EMA/320584/2024

European Medicines Agency decision

P/0235/2024

of 18 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for cariprazine (hydrochloride) (Reagila), (EMEA-001652-PIP01-14-M06) 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/0156/2015 issued on 10 July 2015, the decision P/0076/2016 issued on 18 March 2016, the decision P/0301/2018 issued on 12 September 2018, the decision P/0105/2021 issued on 17 March 2021, the decision P/0061/2023 issued on 24 February 2023 and the decision P/0162/2023 issued on 12 May 2023,

Having regard to the application submitted by Gedeon Richter Plc on 22 February 2024 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 31 May 2024, 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.

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

[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 cariprazine (hydrochloride) (Reagila), capsule, hard, orodispersible tablet, oral use, 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 Gedeon Richter Plc., GYömrői út 19-21, 1103 – Budapest, Hungary.

EMA/PDCO/93798/2024
Amsterdam, 31 May 2024

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

EMEA-001652-PIP01-14-M06

Scope of the application

Active substance(s):

Cariprazine (hydrochloride)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of schizophrenia

Pharmaceutical form(s):

Capsule, hard

Orodispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gedeon Richter Plc

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gedeon Richter Plc submitted to the European Medicines Agency on 23 February 2024 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/0156/2015 issued on 10 July 2015, the decision P/0076/2016 issued on 18 March 2016, the decision P/0301/2018 issued on 12 September 2018, the decision P/0105/2021 issued on 17 March 2021, the decision P/0061/2023 issued on 24 February 2023 and the decision P/0162/2023 issued on 12 May 2023.

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

The procedure started on 2 April 2024.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.
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;
- hard capsule, orodispersible tablet, for 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(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of schizophrenia

2.1.1. Indication(s) targeted by the PIP

Treatment of schizophrenia

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

From 13 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

Orodispersible tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Stability and compatibility assessment of the content of opened cariprazine capsules sprinkled on food
Non-clinical studies	**Study 2** *This study was deleted in procedure EMEA-001652-PIP01-14-M01.* **Study 3** *This study was deleted in procedure EMEA-001652-PIP01-14-M01.*

Clinical studies	**Study 4** Open-label, multicentre, multiple dose study to evaluate pharmacokinetics, safety and tolerability of cariprazine in adolescent subjects (and adults) with schizophrenia, schizoaffective disorder and schizophreniform disorder (RGH-188-201) **Study 5** Randomised, 6 week, double blind, multicentre, placebo controlled, parallel group efficacy and safety study of cariprazine in adolescent subjects with schizophrenia (RGH-MD-20/RGH-188-202) **Study 6** Open label, 2 year safety study of cariprazine in adolescents with schizophrenia (RGH-188-203)
Extrapolation, modelling and simulation studies	**Study 7** Data extrapolation from the to be performed paediatric studies, adult cariprazine studies and literature to support assumptions about the maintenance of antipsychotic effect of cariprazine in adolescent schizophrenia (RGH-188-204)
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 September 2025
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:

Condition(s) and authorised indication(s)

1. Treatment of schizophrenia

Authorised indication(s):

- Treatment of schizophrenia in adult patients
  - Invented name(s): Reagila
  - Authorised pharmaceutical form(s): Capsule, hard
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure