EMA/215121/2019

European Medicines Agency decision

P/0147/2019

of 17 April 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for oteseconazole (EMEA-002392-PIP01-18) 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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on the agreement of a paediatric investigation plan and on the granting of a waiver for oteseconazole (EMEA-002392-PIP01-18) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Mycovia Pharmaceuticals Inc on 21 May 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 oteseconazole, 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 waiver for oteseconazole, 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

This decision is addressed to Mycovia Pharmaceuticals Inc, 4505 Emperor Boulevard, Suite 300, 27703 – Durham, United States.

EMA/PDCO/850554/2018
London, 1 March 2019

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

EMEA-002392-PIP01-18

Scope of the application

Active substance(s):

Oteseconazole

Invented name:

Not available

Condition(s):

Treatment of vulvovaginal candidiasis

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Mycovia Pharmaceuticals Inc

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Mycovia Pharmaceuticals Inc submitted for agreement to the European Medicines Agency on 21 May 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 26 June 2018.

Supplementary information was provided by the applicant on 22 November 2018. 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 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; and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 subsets of the paediatric population and condition 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 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	3	**Study 1** Multicentre, randomized, double-blind, placebo-controlled, parallel-group study to assess pharmacokinetics (PK), efficacy and safety of Oteseconazole vs placebo in female post-menarche adolescents from 12 to less than 18 years (and adults) with history of recurrent vulvovaginal candidiasis (VVC) with a current diagnosis of an acute VVC episode. **Study 2** Multicentre, randomized, double-blind, placebo-controlled, parallel-group study to assess pharmacokinetics (PK), efficacy and safety of Oteseconazole vs placebo in female post-menarche adolescents from 12 to less than 18 years (and adults) with history of recurrent vulvovaginal candidiasis (VVC) with a current diagnosis of an acute VVC episode. **Study 3** Multicentre, randomised, double-blind, placebo-controlled, parallel-group study to assess pharmacokinetics (PK), efficacy and safety of Oteseconazole vs Fluconazole and placebo in female post-menarche adolescents from 12 to less than 18 years (and adults) with history of recurrent vulvovaginal candidiasis (VVC) with a current diagnosis of an acute VVC episode.
Extrapolation, modelling and simulation studies	2	**Study 4** Modelling and simulation study to evaluate the dosing of Oteseconazole in females from 12 to less than 18 years of age with history of recurrent vulvovaginal candidiasis (VVC) and with a current diagnosis of an acute vulvovaginal candidiasis episode. **Study 5** Extrapolation study of efficacy and safety of Oteseconazole from female adults to female adolescents from 12 to less than 18 years of age with history of recurrent vulvovaginal candidiasis (VVC) and with a current diagnosis of an acute vulvovaginal candidiasis episode.
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 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No