EMA/35172/2011

European Medicines Agency decision

P/36/2011

of 28 January 2011

on the refusal of a product specific waiver for recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein (EMEA-001042-PIP01-10) 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 Teva Pharmaceuticals Europe B.V on 6 September 2010 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 10 December 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 refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing 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 recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein, solution for injection, subcutaneous 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 refused.

Article 2

This decision is addressed to Teva Pharmaceuticals Europe B.V, Building V, the London Road Campus, London Road, CM17 9LP Harlow, Essex, United Kingdom.

Done at London, 28 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

EMA/PDCO/669697/2010

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

EMEA-001042-PIP01-10

Active substance(s):

Recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein

Condition(s):

Prevention of chemotherapy induced neutropenia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Teva Pharmaceuticals Europe B.V

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Teva Pharmaceuticals Europe B.V submitted to the European Medicines Agency on 6 September 2010 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 October 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 refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition as it does not meet the grounds detailed in Article 11(1) of said Regulation.

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

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in Annex I.

This opinion is forwarded to the applicant(s) and the Executive Director of the European Medicines Agency, together with its annex and appendix(ces).

London, 10 December 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Annex I

Grounds for the refusal of the waiver

1. Waiver

The waiver is refused for the following:

1.1. Condition: Prevention of chemotherapy induced neutropenia

The request for the waiver applied to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for solution for injection, subcutaneous use,

as the waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

(a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

(c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;

because:

the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.