MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-100191-PIP02-22

Scope of the Application

Active Substance(s)

albaconazole

Condition(s)

Treatment of 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 the Decision

Pursuant to the Human Medicines Regulations 2012, Palau Pharma, S.L. submitted to the licensing authority on 01/07/2022 14:46 BST an application for a Paediatric Investigation Plan

The procedure started on 23/01/2023 07:46 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100191-PIP02-22

Of 24/04/2024 06:51 BST

On the adopted decision for albaconazole (MHRA-100191-PIP02-22) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for albaconazole , Capsule, hard , ORAL USE .

This decision is addressed to Palau Pharma, S.L., Avda del Camí Reial , 51-57, Palau-solità i Plegamans (Barcelona), SPAIN, 08184

ANNEX I

1. Waiver

1.1 Condition:

Treatment of vulvovaginal candidiasis The waiver applies / applied to: Paediatric Subset(s): Males from birth to less than 18 years and pre-pubertal females Pharmaceutical form(s): Capsule, hard Route(s) of administration: ORAL USE Reason for granting waiver: For males from birth to less than 18 years: 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). For pre-pubertal females: 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(s):

Treatment of vulvovaginal candidiasis

2.2 Indication(s) targeted by the PIP:

Treatment of acute vulvovaginal candidiasis

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

Females from menarche to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (DC13ALB/2/21) Randomised, double-blind, dose-finding, multicentre study to assess the efficacy, safety and pharmacokinetics (PK) of albaconazole versus fluconazole and placebo in female post menarche adolescents (and adults) with acute vulvovaginal candidiasis (VVC). Study 2 Randomised, double-blind, multicentre study to evaluate efficacy and safety of albaconazole versus fluconazole and placebo in female post menarche adolescents (and adults) with acute vulvovaginal candidiasis (VVC).
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to evaluate the dosing of albaconazole in the paediatric subset of post-menarche patients with acute VVC. Study 4 Modelling and simulation study to assess the PK/ PD relationship of albaconazole and to support the extrapolation of efficacy from adult to the paediatric subset of post-menarche patients with acute VVC.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	28/02/2027
Deferral of one or more studies contained in the paediatric investigation plan:	No