EMA/252168/2014

European Medicines Agency decision

P/0155/2014

of 16 June 2014

on the refusal of a paediatric investigation plan and on the granting of a waiver and on the granting of a waiver ex officio for freeze-dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35) (EMEA-001541-PIP01-13) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Probionov on 2 August 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 25 April 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation and of its own motion in accordance with Article 12 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 refusal of a paediatric investigation plan and on the granting of a waiver and on the granting of a waiver ex officio.

(2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

(4) It is therefore appropriate to adopt a decision granting a waiver ex officio.

[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 freeze-dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35), vaginal capsule, hard, vaginal 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 refused.

Article 2

A product-specific waiver for freeze-dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35), vaginal capsule, hard, vaginal 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

A product-specific waiver ex officio for freeze-dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35), vaginal capsule, hard, vaginal 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 4

This decision is addressed to Probionov, Rue des frères lumière, 15130 - Arpajon-sur-Cère, France.

Done at London, 16 June 2014

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

EMA/PDCO/190734/2014 Corr

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001541-PIP01-13

Scope of the application

Active substance(s):

Freeze-dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35)

Condition(s):

Prevention of vulvo-vaginal candidiasis

Prevention of bacterial vaginosis

Pharmaceutical form(s):

Vaginal capsule, hard

Route(s) of administration:

Vaginal use

Name/corporate name of the PIP applicant:

Probionov

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Probionov submitted for agreement to the European Medicines Agency on 2 August 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 10 October 2013.

Supplementary information was provided by the applicant on 29 January 2014. The applicant proposed modifications to the paediatric investigation plan.

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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 refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;
   - to grant a product-specific waiver for all subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population and on its own motion in accordance with Article 12 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in 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, 25 April 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Prevention of vulvo-vaginal candidiasis

The waiver applies to:

- boys from birth to less than 18 years of age, and girls from birth to menarche;
- for vaginal capsule, hard. Vaginal use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

And to:

- girls from menarche to less than 18 years of age;
- for vaginal capsule, hard. Vaginal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.2. Condition:

Prevention of bacterial vaginosis

The waiver applies to:

- boys from birth to less than 18 years of age, and girls from birth to menarche;
- for vaginal capsule, hard. Vaginal use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

And to:

- girls from menarche to less than 18 years of age;
- for vaginal capsule, hard. Vaginal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).