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

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Decision Cover Letter

Decision of the licensing authority to:

grant a full product specific waiver

MHRA-100055-PIP01-21

Scope of the Application

Active Substance(s)

Edaravone

Condition(s)

Treatment of Amyotrophic lateral sclerosis

Pharmaceutical Form(s)

Solution for infusion, Oral suspension

Route(s) of Administration

Intravenous use, Oral use

Name / Corporate name of the PIP applicant

Mitsubishi Tanabe Pharma Europe Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Mitsubishi Tanabe Pharma Europe Ltd. submitted to the licensing authority on 12/04/2021 16:02 BST an application for a Waiver

The procedure started on 20/09/2021 10:49 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 grant a full product specific 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-100055-PIP01-21

Of 24/09/2021 11:11 BST

On the adopted decision for Edaravone (MHRA-100055-PIP01-21) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for Edaravone, Solution for infusion, Oral suspension , Intravenous use, Oral use .

This decision is addressed to Mitsubishi Tanabe Pharma Europe Ltd., Dashwood House, 69 Old Broad Street, London, United Kingdom, EC2M 1QS

ANNEX I

1. Waiver

1.1 Condition:

Condition: Treatment of Amyotrophic lateral sclerosis 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): Solution for infusion; Oral suspension Route(s) of administration: Intravenous use; Oral 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):

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:	