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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and grant a product specific waiver.

MHRA-101073-PIP01-23-M02

Scope of the Application

Active Substance(s)

MIRABEGRON

Condition(s)

Treatment of idiopathic overactive bladder.

Pharmaceutical Form(s)

Prolonged-release granules for oral suspension, Prolonged-release tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Astellas Pharma Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Astellas Pharma Ltd submitted to the licensing authority on 05/02/2024 15:03 GMT an application for a Modification

The procedure started on 24/04/2024 09:22 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 accept change(s) to the agreed paediatric investigation plan and to grant a 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-101073-PIP01-23-M02

Of 02/05/2024 13:53 BST

On the adopted decision for MIRABEGRON (MHRA-101073-PIP01-23-M02) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for MIRABEGRON, Prolonged-release granules for oral suspension, Prolonged-release tablet , ORAL USE .

This decision is addressed to Astellas Pharma Ltd, 300 Dashwood Lang Road, Bourne Business Park, Addlestone, UNITED KINGDOM, KT15 2NX

ANNEX I

1. Waiver

1.1 Condition:

Treatment of idiopathic overactive bladder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age. Pharmaceutical form(s): Prolonged-release granules for oral suspension Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit over existing treatments The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Prolonged-release tablet Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit over existing treatments The waiver applies / applied to: Paediatric Subset(s): The paediatric population from 5 years to less than 18 years of age. Pharmaceutical form(s): Prolonged-release granules for oral suspension; Prolonged-release tablet Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1, 2, 3, 4, 7, 9, 13, 14 and 15 were deleted during procedure MHRA-101073-PIP01-23-M02 and replaced with a full product specific waiver.

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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	