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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100846-PIP01-23-M01

Scope of the Application

Active Substance(s)

ENALAPRIL MALEATE

Condition(s)

Treatment of heart failure

Pharmaceutical Form(s)

AGE-APPROPRIATE ORAL SOLID DOSAGE FORM

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Proveca Pharma Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Proveca Pharma Limited submitted to the licensing authority on 20/01/2023 16:29 GMT an application for a Modification

The procedure started on 17/04/2023 20:40 BST

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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100846-PIP01-23-M01

Of 24/04/2023 16:38 BST

On the adopted decision for ENALAPRIL MALEATE (MHRA-100846-PIP01-23-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for ENALAPRIL MALEATE, Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Proveca Pharma Limited, 2 Dublin Landings, North Wall Quay, Dublin, IRELAND, Dublin 1

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of heart failure.

2.2 Indication(s) targeted by the PIP:

Treatment of heart failure.

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

The paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Age-appropriate oral solid dose form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 (WP08) Prospective, open-label single and multiple dose pharmacokinetic bridging study with exploratory pharmacodynamic assessments in patients aged from 1 month to less than 12 years. Study 3 (WP09) Prospective, open-label single and multiple dose pharmacokinetic bridging study with exploratory pharmacodynamic assessments in patients from birth to less than 6 years of age. Study 4 (WP10) Prospective open-label multi-centre extension safety study in infants and children.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Systematic literature review, data extrapolation and modelling.
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:	30/04/2021
Deferral of one or more studies contained in the paediatric investigation plan:	No