

EMA/75596/2018

European Medicines Agency decision

P/0076/2018

of 16 March 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for fluticasone furoate / umecclidinium bromide / vilanterol trifenate (EMA-002153-PIP01-17) 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 726/2004¹,

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 application submitted by GlaxoSmithKline Trading Services Limited on 12 April 2017 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 26 January 2018, in accordance with Article 17 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 granting 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 granting 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 fluticasone furoate / umeclidinium bromide / vilanterol trifenate, inhalation powder, pre-dispensed, inhalation 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 fluticasone furoate / umeclidinium bromide / vilanterol trifenate, inhalation powder, pre-dispensed, inhalation 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 3

A waiver for fluticasone furoate / umeclidinium bromide / vilanterol trifenate, inhalation powder, pre-dispensed, inhalation 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 GlaxoSmithKline Trading Services Limited, Currabinny, Carrigaline, Co. Cork, Ireland.

EMA/PDCO/744122/2017

London, 26 January 2018

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

EMA-002153-PIP01-17

Scope of the application

Active substance(s):

Fluticasone furoate / umecclidinium bromide / vilanterol trifenate

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:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted for agreement to the European Medicines Agency on 12 April 2017 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 24 May 2017.

Supplementary information was provided by the applicant on 6 November 2017. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) of said Regulation;
- to grant 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, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees 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 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

1.1. Condition

Treatment of asthma

The waiver applies to:

- the paediatric population from birth to less than 5 years;
- inhalation powder, pre-dispensed, inhalation 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 asthma

2.1.1. Indication(s) targeted by the PIP

Maintenance treatment of asthma in patients aged 5 years or older who have inadequately controlled asthma despite therapy with inhaled corticosteroids and long acting beta agonists

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

From 5 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation powder, pre-dispensed

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	Study 1 (206867) Double-blind, randomised 52-week study comparing the safety and efficacy and pharmacokinetics (PK) of fluticasone furoate (FF) / umeclidinium bromide (UMEC)/ vilanterol (VI) with FF/VI in adolescents with inadequately controlled asthma on stable maintenance therapy with inhaled corticosteroids (ICS) and long-acting β adrenoceptor agonists (LABA).

		Study 2 (206868) Double-blind, 3-period, 4 treatment balanced incomplete block cross-over, single-dose study to evaluate the PK and bronchodilatory effect of UMEC when added to FF/VI in children 5 to less than 12 years of age with asthma. Study 3 (207717) Double-blind, randomised 52-week study comparing the safety and efficacy of FF / UMEC/ VI with FF/VI in children with asthma 5 to less than 12 years of age.
Extrapolation, modelling and simulation studies	2	Study 4 Population PK models to predict the systemic exposure for each analyte in children and adolescents with asthma. Study 5 Physiological based pharmacokinetics (PBPK) model to predict the UMEC systemic PK following inhalation of FF/UMEC/VI in children 5 to less than 12 years of age and to evaluate the CYP2D6 activity.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 December 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes