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European Medicines Agency decision

P/267/2011

of 28 October 2011

on the acceptance of a modification of an agreed paediatric investigation plan for pitavastatin (calcium) (Vezepra and associated names) (EMEA-000301-PIP01-08-M02) 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 8409
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 European Medicines Agency's decision P/37/2008 issued on 24 June 2008,

Having regard to the application submitted by Kowa Pharmaceutical Europe Company Ltd on 24 June 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for pitavastatin (calcium) (Vezepra and associated names), film-coated tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Kowa Pharmaceutical Europe Company Ltd, 105 Wharfedale Road, Winnersh Triangle, Wokingham, RG41 5RB, United Kingdom.

Done at London, 28 October 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000301-PIP01-08-M02

Scope of the application

Active substance(s):

Pitavastatin (calcium)

Invented name:

Vezepra and associated names

Condition(s):

Treatment of disorders of lipoprotein metabolism and other lipidaemias

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Kowa Pharmaceutical Europe Company Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Kowa Pharmaceutical Europe Company Ltd submitted to the European Medicines Agency on 24 June 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/37/2008 issued on 24 June 2008.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 13 July 2011.

Scope of the modification

Some measures and/or timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 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, 9 September 2011

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: Heterozygous familial hypercholesterolaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age;
- for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: Familial mixed (combined) hypercholesterolaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age;
- for for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.3. Condition: Dyslipidaemia in Diabetes mellityus II (NIDDM)

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age;
- for for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.4. Condition: Homozygous familial hypercholesterolaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of disorders of lipoprotein metabolism and other lipidaemias

2.1.1. Indication(s) targeted by the PIP

Heterozygous familial hypercholesterolaemia

Familial mixed (combined) hypercholesterolaemia

Dyslipidaemia in Diabetes mellitus II (NIDDM)

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

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	2	Study 1 • Inclusion of the current 1 mg strength in addition to the 2 and 4 mg tablets in the paediatric development programme. • Possibility to disperse the tablet in water or milk.
Non-clinical	0	Not applicable.
Clinical	1	Study 2 Double blind, randomised, placebo-controlled, parallel-group, multicentre, 12-week study of pitavastatin in paediatric patients aged 6 to less than 18 years with high risk hyperlipidaemia. Study 3 52-week open-label safety study in paediatric patients from 6 to less than 18 years with high-risk hyperlipidaemia.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of disorders of lipoprotein metabolism and other lipidaemias

Authorised indication(s):

Vezepra and associated names is indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adult patients with primary hypercholesterolaemia, including heterozygous familial hypercholesterolaemia, and combined (mixed) dyslipidaemia, when response to diet and other non-pharmacological measures is inadequate.

Invented name	**Strength**	**Pharmaceutical form**	**Route of administration**
Vezepra	1, 2 or 4mg	Film coated tablets	Oral use
Lypref	1, 2 or 4mg	Film coated tablets	Oral use
Kadosyn	1, 2 or 4mg	Film coated tablets	Oral use