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European Medicines Agency decision

P/167/2011

of 6 July 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for risperidone (Risperdal and associated names) (EMEA-001034-PIP01-10) 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 Wockhardt UK Ltd on 11 October 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 May 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 risperidone (Risperdal and associated names), film-coated tablet, 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 waiver for risperidone (Risperdal and associated names), film-coated tablet, 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

This decision is addressed to Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF Wrexham, United Kingdom.

Done at London, 6 July 2011

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

EMA/PDCO/321959/2011

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

EMEA-001034-PIP01-10

Scope of the application

Active substance(s):

Risperidone

Invented name:

Risperdal and associated names

Condition(s):

Treatment of conduct disorder

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Wockhardt UK Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Wockhardt UK Ltd submitted for agreement to the European Medicines Agency on 11 October 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 22 December 2010.

Supplementary information was provided by the applicant on 7 March 2011. The applicant proposed modifications to the paediatric investigation plan.

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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   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, 20 May 2011

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 conduct disorder

The waiver applies to:

- Children from birth to less than 2 years of age;
- for film-coated tablet 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(s).

The waiver applies to:

- Children from 2 to less than 5 years of age;
- for film-coated tablet for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of conduct disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of conduct disorder in children and adolescents with average IQ

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

From 5 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet for oral use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Study 1: A double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of risperidone in paediatric patients from 5 to less than 18 years of age with average IQ suffering from conduct disorder. (PERS-001 / CONCA) Study 2: A double-blind, randomised, placebo-controlled discontinuation (relapse prevention) trial to evaluate safety and efficacy of risperidone in paediatric patients from 5 to less than 18 years of age with average IQ suffering from conduct disorder. (PERS-002 / DIS-CONCA) Study 3: An open-label, multicentre, longitudinal, naturalistic, prospective trial to evaluate safety of risperidone in paediatric patients from 5 to less than 18 years of age. (PERS-003 / SAFE-CONCA)

3. 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 May 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of conduct disorder

   Authorised indications:

- Risperdal Consta is indicated for the maintenance treatment of schizophrenia in patients currently stabilised with oral antipsychotics.
- Risperdal is indicated for the treatment of schizophrenia.
- Risperdal is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.
- Risperdal is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.
- Risperdal is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
- Risperidone is indicated for the treatment of schizophrenia.
- Risperidone is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorder.
- Risperidone is indicated for the short-term treatment (up to six weeks) of persistent aggression in patients with moderate to severe Alzheimer’s dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.
- Risperidone is indicated for the short-term symptomatic treatment (up to six weeks) of persistent aggression in conduct disorder in children from the age of five years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacological treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
- Risperidone 1 mg/ml oral solution is indicated for the treatment of
  - schizophrenia. Risperidone is effective as maintenance therapy for the prevention of relapse in chronic schizophrenic patients who have shown an initial treatment response with risperidone.
  - moderate to severe manic episodes in patients with bipolar affective disorder

Invented name	Strength	Pharmaceutical form	Route of administration
Risperidone	0.5mg, 1mg, 2mg, 3mg, 4mg, 6mg	Film-coated tablet	Oral use
Risperidone	1mg/ml	Oral Solution	Oral use
Risperidone	0.25mg	Film-coated tablet	Oral use
Risperdal	0.5mg, , 1mg, 2mg, 3mg, 4mg, 6mg	Film-coated tablet	Oral use
Risperdal Quicklet	0.5mg, 1mg	Orodispersible tablet	Oral use
Risperdal Quicklet	2mg, 3mg, 4mg	Orodispersible tablet	Oral use
Risperdal liquid	1mg/ml	Oral solution	Oral use
Risperdal consta	25 mg, 37.5 mg or 50 mg	Powder and solvent for prolonged-release suspension for injection	Intramuscular use
Risperidone	0.5mg, , 1mg, 2mg, 3mg, 4mg, 6mg	Film-coated tablet	Oral use
Risperidone	1mg/ml	Oral solution	Oral use
Risperidone	1mg/ml	Oral solution	Oral use