EMA/37992/2011

European Medicines Agency decision

P/27/2011

of 28 January 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for rizatriptan benzoate (Maxalt and associated names), (EMEA-000084-PIP02-10) 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 application submitted by Merck Sharp & Dohme (Europe) Inc. on 30 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 December 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for rizatriptan benzoate (Maxalt and associated names), tablet, oral lyophilisate, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for rizatriptan benzoate (Maxalt and associated names), tablet, oral lyophilisate, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for rizatriptan benzoate (Maxalt and associated names), tablet, oral lyophilisate, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Merck Sharp & Dohme (Europe) Inc., Clos du Lynx, 5, 1200 – Brussels, Belgium.

Done at London, 28 January 2011

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

EMA/PDCO/657347/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000084-PIP02-10

Scope of the application

Active substance(s):

Rizatriptan

Invented name:

Maxalt and associated names

Condition(s):

Treatment of migraine

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Oral lyophilisate

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe) Inc.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted for agreement to the European Medicines Agency on 30 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 10 June 2010.

Supplementary information was provided by the applicant on 1 October 2010.

A meeting with the Paediatric Committee took place on 11 November 2010.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 agreed 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, 10 December 2010

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 migraine

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age,
- for oral lyophilisate, oral use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for tablet, oral use,
- on the grounds that this formulation is not considered to be age-appropriate for the paediatric population.

Paediatric Investigation Plan

1.2. Condition: Treatment of migraine

1.2.1. Indication(s) targeted by the PIP

Treatment of migraine.

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

From 6 to less than 18 years of age.

1.2.3. Pharmaceutical form(s)

Oral lyophilisate

1.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Study 1 Open label study to assess the palatability of rizatriptan oral lyophilisate in children aged 6 to less than 12 years using a rating scale assessing taste. Study 2 Randomized, double-blind, placebo-controlled study to evaluate safety, tolerability, and single-dose pharmacokinetics of rizatriptan oral lyophilisate in paediatric patients aged 6 to less than 18 years. Study 3 Randomized, double blind, placebo-controlled, parallel group clinical trial to evaluate safety and efficacy of rizatriptan oral lyophilisate for the acute treatment of a single acute migraine attack in children aged from 12 to less than 18 years. Study 3 Randomized, double blind, placebo-controlled, parallel group clinical trial to evaluate safety and efficacy of rizatriptan oral lyophilisate for the acute treatment of a single acute migraine attack in children aged from 6 to less than 12 years.

Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2011
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):

Condition: Treatment of Migraine

Authorised indications: Acute treatment of the headache phase of migraine attacks with or without aura (Adults)

Invented name Name	**Strength**	**Pharmaceutical form**	**Route of administration**
Maxalt and associated names	5 mg	Tablet	Oral use
Maxalt and associated names	10 mg	Tablet	Oral use
Maxalt and associated names	5 mg	Oral lyophylisate	Oral use
Maxalt and associated names	10 mg	Oral lyophylisate	Oral use