EMA/765281/2016

European Medicines Agency decision

P/0335/2016

of 2 December 2016

on the acceptance of a modification of an agreed paediatric investigation plan for fentanyl (hydrochloride) (IONSYS), (EMEA-001509-PIP01-13-M01) 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 fentanyl (hydrochloride) (IONSYS), (EMEA-001509-PIP01-13-M01) 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/0111/2014 issued on 5 May 2016,

Having regard to the application submitted by Incline Therapeutics Europe Ltd. on 11 July 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 14 October 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.

(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.

[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 fentanyl (hydrochloride) (IONSYS), transdermal system, transdermal use, including changes to the deferral, 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 Incline Therapeutics Europe Ltd., 21 St. Thomas Street, BS1 6JS – Bristol, United Kingdom.

EMA/PDCO/515075/2016
London, 14 October 2016

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

EMEA-001509-PIP01-13-M01

Scope of the application

Active substance(s):

Fentanyl (hydrochloride)

Invented name:

IONSYS

Condition(s):

Treatment of acute pain

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Transdermal system

Route(s) of administration:

Transdermal use

Name/corporate name of the PIP applicant:

Incline Therapeutics Europe 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, Incline Therapeutics Europe Ltd. submitted to the European Medicines Agency on 11 July 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/0111/2014 issued on 5 May 2016.

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

The procedure started on 16 August 2016.

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 and to the deferral 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 acute pain

The waiver applies to:

- The paediatric population from birth to less than 2 years of age;
- for transdermal system for transdermal 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 acute pain

2.1.1. Indication(s) targeted by the PIP

Management of acute moderate to severe post-operative pain for use in children from 2 to less than 18 years of age in a hospital setting only

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Transdermal system

2.1.4. Measures

Area	Number of measures	Description
Quality	2	**Study 1:** Development of an age-appropriate 25 mcg/dose transdermal system for use in paediatric patients from 6 to less than 12 years of age. **Study 2:** Development of an age-appropriate 10 mcg/dose transdermal system for use in paediatric patients from 2 to less than 6 years of age.
Non-clinical	0	Not applicable.

Clinical	4	**Study 3:** Multicentre, single-arm, open-label study to evaluate the safety, effectiveness and clinical utility of fentanyl 40 mcg transdermal system in paediatric patients from 12 to less than 18 years of age (PD2013-002) **Study 4:** Deleted in EMEA-001509-PIP01-13-M01 **Study 5:** Deleted in EMEA-001509-PIP01-13-M01 **Study 6:** Multicentre, randomised, two arm open-label study to evaluate the safety, effectiveness and clinical utility of fentanyl 25 mcg transdermal system in paediatric post-operative patients from 6 to less than 12 years of age (PD2013-003) **Study 7:** Deleted in EMEA-001509-PIP01-13-M01 **Study 8:** Single-centre, open-label, human factors study to validate usability of the placebo fentanyl 10 mcg transdermal system by paediatric nurses and by healthy paediatric volunteers from 2 to less than 6 years of age (HF2013-007) **Study 9:** Multicentre, single arm open-label study to evaluate the safety, effectiveness and clinical utility of fentanyl 10 mcg transdermal system in paediatric post-operative patients from 2 to less than 6 years of age (PD2013-004)
Other	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 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 acute pain

Authorised indication(s):

- IONSYS is indicated for the management of acute moderate to severe post-operative pain in adult patients

Authorised pharmaceutical form(s):

Transdermal system

Authorised route(s) of administration:

Transdermal use