EMA/261727/2010

European Medicines Agency decision

P/79/2010

of 7 May 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for perampanel (EMEA-000467-PIP01-08) 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 Eisai Ltd. on 18 June 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting 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 March 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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,

(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.

[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 perampanel, tablet, oral suspension, 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 deferral for perampanel, tablet, oral suspension, 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 granted.

Article 3

This decision is addressed to Eisai Ltd., European Knowledge Centre, Mosquito Way, Hatfield, AL10 9SN, United Kingdom.

Done at London, 7 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/135598/2010

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

EMEA-000467-PIP01-08

Scope of the application

Active substance(s):

Perampanel

Condition(s):

Treatment-resistant epilepsies (localisation-related or generalised epilepsies and age-related epilepsy syndromes)

Pharmaceutical form(s):

Tablet

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eisai Ltd. submitted for agreement to the European Medicines Agency on 18 June 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 23 July 2009.

Supplementary information was provided by the applicant on 17 December 2009.

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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,

   The Norwegian Paediatric Committee member(s) agree(s) 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 European Medicines Agency, together with its annex(es) and appendix.

London, 19 March 2010

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

1. Condition(s)

Treatment-resistant epilepsies (localisation-related or generalised epilepsies and age-related epilepsy syndromes)

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Treatment-resistant epilepsies (localisation-related or generalised epilepsies and age-related epilepsy syndromes)

3.1.1. Indication targeted by the PIP

- Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

- Adjunctive therapy in patients with other paediatric epilepsies

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

From birth to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Tablet

Oral suspension

3.1.4. Studies

Area	Number of studies	Description
Quality	1	1. Development of an oral liquid formulation (< 0.5mg/ml) and a dosing device suitable for treatment of children of all ages including preterm neonates
Non-clinical	1	2. 33-week oral gavage toxicity study in the juvenile dog
Clinical	8	3. Pooled subgroup analyses of the efficacy, pharmacokinetics and safety of perampanel in the adolescent population included in three double-blind, placebo-controlled studies in patients with refractory partial seizures 4. Open-label extension to double-blind, placebo-controlled, dose-escalation, parallel-group studies to evaluate the efficacy, pharmacokinetics and safety of perampanel as adjunctive therapy

Area	Number of studies	Description
		in adolescents and adults with refractory partial seizures 5. Randomized, double-blind, placebo-controlled, parallel-group study with an open-label extension phase to evaluate the effect of perampanel on cognition, safety, tolerability and pharmacokinetics when administered as an adjunctive therapy in adolescents with inadequately controlled partial onset seizures 6. Randomized, open-label, crossover study to demonstrate relative bioavailability between a 4 mg oral suspension of perampanel and a 4 mg tablet of perampanel in healthy adult subjects 7. Open-label study with an extension phase to evaluate the pharmacokinetics (PK), safety and tolerability of perampanel in children (age 1 month to less than 12 years) with epilepsy 8. Exploratory, open-label study with an extension phase to evaluate preliminary efficacy, safety and tolerability of perampanel administered as an adjunctive therapy in paediatric patients (age 1 month to less than 18 years) with childhood epilepsy 9. Randomized, double-blind, placebo-controlled, dose-escalation, parallel-group study with an extension phase to evaluate the efficacy, safety and tolerability of perampanel suspension and tablets when administered as an adjunctive therapy in paediatric and adolescent patients (age 2 to less than 18 years) with partial seizures. 10. Open-label, multiple-dose study to explore the safety, tolerability and pharmacokinetics of perampanel as an adjunctive therapy in neonates with seizures, aged from birth to less than 28 days, followed by an open label extension study (up to 1 year).

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and/or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes