EMA/4124/2016

European Medicines Agency decision

P/0007/2016

of 29 January 2016

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMEA-000069-PIP01-07-M04) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0007/2016

of 29 January 2016

on the acceptance of a modification of an agreed paediatric investigation plan for mepolizumab (EMEA-000069-PIP01-07-M04) 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, the decision P/164/2010 issued on 31 August 2010 and the decision P/0083/2015 issued on 8 May 2015,

Having regard to the application submitted by GSK Trading Services Limited on 17 September 2015 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 11 December 2015, 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 infusion, intravenous 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, Currabinny, Carrigaline, Country Cork, Cork, Ireland.

Done at London, 29 January 2016

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

EMA/PDCO/640420/2015
London, 11 December 2015

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

EMEA-000069-PIP01-07-M04

Scope of the application

Active substance(s):

Mepolizumab

Condition(s):

Treatment of hypereosinophilic syndrome

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous 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 17 September 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/52/2008 issued on 20 July 2008, the decision P/94/2009 issued on 19 May 2009, the decision P/164/2010 issued on 31 August 2010 and the decision P/0083/2015 issued on 8 May 2015.

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

The procedure started on 13 October 2015.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Scope of the modification

Timelines of the Paediatric Investigation Plan and the deferral have been modified.

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 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 and appendix.

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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of hypereosinophilic syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of hypereosinophilic syndrome

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

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

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	2	**Study 1** Fertility, early embryonic and embryo-fetal development in mice. (RSD 100P8V) **Study 2** Pre - and postnatal development in Cynomolgus monkeys. (CD2003/01020/00)
Clinical studies	1	**Study 3** 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. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes