EMA/400402/2023

European Medicines Agency decision

P/0400/2023

of 27 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for evenamide (EMEA-002519-PIP03-21-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0517/2021 issued on 3 December 2021,

Having regard to the application submitted by Newron Pharmaceuticals S.p.A. on 29 May 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for evenamide, capsule, hard, oral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Newron Pharmaceuticals S.p.A., Via A. Meucci, 3, 20091 - Bresso (Milan), Italy.

EMA/PDCO/282867/2023
Amsterdam, 8 September 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002519-PIP03-21-M01

Scope of the application

Active substance(s):

Evenamide

Invented name and authorisation status:

See Annex II

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 S.p.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Newron Pharmaceuticals S.p.A. submitted to the European Medicines Agency on 29 May 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0517/2021 issued on 3 December 2021.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 10 July 2023.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of schizophrenia

The waiver applies to:

- the paediatric population from birth to less than 13 years of age;
- capsule hard, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric investigation plan

2.1. Condition:

Treatment of schizophrenia

2.1.1. 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

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 13 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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. (Newron Study Ped 1)

	Study 2 Randomized, 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. (Newron Study Ped 2) **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. (Newron Study Ped 3)
Extrapolation, modelling and simulation studies	**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. (Newron Ped 4)
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.