EMA/264450/2010

European Medicines Agency decision

P/68/2010

of 4 May 2010

on the granting of a product specific waiver for sorafenib (as tosylate) (Nexavar) (EMEA-000781-PIP01-09) 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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An agency of the European Union

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on the granting of a product specific waiver for sorafenib (as tosylate) (Nexavar) (EMEA-000781-PIP01-09) 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 Bayer Schering Pharma AG on 3 December 2009 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 19 March 2010 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 sorafenib (as tosylate) (Nexavar), film-coated tablets, 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 Bayer Schering Pharma AG, Müllerstrasse 178, 13353 Berlin, Germany.

Done at London, 4 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/137468/2010

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

EMEA-000781-PIP01-09

Scope of the application

Active substance(s):

Sorafenib (as tosylate)

Invented name:

Nexavar

Condition(s):

Differentiated thyroid cancer

Pharmaceutical form(s):

Film-coated tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bayer Schering Pharma AG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Bayer Schering Pharma AG submitted to the European Medicines Agency on 3 December 2009 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 21 January 2010.

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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 Norwegian Paediatric Committee member(s) agree(s) 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, 19 March 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. GROUNDS FOR THE GRANTING OF THE WAIVER

1.1. Condition differentiated thyroid cancer

Differentiated thyroid cancer

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for film-coated tablets, 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

EU Number	Invented name Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/06/342/001	Nexavar	200 mg	Film-coated tablets	Oral use	Transparent (PP/Aluminium) blister packs	4 x 28 tablets/pack	112 tablets