EMA/755906/2014

European Medicines Agency decision

P/0326/2014

of 22 December 2014

on the agreement of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver for mepolizumab (EMEA-000069-PIP04-13) 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 GSK Trading Services Limited on 30 August 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 agreement of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver.

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

(3) It is therefore appropriate to adopt a decision refusing a deferral.

(4) 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 mepolizumab, powder for solution for injection or infusion, 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 agreed.

Article 2

A deferral for mepolizumab, powder for solution for injection or infusion, 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 3

A waiver for mepolizumab, powder for solution for injection or infusion, 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 4

This decision is addressed to GSK Trading Services Limited, Currabinny, Carrigaline, County Cork, Cork, Ireland.

Done at London, 22 December 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
Signature on file

EMA/PDCO/546280/2014

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver and on the refusal of a deferral

EMEA-000069-PIP04-13

Scope of the application

Active substance(s):

Mepolizumab

Condition(s):

Treatment of Vasculitides

Pharmaceutical form(s):

Powder for solution for injection or infusion

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

GSK Trading Services Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GSK Trading Services Limited submitted for agreement to the European Medicines Agency on 30 August 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 10 October 2014.

Supplementary information was provided by the applicant on 20 August 2014.

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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 refuse a deferral in accordance with Article 21 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)(c) of said Regulation, that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 European Medicines Agency, together with its annexes and appendix.

London, 14 November 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of Vasculitides

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- Powder for solution for injection or infusion, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Vasculitides

2.1.1. Indication(s) targeted by the PIP

Treatment of eosinophilic granulomatosis with polyangiitis

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 or infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies		Not applicable.
Extrapolation, modelling and simulation studies	4	**Study 1:** Modelling and simulation study to evaluate the use of mepolizumab in the treatment of adult with eosinophilic granulomatosis with polyangiitis. **Study 2**

Area	Number of measures	Description
		Modelling and simulation study to evaluate the exposure-response of mepolizumab in adult and children with eosinophilic esophagitis, asthma, hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis. **Study 3** Modelling and simulation study to evaluate the PD response of mepolizumab in adult and children with eosinophilic esophagitis, asthma, hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis. **Study 4** Extrapolation study to evaluate the use of mepolizumab in adult and children of mepolizumab on eosinophilic esophagitis, asthma, hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No