EMA/21175/2023

European Medicines Agency decision

P/0057/2023

of 24 January 2023

on the acceptance of a modification of an agreed paediatric investigation plan for methylphenidate (hydrochloride) (EMEA-003189-PIP01-22-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0203/2022 issued on 10 June 2022,

Having regard to the application submitted by Laboratorios Lesvi, S.L. on 22 December 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 January 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for methylphenidate (hydrochloride), chewable tablet, oral suspension, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Laboratorios Lesvi, S.L., Av. Barcelona, 69, 08970 - Sant Joan Despí (Barcelona), Spain.

EMA/PDCO/13024/2023
Amsterdam, 20 January 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-003189-PIP01-22-M01

Scope of the application

Active substance(s):

Methylphenidate (hydrochloride)

Invented name and authorisation status:

See Annex II

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 opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Laboratorios Lesvi, S.L. submitted to the European Medicines Agency on 22 December 2022 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0203/2022 issued on 10 June 2022.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 10 January 2023.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
    - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion;
2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of attention-deficit hyperactivity disorder

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- chewable tablet; oral suspension; oral use;
- 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:

Treatment of attention-deficit hyperactivity disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of attention-deficit hyperactivity disorder

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Chewable tablet

Oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (NWP06-PPK-101)** Open-label, non-comparative study to evaluate pharmacokinetics (PK) of orally administered methylphenidate hydrochloride as extended release powder for oral suspension in children from 6 years to less than 18 years with attention deficit hyperactivity disorder (ADHD). **Study 2 (NWP06-ADD-100)** Double-blind, randomised, placebo-controlled, crossover study to evaluate pharmacokinetics (PK), safety and efficacy to evaluate

	superiority of methylphenidate hydrochloride as extended-release liquid formulation compared with placebo in children from 6 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 superiority of methylphenidate hydrochloride as extended release chewable tablet compared with placebo in children from 6 to less than 12 years of age with attention-deficit/hyperactivity disorder (ADHD).
Extrapolation, modelling and simulation studies	**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	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	January 2023
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.