013

on the agreement of a paediatric investigation plan and on granting for sodium benzylpenilloate / benzylpenicilloyl octa- L-lysine (EMEA-001398-PIP02-13) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 application submitted by Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A. on 2 July 2013 under Article 16(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 October 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 sodium benzylpenilloate / benzylpenicilloyl octa- L-lysine, powder and solvent for solution for injection, skin scarification, intradermal 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 sodium benzylpenilloate / benzylpenicilloyl octa- L-lysine, powder and solvent for solution for injection, skin scarification, intradermal 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 Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A, Avda. Gregorio Peces Barbas, nº2 Parque Tecnológico de Leganés, 28918 – Leganés, Spain.

Done at London, 29 November 2013

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

EMA/PDCO/566409/2013

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

EMEA-001398-PIP02-13

Scope of the application

Active substance(s):

Sodium benzylpenilloate / benzylpenicilloyl octa- L-lysine

Condition(s):

Diagnosis of beta-lactam allergy

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Skin scarification

Intradermal use

Name/corporate name of the PIP applicant:

Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A. submitted for agreement to the European Medicines Agency on 2 July 2013 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 August 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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 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 October 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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: diagnosis of beta-lactam allergy

The waiver applies to:

- the paediatric population from birth to less than 24 months of age;
- for powder and solvent for solution for injection for skin scarification and intradermal use;
- on the grounds that the specific medicinal product is likely to be ineffective;

2. Paediatric Investigation Plan

2.1. Condition: diagnosis of beta-lactam allergy

2.1.1. Indication(s) targeted by the PIP

Diagnostis of beta-lactam allergy.

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

From 2 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Measure 1: Analysis of existing in-house and literature data on penicillin allergy diagnostics in the concerned condition.

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 2014
Deferral for one or more measures contained in the paediatric investigation plan:	No