EMADOC-1700519818-1809705

European Medicines Agency decision

EMA/PE/0000181174

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for dasiglucagon (Zegalogue) 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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on the acceptance of a modification of an agreed paediatric investigation plan for dasiglucagon (Zegalogue) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 European Medicines Agency's decision P/0220/2018 issued on 19 July 2018, the decision P/0393/2021 issued on 8 September 2021 and the decision P/0176/2023 issued on 15 May 2023,

Having regard to the application submitted by Zealand Pharma A/S on 12 August 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 November 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for dasiglucagon (Zegalogue), 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 Zealand Pharma A/S, Sydmarken 11, 2860 - Soeborg, Denmark.

EMADOC-1700519818-1671377
Amsterdam, 15 November 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000181174

Scope of the application

Active substance(s):

Dasiglucagon

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypoglycaemia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Zealand Pharma A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Zealand Pharma A/S submitted to the European Medicines Agency on 12 August 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0220/2018 issued on 19 July 2018, the decision P/0393/2021 issued on 8 September 2021 and the decision P/0176/2023 issued on 15 May 2023.

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

The procedure started on 16 September 2024.

Scope of the modification

Some 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 Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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

Not applicable.

1.1. Condition:

Treatment of hypoglycaemia

The request for the waiver applied to:

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

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

- the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Because:

- the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.

The waiver request is therefore refused by the PDCO.

2. Paediatric investigation plan

2.1. Condition:

Treatment of hypoglycaemia

2.1.1. Indication(s) targeted by the PIP

Acute treatment of severe hypoglycaemia in children from 0 to less than 18 years of age

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.

Clinical studies	**Study 1** Blinded, randomised, 3-arm, parallel trial in paediatric patients aged from 6 to less than 18 years of age with Type 1 diabetes mellitus to evaluate the ability of dasiglucagon to increase plasma glucose relative to placebo and GlucaGen. The primary objective is demonstration of superiority of dasiglucacon over placebo. **Study 2** Open-label trial in paediatric patients from birth to less than 6 years with Type 1 diabetes mellitus to evaluate the ability of dasiglucagon to increase plasma glucose as well as its safety and PK.
Extrapolation, modelling and simulation studies	**Study 3** Population pharmacokinetic (pop-PK) and pharmacokinetic-pharmacodynamic (PKPD) modelling to inform dose finding and optimize the subsequent clinical study in children with hypoglycaemia from 6 to less than 18 years of age (PIP Study 1, ZP4207-17086). **Study 4** Population pharmacokinetic (pop-PK) and pharmacokinetic-pharmacodynamic (PKPD) modelling to inform dose finding and optimize the subsequent clinical study in children with hypoglycaemia from birth to less than 6 years of age (PIP Study 2).
Other studies	Not applicable.
Other measures	Not applicable.

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 December 2024
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:

Condition(s) and authorised indication(s)

1. Treatment of hypoglycaemia

Authorised indication(s):

- Indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 6 years and over with diabetes mellitus
  - Invented name(s): Zegalogue
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: subcutaneous
  - Authorised via centralised procedure