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-100515-PIP01-22-M01

Scope of the Application

Active Substance(s)

VORTIOXETINE

Condition(s)

Treatment of Major Depressive Disorder

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral liquid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

H. Lundbeck A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, H. Lundbeck A/S submitted to the licensing authority on 06/05/2022 12:25 BST an application for a Modification

The procedure started on 20/12/2022 14:47 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-100515-PIP01-22-M01

Of 19/01/2023 11:25 GMT

On the adopted decision for VORTIOXETINE (MHRA-100515-PIP01-22-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 VORTIOXETINE, Film-coated tablet; Age-appropriate oral liquid dosage form , ORAL USE .

This decision is addressed to H. Lundbeck A/S, Ottiliavej 9, Valby, DENMARK, 2500

ANNEX I

1. Waiver

1.1 Condition:

1.Waiver 1.1 Condition: Treatment of major depressive disorder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 7 years of age: Pharmaceutical form(s): Film-coated tablet. Age-appropriate oral liquid dosage form. Route(s) of administration: ORAL USE Reason for granting waiver: - From birth to less than 24 months of age 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). - From 24 months to less than 7 years of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of major depressive disorder

2.2 Indication(s) targeted by the PIP:

Treatment of major depressive disorder

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

The paediatric population from 7 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral liquid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate liquid formulation for oral use.
Non-Clinical Studies	3	Study 2 Toxicokinetic study in juvenile animals. Study 3 Dose-range finding study in juvenile animals. Study 4 Toxicity study in juvenile animals.
Clinical Studies	5	Study 5 (12708A) Open-label study to assess the pharmacokinetics and tolerability of multiple oral dosing of vortioxetine in children and adolescent patients with a DSM-IV diagnosis of depressive or anxiety disorder. Study 6 (12709A) Two-phase, single- and double-blind, randomised, placebo controlled, multicentre, short-term study of vortioxetine and fluoxetine in paediatric patients with major depressive disorder (MDD) from 7 to less than 12 years of age. Study 7 (12710A) Two-phase, single- and double-blind, randomised, placebo controlled and active comparator, 4 arm, multicentre, short-term study of vortioxetine and fluoxetine in paediatric patients with major depressive disorder (MDD) from 12

		to less than 18 years of age. Study 8 (13546A) Deleted during procedure MHRA-100515-PIP01-22-M01. Study 9 (12712A) Long-term, open-label, flexible-dose, extension study of vortioxetine in paediatric patients with major depressive disorder (MDD) from 7 to less than 18 years of age. Study 10 (12712B) Long-term, open-label, flexible-dose, extension study of vortioxetine in paediatric patients with major depressive disorder (MDD) from 7 to less than 18 years of age who have completed Study 12712A.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes