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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100878-PIP01-23

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 27/02/2023 10:55 GMT an application for a

The procedure started on 21/06/2023 10:14 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 agree a paediatric investigation plan and grant a deferral and grant a 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

Of 21/07/2023 09:04 BST

On the adopted decision for vibegron (MHRA-100878-PIP01-23) 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 a paediatric investigation plan

This decision applies to a for vibegron , Film-coated tablet, Granules , ORAL USE .

This decision is addressed to Pierre Fabre Limited, 250 Longwater Avenue, Green Park, Reading, , 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): The paediatric population from birth to less than 6 months 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):

Treatment of myoneurogenic bladder disorders

2.2 Indication(s) targeted by the PIP:

Treatment of detrusor overactivity in children with neurogenic bladder dysfunction

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Granules

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an immediate release granules formulation for paediatric use. Study 2 Development of an immediate release 50 mg film-coated tablet for paediatric use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 3 (URO-901-3007) Open-label, baseline-controlled, multicentre, long-term study to evaluate the safety, efficacy, and pharmacokinetics of vibegron in paediatric subjects 2 years to less than 18 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation. Study 4 (URO-901-3009) Double-blind, active-controlled, multicentre study to evaluate the safety and efficacy of vibegron compared to oxybutynin in paediatric patients 5 years to less than 18 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation. Study 5 (URO-901-3008) Open-label, baseline-controlled, multicentre, long-term study designed to evaluate the safety, efficacy, and pharmacokinetics of vibegron in paediatric patients 6 months to less than 2 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation.

Extrapolation, Modeling & Simulation Studies	1	Study 6 Population PK (PPK) study to describe the PK of vibegron in paediatric patients and to establish the dose based on target adult exposure in patients from 12 years to less than 18 years and in patients from 2 years to less than 12 years of age.
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:	No
Date of completion of the paediatric investigation plan:	30/11/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes