EMA/546451/2012

European Medicines Agency decision

P/0190/2012

of 24 August 2012

on the acceptance of a modification of an agreed paediatric investigation plan for lubiprostone (EMEA-000245-PIP01-08-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for lubiprostone (EMEA-000245-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/84/2011 issued on 8 April 2011,

Having regard to the application submitted by Sucampo Pharma Europe Ltd on 23 April 2012 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 6 July 2012, 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 lubiprostone, capsule, soft, age-appropriate oral liquid dosage form, 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 Sucampo Pharma Europe Ltd, John Eccles House, Robert Robinson Avenue, Oxford Science Park, Oxford Ox4 4GP, United Kingdom.

Done at London, 24 August 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/292116/2012

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

EMEA-000245-PIP01-08-M01

Scope of the application

Active substance(s):

Lubiprostone

Condition(s):

Treatment of constipation

Pharmaceutical form(s):

Capsule, soft

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Sucampo Pharma Europe Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sucampo Pharma Europe Ltd submitted to the European Medicines Agency on 23 April 2012 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/84/2011 issued on 8 April 2011.

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

The procedure started on 15 May 2012.

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Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Amendment of the scope of the Paediatric Investigation Plan to include another indication.

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 annex(es) and appendix.

Langen, Germany, 6 July 2012

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:

Treatment of constipation

The waiver applies to:

- The paediatric population from birth to less than 6 months of age;
- For Capsule, soft and oral liquid dosage form (to be developed), for 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.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of constipation

2.1.1. Indication(s) targeted by the PIP

Treatment of functional constipation

Treatment of opioid induced constipation.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, soft.

Age-appropriate oral liquid dosage form.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of an age-appropriate oral liquid dosage form dispensed in a metering pump.
Non-clinical	1	Study 2: Oral toxicity study.
Clinical	4	Study 3: Multi-centre, double-blinded, placebo-controlled study of lubiprostone to evaluate efficacy pharmacokinetic, pharmacodynamic in children from 6 years to less than 18 years with functional constipation, stratified according to patients age. Study 4: Multi-centre, double-blinded, placebo- controlled study of lubiprostone to evaluate efficacy pharmacokinetic, pharmacodynamic in children from 6 months to less than 6 years with functional constipation,

Area	Number of studies	Description
		stratified according to patients age. Study 5: Multi-centre, open-labelled safety study of lubiprostone in children from 6 months to less than 18 years with functional constipation. Study 6: Model-based bridging of clinical data to children and adolescents from 6 months to less than 18 years of age with opioid induced constipation.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes