EMA/77087/2023 Corr

European Medicines Agency decision

P/0064/2023

of 10 March 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for insulin lispro (BC222), (EMEA-003166-PIP01-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Adocia on 20 December 2022 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 January 2023, in accordance with Article 17 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for insulin lispro (BC222), solution for injection/infusion, 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 insulin lispro (BC222), solution for injection/infusion, 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 insulin lispro (BC222), solution for injection/infusion, 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 Adocia, 115 avenue Lacassagne, 69003 - LYON, France.

EMA/PDCO/845676/2022
Amsterdam, 20 January 2022

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

EMEA-003166-PIP01-21

Scope of the application

Active substance(s):

Insulin lispro (BC222)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of type 1 diabetes mellitus

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Adocia

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Adocia submitted for agreement to the European Medicines Agency on 20 December 2021 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 31 January 2022.

Supplementary information was provided by the applicant on 11 October 2022. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) 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 Paediatric Committee member of Norway 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 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 1 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- solution for injection/infusion, 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.

1.2. Condition:

Treatment of type 2 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 10 years of age;
- solution for injection/infusion, 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.

2. Paediatric investigation plan

2.1. Condition: Treatment of type 1 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of diabetes mellitus

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Compatibility and in-use stability studies in the paediatric pens. **Study 2** Compatibility and in-use stability studies in the CE marked insulin pumps authorized for children (hybrid closed loop insulin pump and patch pump)
Non-clinical studies	**Study 3** Pre- and postnatal development study in rats with histopathology of the kidneys and urinary ionogram
Clinical studies	**Study 4** Open-label, randomized, active controlled, crossover trial to characterize pharmacokinetics (PK) and pharmacodynamics (PD) of BC222 insulin lispro administered at mealtime or post-meal in children from 6 years to less than 18 years of age with type 1 diabetes mellitus, compared to the approved insulin lispro administered at mealtime **Study 5** Open-label, randomized, active controlled study to determine the efficacy and safety of BC222 insulin lispro in children from 1 year to less than 18 years of age with type 1 diabetes mellitus
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Study 5 is part of an extrapolation plan covering the paediatric population from 1 year to less than 18 years of age with type 1 diabetes mellitus intended to use continuous subcutaneous insulin infusion (CSII), as agreed by the PDCO

2.2. Condition: Treatment of type II diabetes mellitus

2.2.1. Indication(s) targeted by the PIP

Treatment of diabetes mellitus

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

From 10 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

solution for injection/infusion

2.2.4. Measures

Area	Description
Quality-related studies	Study 1: same as for condition "treatment of type I diabetes mellitus" Study 2: same as for condition "treatment of type I diabetes mellitus"
Non-clinical studies	Study 3: same as for condition "treatment of type I diabetes mellitus"
Clinical studies	Study 4: same as for condition "treatment of type I diabetes mellitus" Study 5: same as for condition "treatment of type I diabetes mellitus"
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Study 5 is part of an extrapolation plan covering the paediatric population from 10 years to less than 18 years of age with type 2 diabetes mellitus, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.