



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/802543/2012

European Medicines Agency decision

P/0293/2012

of 18 December 2012

on the acceptance of a modification of an agreed paediatric investigation plan for prucalopride (Resolor), (EMEA-000459-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.



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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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/210/2010 issued on 29 October 2010, and the decision P/0056/2012 issued on 26 March 2012,

Having regard to the application submitted by Shire-Movetis NV on 16 August 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 9 November 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 prucalopride (Resolor), film-coated tablet, oral solution, 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 Shire-Movetis NV, Veedijk 58 (1004), 2300 – Turnhout, Belgium.

Done at London, 18 December 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/564079/2012

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

EMA-000459-PIP01-08-M02

Scope of the application

Active substance(s):

Prucalopride

Invented name:

Resolor

Condition(s):

Treatment of chronic constipation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Oral solution

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Shire-Movetis NV

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shire-Movetis NV submitted to the European Medicines Agency on 16 August 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/210/2010 issued on 29 October 2010, and the decision P/0056/2012 issued on 26 March 2012.

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

The procedure started on 12 September 2012.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to exclude one condition

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 November 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 chronic constipation

The waiver applies to:

- the paediatric population from birth to less than 6 months.
- for film-coated tablets and oral solution, for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of chronic constipation

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of functional constipation in children aged from 6 months to 18 years.

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)

- Film-coated tablet, 2 mg.
- Oral solution 0.4, mg/ml.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of liquid age appropriate formulation and strength for oral use.
Non-clinical	1	Study 2 Non-clinical study to investigate the toxicity and toxicokinetics of prucalopride in juvenile rats.
Clinical	1	Study 3 Double-blind placebo-controlled trial to evaluate efficacy, safety, tolerability and pharmacokinetics of prucalopride in children with functional constipation from 6 months to less than 18 years of age, with open-label comparator (PEG) controlled extension to evaluate safety

Area	Number of studies	Description
		and tolerability up to 24 weeks.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes.
Date of completion of the paediatric investigation plan:	By March 2013.
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 chronic constipation****Authorised indications:**

Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

Authorised Pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use