European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 3 November 2008

on the application for agreement of a Paediatric Investigation Plan for paracetamol (EMEA-000130-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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on the application for agreement of a Paediatric Investigation Plan for paracetamol (EMEA-000130-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Baxter World Trade SA/NV on 11 January 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 August 2008 and amended on 17 October 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, has given a positive opinion.

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a waiver.

(4) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for paracetamol solution for infusion, intravenous, 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 paracetamol solution for infusion, intravenous, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for paracetamol solution for infusion, intravenous, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Baxter World Trade SA/NV, Boulevard de la Plaine 5, 1050 Brussels, Belgium.

Done at London, 3 November 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/53271/2008
EMEA-000130-PIP01-07

AMENDED POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Paracetamol

Condition(s):
Moderate pain and fever

Pharmaceutical form(s):
Solution for infusion

Route(s) of administration:
Intravenous

Name/corporate name of the PIP applicant:
Baxter World Trade SA/NV

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Baxter World Trade SA/NV submitted for agreement to the EMEA on 11 January 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 14 February 2008.

Supplementary information was provided by the applicant on 7 July 2008.
A meeting with the Paediatric Committee took place on 18 September 2008.

An Opinion was adopted by the Paediatric Committee on 19September 2008.

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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, revises its opinion of 19 September 2008 and recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix(ces).

London, 17 October 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S) / DISEASE(S)
Moderate Pain
Fever

B. WAIVER

- **Moderate Pain**

    - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Infants & toddlers (28 d-23 m), Children (2-11 y), and Adolescents (12-16/18 y) for Solution for intravenous infusion

B. WAIVER

- **Fever**

    - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Infants & toddlers (28 d-23 m), Children (2-11 y), and Adolescents (12-16/18 y) for Solution for intravenous infusion

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Moderate Pain and Fever

- **Subset(s) covered**

From Preterm newborn infants to less than 28 days

- **Formulation(s)**

Solution for intravenous infusion

- **Studies / Measures**

Area	Number of studies	Description
Clinical	1	Single and multiple dose trial to evaluate pharmacokinetics/ pharmacodynamic, safety and efficacy of Paracetamol in children from preterm to less than 28 days of age

Measures to address long term follow-up of potential safety issues, efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By September 2011**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**