EMA/160447/2023

# European Medicines Agency decision

P/0166/2023

of 15 May 2023

on the acceptance of a modification of an agreed paediatric investigation plan for peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain (EMEA-002942-PIP02-20-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 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/0173/2022 issued on 13 May 2022,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 15 December 2022 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 31 March 2023, 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 peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain, solution for injection in pre-filled syringe, subcutaneous use, 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 Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/954461/2022
Amsterdam, 31 March 2023

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

EMEA-002942-PIP02-20-M01

## Scope of the application

**Active substance(s):**

Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of obesity

**Pharmaceutical form(s):**

Solution for injection in pre-filled syringe

**Route(s) of administration:**

Subcutaneous use

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

Boehringer Ingelheim International GmbH

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 15 December 2022 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/0173/2022 issued on 13 May 2022.

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

The procedure started on 30 January 2023.

## 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 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 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 obesity

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- solution for injection in pre-filled syringe, subcutaneous 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 obesity

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

Treatment of obesity in children and adolescents from 6 years to less than 18 years of age

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

From 6 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 1 (1404-0051)**<br>Randomised, double blind, parallel group, placebo-controlled study in paediatric patients from 6 years to less than 18 years of age with obesity or overweight grouped by age to establish safety, efficacy, and pharmacokinetics of BI 456906 |
| Extrapolation, modelling and simulation studies | **Study 2 (M&S1)**<br>Population pharmacokinetic (PK) model to select an appropriate dosing recommendation for the paediatric study (study 1 of the PIP). |

| | |
|---|---|
| | **Study 3 (M&S2)**<br>Population pharmacokinetic (PK) model to perform update simulations of anticipated paediatric exposure.<br>**Study 4 (M&S3)**<br>Population pharmacokinetic (PK) and PK/pharmacodynamic (PD) models |
| 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 2032 |
| 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.**