EMA/169011/2014

European Medicines Agency decision

P/0111/2014

of 5 May 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for fentanyl (hydrochloride) (EMEA-001509-PIP01-13) 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 application submitted by Incline Therapeutics Europe Ltd. on 2 August 2013 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 21 March 2014, in accordance with Article 18 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 fentanyl (hydrochloride), transdermal system, transdermal 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 fentanyl (hydrochloride), transdermal system, transdermal 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 fentanyl (hydrochloride), transdermal system, transdermal 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 Incline Therapeutics Europe Ltd., 21 St. Thomas Street, BS1 6JS - Bristol, United Kingdom.

Done at London, 5 May 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/5026/2014

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

EMEA-001509-PIP01-13

Scope of the application

Active substance(s):

Fentanyl (hydrochloride)

Condition(s):

Treatment of acute pain

Pharmaceutical form(s):

Transdermal system

Route(s) of administration:

Transdermal use

Name/corporate name of the PIP applicant:

Incline Therapeutics Europe Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Incline Therapeutics Europe Ltd. submitted for agreement to the European Medicines Agency on 2 August 2013 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 12 September 2013.

Supplementary information was provided by the applicant on 18 December 2013.

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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 18 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 Icelandic and the Norwegian Paediatric Committee members agree 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 annex and appendix.

London, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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

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	7	**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).

Area	Number of measures	Description
		Study 4: Single-centre, open-label, non-randomized study to evaluate the placebo fentanyl 25 mcg transdermal system's adherence to the skin of healthy paediatric volunteers from 6 to less than 12 years of age (AD2013-006). **Study 5:** Single-centre, open-label, human factors study to validate usability of the placebo fentanyl 25 mcg transdermal system by healthy paediatric volunteers from 6 to less than 12 years of age (HF2013-005). **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:** Single-centre, open-label, non-randomized study to evaluate the placebo fentanyl 10 mcg transdermal system's adherence to the skin of healthy paediatric volunteers from 2 to less than 6 years of age (AD2013-008). **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 September 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes