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-102356-PIP01-26

Scope of the Application

Active Substance(s)

TACROLIMUS MONOHYDRATE

Condition(s)

Treatment of vernal keratoconjunctivitis

Pharmaceutical Form(s)

Eye drops, suspension

Route(s) of Administration

OCULAR USE

Name / Corporate name of the PIP applicant

Laboratoires THEA

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Laboratoires THEA submitted to the licensing authority on 18/03/2026 16:50 GMT an application for a Paediatric Investigation Plan

The procedure started on 22/04/2026 13:11 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 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-102356-PIP01-26

Of 25/09/2026 16:20 BST

On the adopted decision for TACROLIMUS MONOHYDRATE (MHRA-102356-PIP01-26) 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 TACROLIMUS MONOHYDRATE, Eye drops, suspension , OCULAR USE .

This decision is addressed to Laboratoires THEA, 12 rue Louis Blériot, Clermont-Ferrand, FRANCE, 63100

ANNEX I

1. Waiver

1.1 Condition:

Treatment of vernal keratoconjunctivitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 4 years of age Pharmaceutical form(s): Eye drops, suspension Route(s) of administration: Ocular use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible;

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of vernal keratoconjunctivitis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe vernal keratoconjunctivitis

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

The paediatric population from 4 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Eye drops, suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	4	Study 1 (T1695-3624-03) Non-clinical study to evaluate the ocular tolerance of T1695 after multiple daily applications in albino rabbits for 14 days. Study 2 (T1695-3624-04) Non-clinical study to evaluate the ocular tolerance and the systemic exposure of T1695 after multiple daily applications in albino rabbits for 3 months followed by a 2-week recovery period. Study 3 (T1695-2324-05) Non-clinical study to evaluate the pharmacokinetic profile of the applicant's proposed formulation of tacrolimus monohydrate compared to the marketed product Talymus in cornea, conjunctivae, lens, aqueous humour and whole blood following a single and multiple ocular topical administration(s) in rabbits. Study 4 (T1695-3724-06) In vitro study to evaluate the in vitro phototoxicity of tacrolimus in 3T3 fibroblasts.
Clinical Studies	2	Study 5 (LT1695-201) Investigator-blinded active comparator study to evaluate the efficacy, safety, tolerability and systemic exposure of tacrolimus 0.1% suspension versus ciclosporin 0.1% ophthalmic emulsion for treatment of moderate to severe vernal keratoconjunctivitis

		(VKC) in paediatric patients from 4 years to less than 18 years of age. Study 6 (LT1695-301) Randomised active-controlled trial to evaluate efficacy and safety of tacrolimus 0.1% ophthalmic suspension in children from 4 years to less than 18 years of age with moderate to severe VKC.
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:	31/12/2029
Deferral of one or more studies contained in the paediatric investigation plan:	No