EMA/524353/2010

European Medicines Agency decision

P/153/2010

of 27 August 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for rufinamide (Inovelon), (EMEA-000709-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 11 September 2009 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 6 August 2010, 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 rufinamide (Inovelon), oral suspension, tablets, 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 rufinamide (Inovelon), oral suspension, tablets, 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

A waiver for rufinamide (Inovelon), oral suspension, tablets, 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 4

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

Done at London, 27 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/487091/2010

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

EMEA-000709-PIP01-09

Scope of the application

Active substance(s):

Rufinamide

Invented name:

Inovelon

Condition(s):

Treatment of Lennox-Gastaut Syndrome

Pharmaceutical form(s):

Oral suspension, tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Ltd.

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, Eisai Ltd. submitted for agreement to the European Medicines Agency on 11 September 2009 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 15 October 2009.

Supplementary information was provided by the applicant on 28 May 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and 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 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 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, 6 August 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Treatment of Lennox-Gastaut syndrome

1.1. Authorised Indication(s)

Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome

2. Waiver

2.1. Condition(s)

Treatment of Lennox-Gastaut syndrome

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 months of age
- for oral suspension, oral use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s),

and to:

- All subsets of the paediatric population from 4 to less than 18 years of age
- for oral suspension and tablets, oral use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Lennox-Gastaut syndrome

3.1.1. Indication(s) targeted by the PIP

Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome.

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

From 1 to less than 4 years of age.

3.1.3. Pharmaceutical form(s)

Oral suspension

3.1.4. Studies

Area	Number of studies	Description	
Quality	1	Study 1.	Palatability and acceptability assessment of the oral suspension in children with Lennox-Gastaut syndrome
Non-clinical	1	Study 2.	13-week oral toxicity Study in juvenile dogs
Clinical	1	Study 3.	Multicentre, randomised, controlled, open-label study to evaluate the effect on cognitive development, safety, and pharmacokinetics of adjunctive rufinamide treatment in paediatric subjects 1 to less than 4 years of age with inadequately controlled Lennox-Gastaut syndrome

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/06/378/001	Inovelon	100 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	10 tablets
EU/1/06/378/002	Inovelon	100 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	30 tablets
EU/1/06/378/003	Inovelon	100 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	50 tablets
EU/1/06/378/004	Inovelon	100 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	60 tablets
EU/1/06/378/005	Inovelon	100 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	100 tablets
EU/1/06/378/006	Inovelon	200 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	10 tablets
EU/1/06/378/007	Inovelon	200 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	30 tablets
EU/1/06/378/008	Inovelon	200 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	50 tablets
EU/1/06/378/009	Inovelon	200 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	60 tablets
EU/1/06/378/010	Inovelon	200 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	100 tablets
EU/1/06/378/011	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	10 tablets
EU/1/06/378/012	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	30 tablets
EU/1/06/378/013	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	50 tablets
EU/1/06/378/014	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	60 tablets
EU/1/06/378/015	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	100 tablets
EU/1/06/378/016	Inovelon	400 mg	Film-coated tablet	Oral use	blister (PA/AL/PVC)	200 tablets