EMA/75621/2013

European Medicines Agency decision

P/0026/2013

of 26 February 2013

on the granting of a product specific waiver for aztreonam (Cayston), (EMEA-000827-PIP03-11) 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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on the granting of a product specific waiver for aztreonam (Cayston), (EMEA-000827-PIP03-11) 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 Gilead Sciences International Ltd on 4 November 2011 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 January 2013 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.

[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 waiver for aztreonam (Cayston), powder and solvent for nebuliser solution, inhalation 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 Gilead Sciences International Ltd, Granta Park, CB21 6GT – Abington, United Kingdom.

Done at London, 26 February 2013

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

EMA/PDCO/696058/2012

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

EMEA-000827-PIP03-11

Scope of the application

Active substance(s):

Aztreonam

Invented name:

Cayston

Condition(s):

Treatment of gram-negative endobronchial infection in bronchiectasis patients

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for nebuliser solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd submitted for agreement to the European Medicines Agency on 4 November 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

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The procedure started on 14 December 2011.

Supplementary information was provided by the applicant on 17 October 2012.

The applicant withdrew its proposed paediatric investigation plan and proposed to extend the scope of the waiver to cover all subsets of the paediatric population.

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(s) 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 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.

London, 11 January 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: treatment of gram-negative endobronchial infection in bronchiectasis patients

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for nebuliser solution, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis (CF).

   Authorised indications:

   - Cayston is indicated for the suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 6 years and older.

Authorised pharmaceutical formulation(s):

Powder and solvent for nebuliser solution

Authorised route(s) of administration:

Inhalation use