MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100209-PIP01-21-M01

Scope of the Application

Active Substance(s)

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

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Boehringer Ingelheim International GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Boehringer Ingelheim International GmbH submitted to the licensing authority on 01/12/2023 16:42 GMT an application for a Modification

The procedure started on 19/03/2024 14:33 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100209-PIP01-21-M01

Of 28/03/2024 10:13 GMT

On the adopted decision for Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain (MHRA-100209-PIP01-21-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, Ingelheim am Rhein, GERMANY, 55216

ANNEX I

1. Waiver

1.1 Condition:

Treatment of obesity The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of obesity.

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (1404-0051) Randomised, double blind, parallel group, placebo-controlled study in paediatric patients from 6 years to less than 18 years with obesity or overweight grouped by age to establish safety, efficacy, and pharmacokinetics of BI 456906.
Extrapolation, Modeling & Simulation Studies	3	Study 2 (M&S1) Population pharmacokinetic (PK) model to select an appropriate dosing recommendation for the paediatric study (study 1 of the PIP). Study 3 (M&S2) Population pharmacokinetic (PK) model to perform updated simulations of anticipated paediatric exposure. Study 4 (M&S3) Population PK and PK/ pharmacodynamic (PD) models.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes