EMA/8189/2022

European Medicines Agency decision

P/0017/2022

of 31 January 2022

on the acceptance of a modification of an agreed paediatric investigation plan for phenobarbital (EMEA-002532-PIP01-18-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for phenobarbital (EMEA-002532-PIP01-18-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0422/2019 issued on 6 December 2019 and the decision P/0301/2021 issued on 13 August 2021,

Having regard to the application submitted by Proveca Pharma Limited on 10 September 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 December 2021, 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 phenobarbital, oral suspension, oral use, gastric 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 Proveca Pharma Limited, Marine House, Clanwilliam Place, Dublin 2 – Dublin, Ireland.

EMA/PDCO/522830/2021
Amsterdam, 17 December 2021

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

EMEA-002532-PIP01-18-M02

Scope of the application

Active substance(s):

Phenobarbital

Condition(s):

Treatment of epilepsy

Pharmaceutical form(s):

Oral suspension

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Proveca Pharma Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Proveca Pharma Limited submitted to the European Medicines Agency on 10 September 2021 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0422/2019 issued on 6 December 2019 and the decision P/0301/2021 issued on 13 August 2021.

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

The procedure started on 19 October 2021.

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.

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

2. The measures and timelines of the paediatric investigation plan 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of epilepsy

2.1.1. Indication(s) targeted by the PIP

Treatment of all forms of epilepsy except absence seizures

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate ethanol-free oral liquid suspension
Non-clinical studies	Not applicable	Not applicable
Clinical studies	2	**Study 2** Randomised, single-dose, open label, two-way, crossover, bioequivalence study comparing an ethanol-free oral liquid suspension of phenobarbital with an authorised formulation under fasted conditions in healthy adult volunteers. **Study 3** Acceptability and palatability study of the age-appropriate ethanol-free oral liquid suspension in the paediatric population
Extrapolation, modelling and simulation studies	Not applicable	Not applicable

Other studies	1	**Study 4** Systematic literature review of the use of phenobarbital in the paediatric population for the treatment of epilepsy to support its safety and efficacy.
Other measures	Not applicable.	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:	By May 2023
Deferral for one or more measures contained in the paediatric investigation plan:	No