EMA/656702/2010

European Medicines Agency decision

P/231/2010

of 23 November 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for fentanyl citrate, (EMEA-000712-PIP01-09) 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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An agency of the European Union

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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 EPMC Pharma SPRL on 19 October 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 October 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 citrate, solution for injection, intravenous 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 waiver for fentanyl citrate, solution for injection, intravenous 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

This decision is addressed to EPMC Pharma SPRL, Waterhoenlaan, 5, 1860 Meise, Belgium.

Done at London, 23 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/615648/2010

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

EMEA-000712-PIP01-09

Scope of the application

Active substance(s):

Fentanyl citrate

Condition(s):

Prevention of acute pain

Treatment of acute pain

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

EPMC Pharma SPRL

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, EPMC Pharma SPRL submitted for agreement to the European Medicines Agency on 19 October 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 19 November 2009.

Supplementary information was provided by the applicant on 2 August 2010.

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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 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(es) and appendix.

London, 8 October 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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: Prevention of acute pain

The waiver applies to:

- All subsets of the paediatric population from 2 to less than 18 years of age
- for solution for injection for intravenous use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.2. Condition: Treatment of acute pain

The waiver applies to:

- All subsets of the paediatric population from 2 to less than 18 years of age
- for solution for injection for intravenous use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of acute pain

2.1.1. Indication(s) targeted by the PIP

Pre-medication before a painful medical procedure

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

From birth to less than 2 years of age.

For pre-term neonates the corrected age according to maturity shall be taken into account; exact definition is in the study details.

2.1.3. Pharmaceutical form(s)

Solution for injection for intravenous use.

2.1.4. Studies

Area	Number of studies	Description
Quality	2	Study 1: Development of the intravenous formulation for neonatal use Study 2: Stability testing
Non-clinical	0	Not applicable.
Clinical	3	Study 3: A PK/PD trial to establish the (log) concentration versus effect curve of intravenous fentanyl in newborn children undergoing painful medical procedures. Study 4: A prospective, open-label, observational and descriptive study to evaluate the use of an optimal fentanyl dose derived from the PK/PD study (Study 3) and to collect safety data in newborn children undergoing painful medical procedures. Study 5: Interpolation and modeling study to extend dosing recommendations of intravenous fentanyl for the treatment of acute pain, on the basis of available adult and paediatric data including the results of studies 3 and 4, to infants from one month to two years of age.

2.2. Condition: Treatment of acute pain

2.2.1. Indication(s) targeted by the PIP

Pre-medication before a painful medical procedure

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

From birth to less than 2 years of age.

For pre-term neonates the corrected age according to maturity shall be taken into account; exact definition is in the study details.

2.2.3. Pharmaceutical form(s)

Solution for injection for intravenous use.

2.2.4. Studies

Studies to be performed are the same as for the condition Prevention of acute pain

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No