EMA/631880/2019

European Medicines Agency decision

P/0422/2019

of 6 December 2019

on the agreement of a paediatric investigation plan for phenobarbital (EMEA-002532-PIP01-18) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Proveca Limited on 20 December 2018 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2019, in accordance with Article 17 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 agreement of a paediatric investigation plan.

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

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

Has adopted this decision:

Article 1

A paediatric investigation plan for phenobarbital, oral suspension, oral use, gastric 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

This decision is addressed to Proveca Limited, Neo, Charlotte Street, M1 4ET – Manchester United Kingdom.

EMA/PDCO/410629/2019
Amsterdam, 18 October 2019

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

EMEA-002532-PIP01-18

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 Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Proveca Limited submitted for agreement to the European Medicines Agency on 20 December 2018 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 29 January 2019.

Supplementary information was provided by the applicant on 11 July 2019. The applicant proposed modifications to the paediatric investigation plan.

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.

   The Norwegian Paediatric Committee member 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(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 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 the reference product Fenemal 15 mg tablets (Meda AB, Sweden) 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 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No