EMA/72934/2021

European Medicines Agency decision

P/0092/2021

of 19 March 2021

on the acceptance of a modification of an agreed paediatric investigation plan for fluticasone (furoate) / vilanterol (Relvar Ellipta and associated names), (EMEA-000431-PIP01-08-M12) 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, the decision P/119/2011 issued on 7 June 2011, the decision P/0049/2012 issued on 1 March 2012, the decision P/0021/2013 issued on 15 February 2013, the decision P/0216/2013 issued on 30 August 2013, the decision P/0291/2014 issued on 24 October 2014, the decision P/0164/2015 issued on 7 August 2015, the decision P/0276/2016 issued on 10 October 2016, the decision P/0157/2017 issued on 9 June 2017 and the decision P/0374/2020 issued on 9 September 2020,

Having regard to the application submitted by Glaxo Group Limited on 21 October 2020 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 29 January 2021, 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) / vilanterol (Relvar Ellipta and associated name), 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, Brentford - TW8 9GS, United Kingdom.

EMA/PDCO/577744/2020
Amsterdam, 29 January 2021

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

EMEA-000431-PIP01-08-M12

Scope of the application

Active substance(s):

Fluticasone (furoate) / vilanterol

Invented name:

Relvar Ellipta and associated names

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Glaxo Group Limited

Information about the authorised medicinal product:

See Annex II

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 21 October 2020 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, the decision P/0021/2013 issued on 15 February 2013, the decision P/0216/2013 issued on 30 August 2013, the decision P/0291/2014 issued on 24 October 2014, the decision P/0164/2015 issued on 7 August 2015, the decision P/0276/2016 issued on 10 October 2016, the decision P/0157/2017 issued on 9 June 2017 and the decision P/0374/2020 issued on 9 September 2020.

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

The procedure started on 1 December 2020.

Scope of the modification

A measure of the Paediatric Investigation Plan has 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 annexes 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 of age;
- 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 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	1	**Study 16** Repeat dose toxicity and toxicokinetic study in the juvenile dog.
Clinical studies	14	*Studies in adolescents (12 to less than 18 years of age) and adults:* **Study 1** 12 week efficacy and safety study of low-dose fluticasone (furoate) / vilanterol combination in adolescent (and adult) subjects with persistent asthma.

		Study 2 12 week efficacy and safety study of high-dose fluticasone (furoate) / vilanterol combination in adolescent (and adult) subjects with persistent asthma. **Study 3** 12 week efficacy study for vilanterol (as an add-on to inhaled steroid) in adolescent (and adult) subjects with persistent asthma. **Study 4** Long-term safety study of fluticasone (furoate) /vilanterol combination in adolescent (and adult) subjects with persistent asthma. **Study 5** Exacerbation study of fluticasone (furoate) /vilanterol combination in adolescent (and adult) subjects with persistent asthma. **Study 6** Efficacy study of low-dose fluticasone (furoate) in adolescent (and adult) subjects with persistent asthma. *Studies in children (5 to less than 12 years of age):* **Study 7** Repeat dose Pharmacokinetic (PK)/Pharmacodynamic (PD), safety and tolerability study of fluticasone (furoate) in children 5 to less than 12 years of age with persistent asthma. **Study 8** Dose ranging study of fluticasone (furoate) in children 5 to less than 12 years of age with persistent asthma. **Study 9** PK/PD, safety and tolerability study of vilanterol in children 5 to less than 12 years of age with persistent asthma. **Study 10** Dose ranging study of vilanterol in children 5 to less than 12 years of age with persistent asthma. **Study 11** PK/PD, safety and tolerability study of fluticasone (furoate) /vilanterol combination in children 5 to less than 12 years of age with persistent asthma.

		Study 12 Efficacy and safety study of fluticasone (furoate) /vilanterol combination in children 5 to less than 12 years of age with asthma. **Study 13** Fluticasone (furoate) knemometry study in children 5 to less than 12 years of age with persistent asthma. ***Study 14*** *This study was deleted as a result of procedure EMEA-000431-PIP01-08-M06.* **Study 15** Phase IV study to assess the effect of fluticasone (furoate) on growth velocity in pre-pubertal children with asthma.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 October 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indication(s):

- Regular treatment of asthma in adults and adolescents aged 12 years and older, where use of a combination product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate:
  - Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta2-agonists.

2. Treatment of chronic obstructive pulmonary disease (COPD)

Authorised indication(s):

- Symptomatic treatment of adults with COPD with a FEV1 <70% predicted normal (post-bronchodilator) in patients with an exacerbation history despite bronchodilator therapy.

Authorised pharmaceutical form(s):

Inhalation powder, pre-dispensed

Authorised route(s) of administration:

Inhalation use