



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/686891/2009
P/214/2009

EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for bromocriptine mesilate (EMEA-000487-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

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 Agency²,

Having regard to the application submitted by VeroScience EU Ltd on 24 December 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 bromocriptine mesilate, 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 deferral for bromocriptine mesilate, 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

A waiver for bromocriptine mesilate, 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 4

This decision is addressed to VeroScience EU Ltd, 20-22 Bedford Row, London, WC1R 4JS, United Kingdom.

Done at London, 30 October 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/477187/2009
EMEA-000487-PIP01-08

**OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER**

Scope of the application

Active substance(s):

Bromocriptine (mesylate)

Condition(s):

Type 2 diabetes mellitus

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

VeroScience EU Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, VeroScience EU Ltd submitted for agreement to the EMA on 24 December 2008 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 5 February 2009.

Supplementary information was provided by the applicant on 10 July 2009.

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)(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 Agency, together with its annex and appendix.

London, 18 September 2009

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

A. CONDITION(S)

Type 2 diabetes mellitus

B. WAIVER

• Condition

Type 2 diabetes mellitus

The waiver applies to:

- Children from birth to less than 10 years;
- for bromocriptine mesilate, tablet, 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.

C. PAEDIATRIC INVESTIGATION PLAN

• Condition to be investigated

Type 2 diabetes mellitus

• Proposed PIP indication

Treatment of type 2 diabetes mellitus

• Subset(s) of the paediatric population concerned by the paediatric development

From 10 to less than 18 years.

• Formulation(s)

tablet, oral use, 0.8 mg

• Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	• Single-dose pharmacokinetics study of bromocriptine mesilate in children and adolescents from 10 years to less than 18 years old, with type 2 diabetes mellitus • Randomized, double-blind, placebo-controlled, add-on study to metformin, to evaluate the efficacy and safety of bromocriptine mesilate in children and adolescents with type 2 diabetes mellitus, from 10 years to less than 18 years old, with open-label extension to assess long term safety.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:

Yes

Date of completion of the paediatric investigation plan:	By January 2013
Deferral for some or all studies contained in the paediatric investigation plan:	Yes