European Medicines Agency

Doc. Ref. EMEA/64242/2009
P/20/2009

EUROPEAN MEDICINES AGENCY DECISION

of 6 February 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for anastrozole, Arimidex and associated names (EMEA-000283-PIP-01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 AstraZeneca AB on 27 May 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended 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 {9 January 2009}, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation,

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting 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 anastrozole, Arimidex and associated names, 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 agreed.

Article 2

A waiver for anastrozole, Arimidex and associated names, 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 3

This decision is addressed to AstraZeneca AB, AstraZeneca European Regulatory Affairs, Building 411A Floor 4, S-151 85, Södertälje , Sweden.

Done at London, 6 February 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/637134/2008
EMEA-000283-PIP-01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER

Scope of the application

Active substance:
Anastrozole

Invented name:
Arimidex and associated names

Condition(s):
Gynaecomastia
McCune-Albright syndrome
Testotoxicosis
Short stature due to Growth Hormone deficiency

Pharmaceutical form(s):
Tablets

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
AstraZeneca AB

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the EMEA on 27 May 2008 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 1 July 2008.

Supplementary information was provided by the applicant on 31 October.

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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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective in part or all of the paediatric population, with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subsets of the paediatric population, and 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 the specified subsets of the paediatric population.

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

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 9 January 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Gynaecomastia
McCune-Albright syndrome
Testotoxicosis
Short stature due to Growth Hormone deficiency

B. WAIVER

- **Condition**

Gynaecomastia

The waiver applies to anastrozole tablets, oral use, in the following paediatric subsets:

- girls from birth to less than 18 years of age, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset;

- prepubertal boys, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset;

- pubertal and postpubertal boys to less than 18 years of age, on the grounds that the specific medicinal product is likely to be ineffective.

- **Condition**

McCune-Albright syndrome

The waiver applies to anastrozole tablets, oral use, in the following paediatric subsets:

- all paediatric subsets, on the grounds that the specific medicinal product is likely to be ineffective.

- **Condition**

Testotoxicosis

The waiver applies to anastrozole tablets, oral use, in the following paediatric subsets:

- girls from birth to less than 18 years of age, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset;

- boys from birth to less than 2 years, on the grounds that specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible in this paediatric subset.

- **Condition**

Short stature due to Growth Hormone deficiency

The waiver applies to anastrozole tablets, oral use, in the following paediatric subsets:

- girls from birth to less than 18 years of age, on the grounds that the specific medicinal product is likely to be unsafe;

- prepubertal boys, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments;

- postpubertal boys who have reached final height, on the grounds that the specific medicinal product is likely to be ineffective.

C. PAEDIATRIC INVESTIGATION PLAN

C.1

- **Condition to be investigated**

  Short stature due to Growth Hormone deficiency

- **Proposed PIP indication**

  Treatment of short stature in pubertal boys with growth hormone deficiency, in association with exogenous growth hormone

- **Subset of the paediatric population concerned by the paediatric development**

  Pubertal and postpubertal boys who have not reached final height

- **Formulation(s)**

  Tablets, oral use

- **Studies**

Area	Number of studies	Description
Quality	-	Not applicable
Non-clinical	-	Not applicable
Clinical	1	Randomised, double-blind, placebo-controlled study of the safety and efficacy of anastrozole in delaying epiphyseal fusion and increasing height potential of adolescent males with growth hormone deficiency.

C.2

- **Condition to be investigated**

  Testotoxicosis

- **Proposed PIP indication**

  Treatment of testotoxicosis, in association with bicalutamide

- **Subset(s) of the paediatric population concerned by the paediatric development**

  Boys from 2 to less than 18 years

- **Formulation(s)**

  Tablets, oral use

- **Studies**

Area	Number of studies	Description
Quality	-	Not applicable
Non-clinical	-	Not applicable
Clinical	1	Open-label, non-comparative, multi-centre study to assess the efficacy and safety of anastrozole when used in combination with bicalutamide for the treatment of gonadotropin-independent precocious puberty in boys with testotoxicosis.

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By May 2008**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**No**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU N.	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
	Arimidex and associated names	1 mg	Film-coated tablets	Oral use			