EMADOC-1700519818-2039230

European Medicines Agency decision

EMA/PE/0000238977

of 14 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for Eubacterial spores, purified from allogeneic faecal donations 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0390/2018 issued on 7 December 2018,

Having regard to the application submitted by Aimmune Nestle Health Science US R&D LLC on 25 November 2024 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 28 February 2025, 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.

(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.

[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 Eubacterial spores, purified from allogeneic faecal donations, including changes to the deferral, 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 Aimmune Nestle Health Science US R&D LLC, 1007 US Highway 202/206 Bldg Jr2 Suite E102, Bridgewater 08807-1275, United States.

EMADOC-1700519818-1803943
Amsterdam, 28 February 2025

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

EMA/PE/0000238977

Scope of the application

Active substance(s):

Eubacterial spores, purified from allogeneic faecal donations (SER-109)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of *Clostridium difficile* infection

Pharmaceutical form(s):

Capsule, hard

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Aimmune Nestle Health Science US R&D LLC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Aimmune Nestle Health Science US R&D LLC submitted to the European Medicines Agency on 25 November 2024 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/0390/2018 issued on 7 December 2018.

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

The procedure started on 2 January 2025.

Scope of the modification

Some timelines 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 and to the deferral 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 Clostridium difficile infection

The waiver applies to:

- the paediatric population from birth to less than 4 years of age;
- capsule, hard, oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective or unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Clostridium difficile infection (CDI)

2.1.1. Indication(s) targeted by the PIP

Reduction of recurrences of *Clostridium difficile* infection (CDI) in patients who have received antibacterial drug treatment for recurrent CDI.

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

From 4 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard

Oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of a liquid formulation for oral use, including administration through enteral tube.
Non-clinical studies	Not applicable.
Clinical studies	Study 2 Open label, multicentre, dose escalating study to evaluate the safety and tolerability of SER-109 in children from 4 years to less than 18 years with recurrent CDI who have received antibacterial drug treatment for CDI.

	Study 3 Double-blind, randomised, placebo-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of SER-109 versus placebo to reduce recurrence of CDI in paediatric subjects aged from 4 years to less than 18 years with recurrent CDI who have received antibacterial drug treatment for CDI.
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/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2031
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:

The product is not authorised anywhere in the European Community.