

EMA/227156/2019

European Medicines Agency decision

P/0179/2019

of 15 May 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993) (Trimbow and associated names), (EMA-001875-PIP02-18) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993) (Trimbow and associated names), (EMA-001875-PIP02-18) 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 726/2004¹,

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 Chiesi Farmaceutici S.p.A. on 22 March 2018 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 29 March 2019, 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 beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993) (Trimbow and associated names), pressurised inhalation, solution, inhalation powder, 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 beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993) (Trimbow and associated names), pressurised inhalation, solution, inhalation powder, 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 beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993) (Trimbow and associated names), pressurised inhalation, solution, inhalation powder, 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 Chiesi Farmaceutici S.p.A., Via Palermo 26/A, 43122 – Parma, Italy.

EMA/PDCO/908806/2019
Amsterdam, 29 March 2019

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

EMA-001875-PIP02-18

Scope of the application

Active substance(s):

Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993)

Invented name:

Trimbow and associated names

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Pressurised inhalation, solution

Inhalation powder

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Chiesi Farmaceutici S.p.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted for agreement to the European Medicines Agency on 22 March 2018 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 2 May 2018.

Supplementary information was provided by the applicant on 19 December 2018. 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 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 6 years of age;
 - pressurised inhalation, solution, inhalation use;
 - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments;
- and
- all subsets of the paediatric population from birth to less than 18 years of age;
 - inhalation powder, 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 in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Pressurised inhalation, solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.

Area	Number of measures	Description
Non-clinical studies	0	Not applicable.
Clinical studies	4	Study 1 (CLI-05993CB1-01) Open label, non-randomised, single dose pharmacokinetic (PK)/pharmacodynamic (PD) study of CHF 5993 in adolescent asthmatic patients 12 years to less than 18 years of age (and adult asthmatic patients). Study 2 (CLI-05993CB1-02) Double blind, parallel group, study to assess safety and efficacy of CHF 5993 vs. the free combination of Atimos (formoterol fumarate dihydrate (FF)) pMDI and Qvar (beclometasone dipropionate (BDP)) pMDI as comparator in adolescents 12 years to less than 18 years of age with uncontrolled asthma. Study 3 Double-blind randomised, crossover, active-controlled study to evaluate pharmacokinetics (PK), efficacy, safety and tolerability of CHF 5993 in children from 6 years to less than 12 years of age with uncontrolled asthma. Study 4 Double-blind, randomised, parallel-group active controlled study to evaluate the efficacy and safety of CHF 5993 in children from 6 years to less than 12 years of age with uncontrolled 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:	No
Date of completion of the paediatric investigation plan:	By December 2030
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 chronic obstructive pulmonary disease (COPD)

Authorised indication(s):

- Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist.

Authorised pharmaceutical form(s):

Pressurised inhalation, solution (pressurised inhalation)

Authorised route(s) of administration:

Inhalation use