EMA/441052/2016

European Medicines Agency decision

P/0212/2016

of 12 August 2016

on the acceptance of a modification of an agreed paediatric investigation plan for budesonide (EMEA-001087-PIP02-12-M02) 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 acceptance of a modification of an agreed paediatric investigation plan for budesonide (EMEA-001087-PIP02-12-M02) 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 726/2004[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/0218/2013 issued on 6 September 2013,

Having regard to the application submitted by Vectura Limited on 31 March 2016 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 24 June 2016, 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 and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and to the 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

Changes to the agreed paediatric investigation plan for budesonide, nebuliser suspension, inhalation use, including changes to the deferral and to the waiver, 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 Vectura Limited, One Prospect West, SN14 6FH – Chippenham, United Kingdom.

EMA/PDCO/268411/2016
London, 24 June 2016

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

EMEA-001087-PIP02-12-M02

Scope of the application

Active substance(s):

Budesonide

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Nebuliser suspension

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Vectura Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Vectura Limited submitted to the European Medicines Agency on 31 March 2016 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/0218/2013 issued on 6 September 2013.

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

The procedure started on 26 April 2016.

A meeting with the Paediatric Committee took place on 23 June 2016.

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Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the deferral and to the waiver 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.

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 12 years of age;
- for nebuliser suspension, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

1.2 Condition: treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Add-on therapy for the treatment of uncontrolled asthma, despite treatment with high dose inhaled corticosteroids and at least a second controller, in patients from 12 to less than 18 years of age with history of exacerbations with/without dependence on oral corticosteroids

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

From 12 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nebuliser suspension

2.1.4. Measures

Area	Number of measures	Description
Quality	0	**Study 1** Deleted during procedure EMEA-001087-PIP02-12-M02
Non-clinical	0	Not applicable.
Clinical	1	**Study 2** Deleted during procedure EMEA-001087-PIP02-12-M02 **Study 3** Deleted during procedure EMEA-001087-PIP02-12-M02 **Study 4** Deleted during procedure EMEA-001087-PIP02-12-M02

Area	Number of measures	Description
		Study 5 Double-blind, randomised, placebo and active-controlled, parallel group trial to evaluate the efficacy and safety of two doses of nebulised budesonide delivered by the VR475 Inhalation System with an open-label comparison to conventionally nebulised budesonide in children from 12 to less than 18 years of age (and adults) 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 issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No