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-101394-PIP01-24

Scope of the Application

Active Substance(s)

clascoterone

Condition(s)

Treatment of acne vulgaris

Pharmaceutical Form(s)

Cream

Route(s) of Administration

TOPICAL USE

Name / Corporate name of the PIP applicant

Glenmark Pharmaceuticals Europe Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Glenmark Pharmaceuticals Europe Limited submitted to the licensing authority on 21/03/2024 15:12 GMT an application for a Paediatric Investigation Plan

The procedure started on 22/03/2024 13:29 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-101394-PIP01-24

Of 27/03/2024 15:44 GMT

On the adopted decision for clascoterone (MHRA-101394-PIP01-24) 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 clascoterone , Cream , TOPICAL USE .

This decision is addressed to Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2-B Draycott Avenue, Kenton, Middlesex , Harrow, UNITED KINGDOM, HA3 0BU

ANNEX I

1. Waiver

1.1 Condition:

Treatment of acne vulgaris The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 9 years of age Pharmaceutical form(s): Cream Route(s) of administration: TOPICAL USE Reason for granting waiver: 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(s):

Treatment of acne vulgaris

2.2 Indication(s) targeted by the PIP:

Treatment of acne vulgaris

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

The paediatric population from 9 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Cream

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	5	Study 1 (CB-03-01/25) Double-blind, randomised, single dose, placebo-controlled trial to evaluate safety and efficacy of clascoterone in children from 9 years to less than 18 years of age with facial acne vulgaris. Study 2 (CB-03-01/ 28) Open-label, single dose trial to evaluate pharmacokinetics and safety of clascoterone in children from 9 years to less than 12 years of age with facial and truncal acne vulgaris. Study 3 (171- 7151- 201) Double-blind, randomised, multiple dose, placebo-controlled trial to evaluate safety and efficacy of clascoterone in children from 12 years to less than 18 years of age (and adults) with facial acne vulgaris. Study 4 (CB-03-01/26) Double-blind, randomised, single dose, placebo-controlled trial to evaluate safety and efficacy of clascoterone in children from 9 years to less than 18 years of age with facial acne vulgaris. Study 5 (171-7151- 202) Open-label, single dose trial to evaluate pharmacokinetics and safety of clascoterone in children from 12 years to less than 18 years of age with facial and truncal acne vulgaris.

Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	28/02/2023
Deferral of one or more studies contained in the paediatric investigation plan:	No