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-102178-PIP01-25

Scope of the Application

Active Substance(s)

LECANEMAB

Condition(s)

Treatment of Alzheimer's Disease

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes of administration

Name / Corporate name of the PIP applicant

Eisai Europe Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eisai Europe Limited submitted to the licensing authority on 10/10/2025 18:21 BST an application for a Waiver

The procedure started on 13/10/2025 12:45 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-102178-PIP01-25

Of 14/10/2025 07:31 BST

On the adopted decision for LECANEMAB (MHRA-102178-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:

Confirmation of the applicability of the Class Waiver

This decision applies to a Waiver for LECANEMAB, All pharmaceutical forms , All routes of administration .

This decision is addressed to Eisai Europe Limited, Eisai Ltd, EMEA Knowledge Centre, Mosquito Way, Hatfield, UNITED KINGDOM, AL10 9SN

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Alzheimer's Disease The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: The product belongs to “all classes of medicinal products for treatment of Alzheimer’s disease”, 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:	