EMA/535848/2010

European Medicines Agency decision

P/164/2010

of 31 August 2010

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMEA-000069-PIP01-07-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMEA-000069-PIP01-07-M02) 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 European Medicines Agency's decision P/52/2008 issued on 20 July 2008, the decision P/94/2009 issued on 19 May 2009,

Having regard to the application submitted by Glaxo Group Limited on 26 April 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 July 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mepolizumab, powder for solution for infusion, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Glaxo Group Limited, GlaxoWellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom.

Done at London, 31 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000069-PIP01-07-M02

Scope of the application

Active substance(s):

Mepolizumab

Condition(s):

Hypereosinophilic Syndrome

Eosinophilic Esophagitis

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Glaxo Group Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Glaxo Group Limited submitted to the European Medicines Agency on 26 April 2010 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/94/2009 issued on 19 May 2010 and the decision P/52/2008 of 20 July 2008 issued on 20 July 2008.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 20 May 2010.

Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify and revise some of the agreed measures and timelines.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

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

London, 16 July 2010

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

1. Condition(s)

Hypereosinophilic Syndrome

Eosinophilic Esophagitis

2. Waiver

Not applicable.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Hypereosinophilic Syndrome

3.1.1. Indication(s) targeted by the PIP

Treatment of Hypereosinophilic Syndrome

3.1.2. Subset(s) of the paediatric population concerned by the paediatric development

Neonates, infants, children and adolescents from 0 to less than 18 years.

3.1.3. Pharmaceutical form(s)

Powder for solution for infusion.

3.1.4. Studies

Area	**Number of studies**	**Description**
Quality	n/a	n/a
Non-Clinical	2	Fertility, early embryonic and embryo-fetal development in mice. Pre - and postnatal development in Cynomolgus monkeys.
Clinical Safety, tolerability, pharmacokinetics, efficacy	1	Prospective open-label clinical trial of monthly doses of intravenous mepolizumab with a duration of up to 12 months and a 2 year follow up period in paediatric patients with Hypereosinophilic Syndrome, aged from 0 to less than 18 years.

3.2. Condition to be investigated

Eosinophilic Esophagitis

3.2.1. Indication(s) targeted by the PIP

Treatment of Eosinophilic Esophagitis

3.2.2. Subset(s) of the paediatric population concerned by the paediatric development

Neonates, infants, children and adolescents from 0 to less than 18 years.

3.2.3. Pharmaceutical form(s)

Powder for solution for infusion.

3.2.4. Studies

Area	Number of studies	Description
Quality	n/a	n/a
Non-Clinical	2	Fertility, early embryonic and embryo-fetal development in mice. Pre - and postnatal development in Cynomolgus monkeys.
Clinical	3	Randomised, double-blind, parallel group, multicentre clinical trial of intravenous mepolizumab in paediatric patients with Eosinophilic Esophagitis aged from 2 to less than 18 years. Randomised, double-blind, parallel group, multicentre clinical trial of intravenous mepolizumab in paediatric patients with Eosinophilic Esophagitis aged from 0 to less than 2 years. Clinical trial in paediatric patients aged from 0 to less than 18 years with Eosinophilic Esophagitis who have failed prior therapy with dietary treatment and treatment with corticosteroids.

Follow-up, completion and deferral of PIP

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 June 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes