MHRA
10 South Colonnade
Canary Wharf
London
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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-100430-PIP01-22

Scope of the Application

Active Substance(s)

±3,4-methylenedioxymethamphetamine hydrochloride (MDMA)

Condition(s)

Treatment of post-traumatic stress disorder

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Multidisciplinary Association for Psychedelic Studies (MAPS) Europe B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Multidisciplinary Association for Psychedelic Studies (MAPS) Europe B.V. submitted to the licensing authority on 29/07/2022 10:52 BST an application for a Paediatric Investigation Plan

The procedure started on 23/01/2023 07:21 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 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-100430-PIP01-22

Of 16/06/2023 17:28 BST

On the adopted decision for ±3,4-methylenedioxymethamphetamine hydrochloride (MDMA) (MHRA-100430-PIP01-22) 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 ±3,4-methylenedioxymethamphetamine hydrochloride (MDMA) , Capsule, hard , ORAL USE .

This decision is addressed to Multidisciplinary Association for Psychedelic Studies (MAPS) Europe B.V., Tine van Dethstratt, 83, Leiden, NETHERLANDS, 2331CD

ANNEX I

1. Waiver

1.1 Condition:

Treatment of post-traumatic stress disorder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Capsule, hard Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of post-traumatic stress disorder

2.2 Indication(s) targeted by the PIP:

Treatment of post-traumatic stress disorder

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

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

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 1 (CRL-406578) Definitive toxicity study in juvenile rats.
Clinical Studies	2	Study 2 (MAPP4) Randomised, double-blind, placebo-controlled, trial to evaluate the pharmacokinetics, safety and efficacy of MDMA compared to placebo in adolescents from 13 years to less than 18 years of age with post-traumatic stress disorder (PTSD). Study 3 (MAPP5) Randomised, double-blind, placebo-controlled, trial to evaluate the pharmacokinetics (PK), safety and efficacy of MDMA compared to placebo in children from 6 years to less than 12 years of age with post-traumatic stress disorder (PTSD).
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to support the dose finding of MDMA in children from 6 years to less than 18 years of age with post-traumatic stress disorder (PTSD).
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:	30/06/2030

Deferral of one or more studies contained in the paediatric investigation plan:	Yes