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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100878-PIP01-23) and to grant a product specific waiver

MHRA-100878-PIP01-23-M01

Scope of the Application

Active Substance(s)

VIBEGRON

Condition(s)

Treatment of myoneurogenic bladder disorders

Pharmaceutical Form(s)

Film-coated tablet, Granules

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Pierre Fabre Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pierre Fabre Limited submitted to the licensing authority on 22/01/2025 12:28 GMT an application for a Modification

The procedure started on 05/03/2025 17:13 GMT

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-100878-PIP01-23-M01

Of 08/05/2025 08:19 BST

On the adopted decision for VIBEGRON (MHRA-100878-PIP01-23-M01) 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 VIBEGRON, Film-coated tablet, Granules , ORAL USE .

This decision is addressed to Pierre Fabre Limited, 250 Longwater Avenue, Green Park, Reading, UNITED KINGDOM, RG2 6GP

ANNEX I

1. Waiver

1.1 Condition:

Treatment of myoneurogenic bladder disorders 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): Film-coated tablet Granules Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

All studies were deleted during procedure MHRA-100878-PIP01-23-M01 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:	