

EMA/542030/2018

European Medicines Agency decision

P/0301/2018

of 12 September 2018

on the acceptance of a modification of an agreed paediatric investigation plan for cariprazine (hydrochloride) Reagila (EMA-001652-PIP01-14-M02) 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 European Medicines Agency's P/0156/2015 issued on 10 July 2015 and the decision P/0076/2016 issued on 18 March 2016,

Having regard to the application submitted by Gedeon Richter Plc. on 7 May 2018 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 27 July 2018, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cariprazine (hydrochloride) (Reagila), 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 Gedeon Richter Plc., Gyömrői út 19-21, 1103 - Budapest, Hungary.

EMA/352659/2018 **Corr**

London, 27 July 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001652-PIP01-14-M02

Scope of the application

Active substance(s):

Cariprazine (hydrochloride)

Invented name:

Reagila

Condition(s):

Treatment of schizophrenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Gedeon Richter Plc.

Information about the authorised medicinal product:

See Annex II

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 7 May 2018 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 and the decision P/0076/2016 issued on 18 March 2016.

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

The procedure started on 29 May 2018.

Scope of the modification

Some measures and 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 Norwegian Paediatric Committee member 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, 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

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Stability and compatibility assessment of the content of opened cariprazine capsules sprinkled on food
Non-clinical studies	0	Study 2: <i>This study was deleted in procedure EMEA-001652-PIP01-14-M01.</i> Study 3: <i>This study was deleted in procedure EMEA-001652-PIP01-14-M01.</i>

Area	Number of measures	Description
Clinical studies	3	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	1	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	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 September 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of schizophrenia

Authorised indication(s):

- Treatment of schizophrenia in adult patients

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use