**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 and to the deferral

MHRA-100175-PIP01-21-M01

# Scope of the Application

## Active Substance(s)

AGOMELATINE

## Condition(s)

Treatment of major depressive episodes

## Pharmaceutical Form(s)

Tablet, Film-coated tablet

## Route(s) of Administration

Oral use

## Name / Corporate name of the PIP applicant

LES LABORATOIRES SERVIER

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, LES LABORATOIRES SERVIER submitted to the licensing authority on 13/07/2021 18:49 BST an application for a Modification

The procedure started on 13/05/2022 10:48 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 the deferral

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-100175-PIP01-21-M01

Of 16/06/2022 14:18 BST

On the adopted decision for AGOMELATINE (MHRA-100175-PIP01-21-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 AGOMELATINE, Tablet, Film-coated tablet , Oral use .

This decision is addressed to LES LABORATOIRES SERVIER, 50 rue Carnot, Suresnes Cedex, France, 92284

# ANNEX I

## 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of major depressive episodes The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 7 years of age Pharmaceutical form(s): Film-coated tablet; Tablet Route(s) of administration: Oral use Reason for granting waiver: From birth to less than 24 months of age, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). From 2 years to less than 7 years of age, 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):

| |
|---|
| Treatment of major depressive episodes |

### 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of major depressive episodes |

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

| |
|---|
| The paediatric population from 7 years to less than 18 years of age |

### 2.4 Pharmaceutical Form(s):

| |
|---|
| Film-coated tablet; Tablet |

### 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable |
| **Non-Clinical Studies** | 1 | Study 1 10 weeks toxicity study of agomelatine in juvenile rats. |
| **Clinical Studies** | 2 | Study 2 (CL2-20098-075) Open-label, multicentre, three dose levels, trial to evaluate pharmacokinetics of agomelatine in children from 7 to less than 18 years of age with depressive or anxiety disorder. Study 3 (CL3-20098-076) Double blind, randomised, multicentre, two dose levels, active and placebo controlled, trial to evaluate efficacy and safety of agomelatine to treat children from 7 to less than 18 years of age with major depressive disorder. Study 4 (CL3-20098-090) Deleted during procedure MHRA100175-PIP01-21-M01. |
| **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:** | Yes |
| **Date of completion of the paediatric investigation plan:** | 31/01/2022 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |