EMA/275700/2022 Corr

European Medicines Agency decision

P/0203/2022

of 10 June 2022

on the agreement of a paediatric investigation plan and on the granting of a waiver for methylphenidate (hydrochloride) (EMEA-003189-PIP01-22) 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 application submitted by Laboratorios Lesvi, S.L. on 24 January 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 April 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[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

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

Article 2

A waiver for methylphenidate (hydrochloride), chewable tablet, oral suspension, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

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

EMA/PDCO/209765/2022
Amsterdam, 22 April 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-003189-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 opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Laboratorios Lesvi, S.L. submitted for agreement to the European Medicines Agency on 24 January 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 21 February 2022.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition 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 annex 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 study to evaluate pharmacokinetics (PK), safety and efficacy 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