



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1976496

European Medicines Agency decision

EMA/PE/0000232755

of 20 March 2025

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

Only the English text is authentic.



European Medicines Agency decision

EMA/PE/0000232755

of 20 March 2025

on the refusal of a paediatric investigation plan for dasiglucagon 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Zealand Pharma A/S on 25 April 2024 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 January 2025, in accordance with Article 17 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 refusal of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.

Has adopted this decision:

Article 1

A paediatric investigation for dasiglucagon, 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 refused.

Article 2

This decision is addressed to Zealand Pharma A/S, Sydmarken 11, 2860 – Soeborg, Denmark.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1879006 Corr¹
Amsterdam, 31 January 2025

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation plan

EMA/PE/0000232755

Scope of the application

Active substance(s):

Dasiglucagon

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of congenital hyperinsulinism

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 16(1) of Regulation (EC) No 1901/2006 as amended, Zealand Pharma A/S submitted for agreement to the European Medicines Agency on 25 April 2024 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 25 November 2024.

Supplementary information was provided by the applicant on 21 October 2024. The applicant proposed modifications to the paediatric investigation plan.

¹ 13 March 2025



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 refuse the paediatric investigation plan in accordance with Article 17(1) of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit.

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

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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

Annex I

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.