EMADOC-1700519818-2038862

European Medicines Agency decision

EMA/PE/0000182928

of 15 April 2025

on the agreement of a paediatric investigation plan for propranolol hydrochloride 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 agreement of a paediatric investigation plan for propranolol hydrochloride 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 application submitted by Proveca Pharma Limited on 05 July 2024 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 28 February 2025, 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.

Has adopted this decision:

Article 1

A paediatric investigation plan for propranolol hydrochloride, 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 Pharma Limited, Dublin Landings 2, North Wall Quay, Dublin 1, Ireland.

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

EMADOC-1700519818-1797661
Amsterdam, 28 February 2025

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

EMA/PE/0000182928

Scope of the application

Active substance(s):

Propranolol (hydrochloride)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of arrhythmias

Pharmaceutical form(s):

Orodispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Proveca Pharma Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Proveca Pharma Limited submitted for agreement to the European Medicines Agency on 5 July 2024 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 19 August 2024.

Supplementary information was provided by the applicant on 21 November 2024. 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 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of arrhythmias.

2.1.1. Indication(s) targeted by the PIP

Treatment of arrhythmias from birth.

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)

Orodispersible tablet.

2.1.4. Measures

Area	**Description**
Quality-related studies	Study 1: Development of a solid propranolol formulation (orodispersible tablet: ODT) suitable for oral administration in the paediatric population from birth to less than 18 years. Study 2: Study in healthy participants to assess the acceptability and palatability of the propranolol ODT via a quinine placebo ODT which mimics the taste profile of the final formulation. Study 3: In vitro assessment of dose recovery of the propranolol ODT through nasogastric/gastrostomy feeding tubes.
Non-clinical studies	Not applicable
Clinical studies	Not applicable
Modelling and simulation analyses	Not applicable
Other studies	Not applicable
Extrapolation plan	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 January 2028
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.