EMA/846762/2011

# European Medicines Agency decision

P/262/2011

of 28 October 2011

on the granting of a product specific waiver for temsirolimus (Torisel) (EMEA-000026-PIP02-11) 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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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 Pfizer Limited on 11 April 2011 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 9 September 2011 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 temsirolimus (Torisel), concentrate and diluent 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 Pfizer Limited, Ramsgate Road, CT13 9NJ Sandwich, Kent, United Kingdom.

Done at London, 28 October 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/672112/2011

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

EMEA-000026-PIP02-11

## Scope of the application

**Active substance(s):**

Temsirolimus

**Invented name:**

Torisel

**Condition(s):**

Treatment of mantle cell lymphoma

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Concentrate and diluent for solution for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Pfizer Limited

**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, Pfizer Limited submitted to the European Medicines Agency on 11 April 2011 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 July 2011.

## 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 for 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.

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, 9 September 2011

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 mantle-cell lymphoma*

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for concentrate and diluent for solution for infusion;
- on the grounds that the disease or condition for which the specific medicinal product is intended only occurs in adults.

# Annex II

# Information about the authorised medicinal product

**Condition(s) and authorised indication(s):**

1. Treatment of renal cell carcinoma

   Authorised indications:

   Torisel is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC) who have at least three of six prognostic risk factors.

2. Treatment of mantle-cell lymphoma

   Authorised indications:

   Torisel is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma (MCL).

| **EU Number** | **Invented name** | **Strength** | **Pharmaceutical Form** | **Route of Administration** | **Packaging** | **Content (concentration)** | **Package size** |
|---|---|---|---|---|---|---|---|
| EU/1/07/424/001 | Torisel | 30 mg | Concentrate and diluent for solution for infusion | Intravenous use | Vial (glass) | Concentrate: 1.2 ml; diluent: 1.8 ml | 1 vial + 1 vial |