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-100507-PIP01-22-M02) and to the deferral

MHRA-100507-PIP01-22-M03

Scope of the Application

Active Substance(s)

BREXPIPRAZOLE

Condition(s)

Treatment of schizophrenia

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Otsuka Pharma GmbH (ex. Otsuka Pharmaceutical Development & Commercialisation Europe GmbH)

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Otsuka Pharma GmbH (ex. Otsuka Pharmaceutical Development & Commercialisation Europe GmbH) submitted to the licensing authority on 06/12/2024 19:38 GMT an application for a Modification

The procedure started on 14/01/2025 22:16 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-100507-PIP01-22-M03

Of 28/01/2025 17:45 GMT

On the adopted decision for BREXPIPRAZOLE (MHRA-100507-PIP01-22-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 BREXPIPRAZOLE, Film-coated tablet , ORAL USE .

This decision is addressed to Otsuka Pharma GmbH (ex. Otsuka Pharmaceutical Development & Commercialisation Europe GmbH), Europa-Allee 52 , Frankfurt am Main, GERMANY, 60327

ANNEX I

1. Waiver

1.1 Condition:

Treatment of schizophrenia. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 13 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 schizophrenia.

2.2 Indication(s) targeted by the PIP:

Treatment of schizophrenia.

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

The paediatric population from 13 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	3	Study 1 (331-10-233) Open-label, multicentre, sequential cohort dose escalation trial to assess the safety, tolerability and pharmacokinetics of oral brexpiprazole in adolescents with schizophrenia spectrum or psychotic disorder, and with other psychiatric disorders for which antipsychotic treatments are used in specialist child and adolescent psychiatry clinical practice. Study 2 (331-10-234) Randomised, multicentre, double-blind, placebo- and active-controlled trial to evaluate the short-term efficacy of brexpiprazole monotherapy for the treatment of adolescents with schizophrenia. Study 3 (331-10-236) Open-label, long-term, multicentre trial to evaluate the safety and tolerability of flexible-dose brexpiprazole as maintenance treatment in adolescents with schizophrenia.
Extrapolation, Modeling & Simulation Studies	1	Study 4 (331-201-00185) Extrapolation study based on data from brexpiprazole adult and paediatric trials and literature to support the maintenance of the antipsychotic effect of brexpiprazole in adolescents with schizophrenia.

		Added in procedure EMEA-001185-PIP01-M05.
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:	31/12/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes