EMA/160497/2023

European Medicines Agency decision

P/0168/2023

of 15 May 2023

on the agreement of a paediatric investigation plan and on the granting of a waiver for albaconazole (EMEA-003279-PIP01-22) 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 application submitted by Palau Pharma, S.L. on 1 July 2022 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 31 March 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for albaconazole, 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 albaconazole, 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 Palau Pharma, S.L., Avda del Camí Reial , 51-57, 08184 - Palau-solità i Plegamans, Barcelona, Spain.

EMA/PDCO/19259/2023
Amsterdam, 31 March 2023

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

EMEA-003279-PIP01-22

Scope of the application

Active substance(s):

Albaconazole

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute vulvovaginal candidiasis

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Palau Pharma, S.L.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Palau Pharma, S.L. submitted for agreement to the European Medicines Agency on 1 July 2022 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 16 August 2022.

Supplementary information was provided by the applicant on 19 December 2022. 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 Paediatric Committee member Norway 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 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 acute vulvovaginal candidiasis

The waiver applies to:

- boys from birth to less than 18 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(s);

and to:

- pre-menarche girls;
- 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 acute vulvovaginal candidiasis

2.1.1. Indication(s) targeted by the PIP

Treatment of acute vulvovaginal candidiasis

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

Girls from menarche to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1:** Double-blind, randomised, active (fluconazole) and placebo-controlled dose-finding trial to evaluate efficacy, safety and pharmacokinetics (PK) of a single dose of different dosages of albaconazole in post-

	menarche girls (and adult women) with acute vulvovaginal candidiasis. (DC13ALB/2/21) **Study 2:** Double-blind, randomised, active (fluconazole) and placebo-controlled trial to evaluate efficacy and safety of the selected dose of albaconazole in post-menarche girls (and adult women) with acute vulvovaginal candidiasis.
Modelling and simulation studies	**Study 3:** Simulation of plasma concentrations of albaconazole in adolescent girls with different ages and body weights following administration of single oral doses, and comparison with adult levels (M&S-001) **Study 4:** Modelling and simulation study to evaluate the use of albaconazole in adolescent girls following administration of single oral doses, and comparison with adult levels (M&S-002)
Other studies	Not applicable
Extrapolation plan	Studies 1, 3, and 4 are part of the extrapolation plan of efficacy data from adult women to post-menarche girls with acute vulvovaginal candidiasis.

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 April 2027
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.