EMA/492880/2012

European Medicines Agency decision

P/0213/2012

of 28 September 2012

on the granting of a product specific waiver for lapatinib (ditosylate monohydrate) (Tyverb), (EMEA-000404-PIP02-12) 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 lapatinib (ditosylate monohydrate) (Tyverb), (EMEA-000404-PIP02-12) 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 Glaxo Group Ltd on 14 May 2012 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 17 August 2012 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 Lapatinib (ditosylate monohydrate) (Tyverb), film-coated tablet, powder for oral suspension, 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 Glaxo Group Ltd, Glaxo Wellcome House, Berkeley Avenue, UB6 0NN Greenford, United Kingdom.

Done at London, 28 September 2012

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

EMA/PDCO/391771/2012

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

EMEA-000404-PIP02-12

Scope of the application

Active substance(s):

Lapatinib (ditosylate monohydrate)

Invented name:

Tyverb

Condition(s):

Treatment of oesophageal adenocarcinoma

Treatment of gastro oesophageal junction adenocarcinoma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Glaxo Group Ltd

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, Glaxo Group Ltd submitted to the European Medicines Agency on 14 May 2012 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 19 June 2012.

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 all 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 Norwegian Paediatric Committee member 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 annex and appendix.

London, 17 August 2012

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 oesophageal adenocarcinoma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet and powder for oral suspension, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended only occurs in adults.

1.2. Condition: Treatment of gastro oesophageal junction adenocarcinoma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet and powder for oral suspension, oral use;
- 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 Breast cancer

   Authorised indications:

   Tyverb is indicated for the treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2);

   - in combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting (see section 5.1).
   - in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor (See section 5.1).

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/07/440/001	Tyverb	250 mg	Film-coated tablet	Oral use	blister (PA/alu/PVC/alu)	70 tablets
EU/1/07/440/002	Tyverb	250 mg	Film-coated tablet	Oral use	blister (PA/alu/PVC/alu)	2 x 70 tablets
EU/1/07/440/003	Tyverb	250 mg	Film-coated tablet	Oral use	blister (PA/alu/PVC/alu)	84 tablets
EU/1/07/440/004	Tyverb	250 mg	Film-coated tablet	Oral use	bottle (HDPE)	70 tablets
EU/1/07/440/005	Tyverb	250 mg	Film-coated tablet	Oral use	bottle (HDPE)	140 tablets
EU/1/07/440/006	Tyverb	250 mg	Film-coated tablet	Oral use	bottle (HDPE)	84 tablets
EU/1/07/440/007	Tyverb	250 mg	Film-coated tablet	Oral use	bottle (HDPE)	105 tablets