European Medicines Agency

Doc. Ref. EMEA/90603/2009
P/34/2009

EUROPEAN MEDICINES AGENCY DECISION

of 24 February 2009

on the granting of a product-specific waiver for pemetrexed disodium (Alimta) (EMEA-000126-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Eli Lilly & Company on 6 February 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 January 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

WHEREAS:

(1) The Paediatric Committee has 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 pemetrexed disodium (Alimta), powder for concentrate for solution for infusion, intravenous 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 Eli Lilly & Company, Erl Wood Manor, Sunninghill Road, GU20 6PH Windlesham, Surrey, United Kingdom.

Done at London, 24 February 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

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EMEA-000126-PIP01-07

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance:
Pemetrexed disodium

Invented name:
Alimta

Condition(s):
Malignant pleural mesothelioma
Carcinoma of the head and neck
(Covered by class waiver: oropharyngeal epithelial carcinoma, excluding nasopharyngeal carcinoma)

Pharmaceutical form(s):
Powder for concentrate for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Eli Lilly & Company

Information about the authorised medicinal product:
See Annex I

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Eli Lilly & Company submitted to the EMEA on 6 February 2008 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 13 March 2008.

Supplementary information was provided by the applicant on 13 November 2008.

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Opinion

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations,

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix.

London, 9 January 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU-Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
EU/1/04/290/001	Alimta	500 mg	Powder for concentrate for solution for infusion	Intravenous use	Vial (glass)	1 vial
EU/1/04/290/002	Alimta	100 mg	Powder for concentrate for solution for infusion	Intravenous use	Vial (glass)	1 vial