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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan

MHRA-101905-PIP01-25

Scope of the Application

Active Substance(s)

FUROSEMIDE

Condition(s)

Treatment of fluid retention

Pharmaceutical Form(s)

Orodispersible tablet

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 30/04/2025 12:33 BST an application for a Paediatric Investigation Plan

The procedure started on 09/06/2025 17:50 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 agree a paediatric investigation plan

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-101905-PIP01-25

Of 01/08/2025 09:00 BST

On the adopted decision for FUROSEMIDE (MHRA-101905-PIP01-25) 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 FUROSEMIDE, Orodispersible tablet , 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 fluid retention

2.2 Indication(s) targeted by the PIP:

Treatment of all conditions requiring prompt diuresis, including cardiac, pulmonary, hepatic and renal oedema, peripheral oedema due to mechanical obstruction or venous insufficiency and hypertension

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Orodispersible tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 (PRO/FUR/001) Development of a solid furosemide formulation suitable for oral administration in the paediatric population from birth to less than 18 years.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (PRO/FUR/002) Open label single-dose study to assess the acceptability and palatability of the final proposed furosemide oral formulation in children and adolescents already taking an alternative formulation of oral furosemide.
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:	No
Date of completion of the paediatric investigation plan:	03/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	No