EMA/724324/2017

European Medicines Agency decision

P/0352/2017

of 1 December 2017

on the acceptance of a modification of an agreed paediatric investigation plan for secukinumab (Cosentyx) (EMEA-000380-PIP01-08-M04) 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/154/2009 issued on 11 August 2009, the decision P/0144/2014 issued on 13 June 2014, the decision P/0011/2015 issued on 30 January 2015, and the decision P/0140/2015 issued on 10 July 2015,

Having regard to the application submitted by Novartis Europharm Ltd on 24 July 2017 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 13 October 2017, 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 secukinumab (Cosentyx), powder for solution for injection, solution for injection, subcutaneous 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 Novartis Europharm Ltd, Frimley Business Park, GU167SR – Camberley, United Kingdom.

EMA/PDCO/501578/2017 Corr
London, 13 October 2017

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

EMEA-000380-PIP01-08-M04

Scope of the application

Active substance(s):

Secukinumab

Invented name:

Cosentyx

Condition(s):

Treatment of psoriasis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd submitted to the European Medicines Agency on 24 July 2017 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/154/2009 issued on 11 August 2009, the decision P/0144/2014 issued on 13 June 2014, the decision P/0011/2015 issued on 30 January 2015, and the decision P/0140/2015 issued on 10 July 2015.

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

The procedure started on 15 August 2017.

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 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 psoriasis

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- powder for solution for injection, solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition

Treatment of psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to non-biologic systemic therapies

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical forms

Powder for solution for injection

Solution for injection (pre-filled syringe or pen)

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable
Non-clinical studies	2	**Study 1** Fertility and early embryonic development (FEED) study in mice using a surrogate antibody **Study 2** Peri- and postnatal study in mice using a surrogate antibody

Clinical studies	2	**Study 3: CAIN457A2310** Double-blind, randomized, placebo-controlled, active comparator (etanercept as single-blinded arm) multicentre trial with secukinumab in children from 6 to less than 18 years of age with severe plaque psoriasis to demonstrate the efficacy of secukinumab as compared to placebo and compared to etanercept **Study 4** Open label, uncontrolled multicentre trial with secukinumab in children from 6 to less than 18 years of age with moderate to severe plaque psoriasis to evaluate the efficacy, safety and pharmacokinetics of secukinumab
Extrapolation, modelling and simulation studies	1	**Study 5** Extrapolation for exposure-response analysis to support the use of secukinumab for the treatment of children from 6 to less than 18 years of age with psoriasis
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:	No
Date of completion of the paediatric investigation plan:	By June 2023
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 psoriasis

Authorised indication(s):

- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy

2. Treatment of chronic idiopathic arthritis

Authorised indication(s):

- Treatment (alone or in combination with methotrexate (MTX)) of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate
- Treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Authorised pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Authorised route(s) of administration:

Subcutaneous use