EMA/584737/2018

European Medicines Agency decision

P/0299/2018

of 12 September 2018

on the acceptance of a modification of an agreed paediatric investigation plan for retigabine (Trobalt), (EMEA-000116-PIP01-07-M09) 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 European Medicines Agency's decision P/77/2008 issued on 12 September 2008, the decision P/153/2009 issued on 9 October 2009, the decision P/35/2010 issued on 31 March 2010, the decision P/174/2010 issued on 20 September 2010, the decision P/156/2011 issued on 4 July 2011, the decision P/0225/2012 issued on 3 October 2012, the decision issued P/0081/2013 on 27 March 2013, the decision P/0286/2013 issued on 29 November 2013 and the decision P/0009/2016 issued on 29 January 2016,

Having regard to the application submitted by Glaxo Group Limited on 4 May 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 July 2018, 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 and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and to the 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

Changes to the agreed paediatric investigation plan for retigabine (Trobalt), film-coated tablet, dispersible / chewable tablet, powder for solution for injection, powder for solution for infusion, oral use, intravenous use, including changes to the deferral and to the waiver 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 Glaxo Group Limited, 980 Great West Road, TW8 9GS – Brentford, United Kingdom.

EMA/PDCO/298073/2018 Corr
London, 27 July 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000116-PIP01-07-M09

Scope of the application

Active substance(s):

Retigabine

Invented name:

Trobalt

Condition(s):

Treatment of epilepsy with partial onset seizures

Treatment of Lennox-Gastaut Syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Dispersible / chewable tablet

Powder for solution for injection

Powder for solution for infusion

Route(s) of administration:

Oral use

Intravenous use

Name/corporate name of the PIP applicant:

Glaxo Group Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Glaxo Group Limited submitted to the European Medicines Agency on 4 May 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/77/2008 issued on 12 September 2008, the decision P/153/2009 issued on 9 October 2009, the decision P/35/2010 issued on 31 March 2010, the decision P/174/2010 issued on 20 September 2010, the decision P/156/2011 issued on 4 July 2011, the decision P/0225/2012 issued on 3 October 2012, the decision issued P/0081/2013 on 27 March 2013, the decision P/0286/2013 issued on 29 November 2013 and the decision P/0009/2016 issued on 29 January 2016.

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

The procedure started on 29 May 2018.

Scope of the modification

Amendment of the scope of the waiver to cover all paediatric subsets for both conditions.

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 and to the deferral and to amend the scope of the waiver in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, as set out in Annex I of this opinion.

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of epilepsy with partial onset seizures

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablet, dispersible / chewable tablet, powder for solution for injection, powder for solution for infusion, oral use, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

1.2. Condition

Treatment of Lennox-Gastaut Syndrome

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablet, dispersible / chewable tablet, powder for solution for injection, powder for solution for infusion, oral use, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment epilepsy with partial-onset seizures

Authorised indications:

- Trobalt is indicated as adjunctive treatment of drug-resistant partial onset seizures with or without secondary generalization in patients aged 18 years or older with epilepsy, where other appropriate drug combinations have proved inadequate or have not been tolerated.

Authorised pharmaceutical formulation(s)

Film-coated tablet

Authorised route(s) of administration

Oral use