EMA/532345/2021

European Medicines Agency decision

P/0460/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for oteseconazole (EMEA-002392-PIP01-18-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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0147/2019 issued on 17 April 2019,

Having regard to the application submitted by Gedeon Richter Plc. on 4 June 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 21 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision granting a 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 oteseconazole, capsule, hard, 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

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

Article 3

This decision is addressed to Gedeon Richter Plc., 19-21 Gyömrői út, 1103 – Budapest, Hungary.

EMA/PDCO/324033/2021
Amsterdam, 10 September 2021

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

EMEA-002392-PIP01-18-M02

Scope of the application

Active substance(s):

Oteseconazole

Condition(s):

Treatment of vulvovaginal candidiasis

Pharmaceutical form(s):

Capsule, hard

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 4 June 2021 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0147/2019 issued on 17 April 2019.

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

The procedure started on 12 July 2021.

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 in the scope set out in the Annex I of this opinion;
   - to grant a deferral, the details of which are 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 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 vulvovaginal candidiasis

The waiver applies to:

- males from birth to less than 18 years;
- 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;

and to:

- females from birth to less than 12 years;
- capsule, hard, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of vulvovaginal candidiasis

2.1.1. Indication targeted by the PIP

Treatment and prevention of recurrent vulvovaginal candidiasis

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

Female adolescents from 12 years to less than 18 years of age

2.1.3. Pharmaceutical form

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	0	**Study 1** Study deleted during procedure EMEA-002392-PIP01-18-M02 **Study 2** Study deleted during procedure EMEA-002392-PIP01-18-M02 **Study 3** Study deleted during procedure EMEA-002392-PIP01-18-M02
Extrapolation, modelling and simulation studies	1	**Study 4** Study deleted during procedure EMEA-002392-PIP01-18-M02 **Study 5** Study deleted during procedure EMEA-002392-PIP01-18-M02 **Study 6** Study added during procedure EMEA-002392-PIP01-18-M02 Extrapolation study to support the use of oteseconazole in female adolescent patients from 12 years to 18 years of age and >40 kg bodyweight with vulvovaginal candidiasis (VVC).
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:	Yes
Date of completion of the paediatric investigation plan:	By September 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes