

EMA/66787/2013

European Medicines Agency decision

P/0035/2013

of 27 February 2013

on the acceptance of a modification of an agreed paediatric investigation plan for lixisenatide, (EMA-000916-PIP01-10-M03) 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 726/2004¹,

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 European Medicines Agency's decision P/18/2011 issued on 24 January 2011, the decision P/225/2011 issued on 27 September 2011, and P/0076/2012 issued on 25 April 2012,

Having regard to the application submitted by Sanofi-Aventis R&D on 22 October 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 January 2013, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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 lixisenatide solution for injection in a pre-filled pen, subcutaneous use, including changes to the deferral, 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

This decision is addressed to Sanofi-Aventis R&D, 1 Avenue Pierre Brossolette, 91385 - Chilly-Mazarin France.

Done at London, 27 February 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/66787/2013

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000916-PIP01-10-M03

Scope of the application

Active substance(s):

Lixisenatide

Condition(s):

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Solution for injection in a pre-filled pen

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

Sanofi-Aventis R&D

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-Aventis R&D submitted to the European Medicines Agency on 22 October 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/18/2011 issued on 24 January 2011, the decision P/225/2011 issued on 27 September 2011, and P/0076/2012 issued on 25 April 2012.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 14 November 2012.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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 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 and appendix.

London, 11 January 2013

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 type 2 diabetes mellitus

The waiver applies to:

- The paediatric population from birth to less than 10 years;
- for solution for injection in a pre-filled pen, subcutaneous 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).

2. Paediatric Investigation Plan

2.1. Condition: treatment of type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of type 2 diabetes mellitus

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

From 10 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection in a pre-filled pen

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: development of a disposable fixed-dose pen administering 0.1 mL / 5 micrograms per dose, for subcutaneous use.
Non-clinical	3	Study 2: Exploratory 2-week twice a day (BID) subcutaneous pharmacokinetic study in male juvenile dogs Study 3: 8-month BID/QD subcutaneous toxicity study in male juvenile dogs with a 2 month recovery period Study 4: Toxicity Study in Juvenile Rat
Clinical	2	Study 5: (PKD11475) Randomized, double-blind, placebo controlled trial to assess safety, tolerability, pharmacokinetics and pharmacodynamics of lixisenatide in paediatric and adult patients with type 2 diabetes mellitus. Study 6: (EFC11476) Safety and efficacy study of lixisenatide as monotherapy and add on treatment to metformin in paediatric patients with type 2 diabetes mellitus

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes.
Date of completion of the paediatric investigation plan:	By June 2018.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.