



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/623108/2021

European Medicines Agency decision P/0517/2021

of 3 December 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for evenamide (EMEA-002519-PIP03-21) 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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Newron Pharmaceuticals SpA on 11 February 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for evenamide, capsule, hard, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for evenamide, capsule, hard, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for evenamide, capsule, hard, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Newron Pharmaceuticals SpA, Via Meucci, 3, 20091 - Bresso (MI), Italy.

EMA/PDCO/415312/2021
Amsterdam, 15 October 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-002519-PIP03-21

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 opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Newron Pharmaceuticals SpA submitted for agreement to the European Medicines Agency on 11 February 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 23 March 2021.

Supplementary information was provided by the applicant on 9 July 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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

2. The measures and timelines of the agreed 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 annex 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	Number of measures	Description
Quality-related studies	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. (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	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. (Newron Ped 4)
Other studies	0	Not applicable
Other measures	0	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 June 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes