EMA/87155/2013

European Medicines Agency decision

P/0021/2013

of 15 February 2013

on the acceptance of a modification of an agreed paediatric investigation plan for fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl) amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (EMEA-000431-PIP01-08-M05) 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 European Medicines Agency's decision P/202/2009 issued on 12 October 2009, the decision P/30/2010 issued on 5 March 2010, the decision P/165/2010 issued on 31 August 2010, and the decision P/119/2011 issued on 7 June 2011 and the decision P/0049/2012 issued on 1 March 2012,

Having regard to the application submitted by Glaxo Group Limited on 18 October 2012 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 11 January 2013, 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 fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl) amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol, inhalation powder, pre-dispensed, inhalation 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, Glaxo Wellcome House, Berkeley Avenue, UB6 0NN – Greenford, United Kingdom.

Done at London, 15 February 2013

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

EMA/PDCO/686282/2012

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

EMEA-000431-PIP01-08-M05

Scope of the application

Active substance(s):

Fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl) amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Route(s) of administration:

Inhalation 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 18 October 2012 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/202/2009 issued on 12 October 2009, the decision P/30/2010 issued on 5 March 2010, the decision P/165/2010 issued on 31 August 2010, and the decision P/119/2011 issued on 7 June 2011 and the decision P/0049/2012 issued on 1 March 2012.

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

The procedure started on 14 November 2012.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 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, 11 January 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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: asthma

The waiver applies to:

- the paediatric population from birth to less than 5 years;
- for inhalation powder, pre-dispensed, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Treatment of asthma where use of a combination product (long acting beta agonist and inhaled corticosteroid) is appropriate.

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

From 5 years to less than 18 years.

2.1.3. Pharmaceutical form(s)

Inhalation powder, pre-dispensed.

2.1.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Repeat dose toxicity and toxicokinetic study in the juvenile dog
Clinical	15	1. Phase III 12 week efficacy and safety study of low-dose fluticasone furoate (FF)/ GW642444M*) combination in adolescent (and adult) subjects with persistent asthma; 2. Phase III 12 week efficacy and safety study of high-dose FF/ GW642444M combination in adolescent (and adult) subjects with persistent asthma; 3. Phase III 12 week efficacy study for GW642444 (as an add-on to inhaled steroid) in adolescent (and adult) subjects with persistent asthma; 4. Phase III long-term safety study of FF/GW642444M combination in adolescent (and adult) subjects with persistent asthma;

		5. Phase III exacerbation study of FF/GW642444M combination in adolescent (and adult) subjects with persistent asthma; 6. Phase III efficacy study of low-dose FF in adolescent (and adult) subjects with persistent asthma; 7. Ph IIa repeat dose Pharmacokinetic (PK)/Pharmacodynamic (PD), safety and tolerability study of FF in children 5 to less than 12 years with persistent asthma; 8. Ph IIb dose ranging study of FF in children 5 to less than 12 years with persistent asthma; 9. Phase IIa PK/PD, safety and tolerability study of GW642444M in children 5 to less than 12 years with persistent asthma; 10. Ph IIb dose ranging study of GW642444M in children 5 to less than 12 years with persistent asthma; 11. Phase IIa PK/PD, safety and tolerability study of FF/GW642444M combination in children 5 to less than 12 years with persistent asthma; 12. Ph III efficacy and safety study of FF/GW642444M combination in children 5 to less than 12 years with persistent asthma; 13. Ph III fluticasone furoate knemometry study in children 5 to less than 12 years with persistent asthma; 14. Phase III study to assess the effect of fluticasone furoate on the hypothalamic pituitary adrenocortical (HPA) axis in children 5 to less than 12 years with persistent asthma; 15. Ph IV study to assess the effect of fluticasone furoate on growth velocity in pre-pubertal children with persistent asthma.

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 August 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes