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 waiver

MHRA-100706-PIP01-22

Scope of the Application

Active Substance(s)

METHYLPHENIDATE HYDROCHLORIDE

Condition(s)

Treatment of attention-deficit hyperactivity disorder

Pharmaceutical Form(s)

Chewable tablet, Oral suspension

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

LABORATORIOS LESVI, S.L.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, LABORATORIOS LESVI, S.L. submitted to the licensing authority on 23/09/2022 10:56 BST an application for a Paediatric Investigation Plan

The procedure started on 09/03/2023 09:29 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 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-100706-PIP01-22

Of 24/03/2023 14:13 GMT

On the adopted decision for METHYLPHENIDATE HYDROCHLORIDE (MHRA-100706-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 METHYLPHENIDATE HYDROCHLORIDE, Chewable tablet, Oral suspension , ORAL USE .

This decision is addressed to LABORATORIOS LESVI, S.L., Av. Barcelona, 69, spain, SPAIN, 08970

ANNEX I

1. Waiver

1.1 Condition:

Treatment of attention-deficit hyperactivity disorder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Chewable tablet Oral suspension 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 attention-deficit hyperactivity disorder

2.2 Indication(s) targeted by the PIP:

Treatment of attention-deficit hyperactivity 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):

Chewable tablet Oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 1 (NWP06-PPK-101) Open label, non-comparative study to evaluate the pharmacokinetics (PK) of orally administered methylphenidate hydrochloride as an extended release powder for oral suspension in children and adolescents from 6 years to less than 18 years of age with attention deficit hyperactivity disorder (ADHD). Study 2 (NWP06-ADD-100) Double-blind, randomised, placebo controlled, cross over study to evaluate the pharmacokinetics (PK), safety and efficacy and to evaluate the superiority of methylphenidate hydrochloride as an extended-release liquid formulation compared with placebo in children from 6 years to less than 12 years of age with attention-deficit/ hyperactivity disorder (ADHD). Study 3 (NWP09-ADHD-300) Double-blind, randomised, placebo controlled, safety and efficacy study to evaluate the superiority of methylphenidate hydrochloride as an extended-release chewable tablet compared with placebo in children from 6 years to less than 12 years of age with attention-deficit/ hyperactivity disorder (ADHD).

Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to support the evaluation of pharmacokinetic (PK) and pharmacodynamic (PD) properties of methylphenidate hydrochloride in various formulations.
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:	31/01/2023
Deferral of one or more studies contained in the paediatric investigation plan:	No