EMA/115432/2011

European Medicines Agency decision

P/44/2011

of 3 March 2011

on the acceptance of a modification of an agreed paediatric investigation plan for telcagepant (EMEA-000274-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 telcagepant (EMEA-000274-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/68/2009 issued on 20 April 2009,

Having regard to the application submitted by Merck Sharp and Dohme (Europe), Inc. on 5 November 2010 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 14 January 2011, 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 telcagepant, film-coated tablet, age-appropriate formulation, 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 Merck Sharp and Dohme (Europe), Inc., Clos du lynx 5, Brussels, 1200, Belgium.

Done at London, 3 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature of file)

EMA/PDCO/759138/2010

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

EMEA-000274-PIP01-08-M01

Scope of the application

Active substance(s):

Telcagepant

Condition(s):

Migraine with or without aura

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp and Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp and Dohme (Europe), Inc. submitted to the European Medicines Agency on 5 November 2010 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/68/2009 issued on 20 April 2009.
The applicant proposed modifications to the paediatric investigation plan.

The procedure started on 18 November 2010.

Scope of the modification

Some measures and timelines of the original Opinion have been modified.

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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 subsets of the paediatric population and condition 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 and appendix.

London, 14 January 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature of 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 migraine with or without aura

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), children (from 2 to less than 6 years),
- for film-coated tablets, oral use and age-appropriate formulation to be developed, 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(s).

2. Paediatric Investigation Plan

2.1. Condition: migraine with or without aura

2.1.1. Indication(s) targeted by the PIP

Treatment of migraine with or without aura

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

From 6 years to less than 18 years.

2.1.3. Pharmaceutical form(s)

Film-coated tablets

Age-appropriate formulation

2.1.4. Studies

Area	Number of studies	Description
Quality	2	Development of a film-coated tablet with an age-appropriate strength. Development of an age-appropriate formulation.
Non-clinical	Total number of studies	Not applicable.

Clinical	4	Multicentre, open-label, single dose study to evaluate pharmacokinetics, safety and tolerability in children with migraine from 6 to less than 18 years. Multicentre, randomised, double-blind, placebo and active-controlled (Ibuprofen), parallel group study to assess efficacy and safety of telcagepant for treatment of migraine with and without aura in children between 6 years and Tanner Stage II (male) and 6 years and prior to menarche (female). Multicentre, randomised, double-blind, placebo and active-controlled (Ibuprofen) , parallel group study to assess efficacy and safety of telcagepant for treatment of migraine with and without aura in adolescents between Tanner stage III-V and less than 18 years (male) and between postmenarche and less than 18 years (female). Multicentre, double-blind, active-controlled (ibuprofen), parallel group study to evaluate long-term safety and tolerability of telcagepant for treatment of migraine in children from 6 to less than 18 years of age.

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 February 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes