EMA/830331/2010

European Medicines Agency decision

P/346/2010

of 21 December 2010

on the acceptance of a modification of an agreed paediatric investigation plan for paliperidone / paliperidone palmitate (Invega) (EMEA-000014-PIP01-07-M05) 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 paliperidone / paliperidone palmitate (Invega) (EMEA-000014-PIP01-07-M05) 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/13/2008 issued on 31 March 2008, the decision P/149/2009 issued on 7 August 2009, the decision P/229/2009 issued on 4 November 2009, the decision P/231/2009 issued on 27 November 2009, and the decision P/109/2010 issued on 6 July 2010,

Having regard to the application submitted by Janssen-Cilag International NV on 16 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 December 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision on the granting of a 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 paliperidone / paliperidone palmitate (Invega), prolonged-release tablet, suspension for injection, oral use, intramuscular 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

A deferral for paliperidone / paliperidone palmitate (Invega), prolonged-release tablet, suspension for injection, oral use, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, 2340 Beerse, Belgium.

Done at London, 21 December 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/829761/2010

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

EMEA-000014-PIP01-07-M05

Scope of the application

Active substance(s):

Paliperidone
Paliperidone palmitate

Invented name:

Invega

Condition(s):

Schizophrenia

Schizoaffective disorder

Pharmaceutical form(s):

Prolonged-release tablet

Suspension for injection

Route(s) of administration:

Oral use

Intramuscular use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

Information about the authorised medicinal product: see Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 16 December 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/13/2008 issued on 31 March 2008, the decision P/149/2009 issued on 7 August 2009, the decision P/229/2009 issued on 4 November 2009, the decision P/231/2009 issued on 27 November 2009 and the decision P/109/2010 issued on 6 July 2010.

The application for modification proposed a deferral.

The procedure started on 16 December 2010.

Scope of the modification

Some measures of the paediatric investigation plan have been deferred.

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 grant a deferral, the details of which are set out in the Annex I of this opinion.
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.

London, 20 December 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Schizophrenia

Schizoaffective disorder

2. Waiver

2.1. Condition

Schizophrenia

The waiver applies to:

- children from birth to less than 12 years of age
- for prolonged-release tablets and for suspension for injection
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

The waiver applies to:

- Adolescents from 12 to less than 18 years of age
- for suspension for injection
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2.2. Condition

Schizoaffective disorder

The waiver applies to:

- children from birth to less than 12 years of age
- for prolonged-release tablets and for suspension for injection
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

The waiver applies to:

- Adolescents from 12 to less than 18 years of age
- for prolonged-release tablets and for suspension for injection
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Schizophrenia

3.1.1. Indication targeted by the PIP

Treatment of schizophrenia

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

Adolescents from 12 to less than 18 years of age

3.1.3. Pharmaceutical form(s)

Prolonged-release tablets

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Study 1: Assessment of the influence of daily oral administration of paliperidone for 7 weeks to immature rats (from Day 24 to Day 72 of age).
Clinical	3	Study 2: Randomised, 6 weeks double blind multicentre, placebo controlled study, efficacy and safety study of paliperidone extended release tablets for the treatment of schizophrenia in adolescents. Study 3: 26 week, randomised, double blind multicentre, active controlled study, efficacy and safety study of paliperidone extended release tablets for the treatment of schizophrenia in adolescent patients. Study 4: Open label long term safety study of paliperidone in adolescents from 12 to less than 18 years of age.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2012
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EMEA Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EMEA/H/C/000746/0000/001	Invega	3 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/002	Invega	3 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/003	Invega	3 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/004	Invega	3 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/005	Invega	3 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/006	Invega	6 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/007	Invega	6 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/008	Invega	6 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/009	Invega	6 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/010	Invega	6 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/011	Invega	9 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/012	Invega	9 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/013	Invega	9 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/014	Invega	9 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/015	Invega	9 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/016	Invega	12 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/017	Invega	12 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/018	Invega	12 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/019	Invega	12 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	56 tablets

EMEA/H/C/000746/0000/020	Invega	12 mg	Prolonged release tablet	Oral use	blister (PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/021	Invega	3 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/022	Invega	3 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/023	Invega	3 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/024	Invega	3 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/025	Invega	3 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/026	Invega	6 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/027	Invega	6 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/028	Invega	6 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/029	Invega	6 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/030	Invega	6 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/031	Invega	9 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/032	Invega	9 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	30 tablets

EMEA/H/C/000746/0000/033	Invega	9 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/034	Invega	9 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	56 tablets
EMEA/H/C/000746/0000/035	Invega	9 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	98 tablets
EMEA/H/C/000746/0000/036	Invega	12 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	28 tablets
EMEA/H/C/000746/0000/037	Invega	12 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	30 tablets
EMEA/H/C/000746/0000/038	Invega	12 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	49 tablets
EMEA/H/C/000746/0000/039	Invega	12 mg	Prolonged release tablet	Oral use	blister (white PVC/PCTFE/alu)	56 tablets
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EMEA/H/C/000746/0000/041	Invega	3 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	28 tablets
EMEA/H/C/000746/0000/042	Invega	3 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	49 tablets
EMEA/H/C/000746/0000/043	Invega	3 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	56 tablets
EMEA/H/C/000746/0000/044	Invega	3 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	98 tablets
EMEA/H/C/000746/0000/045	Invega	6 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	28 tablets
EMEA/H/C/000746/0000/046	Invega	6 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	49 tablets
EMEA/H/C/000746/0000/047	Invega	6 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	56 tablets
EMEA/H/C/000746/0000/048	Invega	6 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	98 tablets

EMEA/H/C/000746/0000/049	Invega	9 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	28 tablets
EMEA/H/C/000746/0000/050	Invega	9 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	49 tablets
EMEA/H/C/000746/0000/051	Invega	9 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	56 tablets
EMEA/H/C/000746/0000/052	Invega	9 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	98 tablets
EMEA/H/C/000746/0000/053	Invega	12 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	28 tablets
EMEA/H/C/000746/0000/054	Invega	12 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	49 tablets
EMEA/H/C/000746/0000/055	Invega	12 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	56 tablets
EMEA/H/C/000746/0000/056	Invega	12 mg	Prolonged release tablet	Oral use	blister (OPA-Alu-PVC/Alu)	98 tablets
EMEA/H/C/000746/0000/057	Invega	3 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	30 tablets
EMEA/H/C/000746/0000/058	Invega	3 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	350 tablets
EMEA/H/C/000746/0000/059	Invega	6 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	30 tablets
EMEA/H/C/000746/0000/060	Invega	6 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	350 tablets
EMEA/H/C/000746/0000/061	Invega	9 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	30 tablets
EMEA/H/C/000746/0000/062	Invega	9 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	350 tablets
EMEA/H/C/000746/0000/063	Invega	12 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	30 tablets
EMEA/H/C/000746/0000/064	Invega	12 mg	Prolonged release tablet	Oral use	Bottle (HDPE/PP)	350 tablets