EMA/128919/2017

European Medicines Agency decision

P/0083/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for vigabatrin (EMEA-000717-PIP02-13-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 vigabatrin (EMEA-000717-PIP02-13-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 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 European Medicines Agency's decision P/0173/2014 issued on 11 July 2014 and the decision P/0271/2015 issued on 27 November 2015,

Having regard to the application submitted by ORPHELIA Pharma SA on 8 December 2016 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 27 January 2017, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for vigabatrin, soluble tablet, 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 ORPHELIA Pharma SA, 65 rue Rambuteau, 75004 - Paris, France.

EMA/PDCO/851719/2016
London, 27 January 2017

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

EMEA-000717-PIP02-13-M02

Scope of the application

Active substance(s):

Vigabatrin

Condition(s):

Treatment of epilepsy

Pharmaceutical form(s):

Soluble tablet

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

ORPHELIA Pharma SA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ORPHELIA Pharma SA submitted to the European Medicines Agency on 8 December 2016 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/0173/2014 issued on 11 July 2014 and the decision P/0271/2015 issued on 27 November 2015.

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

The procedure started on 3 January 2017.

Scope of the modification

Some measures and timelines of the paediatric investigation plan have been modified.

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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 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

1.1. Condition:

Treatment of epilepsy

The waiver applies to:

- the paediatric population from birth to less than 1 month and from 7 years to less than 18 years;
- for soluble tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for the age group from birth to less than 1 month;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered for the age group from 7 to less than 18 years.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of epilepsy

2.1.1. Indication(s) targeted by the PIP

- Treatment of infantile spasms
- Treatment of refractory partial onset seizures

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

From 1 month to less than 7 years of age.

2.1.3. Pharmaceutical form(s)

Soluble tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a new age-appropriate pharmaceutical form, soluble tablet, for oral use and gastric use (TGO-VGB-ST-01).
Non-clinical	0	Not applicable.
Clinical studies	1	**Study 2** Open label, non-randomised, observational acceptability study to evaluate acceptability/palatability, safety and

		tolerability of the new soluble tablet formulation of vigabatrin in children from age 1 month to less than 7 years with seizure disorders (infantile spasms, refractory partial onset seizures) with a follow-up of 4 weeks (TGO-VGB-III-01).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No