EMA/354911/2014

European Medicines Agency decision

P/0173/2014

of 11 July 2014

on the agreement of a paediatric investigation plan and on the granting of a waiver for vigabatrin (EMEA-000717-PIP02-13) 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 and on the granting of a waiver for vigabatrin (EMEA-000717-PIP02-13) 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 application submitted by Targeon SAS on 6 November 2013 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 23 May 2014, in accordance with Article 18 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for vigabatrin, soluble tablet, 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 vigabatrin, soluble tablet, 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 Targeon SAS, 65 rue Rambuteau, 75004 – Paris, France.

Done at London, 11 July 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/41278/2014

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

EMEA-000717-PIP02-13

Scope of the application

Active substance(s):

Vigabatrin

Condition(s):

Treatment of epilepsy

Pharmaceutical form(s):

Soluble tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Targeon SAS

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Targeon SAS submitted for agreement to the European Medicines Agency on 6 November 2013 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 18 December 2013.

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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 18 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 23 May 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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

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 (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, pharmacokinetics, 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 June 2015
Deferral for one or more measures contained in the paediatric investigation plan:	No