EMA/470764/2021

European Medicines Agency decision

P/0374/2021

of 8 September 2021

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant *Clostridioides difficile* toxoid A / recombinant *Clostridioides difficile* toxoid B (EMEA-002112-PIP01-16-M01) 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/0019/2018 issued on 30 January 2018,

Having regard to the application submitted by Pfizer Europe MA EEIG on 19 April 2021 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 23 July 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Recombinant *Clostridioides difficile* toxoid A / recombinant *Clostridioides difficile* toxoid B , powder and suspension for suspension for injection, intramuscular use, 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 - Brussels, Belgium.

EMA/PDCO/260466/2021
Amsterdam, 23 July 2021

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

EMEA-002112-PIP01-16-M01

Scope of the application

Active substance(s):

Recombinant *Clostridioides difficile* toxoid A / recombinant *Clostridioides difficile* toxoid B

Condition(s):

Prevention of *Clostridioides difficile* infection

Pharmaceutical form(s):

Powder and suspension for suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 19 April 2021 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/0019/2018 issued on 30 January 2018.

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

The procedure started on 25 May 2021.

Scope of the modification

Some measures and 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 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 annex and appendix.

1. Waiver

1.1. Condition:

Prevention of *Clostridioides difficile* infection (CDI)

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- powder and suspension for suspension for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of *Clostridioides difficile* infection (CDI)

2.1.1. Indication(s) targeted by the PIP

Active immunisation for the prevention of primary *Clostridioides difficile* infection

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and suspension for suspension for injection

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1** Open-label trial to evaluate safety, tolerability and immunogenicity of recombinant *Clostridioides difficile* toxoid A / recombinant *Clostridioides difficile* toxoid B vaccine in children from 2 years to less than 18 years of age who are at risk of CDI (e.g. with Inflammatory Bowel Disease (IBD), solid organ transplants and haematological oncology conditions and other conditions requiring frequent healthcare and antibiotic utilisation) (Stage 1) and to infer

		efficacy in the paediatric population utilizing immune-bridging (Stage 2).
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	1	**Study 2** Literature analysis on risk factors and incidence of paediatric CDI
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes