EMA/120501/2017

European Medicines Agency decision

P/0050/2017

of 3 April 2017

on the acceptance of a modification of an agreed paediatric investigation plan for fingolimod (hydrochloride), (Gilenya) (EMEA-000087-PIP01-07-M05) 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/125/2008 issued on 5 December 2008, the decision P/223/2011 issued on 27 September 2011, the decision P/0272/2012 issued on 21 November 2012, the decision P/0117/2013 issued on 26 April 2013 and the decision P/0230/2016 issued on 9 September 2016,

Having regard to the application submitted by Novartis Europharm Limited on 4 November 2016 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 24 March 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, 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 fingolimod (hydrochloride), (Gilenya), hard capsule, oral 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 Novartis Europharm Limited, Frimley Business Park, GU16 7SR - Camberley, United Kingdom.

EMA/PDCO/168370/2017
London, 24 March 2017

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

EMEA-000087-PIP01-07-M05

Scope of the application

Active substance(s):

Fingolimod (hydrochloride)

Invented name:

Gilenya

Condition(s):

Treatment of multiple sclerosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Hard capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 4 November 2016 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/125/2008 issued on 5 December 2008, the decision P/223/2011 issued on 27 September 2011, the decision P/0272/2012 issued on 21 November 2012, the decision P/0117/2013 issued on 26 April 2013 and the decision P/0230/2016 issued on 9 September 2016.

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

An Opinion was adopted by the Paediatric Committee on 27 January 2017. Novartis Europharm Limited received the Paediatric Committee Opinion on 6 February 2017.

On 8 March 2017 Novartis Europharm Limited submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 9 March 2017.

A meeting with the Paediatric Committee took place on 22 March 2017.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures of the paediatric investigation plan in the scope set out in the Annex I of this opinion.

1.2. following re-examination, to amend the scope of the modifications of the paediatric investigation plan.

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

2. The measures and timelines of the agreed paediatric investigation plan and the subsets of the paediatric population and condition 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 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

1.1. Condition: treatment of multiple sclerosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- for hard capsule, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: treatment of multiple sclerosis

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsing remitting forms of multiple sclerosis

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

From 10 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Hard capsule

2.1.4. Studies

Area	Number of studies	Description
Quality-related studies	1	**Study 1** • Development age appropriate strengths if required • Development of possibility to open capsule and administer capsule contents only, including the study of compatibility with common foods and drinks, and evaluation of palatability
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 2** Double-blind, randomized, multicentre, multiple dose, active controlled (interferon beta-1a), parallel group trial to evaluate pharmacokinetics, safety and efficacy of fingolimod in children from 10 to less than 18 years of age followed by a long-term extension. (CFTY720D2311)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Multiple Sclerosis

Authorised indication(s):

Gilenya is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (for exceptions and information about washout periods see sections 4.4 and 5.1).

or

- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

Authorised pharmaceutical form(s):

Hard capsule

Authorised route(s) of administration:

Oral use