EMA/460043/2017

European Medicines Agency decision

P/0225/2017

of 11 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for allantoin (EMEA-001590-PIP01-13-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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on the acceptance of a modification of an agreed paediatric investigation plan for allantoin (EMEA-001590-PIP01-13-M04) 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/0266/2014 issued on 13 October 2014, the decision P/0031/2015 issued on 12 February 2015, the decision P/0138/2016 issued on 20 May 2016 and the decision P/0361/2016 issued on 21 December 2016,

Having regard to the application submitted by Scioderm, Inc. on 3 April 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 June 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 allantoin, cream, topical 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 Scioderm, Inc., 4601 Creekstone Dr., Suite 160, NC 27703 - Durham, United States.

EMA/PDCO/227548/2017
London, 23 June 2017

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

EMEA-001590-PIP01-13-M04

Scope of the application

Active substance(s):

Allantoin

Condition(s):

Treatment of epidermolysis bullosa

Pharmaceutical form(s):

Cream

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Scioderm, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Scioderm, Inc. submitted to the European Medicines Agency on 3 April 2017 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0266/2014 issued on 13 October 2014, the decision P/0031/2015 issued on 12 February 2015, the decision P/0138/2016 issued on 20 May 2016 and the decision P/0361/2016 issued on 21 December 2016.

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

The procedure started on 25 April 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of epidermolysis bullosa

2.1.1. Indication(s) targeted by the PIP

Treatment of epidermolysis bullosa

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 1** Multi-centre, randomized, double-blind, vehicle controlled, study to assess the efficacy and safety of allantoin cream vs. SD-101-0.0 (vehicle) in the treatment of skin lesions in patients with epidermolysis bullosa.
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 July 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No