



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/329215/2014

European Medicines Agency decision

P/0161/2014

of 12 June 2014

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMA-000069-PIP02-10-M03) 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.



European Medicines Agency decision

P/0161/2014

of 12 June 2014

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMA-000069-PIP02-10-M03) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/219/2011 issued on 26 September 2011, the decision P/0054/2013 issued on 25 March 2013, and the decision P/0234/2013 issued on 24 September 2013,

Having regard to the application submitted by GSK Trading Services Limited on 27 February 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 May 2014, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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 injection / infusion, intravenous use, subcutaneous use, including changes to the deferral, 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 GSK Trading Services Limited, GSK Trading Services Limited, Currabinny, Carrigaline, County Cork, Ireland.

Done at London, 12 June 2014

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

EMA/PDCO/140526/2014

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

EMA-000069-PIP02-10-M03

Scope of the application

Active substance(s):

Mepolizumab

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Powder for solution for injection / infusion

Route(s) of administration:

Intravenous use

Subcutaneous use

Name / corporate name of the PIP applicant:

GSK Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GSK Trading Services Limited submitted to the European Medicines Agency on 27 February 2014 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/219/2011 issued on 26 September 2011, the decision P/0054/2013 issued on 25 March 2013, and the decision P/0234/2013 issued on 24 September 2013.

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

The procedure started on 25 March 2014.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified. A deferral to an existing measure has been added.

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 and to the deferral in the scope set out in the Annex I of this opinion.

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 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 European Medicines Agency, together with its annex and appendix.

London, 23 May 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: treatment of asthma

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- for powder for solution for injection / infusion, intravenous use and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Reduction of severe asthma exacerbations.

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

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection / infusion.

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	5	Study 2 Double-blind, randomised, multi-centre, placebo-controlled, parallel-group study to evaluate efficacy and safety of mepolizumab as add-on therapy in children from 12 to less than 18 years old (and in adults) with severe uncontrolled asthma. Study 3 Double-blind, randomised, multi-centre, placebo-controlled, parallel-group study to evaluate efficacy of mepolizumab to reduce steroid use as add-on therapy in children from 12 to less than 18 years old (and in adults) with severe uncontrolled asthma.

		Study 6 Double-blind, randomised, dose ranging, parallel group trial to evaluate PK/PD, safety and tolerability of mepolizumab in children from 2 to less than 18 years of age with eosinophilic esophagitis. Study 7 Open-label, randomised trial to evaluate PK/PD, safety and tolerability of mepolizumab as add-on to best standard of care in children from 6 to less than 12 years of age with severe eosinophilic asthma. Study 8 Analysis of PK, PD, efficacy, safety and tolerability data on mepolizumab from studies 2, 3, 6 and 7 in conditions severe eosinophilic asthma and eosinophilic esophagitis.
Extrapolation, modelling & simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes