European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 24 June 2008

on the application for agreement of a Paediatric Investigation Plan for pitavastatin calcium EMEA-000302-PIP01-08 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 pitavastatin calcium EMEA-000302-PIP01-08 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 Kowa Pharmaceutical Europe Co. Ltd. on 20 September 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 8 May 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 pitavastatin calcium, film-coated 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 pitavastatin calcium, film-coated 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 pitavastatin calcium, film-coated 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 Kowa Pharmaceutical Europe Co. Ltd., 105 Wharfedale Road, Winnersh Triangle, Wokingham, RG4l 5RB, United Kingdom.

Done at London, 24 June 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/247394/2008
EMEA-000302-PIP01-08

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

Scope of the application

Active substance:
Pitavastatin calcium

Conditions:
Disorders of lipoprotein metabolism and other lipidaemias

Pharmaceutical form:
Film coated tablet

Route of administration:
Oral use

Name/corporate name of the PIP applicant:
Kowa Pharmaceutical Europe Ltd.

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Kowa Pharmaceutical Europe Ltd. submitted for agreement to the EMEA on 20 September 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 25 October 2007.

Supplementary information was provided by the applicant on 07 March 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)(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 and the subsets of the paediatric population and conditions 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 and appendix.

London, 8 May 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)
Disorders of lipoprotein metabolism and other lipidaemias

B. WAIVERS

- **Condition**
  Heterozygous familial hypercholesteraemia

    - **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 from 0 to less than 6 years for film-coated tablet and oral use.

- **Condition**
  Familial mixed (combined) hypercholesteraemia

    - **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 from 0 to 1ess than 6 years for film-coated tablet and oral use.

- **Condition**
  Dyslipidaemia in Diabetes Mellitus II (NIDDM)

    - **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 from 0 to 1ess than 6 years for film-coated tablet and oral use.

- **Condition**
  Homozygous familial hypercholesteraemia

    - **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, children and adolescents from 0 to less than 18 years for film-coated tablet and oral use.

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated
Heterozygous familial hypercholesteraemia

- **Subset(s) covered**
  Children from 6 to less than 12 years and adolescents from 12 to less than 18 years.

- **Formulation(s)**
  Film-coated tablet

C.2. Condition to be investigated
Familial mixed (combined) hypercholesteraemia

- **Subset(s) covered**
  Children from 6 to less than 12 years and adolescents from 12 to less than 18 years.

- **Formulation(s)**
  Film-coated tablet

C.3. Condition to be investigated
Dyslipidaemia in Diabetes Mellitus II (NIDDM)

- **Subset(s) covered**
  Children from 6 to less than 12 years and adolescents from 12 to less than 18 years.

- **Formulation(s)**
  Film-coated tablet

- **Studies / Measures**

Area	Subarea	Number	Description
Quality			- inclusion of the current 1 mg strength in addition to the 2 and 4 mg tablets in the paediatric programme - possibility to disperse the tablet in water or milk
Clinical	PK data, safety, tolerability, efficacy	1	Double blind, randomised, placebo-controlled, parallel-group, multicentre, 12-week study of pitavastatin in paediatric hyperlipidaemia with 52-week open label extension phase.

Need for paediatric measures in a EU-Risk Management Plan: Yes

Date of completion of the Paediatric investigation plan: by March 2012

A deferral has been granted: yes