EMA/370819/2017

European Medicines Agency decision

P/0167/2017

of 30 June 2017

on the acceptance of a modification of an agreed paediatric investigation plan for dimethyl fumarate (Tecfidera), (EMEA-000832-PIP01-10-M04) 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/76/2011 issued on 5 April 2011, the decision P/0027/2013 issued on 26 February 2013, the decision P/0144/2015 issued on 10 July 2015 and the decision P/0132/2016 issued on 20 May 2016,

Having regard to the application submitted by Biogen Idec Ltd on 27 February 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 19 May 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 dimethyl fumarate (Tecfidera), capsule, hard, 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 Biogen Idec Ltd, Innovation House, 70 Norden Road, SL6 4AY – Maidenhead, United Kingdom.

EMA/PDCO/153862/2017
London, 19 May 2017

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

EMEA-000832-PIP01-10-M04

Scope of the application

Active substance(s):

Dimethyl fumarate

Invented name:

Tecfidera

Condition(s):

Treatment of multiple sclerosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Biogen Idec Ltd

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, Biogen Idec Ltd submitted to the European Medicines Agency on 27 February 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/76/2011 issued on 5 April 2011, the decision P/0027/2013 issued on 26 February 2013, the decision P/0144/2015 issued on 10 July 2015 and the decision P/0132/2016 issued on 20 May 2016.

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

The procedure started on 21 March 2017.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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 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:

- 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 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Hard capsule

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	1	**Study 1:** Juvenile toxicology study in male rats
Clinical	1	**Study 2:** Open-label, randomised, multicentre, multiple dose, active controlled, parallel-group efficacy and safety study of dimethyl fumarate in children from 10 to less than 18 years of age with relapsing-remitting multiple sclerosis. (Part 1)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2020
Deferral for one or more measures 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):

- Tecfidera is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis

Authorised pharmaceutical form(s):

Gastro-resistant hard capsule

Authorised route(s) of administration:

Oral route