EMA/134752/2023

European Medicines Agency decision

P/0122/2023

of 14 April 2023

on the granting of a product specific waiver for acoltremon (EMEA-003351-PIP01-22) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Aerie Pharmaceuticals Ireland, Ltd on 9 November 2022 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 February 2023 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 acoltremon, eye drops, solution, ocular 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 Aerie Pharmaceuticals Ireland, Ltd, Athlone Business & Technology Park, Garrycastle, Dublin Road, N37 DW40 – Athlone, Ireland.

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

EMA/PDCO/939271/2022
Amsterdam, 24 February 2023

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

EMEA-003351-PIP01-22

Scope of the application

Active substance(s):

Acoltremon

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of dry eye disease

Pharmaceutical form(s):

Eye drops, solution

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Aerie Pharmaceuticals Ireland, Ltd

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Aerie Pharmaceuticals Ireland, Ltd submitted to the European Medicines Agency on 9 November 2022 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 3 January 2023.

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 the above mentioned condition 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 Paediatric Committee member of Norway 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 dry eye disease

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- eye drops, solution; ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.