EMA/646811/2018

European Medicines Agency decision

P/0328/2018

of 8 October 2018

on the granting of a product specific waiver for cell-free solution of lysed *Escherichia coli* culture, strain Laves (Colibiogen oral / Synerga / Colibiogen mild), (EMEA-002393-PIP01-18) 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 Laves-Arzneimittel GmbH on 18 May 2018 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 August 2018 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

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

Has adopted this decision:

Article 1

A waiver for cell-free solution of lysed *Escherichia coli* culture, strain Laves (Colibiogen oral / Synerga / Colibiogen mild), oral solution, oral 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 2

This decision is addressed to Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 - Grenzach-Wyhlen, Germany.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/399349/2018
London, 24 August 2018

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-002393-PIP01-18

Scope of the application

Active substance(s):

Cell-free solution of lysed *Escherichia coli* culture, strain Laves

Invented name:

Colibiogen oral

Synerga

Colibiogen mild

Condition(s):

Treatment of irritable bowel syndrome

Treatment of colitis (excluding infective)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Laves-Arzneimittel GmbH

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Laves-Arzneimittel GmbH submitted to the European Medicines Agency on 18 May 2018 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 26 June 2018.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned conditions 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of irritable bowel syndrome

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- oral solution, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition

Treatment of colitis (excluding infective)

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- oral solution, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of irritable bowel syndrome

Authorised indication(s):

- Treatment of irritable bowel syndrome

2. Treatment of colitis (excluding infective)

Authorised indication(s):

- Treatment of enteritis / colitis, such as radiogenic colitis or Crohn's disease and others in adults

Authorised pharmaceutical form(s):

Oral solution

Authorised route(s) of administration:

Oral use