EMA/598855/2020

European Medicines Agency decision

P/0443/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for lixisenatide (Lyxumia), (EMEA-000916-PIP01-10-M07) 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 European Medicines Agency's decision P/18/2011 issued on 24 January 2011, the decision P/225/2011 issued on 27 September 2011, the decision P/0076/2012 issued on 25 April 2012, the decision P/0035/2013 issued on 27 February 2013, the decision P/0037/2015 issued on 6 March 2015, the decision P/0133/2016 issued on 20 May 2016, and the decision P/0380/2018 issued on 7 December 2018,

Having regard to the application submitted by sanofi-aventis R&D on 9 July 2020 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 16 October 2020, 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 and to the waiver.

(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 and to the 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

Changes to the agreed paediatric investigation plan for lixisenatide (Lyxumia), solution for injection in pre-filled pen, subcutaneous use, including changes to the deferral and to the waiver, 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.

EMA/PDCO/405327/2020 Corr
Amsterdam, 16 October 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000916-PIP01-10-M07

Scope of the application

Active substance(s):

Lixisenatide

Invented name:

Lyxumia

Condition(s):

Type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in pre-filled pen

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

sanofi-aventis R&D

Information about the authorised medicinal product:

See Annex II

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 9 July 2020 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, the decision P/0076/2012 issued on 25 April 2012, the decision P/0035/2013 issued on 27 February 2013, the decision P/0037/2015 issued on 6 March 2015, the decision P/0133/2016 issued on 20 May 2016, and the decision P/0380/2018 issued on 7 December 2018.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 18 August 2020.

Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

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 and to amend the scope of the waiver in accordance with 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, as set out in Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

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 (PIP)

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;
- solution for injection, 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).

and:

- the paediatric population from 10 to less than 18 years;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of type 2 diabetes mellitus

Authorised indication(s):

- Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use