

EMA/929763/2022

European Medicines Agency decision P/0531/2022

of 30 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for siponimod (hemifumarate) (Mayzent), (EMA-000716-PIP01-09-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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/115/2010 issued on 7 July 2010, the decision P/0015/2014 issued on 22 January 2014, the decision P/0098/2017 issued on 11 April 2017, the decision P/0014/2021 issued on 28 January 2021 and the decision P/0119/2022 issued on 13 April 2022,

Having regard to the application submitted by Novartis Europharm Ltd on 5 August 2022 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 11 November 2022, 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, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for siponimod (hemifumarate) (Mayzent), film-coated tablet, 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 Ltd, Vista Building Elm Park, Merrion Road, 4 - Dublin, Ireland.

EMA/PDCO/691481/2022
Amsterdam, 11 November 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000716-PIP01-09-M05

Scope of the application

Active substance(s):

Siponimod (hemifumarate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of multiple sclerosis

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd submitted to the European Medicines Agency on 5 August 2022 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/115/2010 issued on 7 July 2010, the decision P/0015/2014 issued on 22 January 2014, the decision P/0098/2017 issued on 11 April 2017, the decision P/0014/2021 issued on 28 January 2021 and the decision P/0119/2022 issued on 13 April 2022.

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

The procedure started on 12 September 2022.

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 Paediatric Committee member of Norway 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:

- all subsets of the paediatric population from birth to less than 10 years of age;
- film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studie(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 children/adolescent patients (10 to less than 18 years of age) with relapsing remitting 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)

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Study 1 Pre - and postnatal 6-week oral gavage study in rats.
Clinical studies	Study 2 Double-blind, randomised, 3-arm, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in children from 10 to less than 18 years of age with multiple sclerosis.
Extrapolation, modelling and simulation studies	Not applicable

Other studies	Not applicable
Other measures	Not applicable

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 October 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of multiple sclerosis

Authorised indication(s):

- Treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity.
 - Invented name(s): Mayzent
 - Authorised pharmaceutical form(s): film-coated tablet
 - Authorised route(s) of administration: oral use
 - Authorised via centralised procedure