EMA/195514/2016

European Medicines Agency decision

P/0095/2016

of 15 April 2016

on the acceptance of a modification of an agreed paediatric investigation plan for pitavastatin (calcium) (Livazo and associated names) (EMEA-000054-PIP01-07-M04) 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 European Medicines Agency's decision P/35/2008 issued on 24 June 2008, the decision P/0263/2011 issued on 28 October 2011, and the decision P/0230/2012 issued on 05 October 2012,

Having regard to the application submitted by Kowa Pharmaceutical Europe Company Ltd on 7 December 2015 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 26 February 2016, 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) (Livazo 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, RG41 5RB – Wokingham, United Kingdom.

Done at London, 15 April 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/107718/2016
London, 26 February 2016

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000054-PIP01-07-M04

Scope of the application

Active substance(s):

Pitavastatin (calcium)

Invented name:

Livazo and associated names

Condition(s):

Treatment of disorders of lipoprotein metabolism and other lipidaemias

Treatment of homozygous familial hypercholesterolaemia

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

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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 7 December 2015 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/35/2008 issued on 24 June 2008, the decision P/0263/2011 issued on 28 October 2011, and the decision P/0230/2012 issued on 05 October 2012.

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

The procedure started on 4 January 2016.

Scope of the modification

Some measures and 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 Norwegian Paediatric Committee member agrees 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 annexes and appendix.

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 (PIP)

1. Waiver

1.1. Condition

Treatment of disorders of lipoprotein metabolism and other lipidaemias

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

Treatment of homozygous familial hypercholesterolaemia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 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.

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

Treatment of high-risk hyperlipidaemia (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 measures	Description
Quality-related studies	1	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.
Non-clinical studies	0	Not applicable.
Clinical studies	2	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. (NK-104-4.01EU PASCAL 1) Study 3 52-week open-label safety study in paediatric patients from 6 to less than 18 years with high-risk hyperlipidaemia. (NK-104-402EU PASCAL 2)

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):

1. Treatment of disorders of lipoprotein metabolism and other lipidaemias

Authorised indication(s):

- Livazo 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.

Authorised pharmaceutical form(s):

Film coated tablets

Authorised route(s) of administration:

Oral use