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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-100151-PIP01-21

# Scope of the Application

## Active Substance(s)

CANNABIDIOL

## Condition(s)

Treatment of epilepsy with myoclonic-atonic seizures (EMAS)

## Pharmaceutical Form(s)

Oral solution

## Route(s) of Administration

Oral use

## Name / Corporate name of the PIP applicant

GW Research UK Ltd

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GW Research UK Ltd submitted to the licensing authority on 09/07/2021 17:06 BST an application for a Paediatric Investigation Plan

The procedure started on 04/07/2022 11:22 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 agree a paediatric investigation plan 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-100151-PIP01-21

Of 18/07/2022 15:32 BST

On the adopted decision for CANNABIDIOL (MHRA-100151-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:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for CANNABIDIOL, Oral solution , Oral use .

This decision is addressed to GW Research UK Ltd, Sovereign House, Vision Park, Chivers Way, Histon , Cambridge, Cambridge, United Kingdom, CB24 9BZ

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of epilepsy with myoclonic-atonic seizures (EMAS) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Oral solution Route(s) of administration: Oral use Reason for granting waiver: 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). |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of epilepsy with myoclonic-atonic seizures (EMAS) |

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

| |
|---|
| Treatment of epilepsy with myoclonic-atonic seizures (EMAS) |

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

The paediatric population from 1 year to less than 18 years of age

## 2.4 Pharmaceutical Form(s):

Oral solution

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable |
| **Non-Clinical Studies** | 0 | Not applicable |
| **Clinical Studies** | 1 | Study 1 (GWEP20238) Randomised, double-blind, placebo-controlled, study to evaluate the efficacy and safety of cannabidiol in children and adolescents from 1 year to less than 18 years of age with epilepsy with myoclonic-atonic seizures (EMAS). |
| **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:** | No |
| **Date of completion of the paediatric investigation plan:** | 29/02/2024 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | No |