EMA/265569/2010

European Medicines Agency decision

P/81/2010

of 7 May 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for taspoglutide (EMEA-000665-PIP01-09) 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 Roche Registration Limited on 15 July 2009 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 19 March 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 taspoglutide, solution for injection, subcutaneous 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 taspoglutide, solution for injection, subcutaneous 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 taspoglutide, solution for injection, subcutaneous 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 Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom.

Done at London, 7 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/155373/2010

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

EMEA-000665-PIP01-09

Scope of the application

Active substance(s):

Taspoglutide

Condition(s):

Type 2 diabetes mellitus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Roche Registration Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration Limited submitted for agreement to the European Medicines Agency on 15 July 2009 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 20 August 2009.

Supplementary information was provided by the applicant on 28 December 2009.

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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.

   The Norwegian Paediatric Committee member(s) agree(s) 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, 19 March 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)

Type 2 diabetes mellitus

2. Waiver

2.1. Condition

Type 2 diabetes mellitus

The waiver applies to:

- the paediatric population
- from birth to less than 10 years of age
- on the grounds that the condition, for which the specific medicinal product is intended, does not occur in children below the age of 10.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Type 2 diabetes mellitus

3.1.1. Indication targeted by the PIP

Treatment of Type 2 diabetes mellitus

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

From 10 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Solution for injection

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	2	Study 1: Dose range-finding study in the juvenile rat (2-weeks duration). Study 2: RO5073031: 7-week subcutaneous juvenile toxicity study in the rat
Clinical	2	Study 3: Randomised, open label study to evaluate the pharmacokinetics and pharmacodynamics of taspoglutide in children/adolescents from 10 to less than 18 years of age (and adults)

Area	Number of studies	Description
		affected by type 2 diabetes, inadequately controlled with metformin. Study 4: Randomised, double-blind, placebo-controlled study to assess the efficacy and the safety of taspoglutide in children and adolescents from 10 to less than 18 years of age affected by Type 2 diabetes, inadequately controlled with metformin.

4. 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 March 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes