EMA/536151/2016

European Medicines Agency decision

P/0241/2016

of 9 September 2016

on the acceptance of a modification of an agreed paediatric investigation plan for lubiprostone (Amitiza), (EMEA-000245-PIP01-08-M03) 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/84/2011 issued on 8 April 2011, the decision P/0190/2012 issued on 24 August 2012 and the decision P/0142/2014 issued on 13 June 2014,

Having regard to the application submitted by Sucampo Pharma Europe Ltd. on 2 May 2016 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 22 July 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 and to the deferral.

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

Changes to the agreed paediatric investigation plan for lubiprostone (Amitiza), capsule, soft, age-appropriate oral solid dosage form, oral use, including changes to the deferral, 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., 99 Park Drive, Milton Park, OX14 4RY - Abingdon, United Kingdom.

EMA/PDCO/334014/2016
London, 22 July 2016

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

EMEA-000245-PIP01-08-M03

Scope of the application

Active substance(s):

Lubiprostone

Invented name:

Amitiza

Condition(s):

Treatment of constipation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, soft

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Sucampo Pharma Europe 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, Sucampo Pharma Europe Ltd. submitted to the European Medicines Agency on 2 May 2016 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 decision P/0190/2012 issued on 24 August 2012, and the decision P/0142/2014 issued on 13 June 2014.

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

The procedure started on 24 May 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 and to the deferral 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 constipation

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- for capsule, soft and oral solid 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

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 solid dosage form

2.1.4. Measures

Area	Number of studies	Description
Quality	1	**Study 1** Development of an age-appropriate oral solid dosage form.
Non-clinical	1	**Study 2** Oral toxicity study in juvenile rat.
Clinical	4	**Study 3** Multi-centre, double-blind, placebo-controlled study of lubiprostone to evaluate efficacy, safety and pharmacokinetics in children and adolescents from 6 years to less than 18 years with functional constipation.

		Study 4 Multi-centre, double-blind, placebo- controlled study of lubiprostone to evaluate efficacy, safety and pharmacokinetics in children from 6 months to less than 6 years with functional constipation. **Study 5** Deleted during procedure EMEA-000245-PP01-08-M02. **Study 7** Multi-centre, long term open-label safety study to assess long term safety, efficacy and pharmacokinetics in children and adolescents 6 years to less than 18 years of age with functional constipation. **Study 8** Multi-centre, long term open-label safety study to assess long term safety, efficacy and pharmacokinetics in children 6 months to less than 6 years of age with functional constipation.
Extrapolation, modelling & simulation studies	0	**Study 6** Deleted during procedure EMEA-000245-PP01-08-M03.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 June 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of constipation

Authorised indication(s):

- AMITIZA is indicated for the treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g., educational measures, physical activity) are inappropriate.

Authorised pharmaceutical form(s)

Capsules, soft

Authorised route(s) of administration

Oral use