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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100170-PIP01-21-M01)

MHRA-100170-PIP01-21-M02

Scope of the Application

Active Substance(s)

CANAGLIFLOZIN HEMIHYDRATE

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

Janssen-Cilag International NV

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag International NV submitted to the licensing authority on 01/08/2022 15:57 BST an application for a Modification

The procedure started on 23/01/2023 08:51 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

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-100170-PIP01-21-M02

Of 20/02/2023 08:40 GMT

On the adopted decision for CANAGLIFLOZIN HEMIHYDRATE (MHRA-100170-PIP01-21-M02) 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 CANAGLIFLOZIN HEMIHYDRATE, Film-coated tablet , ORAL USE .

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, Beerse, BELGIUM, BE-2340

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	Study 1 deleted during procedure MHRA-100170-PIP01-21-M01. Study 2 deleted during procedure MHRA-100170-PIP01-21-M01.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 3 Open-label, multicentre trial to evaluate the multiple dose pharmacokinetics (PK), pharmacodynamics (PD), and safety of Canagliflozin in children from 10 years to less than 18 years of age with type 2 diabetes mellitus. Study 4 Double-blind, randomised, multicentre, parallel-group, placebo-controlled trial to evaluate the efficacy and safety/tolerability of the addition of Canagliflozin to the treatment of children from 10 years and to less than 18 years of age with type 2 diabetes mellitus who have inadequate glycaemic control on diet and exercise with or without metformin with or without insulin after 26 weeks of therapy, followed by a 26-week placebo-controlled, double-blind extension period.
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:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes