EMA/493077/2013

European Medicines Agency decision

P/0216/2013

of 30 August 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-M06) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

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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, the decision P/119/2011 issued on 7 June 2011, the decision P/0049/2012 issued on 1 March 2012, and the decision P/0021/2013 issued on 15 February 2013,

Having regard to the application submitted by Glaxo Group Limited on 20 May 2013 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 9 August 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, 980 Great West Road, TW8 9GS – Brentford, United Kingdom.

Done at London, 30 August 2013

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

EMA/PDCO/323764/2013

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

EMEA-000431-PIP01-08-M06

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 20 May 2013 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, the decision P/119/2011 issued on 7 June 2011, the decision P/0049/2012 issued on 1 March 2012, and the decision P/0021/2013 issued on 15 February 2013.

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

The procedure started on 12 June 2013.

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Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan 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 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 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, 9 August 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: treatment of 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	**Measure 16** Repeat dose toxicity and toxicokinetic study in the juvenile dog.
Clinical	14	*Studies in adolescents (12 to less than 18 years) and adults:* **Measure 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. **Measure 2** Phase III 12 week efficacy and safety study of high-dose FF/ GW642444M combination in adolescent (and adult) subjects with persistent asthma.

		Measure 3 Phase III 12 week efficacy study for GW642444 (as an add-on to inhaled steroid) in adolescent (and adult) subjects with persistent asthma. **Measure 4** Phase III long-term safety study of FF/GW642444M combination in adolescent (and adult) subjects with persistent asthma. **Measure 5** Phase III exacerbation study of FF/GW642444M combination in adolescent (and adult) subjects with persistent asthma. **Measure 6** Phase III efficacy study of low-dose FF in adolescent (and adult) subjects with persistent asthma. *Studies in children (5 to less than 12 years):* **Measure 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. **Measure 8** Ph IIb dose ranging study of FF in children 5 to less than 12 years with persistent asthma. **Measure 9** Phase IIa PK/PD, safety and tolerability study of GW642444M in children 5 to less than 12 years with persistent asthma. **Measure 10** Ph IIb dose ranging study of GW642444M in children 5 to less than 12 years with persistent asthma. **Measure 11** Phase IIa PK/PD, safety and tolerability study of FF/GW642444M combination in children 5 to less than 12 years with persistent asthma. **Measure 12** Ph III efficacy and safety study of FF/GW642444M combination in children 5 to less than 12 years with persistent asthma. **Measure 13** Ph III fluticasone furoate knemometry study in children 5 to less than 12 years with persistent asthma. ***(Measure 14 was deleted during 000431-PIP01-08-M06)***

		Measure 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 November 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes