

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

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Decision Cover Letter

Decision of the licensing authority to:

confirm the applicability of the Class Waiver.

MHRA-102435-PIP01-26

Scope of the Application

Active Substance(s)

MK-8748/EYE201

Condition(s)

Treatment of diabetic macular oedema

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVITREAL USE

Name / Corporate name of the PIP applicant

Eyebiotec limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eyebiotec limited submitted to the licensing authority on 23/03/2026 10:43 GMT an application for a Waiver

The procedure started on 13/04/2026 12:54 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 confirm the applicability of the Class 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-102435-PIP01-26

Of 01/06/2026 09:56 BST

On the adopted decision for MK-8748/EYE201 (MHRA-102435-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:

Confirmation of the applicability of the Class Waiver for the listed condition(s)

This decision applies to a Waiver for MK-8748/EYE201, Solution for injection , INTRAVITREAL USE .

This decision is addressed to Eyebiotec limited, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of diabetic macular oedema The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAVITREAL USE Reason for granting waiver: the product belongs to "all classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema", as stated in Annex II of the adopted Class Waiver Decision CW/0001/2025, on the ground that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not applicable.

2.2 Indication(s) targeted by the PIP:

Not applicable.

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

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	