EMA/305260/2017

European Medicines Agency decision

P/0143/2017

of 7 June 2017

on the refusal of a modification of an agreed paediatric investigation plan and on the granting of a product-specific waiver for laquinimod (sodium) (EMEA-000972-PIP01-10-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 7523 70405555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0143/2017

of 7 June 2017

on the refusal of a modification of an agreed paediatric investigation plan and on the granting of a product-specific waiver for laquinimod (sodium) (EMEA-000972-PIP01-10-M05) 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/58/2011 issued on 4 March 2011, the decision P/0027/2012 issued on 27 January 2012, the decision P/0015/2013 issued on 25 January 2013, the decision P/0182/2013 issued on 31 July 2013 and the decision P/0086/2014 issued on 4 April 2014,

Having regard to the application submitted by Teva GmbH on 27 January 2017 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 21 April 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 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 refusal of changes to the agreed paediatric investigation plan and to the deferral, and on the granting of a product-specific waiver.

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

(3) It is therefore appropriate to adopt a decision on the granting of a product-specific 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 laquinimod (sodium), capsule, oral use, including changes to the deferral, 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, are hereby refused.

Article 2

A product-specific waiver for laquinimod (sodium), capsule, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Teva GmbH, Graf-Arco-Str. 3, D-89079 – Ulm, Germany.

EMA/PDCO/75416/2017
London, 21 April 2017

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

EMEA-000972-PIP01-10-M05

Scope of the application

Active substance(s):

Laquinimod (sodium)

Condition(s):

Treatment of relapsing remitting multiple sclerosis

Pharmaceutical form(s):

Capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Teva GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva GmbH submitted to the European Medicines Agency on 27 January 2017 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/58/2011 issued on 4 March 2011, the decision P/0027/2012 issued on 27 January 2012, the decision P/0015/2013 issued on 25 January 2013, the decision P/0182/2013 issued on 31 July 2013 and the decision P/0086/2014 issued on 4 April 2014.

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

The procedure started on 21 February 2017.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Opinion

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and the deferral;
- and in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver on its own motion for all subsets of the paediatric population concluded 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.

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 annex and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of relapsing remitting multiple sclerosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for capsule for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.