EMA/371376/2020

# European Medicines Agency decision

P/0301/2020

of 12 August 2020

on the acceptance of a modification of an agreed paediatric investigation plan for glucagon (Baqsimi), (EMEA-001657-PIP01-14-M01) 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/0184/2015 issued on 21 August 2015,

Having regard to the application submitted by Eli Lilly and Company on 24 March 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 26 June 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 glucagon (Baqsimi), nasal powder, intranasal use, 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 Eli Lilly and Company, Papendorpseweg 83, 3528 BJ – Utrecht, The Netherlands.

EMA/PDCO/201935/2020
Amsterdam, 26 June 2020

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

EMEA-001657-PIP01-14-M01

## Scope of the application

**Active substance(s):**

Glucagon

**Invented name:**

Baqsimi

**Condition(s):**

Treatment of hypoglycaemia

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Nasal powder

**Route(s) of administration:**

Intranasal use

**Name/corporate name of the PIP applicant:**

Eli Lilly and Company

**Information about the authorised medicinal product:**

See Annex II

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company submitted to the European Medicines Agency on 24 March 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/0184/2015 issued on 21 August 2015.

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

The procedure started on 30 April 2020.

## 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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 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 hypoglycaemia

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- nasal powder, intranasal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of hypoglycaemia

### 2.1.1. Indication(s) targeted by the PIP

Treatment of severe hypoglycaemia

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

From 1 to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Nasal powder

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 1 | **Study 1**<br>Making available age-appropriate dosing device to administer nasal powder to children from 1 year of age. |
| Non-clinical studies | 0 | Not applicable. |
| Clinical studies | 3 | **Study 2 (AMG103, I8R-MC-IGBB)**<br>Open-label, randomised, active controlled cross-over trial to evaluate pharmacokinetics and pharmacodynamics and safety of intranasal glucagon (AMG504-1) in children from 4 to less than 17 years of age with type 1 diabetes mellitus. |

| | | |
|---|---|---|
| | | **Study 3 (AMG109, I8R-MC-B001)**<br><br>Open-label observational study to evaluate the effectiveness and ease-of-use of intranasal glucagon (AMG504-1) in children from 4 to less than 18 years of age with type 1 diabetes mellitus.<br><br>**Study 4**<br><br>*This study was deleted as a result of procedure EMEA-001657-PIP01-14-M01.*<br><br>**Study 5**<br><br>*This study was deleted as a result of procedure EMEA-001657-PIP01-14-M01.*<br><br>**Study 8 (I8R-MC-IGBO)**<br><br>*(This study was added as a result of procedure EMEA-001657-PIP01-14-M01.)*<br><br>Open-label, single-arm study to evaluate safety, pharmacodynamics and pharmacokinetics of intranasal glucagon in paediatric patients from 1 to less than 4 years of age with type 1 diabetes mellitus. |
| Extrapolation, modelling and simulation studies | 2 | **Study 6 (AMG103a)**<br><br>Modelling and simulation study to evaluate the use of intranasal glucagon (AMG504-1) in children from 1 to less than 4 years of age with hypoglycaemia.<br><br>**Study 7**<br><br>Extrapolation study to evaluate clinical efficacy of intranasal glucagon (AMG504-1) in children from 1 to less than 4 years of age with hypoglycaemia. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | 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 2026 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of hypoglycaemia

Authorised indication(s):

- Treatment of severe hypoglycaemia in adults, adolescents, and children aged 4 years and over with diabetes mellitus.

## Authorised pharmaceutical form(s):

Nasal powder

## Authorised route(s) of administration:

Intranasal use