European Medicines Agency

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P/75/2008

EUROPEAN MEDICINES AGENCY DECISION

of 12 September 2008

on the application for agreement of a Paediatric Investigation Plan for pramipexole dihydrochloride monohydrate, (Mirapexin) (EMEA-000080-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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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 Boehringer Ingelheim International GmbH on 19 October 2007 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 31 July 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 pramipexole dihydrochloride monohydrate, (Mirapexin), immediate release tablet, oral 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 pramipexole dihydrochloride monohydrate, (Mirapexin), immediate release tablet, oral use, 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 pramipexole dihydrochloride monohydrate, (Mirapexin), immediate release tablet, oral use, 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 Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim/Rhein, Germany.

Done at London, 12 September 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/411702/2008
EMEA-000080-PIP01-07

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

Scope of the application

Active substance:
Pramipexole dihydrochloride monohydrate.

Invented name:
Mirapexin

Condition(s):
Combined vocal and multiple motor tic disorder (de la Tourette)
Restless Legs Syndrome

Pharmaceutical form(s):
Immediate Release Tablet

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Boehringer Ingelheim International GmbH.

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted for agreement to the EMEA on 19 October 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 22 November 2007.

Supplementary information was provided by the applicant on 20 May 2008.

A meeting with the Paediatric Committee took place on 29 July 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, 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)(a) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population,
  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 Norwegian Paediatric Committee member agrees 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 Agency, together with its annex(es) and appendix(ces).

London, 31 July 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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)
Combined vocal and multiple motor tic disorder (de la Tourette)
Restless Legs Syndrome

B. WAIVER

- **Condition**

Combined vocal and multiple motor tic disorder (de la Tourette)

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

The waiver applies to:

Preterm newborn infants, Term newborn infants, Infants & toddlers and children less than 6 years, for immediate release tablets for oral use

- **Condition**

Restless Legs Syndrome

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

The waiver applies to:

Preterm newborn infants, Term newborn infants, Infants & toddlers and children less than 6 years, for immediate release tablets for oral use

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Combined vocal and multiple motor tic disorder (de la Tourette)

- **Subset(s) covered**

Children from 6 years old to less than 18 years

- **Formulation(s)**

Immediate release tablets for oral use
Paediatric strength of 0.0625mg shall be developed

C.2. Condition to be investigated

Restless Legs Syndrome

- **Subset(s) covered**

Children from 6 years old to less than 18 years

- **Formulation(s)**

Immediate release tablets for oral use
Paediatric strength of 0.0625mg shall be developed

- **Studies / Measures**

Area	Subarea	Number of studies	Description
Clinical	**PK dose finding. Efficacy and safety**	**1**	**Phase II, randomised, placebo-controlled, 6 week flexible dose study in children of 6 to 17 years with Tourette Syndrome**
Clinical	**Efficacy and safety**	**1**	**Phase III randomised, placebo controlled, 12 weeks fixed dose study in children of 6 to 17 years with Tourette Syndrome**
Clinical	**Efficacy and safety**	**1**	**Open label extension study of 6 to 17 years with Tourette Syndrome**
Clinical	**PK dose finding**	**1**	**Open label pharmacokinetic study of paediatric patients, 6 to 17 years with Restless Legs Syndrome**
Clinical	**Efficacy and safety**	**1**	**Randomised, double-blind, placebo-controlled, four parallel groups of paediatric patients, 6 to 17 years with Restless Legs Syndrome**

Need for paediatric measures in a EU-Risk Management Plan: Yes
Date of completion of the paediatric investigation plan: September 2013
A deferral has been granted: Yes

GENERAL PROVISIONS

Studies or trials which are inconclusive or not interpretable will be considered non-compliant.

Studies and trials have to be registered with the EudraCT database. All investigational medicinal products used in studies or trials must be registered in the EudraVigilance Medicinal Product Dictionary by the sponsor.

The development plan of the agreed PIP is identical to EMEA 000041 PIP 01-07. It is the responsibility of the PIP applicant not to repeat trials unnecessarily**.**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EMEA/1/97/051/001-006+009-012	Mirapexin	0.088,0.18,0.35,0.7, 1.1 mg	Tablet	Oral	Aluminium blister	0.088mg base	30/ 100 Tablets