EMA/419326/2011

European Medicines Agency decision

P/130/2011

of 8 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004) (EMEA-000455-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 H. Lundbeck A/S on 7 June 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 20 April 2011, 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 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004), film-coated tablet, age appropriate oral liquid dosage form, 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 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004), film-coated tablet, age appropriate oral liquid dosage form, 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 1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004), film-coated tablet, age appropriate oral liquid dosage form, 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 H. Lundbeck A/S, Ottiliavej 9, DK-2500 Valby, Denmark.

Done at London, 8 June 2011

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

EMA/PDCO/178799/2011

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

EMEA-000455-PIP02-10

Scope of the application

Active substance(s):

1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl]piperazine (Lu AA21004)

Condition(s):

Treatment of major depressive disorder

Treatment of generalised anxiety disorder

Pharmaceutical form(s):

Film-coated tablet

Age appropriate oral liquid dosage form.

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

H. Lundbeck A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, H. Lundbeck A/S submitted for agreement to the European Medicines Agency on 7 June 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 15 July 2010.

Supplementary information was provided by the applicant on 7 February 2011.

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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 Articles 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 and 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 Norwegian Paediatric Committee member agrees 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 April 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 major depressive disorder

The waiver applies to:

- All subsets of the paediatric population from birth to less than 24 months and from birth to less than 7 years of age;
- for film-coated tablets for oral use and age appropriate oral liquid dosage form;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in children from birth to less than 24 months of age;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible in children from 2 years to less than 7 years of age.

1.2. Condition: Treatment of generalised anxiety disorder

The waiver applies to:

- All subsets of the paediatric population from birth to less than 7 years of age;
- for film-coated tablets for oral use and age appropriate oral liquid dosage form;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of major depressive disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of major depressive disorder.

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

From 7 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablets.

Age appropriate oral liquid dosage form.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age-appropriate liquid formulation for oral use.
Non-clinical	3	Study 2 Toxicokinetic study in juvenile animals. Study 3 Dose-range finding study in juvenile animals. Study 4 Toxicity study in juvenile animals.
Clinical	5	Study 5 Open-label study to assess the pharmacokinetics and tolerability of multiple oral dosing of Lu AA21004 in children and adolescent patients with a DSM-IV diagnosis of depressive or anxiety disorder (12708A). Study 6 Double-blind, randomised, placebo-controlled, multicentre, short-term study of Lu AA21004 and fluoxetine in paediatric patients with major depressive disorder (MDD) from 7 to less than 12 years of age (12709A). Study 7 Double-blind, randomised, placebo-controlled and active comparator, 3 arm, multicentre, short-term study of Lu AA21004 and fluoxetine in paediatric patients with major depressive disorder (MDD) from 12 to less than 18 years of age (12710A). Study 8 Double-blind, randomised, placebo-controlled, multicentre, relapse-prevention study of Lu AA21004 in paediatric patients with major depressive disorder (MDD) from 7 to less than 18 years of age (13546A). Study 9 Long-term, open-label, flexible-dose, extension study of Lu AA21004 in paediatric patients with major depressive disorder (MDD) from 7 to less than 18 years of age (12712A).

2.2. Condition: Treatment of generalised anxiety disorder

2.2.1. Indication(s) targeted by the PIP

Treatment of generalised anxiety disorder.

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

From 7 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Film-coated tablets.

Age appropriate oral liquid dosage form.

2.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Same study as for major depressive disorder.
Non-clinical	3	Studies 2, 3, 4, Same studies as for major depressive disorder.
Clinical	4	Study 5 Same study as for major depressive disorder. Study 10 Double-blind, randomised, placebo-controlled, multicentre, short-term efficacy study of Lu AA21004 in paediatric patients with generalised anxiety disorder (GAD) from 7 to less than 18 years of age (12711A). Study 11 Double-blind, randomised, placebo-controlled, multicentre, relapse - prevention study with Lu AA21004 in paediatric patients with generalised anxiety disorder (GAD) from 7 to less than 18 years of age (13547A). Study 12 Long-term, open-label, extension, flexible-dose, safety study of Lu AA21004 in paediatric patients with generalised anxiety disorder (GAD) from 7 to less than 18 years of age (13996A).

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 January 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes