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-100205-PIP01-21-M01

Scope of the Application

Active Substance(s)

EMPAGLIFLOZIN

Condition(s)

Treatment of type 2 diabetes mellitus

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

Oral 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 13/09/2021 17:24 BST an application for a Modification

The procedure started on 04/02/2022 15:58 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100205-PIP01-21-M01

Of 15/02/2022 16:52 GMT

On the adopted decision for EMPAGLIFLOZIN (MHRA-100205-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 EMPAGLIFLOZIN, Film-coated tablet , Oral 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 type 2 diabetes mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: Oral use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of type 2 diabetes mellitus

2.2 Indication(s) targeted by the PIP:

Treatment of type 2 diabetes mellitus

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 Randomised, single-dose, parallel group, study to investigate the pharmacokinetics and pharmacodynamics of empagliflozin in children and adolescents aged 10 years to less than 18 years (and adults below 25 years) with type 2 diabetes mellitus (1245.87). Study 2 (same as Study 2 in MHRA-100207-PIP01-21-M01 and its subsequent modifications) Double-blind, randomised, placebo controlled, add-on to diet and exercise alone in patients not tolerating metformin, and add-on to metformin and/or insulin therapy trial to evaluate efficacy and safety, with a double-blind safety extension period to 52 weeks, comparing linagliptin and empagliflozin versus placebo in children and adolescents from 10 years to less than 18 years of age with type 2 diabetes mellitus (1218-0091)
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	Yes

Date of completion of the paediatric investigation plan:	31/01/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes