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-100253-PIP01-21-M02)

MHRA-100253-PIP01-21-M03

Scope of the Application

Active Substance(s)

zuranolone

Condition(s)

Treatment of post-partum depression

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Biogen Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Biogen Netherlands B.V. submitted to the licensing authority on 08/12/2025 13:08 GMT an application for a Modification

The procedure started on 12/12/2025 09:29 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-100253-PIP01-21-M03

Of 02/04/2026 09:31 BST

On the adopted decision for zuranolone (MHRA-100253-PIP01-21-M03) 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 zuranolone, Capsule, hard , ORAL USE .

This decision is addressed to Biogen Netherlands B.V., Prins Mauritslaan 13-19, Badhoevedorp, NETHERLANDS, 1171LP

ANNEX I

1. Waiver

1.1 Condition:

Treatment of post-partum depression The waiver applies / applied to: Paediatric Subset(s): Males from birth to less than 18 years of age and prepubertal females Pharmaceutical form(s): Capsule, hard 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 post-partum depression

2.2 Indication(s) targeted by the PIP:

Treatment of post-partum depression

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

Post pubertal females less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 1 (SSN-03751) Juvenile toxicity and toxicokinetic study in rats.
Clinical Studies	1	Study 2 (286PP301) Multicentre, randomised, double-blind, placebo-controlled study to assess the efficacy, safety, tolerability, and pharmacokinetics of zuranolone in post pubertal females less than 18 years of age with postpartum depression (PPD).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation study for selection of dose regimen of zuranolone for post pubertal females less than 18 years of age with post-partum depression.
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:	30/06/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes