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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101794-PIP01-25

Scope of the Application

Active Substance(s)

evenamide

Condition(s)

Treatment of schizophrenia

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Newron Pharmaceuticals SpA

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Newron Pharmaceuticals SpA submitted to the licensing authority on 31/01/2025 17:05 GMT an application for a Paediatric Investigation Plan

The procedure started on 05/03/2025 17:32 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101794-PIP01-25

Of 04/06/2025 09:30 BST

On the adopted decision for evenamide (MHRA-101794-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for evenamide, Capsule, hard , ORAL USE .

This decision is addressed to Newron Pharmaceuticals SpA, Via Antonio Meucci, 3, Bresso (Milan), ITALY, 20091

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): 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 schizophrenia

2.2 Indication(s) targeted by the PIP:

Treatment of patients from 13 years to less than 18 years of age with chronic schizophrenia who are experiencing inadequate benefit for symptoms of their psychosis with their current antipsychotic monotherapy

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):

Capsule, hard

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 Double-blind, add-on study to evaluate the pharmacokinetics (PK), safety, tolerability, and preliminary evidence of efficacy of evenamide in adolescents from 13 years to less than 18 years of age with schizophrenia not responding adequately to their current atypical antipsychotic monotherapy. Study 2 Randomised, double blind, placebo-controlled, multi-centre study evaluating the efficacy, safety, and tolerability, of evenamide as add-on treatment in adolescents from 13 years to less than 18 years of age with schizophrenia not responding adequately to their current atypical antipsychotic monotherapy. Study 3 Open-label, extension study evaluating the long-term safety, tolerability, and efficacy of evenamide as add-on treatment in adolescents from 13 years to less than 18 years of age with schizophrenia not responding adequately to their current atypical antipsychotic monotherapy.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to evaluate the use of evenamide and ensure appropriate doses are selected in adolescents

		from 13 years to less than 18 years of age with schizophrenia not responding adequately to their current atypical antipsychotic monotherapy.
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:	30/06/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes