EMA/463568/2010

European Medicines Agency decision

P/133/2010

of 28 July 2010

on the refusal of a paediatric investigation plan and on the granting of a waiver for omalizumab, (Xolair) (EMEA-000735-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 Novartis Europharm Limited on 16 October 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 June 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 of said Regulation,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the refusal of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.

(3) 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 paediatric investigation plan for omalizumab (Xolair), powder and solvent for solution for injection and solution for injection in pre-filled syringes, 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

A product-specific waiver for omalizumab (Xolair), powder and solvent for solution for injection and solution for injection in pre-filled syringes, 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 granted.

Article 3

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB Horsham, United Kingdom.

Done at London, 28 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/363185/2010

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000735-PIP01-09

Scope of the application

Active substance(s):

Omalizumab

Invented name:

Xolair

Condition(s):

Allergic asthma

Chronic spontaneous/idiopathic urticaria

Pharmaceutical form(s):

Powder and solvent for solution for injection

Solution for injection in pre-filled syringes

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product: see Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 16 October 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 19 November 2009.

Supplementary information was provided by the applicant on 1 April 2010.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - To refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;
   - to grant a product-specific waiver for all subsets of the paediatric population on its own motion in accordance with Article 12 of said Regulation and concluded 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 does 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 annexes and appendix.

London, 11 June 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 1- Allergic Asthma

1.1.1. Authorised indication

Adults and adolescents (12 years of age and older)

Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who have reduced lung function (FEV1 <80%) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily highdose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)

Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma.

1.1.2. Waiver

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- the powder and solvent for solution for injection and for the solution for injection in pre-filled syringes;
- subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

And to:

- The paediatric population from 6 years to less than 18 years of age;
- the powder and solvent for solution for injection and for the solution for injection in pre-filled syringes;
- subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.2. Condition 2 – Chronic spontaneous/idiopathic urticaria

The waiver applies to:

- The paediatric population from birth to less than 18 years of age;
- the powder and solvent for solution for injection and for the solution for injection in pre-filled syringes;

- subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

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/1/05/319/001	Xolair	75 mg	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	powder: 75 mg; solvent: 2 ml	1 vial + 1 ampoule
EU/1/05/319/002	Xolair	150 mg	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	powder: 150 mg; solvent: 2 ml	1 vial + 1 ampoule
EU/1/05/319/003	Xolair	150 mg	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	powder: 150 mg; solvent: 2 ml	4 intermediate packs (1 vial + 1 ampoule)
EU/1/05/319/004	Xolair	150 mg	Powder and solvent for solution for injection	Subcutaneous use	powder: vial (glass); solvent: ampoule (glass)	powder: 150 mg; solvent: 2 ml	10 intermediate packs (1 vial + 1 ampoule)
EU/1/05/319/005	Xolair	75 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/05/319/006	Xolair	75 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	4 intermediate packs (1 pre-filled syringe)
EU/1/05/319/007	Xolair	75 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	10 intermediate packs (1 pre-filled syringe)
EU/1/05/319/008	Xolair	150 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	1.0 ml	1 pre-filled syringe

EU Number	Invented name Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/05/319/009	Xolair	150 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	1.0 ml	4 intermediate packs (1 pre-filled syringe)
EU/1/05/319/010	Xolair	150 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	1.0 ml	10 intermediate packs (1 pre-filled syringe)